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## Patient Decision Aids Improve Patient Safety and Reduce Medical Liability Risk

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## Patient Decision Aids Improve Patient Safety and Reduce Medical Liability Risk

### Cover Page Footnote

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# PATIENT DECISION AIDS IMPROVE PATIENT SAFETY AND REDUCE MEDICAL LIABILITY RISK

Thaddeus Mason Pope

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## PATIENT DECISION AIDS IMPROVE PATIENT SAFETY AND REDUCE MEDICAL LIABILITY RISK

Thaddeus Mason Pope\*

### ABSTRACT

Tort-based doctrines of informed consent have utterly failed to assure that patients understand the risks, benefits, and alternatives to the healthcare they receive. Fifty years of experience with the doctrine of informed consent have shown it to be an abject catastrophe. Most patients lack an even minimal understanding of their treatment options.

But there is hope. Substantial evidence shows that patient decision aids (PDAs) and shared decision making can bridge the gap between the theory and practice of informed consent. These evidence-based educational tools empower patients to make decisions with significantly more knowledge and less decisional conflict than clinician-patient discussions alone.

Unfortunately, despite robust evidence of effectiveness, few clinicians in the United States use PDAs when they deliver healthcare services. This must change. It is time to move PDAs from research to practice and from the lab to the clinic. This Article describes a key tool that can nudge clinicians to use PDAs with their patients: the monetary incentive of a professional liability insurance premium reduction.

Medical malpractice insurance companies should offer premium discounts to clinicians who use PDAs. This incentive will spur PDA use, and PDA use will improve patient safety, which benefits both patients and malpractice insurers.

### INTRODUCTION

Each year, the United States spends more than \$3 trillion on healthcare.<sup>1</sup> Over 60% of that amount is for 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.”<sup>2</sup>

As the term “preference sensitive” suggests, the patient’s own personal values determine the optimal choice at decision junctures. Typically, 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

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1. Anne B. Martin et al., *National Health Spending: Faster Growth In 2015 As Coverage Expands and Utilization Increases*, 36 HEALTH AFFS. 166, 166 (2017).

2. DARTMOUTH ATLAS PROJECT, PREFERENCE-SENSITIVE CARE 1 (2007).

science. Instead, there are usually legitimate alternative options that involve significant value-laden tradeoffs.<sup>3</sup>

For example, some people will prefer to accept a low risk of death to improve kidney function. Others will not make that tradeoff. Some patients prefer to try cancer drugs with serious side effects in exchange for a small chance of remission or prolongation of life. Others prefer palliative measures only, preferring quality over quantity of life. In short, which option is “best” is subjective and value-laden. Consequently, decisions about preference-sensitive interventions should reflect the patient’s own values and wishes.<sup>4</sup>

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 or value the treatments that they are getting.<sup>5</sup> Clinicians always ask, “what is the matter *with* you?” But clinicians rarely ask, “what matters *to* you?”<sup>6</sup>

In other words, clinicians elevate clinical diagnosis over preference diagnosis.<sup>7</sup> 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.<sup>8</sup>

The purpose of this Article is to pave a path toward better patient engagement and informed consent through the increased use of patient decision aids (PDAs). We already know that these evidence-based educational tools result in better informed and engaged patients.<sup>9</sup> But PDAs remain largely ignored in the day-to-day delivery

3. Victor M. Montori et al., *The Optimal Practice of Evidence-Based Medicine: Incorporating Patient Preferences in Practice Guidelines*, 310 JAMA 2503, 2503 (2013).

4. 42 U.S.C. § 299b-36(b)(2) (2010).

5. See Thaddeus M. Pope, *Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law*, 45 J.L. MED. & ETHICS 12, 12 (2017); Susan Peschin on behalf of All. for Aging Rsch., Comment Letter to Centers for Medicare & Medicaid Services on Coverage Criteria for Transcatheter Aortic Valve Replacement (July 26, 2018), [https://www.cms.gov/medicare-coverage-database/view/ncacal-public-comments.aspx?NCAId=293&ExpandComments=n&bc=AABAAAAAQAAA&\[https://perma.cc/BQ7V-4WCQ\]](https://www.cms.gov/medicare-coverage-database/view/ncacal-public-comments.aspx?NCAId=293&ExpandComments=n&bc=AABAAAAAQAAA&[https://perma.cc/BQ7V-4WCQ]); W.J. Mackillop et al., *Cancer Patients’ Perceptions of Their Disease and Its Treatment*, 58 BRITISH J. CANCER 355, 358 (1988); Jorgen Dahlberg et al., *Lack of Informed Consent for Surgical Procedures by Elderly Patients with Inability to Consent: A Retrospective Chart Review from an Academic Medical Center in Norway*, PATIENT SAFETY SURGERY, Jun. 2019 at 1, 5; Susan P. Y. Wong et al., *Care Practices for Patients With Advanced Kidney Disease Who Forgo Maintenance Dialysis*, 179 JAMA INTERNAL MED. 305, 306-10 (2019).

6. NHS SCOTLAND, REALISING REALISTIC MEDICINE 35 (2017); see also W. Savelberg et al., *Does Lack of Deeper Understanding of Shared Decision Making Explains the Suboptimal Performance on Crucial Parts of It? An Example from Breast Cancer Care*, 5 EUR. J. ONCOLOGY NURSING 92, 93 (2019).

7. A. MULLEY ET AL., PATIENTS’ PREFERENCES MATTER: STOP THE SILENT MISDIAGNOSIS 4-5 (2012).

8. See Thaddeus M. Pope, *Legal Briefing: New Penalties for Ignoring Advance Directives and Do-Not-Resuscitate Orders*, 28 J. CLINICAL ETHICS 74, 74-81 (2017).

9. Dawn Stacey et al., *Patient Decision Aids to Engage Adults in Treatment or Screening Decisions*, 318 JAMA 657, 657 (2017). One might analogize to the use of artificial intelligence in radiology. AI can outperform human diagnosis of scans in terms of both speed and accuracy. See, e.g., Ahmed Hosny et al., *Artificial Intelligence in Radiology*, 18 NAT. REV. CANCER 500, 503 (2018). Similarly, PDAs can outperform human diagnosis of preferences.

of healthcare services. Uptake remains sparse and the promise of PDAs remains elusive.<sup>10</sup>

The global thesis of this Article is that medical malpractice insurance companies should encourage clinicians to use PDAs by offering premium discounts. These incentives will spur PDA use, and PDA use will improve patient safety. I make this argument in four stages.

In Section I, I summarize the already enormous and still-growing evidence 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 II, I describe and defend one element of a broader strategy to promote broader uptake. I argue that medical liability insurers should incentivize PDA use by offering premium discounts on their professional liability policies. Because clinicians (or the entities paying for their insurance) will want these cost savings, premium reductions will spur 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.<sup>11</sup> Specifically, I explain that offering these premium incentives will reduce liability risk. The discounts increase PDA use because such use is a required condition for the discount. In turn, PDA use reduces risk in two ways. First, in Section III, I show how PDAs reduce risk from negligent nondisclosure claims. Second, in Section IV, I show how PDAs reduce risk from other types of medical malpractice claims.

I conclude, in the final Section, that the cost-saving incentive from lower malpractice insurance premiums is one key measure that can help push PDAs from research to practice.<sup>12</sup> This will result in more value-congruent care, more patient satisfaction, less unwanted medical treatment, and fewer medical malpractice claims.

## I. UNREALIZED PROMISE OF PATIENT DECISION AIDS

Already, over 100 randomized controlled studies show that PDAs help patients gain significant knowledge and understanding of their treatment choices.<sup>13</sup> The evidence on PDA effectiveness is substantial. But their use remains mostly limited to investigational trials.

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10. See *infra* Section I.C.

11. I do not offer a knock-down, drag out argument for this conclusion. But I demonstrate that it is plausible enough to warrant further study by actuaries and economists. Furthermore, while not mathematically detailed, this Article offers justification for at least a pilot trial with certain high-risk specialists like surgeons or OB/GYNs.

12. Offering a malpractice premium incentive is only one tool that can promote wider uptake of PDAs. Commentators have described other tools. See, e.g., Pope, *supra* note 5, at 23-25. For example, Medicare has increasingly required PDA use as a condition of reimbursement. See *infra* sources cited note 41. Other insurers are starting to integrate PDA use. See, e.g., Joanne Finnegan, *Aetna Partners with Nonprofit to Bring Videos on End-of-Life Issues to Patients with Advanced Illness*, FIERCE HEALTHCARE (July 25, 2019), <https://www.fiercehealthcare.com/practices/aetna-partners-non-profit-to-bring-videos-end-life-issues-to-patients-advanced-illness> [<https://perma.cc/8548-ALLS>].

13. See DAWN STACEY ET AL., DECISION AIDS FOR PEOPLE FACING HEALTH TREATMENT OR SCREENING DECISIONS (REVIEW) 16-21 (2017).

### A. What Are Patient Decision Aids?

PDAs are evidence-based educational tools. They take various forms.<sup>14</sup> “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.’”<sup>15</sup>

Whatever form they take, PDAs help patients do three things. First, PDAs help patients understand their treatment options, including the risks and benefits of each choice.<sup>16</sup> Second, PDAs help patients form and communicate preferences regarding their treatment options.<sup>17</sup> Third, PDAs help patients decide which options are best for them based upon scientific evidence, circumstances, beliefs, and preferences.<sup>18</sup>

PDAs effectively present patients with their treatment options, benefits, and harms. They have three advantages over the traditional informed consent process.<sup>19</sup> First, the PDA information is complete, accurate, and up to date.<sup>20</sup> Second, the information is presented in a balanced manner, free from bias and conflicts of interest.<sup>21</sup> Third, the information is lucidly (often graphically) conveyed to help patients understand and use it. In short, PDAs are truly patient centered.

### B. Patient Decision Aids Are Effective

As the term itself suggests, PDAs are designed to “aid” patient decision making. They succeed in accomplishing this goal. Robust evidence shows that PDAs meaningfully empower patients. In contrast to traditional informed consent, shared

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14. Several websites collect PDAs for various healthcare conditions. See, e.g., *Patient Decision Aids*, OTTAWA HOSP. RSCH. INST., <https://decisionaid.ohri.ca/> [<https://perma.cc/S6ML-4UFJ>] (last visited Dec. 23, 2021); COLO. PROGRAM FOR PATIENT CENTERED DECISIONS, <https://patientdecisionaid.org/> [<https://perma.cc/2JWU-9XPD>] (last visited Dec. 23, 2021); *Patient Decision Aids*, WASH. STATE HEALTH CARE AUTH., <https://www.hca.wa.gov/about-hca/making-informed-health-care-decisions/patient-decision-aids-pdas> [<https://perma.cc/M2P8-4ZF5>] (last visited Dec. 23, 2021).

15. Pope, *supra* note 5, at 21.

16. *Id.*

17. *Id.*

18. *Id.*; see also STACEY ET AL., *supra* note 13; Kathleen A. Leinweber et al., *A Review of Decision Aids for Patients Considering More Than One Type of Invasive Treatment*, 235 J. SURGICAL RSCH. 350 (2019); Tessalyn Morrison et al., *Shared Decision-making in Dermatology: A Scoping Review*, 157 JAMA DERMATOLOGY 330 (2021); Jeanette Finderup & Dawn Stacey, *Quality Patient Decision Aids to Support Healthcare Decision Making*, 30 MED. WRITING 38 (2021).

19. See Pope, *supra* note 5 (contrasting traditional informed consent and shared decision making with PDAs). PDAs are not meant to replace or supplant the physician-patient discussion but rather to supplement that discussion. ANGELA COULTER, NATIONAL STRATEGIES FOR IMPLEMENTING SHARED DECISION MAKING 19 (Bertelsmann Stiftung, 2018); see also Anthony L. Back et al., *Communication About Cancer Near the End of Life*, 113 CANCER 1897 (2008).

20. PDAs vary in quality. But a certification mechanism assures that the PDA meets widely accepted standards of accuracy and trustworthiness. See Pope, *supra* note 5, at 23.

21. PDAs do not advise people to choose one option over another, nor do they replace clinician consultation. See IPDAS 2005: *Criteria for Judging the Quality of Patient Decision Aids*, INT’L PATIENT DECISION AID STANDARDS COLLABORATION, [http://www.ipdas.ohri.ca/IPDAS\\_checklist.pdf](http://www.ipdas.ohri.ca/IPDAS_checklist.pdf) [<https://perma.cc/YAK4-2DU5>] (last visited Dec. 23, 2021).

decision making with PDAs deliberately considers both (1) the best scientific evidence available and (2) the patient's values and preferences.

PDAs meaningfully inform and guide both elements. With regard to scientific evidence, PDAs help patients gain significant knowledge and understanding of their choices by providing relevant information on healthcare options. Moreover, since PDAs are typically used outside of clinical encounters, they give patients control over the pace and timing of their education. This on-demand availability also permits patients to share and discuss that information with family, for example, by watching a video PDA together.<sup>22</sup>

With respect to values and preferences, PDAs encourage reflection, helping patients form and clarify what they want. PDAs then enhance deliberation by helping patients associate these values and preferences with their healthcare options and then communicate those associations to their providers. Consequently, the patient can make a treatment choice aligned with their values. PDAs help make the patient engaged, equipped, empowered, and enabled.<sup>23</sup>

Randomized controlled trials (RCTs) are considered the most reliable form of scientific evidence in the hierarchy of evidence that influences healthcare policy and practice.<sup>24</sup> Over 130 RCTs demonstrate that PDAs significantly enhance patients' knowledge of treatment options, risks, and benefits. Summarizing the benefits identified in these RCTs, a systematic meta-review by Cochrane concluded that patients using PDAs:

- (1) Gain significant knowledge;
- (2) Have a more accurate understanding of risks, harms, and benefits;
- (3) Feel less conflicted about decisions; and
- (4) Rate themselves as less passive and less often undecided.<sup>25</sup>

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 have recognized these benefits.<sup>26</sup> These include the Institute of Medicine, the Joint Commission, and the National Quality Forum.<sup>27</sup> An increasing number of other regulators and

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22. Pope, *supra* note 5, at 21.

23. *Id.*

24. See generally A.K. Akobeng, *Understanding Randomised Controlled Trials*, 90 ARCHIVES DISEASES CHILDHOOD 840, 840 (2005).

25. Stacey et al., *supra* note 9, at 657.

26. See, e.g., Am. Coll. of Obstetricians and Gynecologists Comm. on Ethics, *ACOG Committee Opinion No. 819: Informed Consent and Shared Decision Making in Obstetrics and Gynecology*, 137 OBSTETRICS & GYNECOLOGY e34, e36 (2021) [hereinafter *ACOG No. 819*].

27. See INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 76-77 (2001) [hereinafter IOM]; NAT'L QUALITY FORUM, NATIONAL QUALITY PARTNERS PLAYBOOK: SHARED DECISION MAKING IN HEALTHCARE (2018); *Informed Consent: More Than Getting a Signature*, QUICK SAFETY, (The Joint Commission, Oakbrook Terrace, IL), Feb. 2016, at 2.



professional societies have been making similar endorsements.<sup>28</sup> Furthermore, these organizations have encouraged widespread adoption of PDAs.

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 decisions are consistent with their preferences and values.<sup>29</sup> 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."<sup>30</sup>

### 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.<sup>31</sup> The use of PDAs has not "become the norm."<sup>32</sup> They remain "seldom adopted"<sup>33</sup> and "rare in everyday practice."<sup>34</sup> In other words, the research is here, but implementation remains sparse and incomplete. "Practice lags behind" the evidence.<sup>35</sup>

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28. See, e.g., NAT'L INST. FOR HEALTH & CARE EXCELLENCE, SHARED DECISION MAKING GUIDELINE 5-28 (June 17, 2021); ACOG No. 819, *supra* note 26, at e36.

29. See IOM, *supra* note 27, at chs. 2-3.

30. See Chuck Alston et al., *Shared Decision-Making Strategies for Best Care: Patient Decision Aids*, NAT'L ACAD. MED. (Sept. 18, 2014), <https://doi.org/10.31478/201409f> [<https://perma.cc/44UC-566Z>].

31. COULTER, *supra* note 19, at 5.

32. *Id.* at 10.

33. See Muriel R. Gillick, *Re-engineering Shared Decision-Making*, 41 J. MED. ETHICS 785, 785-88 nn.3-4 (2015).

34. See generally Leah 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 EXCH., Aug. 28, 2013.

35. Alston et al., *supra* note 30, at 2; see also Marie-Anne Durand et al., *Incentivizing Shared Decision Making in the USA—Where Are We Now?* 3 HEALTHCARE 97, 97 (2015) ("This well-documented implementation challenge has led to significant interest in developing incentives . . ."); Logan Trenaman et al., *The Cost-effectiveness of Patient Decision Aids: A Systematic Review*, 2 HEALTHCARE 251 (2014); Annette O'Connor et al., *Toward the 'Tipping Point': Decision Aids and Informed Patient Choice*, 26 HEALTH AFFS. 716 (2007); Annelies Engelen et al., *Patients' Views on Using Decision Support Tools: A Systematic Review*, 4 EUR. J. FOR PERS. CENTERED HEALTHCARE 61 (2016); C. Adrian Austin et al., *Tools to Promote Shared Decision Making in Serious Illness: A Systematic Review*, 175 JAMA INTERNAL MED. 1213 (2015); James Tulsky, *Decision Aids in Serious Illness: Moving What Works into Practice*, 175 JAMA INTERNAL MED. 1221 (2015); Carmen L. Lewis et al., *Developing and Evaluating a Clinic-Based Decision Aid Delivery System*, MDM POL'Y & PRAC., July-Dec. 2016; Michael Barry, *Resolving the Decision Aid Paradox*, 175 JAMA INTERNAL MED. 799 (2015); Christopher E. Cox et al., *Development and Pilot Testing of a Decision Aid for Surrogates of Patients with Prolonged Mechanical Ventilation*, 40 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 (ICU) is incomplete and infrequent."); Gunjan Sinha, *Decision Aids Help Patients but Still Are Not Widely Used*, 106 J. NAT'L CANCER INST. 6 (2014); cf. Margaret L. Schwarze and Michael J. Nabozny, *How People Die in 2014*, 260 ANNALS SURGERY 958, 958 (2014) ("In contrast to the pace and complexity of technological innovation, innovation in communication . . . has been nearly stagnant.").

The Institute of Medicine recently lamented that “the promise of shared decision making remains elusive.”<sup>36</sup> Others also lament that the potential of PDAs remains “unrealized.”<sup>37</sup> In short, a continuing key challenge is to move PDAs from research to use and from the laboratory to the clinic.<sup>38</sup>

## II. MEDICAL LIABILITY INSURERS SHOULD INCENTIVIZE PDA USE BY OFFERING PREMIUM DISCOUNTS

A variety of tools might incentivize greater use of PDAs.<sup>39</sup> For example, regulators can mandate their use or offer liability protection.<sup>40</sup> One of the nation’s biggest payers, Medicare, will not reimburse clinicians for some procedures unless the clinician first uses a PDA.<sup>41</sup> Yet, while not totally unheard of, reimbursement incentives remain sparse.<sup>42</sup>

Fortunately, health insurers are not the only ones who can incentivize PDA use. Medical liability insurers can also offer these incentives. Specifically, they can offer malpractice premium reductions. These are workable tools. Medical malpractice insurers already use premium discounts to incentivize other risk-reducing conduct.<sup>43</sup>

36. Alston et al., *supra* note 30, at 2.

37. See *id.* at 25 (“[T]he road to fully integrating SDM into clinical practice likely will be long and winding.”); see also Hole-Curry, *supra* note 34. 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., Karen R. Sepucha et al., *Ten Years, Forty Decision Aids, and Thousands of Patient Uses: Shared Decision Making at Massachusetts General Hospital*, 35 HEALTH AFFS. 630 (2016); Martha Hostetter & Sarah Klein, *Helping Patients Make Better Treatment Choices with Decision Aids*, THE COMMONWEALTH FUND, <https://www.commonwealthfund.org/publications/newsletter-article/helping-patients-make-better-treatment-choices-decision-aids> [<https://perma.cc/BL23-U6QA>] (last visited Dec. 23, 2021).

38. See Floyd J. Fowler Jr. et al., *Let’s Require Patients to Review a High-quality Decision Aid Before Receiving Important Tests and Treatments*, 59 MED. CARE 1, 1 (2021).

39. Angela Coulter, *Shared Decision Making: Everyone Wants It, So Why Isn’t It Happening?*, 16 WORLD PSYCHIATRY 117, 118 (2017) (“A comprehensive strategy is required to promote wider uptake of SDM.”). For example, state mandated disclosures might be fulfilled through PDAs rather than through dense text heavy documents. See, e.g., *Mandated Standardized Written Information That Must be Provided to Patients*, MED. BD. OF CAL., <https://www.mbc.ca.gov/Resources/Publications/Mandated-Standardized-Written-Information.aspx> [<https://perma.cc/8DT6-AYGN>] (last visited Dec. 23, 2021).

40. See Pope, *supra* note 5.

41. TAMARA SYREK JENSEN ET AL., CTRS. FOR MEDICARE & MEDICAID SERVS., CAG-00439N, *Decision Memo: SCREENING FOR LUNG CANCER WITH LOW DOSE COMPUTED TOMOGRAPHY (LDCT)* 1, 4 (2015); TAMARA SYREK JENSEN ET AL., CTRS. FOR MEDICARE & MEDICAID SERVS., CAG-0045N, *Decision Memo: PERCUTANEOUS LEFT ATRIAL APPENDAGE (LAA) CLOSURE THERAPY* 1, 4 (2016); TAMARA SYREK JENSEN ET AL., CTRS. FOR MEDICARE & MEDICAID SERVS., CAG-00157R4, *Decision Memo: IMPLANTABLE CARDIOVERTER DEFIBRILLATORS* 1, 4 (2018); see also TAMARA SYREK JENSEN ET AL., CTRS. FOR MEDICARE & MEDICAID SERVS., CAG-00430R, *Proposed Decision Memo: TRANSCATHETER AORTIC VALVE REPLACEMENT* 1, 92 (2019) (“CMS recognizes the importance of shared decision making in many clinical scenarios and has required shared decision making in other NCDs . . .”).

42. This conclusion is based on my search for incentives both in the law (statutes and regulations) and in literature (legal, medical, and policy).

43. See *infra* Section II.A.

Given this track record, it is likely that offering premium discounts will spur broader PDA uptake.<sup>44</sup>

*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 our rates. An insured individual with prior car accidents, house fires, or robberies is going to pay higher premiums than someone with a clean (claim-free) record. This is known as “experience rating.”<sup>45</sup> An individual’s claims “experience” determines their “rate.”<sup>46</sup> In addition to experience rating, these insurers offer discounts for engaging in risk-reducing behaviors, such as taking a driving class.<sup>47</sup>

Commentators have traditionally understood medical malpractice insurance—unlike most other types of insurance—to eschew experience rating.<sup>48</sup> The general understanding has been that a clinician’s rate is determined more by geographic location and specialty. For example, because of legislative tort reform, premiums are generally lower in California and Texas and higher in Florida and New York. Similarly, premiums are cheaper for low-risk specialties like dermatology and more expensive for high-risk specialties like obstetrics and surgery.<sup>49</sup>

But this standard story oversimplifies things. First, medical malpractice insurers may not look at claims experience to set base rates among their existing policyholders. But they do look at claims experience for three other reasons. First, they use this information to determine whom to accept as a policyholder in the first place.<sup>50</sup> Second, many carriers consider claims experience to discount “base”

44. Some medical risk management organizations already support the use of PDAs. See, e.g., *Engaging Patients in Their Own Care: Patient Decision Aids*, CAN. MED. PROTECTIVE ASS’N (Dec. 2020), <https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2020/engaging-patients-in-their-own-care-patient-decision-aids> [<https://perma.cc/S2DW-LY2A>].

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

46. *Id.*

47. 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. See, e.g., N.D. CENT. CODE § 26.1-25-04.1 (2021) (requiring “reduction in premium charges” following “successful completion of a motor vehicle accident prevention course”); *How Insurance Premium Reduction Works*, N.Y. STATE DEP’T MOTOR VEHICLES, <https://dmv.ny.gov/tickets/reduce-insurance-premium> [<https://perma.cc/S85R-XJRE>] (last visited Dec. 23, 2021) (“Point and Insurance Reduction Program (PIRP) is a DMV-approved course” that “provides a 10% reduction.”). Other types of insurers offer similar discounts. See, e.g., OSHA, U.S. DEP’T LAB., SAFETY AND HEALTH PROGRAMS IN THE STATES: WHITE PAPER 1, 2 (2016) (“[T]en states . . . require insurers to provide [workers’ compensation] premium discounts of between two percent and 25 percent to employers having a written safety and health program.”).

48. See, e.g., Shirley Svorny, *Could Mandatory Caps on Medical Malpractice Damages Harm Consumers?*, POL’Y ANALYSIS, Oct. 20, 2011, at 4; Gary M. Fournier & Melayne Morgan McInnes, *The Case for Experience Rating in Medical Malpractice Insurance: An Empirical Evaluation*, 68 J. RISK & INS. 255, 255 (2001); William M. Sage, *Medical Malpractice Insurance and the Emperor’s Clothes*, 54 DEPAUL L. REV. 463, 479 (2005).

49. See generally KEITH L. MARTIN, MEDSCAPE MALPRACTICE PREMIUM REPORT 2019 (2019).

50. See Svorny, *supra* note 48, at 6.

premiums up to 20% for favorable claims history.<sup>51</sup> Third, and most relevant to PDA incentives, most carriers adjust rates downward when the policyholder takes affirmative action that reduces liability risk.<sup>52</sup> Here are four examples.

**Example One (Anesthesiology).** The Consolidated Risk Insurance Company (CRICO) is the medical malpractice company owned by, and serving, the Harvard medical community. It insures 32 hospitals, 16,000 physicians, more than 325 other health care organizations, and more than 140,000 other clinicians and employees.<sup>53</sup>

In 2001, CRICO introduced a 6% incentive for anesthesiologists who received training in Crisis Resource Management at the Center for Medical Simulation.<sup>54</sup> 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.<sup>55</sup> So, it increased the discount from about 6% to 19%.<sup>56</sup> Today, premiums for anesthesiologists with simulation training are 43% lower than premiums for physicians without training.<sup>57</sup>

**Example Two (OB/GYN).** Based on this favorable track record for the anesthesiologist training program, CRICO started offering 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 those for physicians without training.<sup>58</sup> In short, clinicians with the training have fewer claims.<sup>59</sup> So, the premium discount more than pays for itself. While 10% might seem like a small discount, for a Miami or New York OB/GYN, a 10% premium reduction would be worth \$20,000.<sup>60</sup> A 26% reduction would be worth \$52,000.<sup>61</sup> Aggregated for multiple clinicians in a practice, the savings will exceed \$1 million after a few years.

**Example Three (Webinar Discounts).** The CRICO programs are not the only examples of medical malpractice insurers offering premium reductions for liability-

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51. *Rewards and Discounts*, TEX. MED. LIAB. TR., <https://www.tmlt.org/medical-liability-insurance/rewards-discounts> [<https://perma.cc/ES6V-BLAV>] (last visited Dec. 23, 2021) (“Experience discounts are offered to policyholders with favorable claim experience. Discounts range from 2% to 20% . . .”).

52. See Sage, *supra* note 48, at 479 n.66 (advocating for expanding “premium discounts using process-based quality indicators”).

53. *About CRICO*, CRICO, <https://www.rmfi.harvard.edu/About-CRICO> [<https://perma.cc/GAV8-N5NG>] (last visited Dec. 23, 2021).

54. See generally Jack McCarthy & Jeffrey B. Cooper, *Malpractice Insurance Carrier Provides Premium Incentive for Simulation-Based Training and Believes It Has Made a Difference*, APSF NEWSLETTER (Anesthesia Patient Safety Found., Rochester, N.Y.), Spring 2007.

55. *Id.*

56. *Id.*

57. Denise W. Gee, *Using Simulation to Decrease Medical Liability Risk*, CRICO (Mar. 14, 2015), [https://www.facs.org/~media/files/education/aei/presentation/value%20panel\\_01%20gee.ashx](https://www.facs.org/~media/files/education/aei/presentation/value%20panel_01%20gee.ashx) [<https://perma.cc/4VKW-QMP6>] (see slide 34).

58. *Id.*

59. *Rewards and Discounts*, *supra* note 51 (“Policyholders who complete a practice review may be eligible for a 5% premium discount after review recommendations are met.”).

60. See JOSÉ R. GUARDADO, MEDICAL PROFESSIONAL LIABILITY INSURANCE PREMIUMS: AN OVERVIEW OF THE MARKET FROM 2008 TO 2017, at 5 (Am. Med. Ass’n, 2018). The savings for other specialties in other geographic areas would also be significant, especially when the premium savings are aggregated for several employed physicians. See MARTIN, *supra* note 49.

61. *Id.*

reducing behavior. NORCAL is the eighth largest medical professional liability insurance carrier in the United States.<sup>62</sup> It covers more than 27,000 policyholders in 35 states.<sup>63</sup>

Just as CRICO offers premium discounts for formal training programs, NORCAL offers discounts for self-paced education. NORCAL encourages its policyholders to take risk management courses.<sup>64</sup> These often take the form of forty-five minute webcast videos. After the policyholder successfully completes several courses, NORCAL credits them with a discount of around 5% in the next policy renewal cycle.<sup>65</sup> This results in savings of hundreds or sometimes thousands of dollars in comparison to a non-discounted premium.<sup>66</sup>

**Example Four (EMR Discounts).** Finally, 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 eliminating some of the most common reasons for claims. These often have to do with oversights on patient record reviews (like reading x-rays) or notifying patients of prescription refills. The EMR discounts generally range from 2.5 to 5% of the premium.<sup>67</sup>

This is not an exhaustive review of premium discount programs. But these four examples illustrate the fact that medical malpractice carriers are already discounting premiums. They do this both to incentivize and to reward risk-reducing behavior. Medical malpractice carriers recognize that policyholders who engage in risk-reducing behavior are safer and cheaper customers to service.

The takeaway point for this Article is that offering discounts for using PDAs is not revolutionary. It fits squarely within an established, proven approach. Discounting premiums for using PDAs entails extending established premium incentive programs to a new type of risk-reducing clinician behavior.

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62. *About Norcal Group*, NORCAL GRP., <https://www.norcal-group.com/about> [<https://perma.cc/FB43-24N2>] (last visited Dec. 23, 2021).

63. *Id.*

64. Other insurers offer similar educational materials. Many of them focus on communication issues. See, e.g., Marilyn Schatz, *Don't Let Treatment Refusal Result in Legal Liability*, DATELINE (MLMIC, New York, N.Y.), Fall 2019, at 1, 9.

65. See *About Norcal Group*, *supra* note 62.

66. See *Rewards and Discounts*, *supra* note 51 (“TMLT policyholders who complete a qualifying 2-hour CME activity may be eligible for a 3% premium discount that will be applied to their next eligible policy period. Two courses can be taken for the discount, for up to 6% per policy term.”); *LAMMICO Risk Management Premium Discount Program*, LAMMICO, <https://www.lammico.com/discount> [<https://perma.cc/PQ9P-LZ9D>] (last visited Dec. 23, 2021) (10% discount); *Seminars & eLearning*, THE DENTIST INS. CO., <https://www.tdicinsurance.com/seminars/current-seminar> [<https://perma.cc/5CXV-C4WC>] (last visited Dec. 23, 2021) (5% discount); *Psychologist Risk Management Resources*, AM. PRO. AGENCY, <https://www.americanprofessional.com/risk-management-psychologist/> [<https://perma.cc/8KG3-C2VP>] (last visited Dec. 23, 2021) (5% discount); *Online CME Courses on Leading Risk Management Topics*, MLMIC INS. CO., <https://www.mlmic.com/why-mlmic/cme> [<https://perma.cc/8NUL-LT7F>] (last visited Dec. 23, 2021) (unreported discount).

67. Carol Power, *Medical Liability Insurance – Factors That Can Affect What You Pay*, COVERMD, <http://www.covermd.com/Resources/Medical-Malpractice-Insurance-Rates.aspx> [<https://perma.cc/SK2A-3Q2D>] (last visited Nov. 1, 2017).

### *B. Offering Discounts Will Spur Broader PDA Uptake*

Medical malpractice insurers have linked premium incentives to training and education programs because those activities reduce risk. Similarly, using PDAs also reduces liability risk. Therefore, medical malpractice insurers should extend premium discounts to clinicians who use PDAs with their patients.

Two bodies of evidence suggest that premium discounts for PDAs would successfully spur broader uptake.<sup>68</sup> First, medical malpractice carriers have already proven that offering premium reductions for risk reducing behaviors like training and education prompts policyholder clinicians to adopt that behavior. After all, everyone wants to save money.<sup>69</sup> Among other contexts, this is illustrated by the commonly repeated refrain of tort reform debates: that clinicians watch and respond to premium rates.<sup>70</sup>

Second, there is some closely related experience with incentives for other consent-enhancing measures. Take, for example, the Barrow Neurological Institute.<sup>71</sup> This elite specialty center in Phoenix, Arizona, routinely offers patients video recordings of their visits.<sup>72</sup> This service helps patients by allowing them to listen to their visit again, thus improving their recall and understanding of medical information. It also allows patients to share and discuss the information with family members.<sup>73</sup> 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.”<sup>74</sup>

With PDAs, medical malpractice insurers can obtain the same objectives and benefits that they now achieve from existing incentives. “The time has come for the

68. Clinicians change their conduct in response to malpractice premium increases. Michelle M. Mello et al., *National Costs of The Medical Liability System*, 29 HEALTH AFFS. 1569, 1572, 1573-74 (2010).

69. Because risk management education is inexpensive, it is easy to conclude that premium discounts are worth the required investment. Whether this is similarly true for PDAs will depend on the cost of the PDAs. But many PDAs are open-access and freely available. See, e.g., *Usage Question*, COLO. PROGRAM FOR PATIENT CENTERED DECISIONS, <https://patientdecisionaid.org/terms-of-use/> [<https://perma.cc/F4LG-3LYD>] (last visited Dec. 23, 2021) (“Our tools are intended to be publicly and freely available for clinic/patient use.”); *A to Z Inventory of Decision Aids*, OTTAWA HOSP. RSCH. INST., <https://decisionaid.ohri.ca/AZinvent.php> [<https://perma.cc/67KB-QZAP>] (last visited Dec. 23, 2021).

70. The case for tort reform is that as premiums rise, clinicians leave to work elsewhere, leaving patients with less access to healthcare. Patrick A. Salvi, *Why Medical Malpractice Caps are Wrong*, 26 N. ILL. U. L. REV. 553, 556 (2006) (“One common argument advanced by damage cap proponents is that, as a result of prohibitively high malpractice premiums, doctors will cease practicing medicine in states without caps, and as a result, patients in those states will experience reduced access to health care.”); cf. Jeffrey Clements & Joshua D. Gottlieb, *Do Physicians Financial Incentives Affect Medical Treatment and Patient Health?*, 104 AM. ECON. REV. 1320, 1347 (2014) (financial incentives influence physician behavior); Ronen Avraham & Max M. Schanzenbach, *The Impact of Tort Reform on Intensity of Treatment: Evidence from Heart Patients*, 39 J. HEALTH ECON. 273, 284 (2015).

71. BARROW NEUROLOGICAL INST., <https://www.barrowneuro.org> [<https://perma.cc/29KH-4NGZ>] (last visited Dec. 23, 2021).

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

73. Maka Tsulukidze et al., *Providing Recording of Clinical Consultation to Patients—A Highly Valued but Underutilized Intervention: A Scoping Review*, 95 PATIENT EDUC. & COUNSELING 297, 299 (2014).

74. Elwyn et al., *supra* note 72, at 513.

actuarial profession to join the patient safety battle, to focus energy on preventing injuries rather than just dealing with their aftermath.”<sup>75</sup>

### III. PDAs REDUCE LIABILITY RISK FROM NEGLIGENT NONDISCLOSURE CLAIMS

Suppose the argument in the last section is convincing and medical liability insurers agree that offering premium discounts will drive clinicians to use PDAs.<sup>76</sup> Their next question is how greater PDA use would help either patients or their own bottom line. 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.<sup>77</sup> Premium discounting must make economic sense for the companies offering the discount.

In this Section, I show how PDAs reduce liability risk from negligent nondisclosure claims. This is also known as informed consent liability or medical malpractice for inadequate informed consent.<sup>78</sup> In the next Section, I show how PDAs reduce liability risk from other types of medical malpractice claims.

Medical liability insurers face significant risk exposure for negligent nondisclosure claims. After describing the scope of that risk, I show how PDAs reduce that liability risk in three ways. 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, PDAs lower risk through better documentation.

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

Medical liability insurers face significant risk exposure for negligent nondisclosure claims. The risk is significant in terms of both frequency and severity. First, negligent nondisclosure is one of the most common types of claims that patients make. Second, these claims are more time-consuming and expensive than other types of medical malpractice claims.

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

76. Admittedly, there are other obstacles to PDA implementation (such as costs) and premium discounts will not overcome all of them. See, e.g., Pope, *supra* note 5, at 22. Among other obstacles, some patients may not want to use the PDA. Yet, here, the clinician can at least document that she offered it.

77. Profit maximization is the presumed goal of most firms. *Economics A-Z*, ECONOMIST, <https://www.economist.com/economics-a-to-z/p#node-21529444> [<https://perma.cc/VCT9-56MT>] (last visited Dec. 23, 2021). Some medical professional liability carriers already support the proposition that PDAs reduce claims risk. See, e.g., *Past Projects*, MASS. GEN. HOSP. HEALTH DECISION SCIS. CTR., <https://mghdecisionsciences.org/our-research/past-projects/> [<https://perma.cc/RKD2-3ZMB>] (last visited Dec. 23, 2021) (describing a study funded by CRICO testing “whether prescription of a patient decision aid prior to these operations increases trust in the surgeon and reduces regret about the decision, which should result in lower malpractice risk”).

78. Pope, *supra* note 5, at 15.

### 1. Negligent Nondisclosure Claims Are Common

Negligent nondisclosure is one of the top reasons that patients sue clinicians. For example, CRICO identified “inadequate consent” as one of the “top contributing factors in [medical professional liability] cases.”<sup>79</sup> When it reviewed cases from 2006 to 2010, CRICO found that 484 of its 1,160 cases involved communication factors such as inadequate informed consent, inadequate discharge instructions, and inadequate follow-up instructions.<sup>80</sup> The insurer incurred \$264 million in these cases.<sup>81</sup>

Other studies confirm these results.<sup>82</sup> For example, in a review of malpractice litigation concerning radical prostatectomy “36% of patients claimed that they did not receive proper informed consent . . . .”<sup>83</sup> Similarly, “[l]ack of informed consent was cited in 34% of [spine surgery malpractice] cases.”<sup>84</sup> A lack of informed consent was the second most common reason (24% of cases) for malpractice litigation among patients undergoing brain tumor surgery.<sup>85</sup> And in a review of claims regarding

79. See CRICO STRATEGIES, MEDICAL MALPRACTICE IN AMERICA: A 10 YEAR ASSESSMENT WITH INSIGHTS 19 (2018).

80. Jock Hoffman & Supriya Raman, *Communication Factors in Malpractice Cases*, CRICO INSIGHTS NEWSL., <https://www.rmfm.harvard.edu/Clinician-Resources/Newsletter-and-Publication/2012/Insight-Communication-Factors-in-Mal-Cases> [<https://perma.cc/8CL6-4B5E>] (last visited Dec. 23, 2021).

81. *Id.*

82. See, e.g., Ann Burke et al., *Surgery Risks: Through the Lens of Malpractice Claims*, COVERYS, Feb. 2020, at 7 (identifying “patient consent” as a “trend to watch”); Edward Kim et al., *Litigations Involving Ureteral Injury Related to Minimally Invasive Gynecologic Surgery: Lessons Learned from a Legal Literature Review*, 26 J. MINIMALLY INVASIVE GYNECOLOGY 608, 609 (2019) (identifying “lack of informed consent” as one of three “overarching allegation patterns”); JACQUELINE ROSS ET. AL., INTERNAL MEDICINE CLOSED CLAIMS STUDY: AN EXPERT ANALYSIS OF MEDICAL MALPRACTICE ALLEGATIONS 8 (Sept. 21, 2016) (finding “inadequate informed consent regarding treatment options” comprised 3% of claims); see also Allen D. Spiegel & Florence Kavalier, *Better Patient Communications Mean Lower Liability Exposure*, 6 MANAGED CARE 119 (1997); Carol Sakala et al., *Maternity Care and Liability: Most Promising Policy Strategies for Improvement*, 23 WOMEN’S HEALTH ISSUES e25, e28 (2013) (identifying “shared decision making using high-quality, up-to-date decision aids” as “quality improvement strategies with potential to reduce liability”). But cf. Richa Patel et al., *A Qualitative Analysis of Malpractice Litigation in Cardiology Using Case Summaries Through a National Legal Database Analysis*, CUREUS (July 28, 2019), <https://www.cureus.com/articles/19993-a-qualitative-analysis-of-malpractice-litigation-in-cardiology-using-case-summaries-through-a-national-legal-database-analysis> [<https://perma.cc/XUJ2-YQAY>] (finding consent comprised just 1.2% of cardiology claims).

83. Marc Colaco et al., *Influencing Factors Leading to Malpractice Litigation in Radical Prostatectomy*, 191 J. UROLOGY 1770, 1770 (2014); see also Ashwin Palaniappan et al., *Medical Malpractice in Heart Transplantation from 1994 to 2019*, 36 J. CARDIAC SURGERY 2786, 2788 (2021) (24.4% of claims concerning heart transplant); Darrell Ranum et al., *Leading Causes of Anesthesia-Related Liability Claims in Ambulatory Surgery Centers*, 17 J. PATIENT SAFETY 513, 518 (2021) (9% of anesthesia claims); Steven M. Coppess et al., *Medical Malpractice Allegations in Nasal Turbinate Surgery*, 35 AM. J. RHINOLOGY & ALLERGY 840, 844 (2021) (almost one-third of nasal surgery claims); Kasra Ziai et al., *A Century in Review: Medicolegal Implications of Facial Nerve Paralysis*, 23 FACIAL PLASTIC SURGERY & AESTHETIC MED. 417, 419 (2021) (about 18% of facial paralysis claims).

84. Melvin C. Makhni et al., *The Medicolegal Landscape of Spine Surgery: How Do Surgeons Fare?*, 18 SPINE J. 209, 209 (2018).

85. Remi A. Kessler et al., *Malpractice Litigation in Brain Tumor Surgery: A 31-Year Analysis of Causative Factors in the United States from the Westlaw Database*, 122 WORLD NEUROSURGERY e1570,



cardiac surgery, “[f]ailure to obtain proper informed consent was listed as an additional allegation in 8.9% of cases.”<sup>86</sup> Finally, a closed claims study found that “[f]ailure to [o]btain [c]onsent” was one of the “[t]op six plastic surgery claims” comprising 3% of total claims.<sup>87</sup>

Surgery is not the only area in which insufficient informed consent is a leading medical malpractice allegation. For example, in a breast cancer imaging study it was responsible for 8% of claims.<sup>88</sup> Similarly, in a study of malpractice claims against OB/GYNs, “[i]mproperly obtaining [or] lack of informed consent” was identified as being responsible for 3% of claims.<sup>89</sup>

Closed claims studies are not the only source of information on the scope of liability for negligent nondisclosure. A review of recent verdicts and settlements more concretely illustrates this data. In recent cases where the sole or primary claim was inadequate consent, plaintiffs were awarded—or settled for—\$12 million in Connecticut,<sup>90</sup> \$4.4 million in Delaware,<sup>91</sup> \$16.2 million in Missouri,<sup>92</sup> and \$25.3 million in Wisconsin.<sup>93</sup>

## 2. Negligent Nondisclosure Claims Are Expensive to Handle

The most obvious way in which PDAs can reduce risk management costs from negligent nondisclosure claims is by avoiding claims in the first place. Alternatively,

e1573 (2018); see also Nathan A. Shlobin et al., *Informed Consent in Neurosurgery: A Systematic Review*, 49 NEUROSURGICAL FOCUS e6, 8 (2020) (“The lack of informed consent is the basis for a large portion of malpractice lawsuits in neurosurgery.”).

86. Ashley Szabo Eltorai, *Malpractice Litigation in Cardiac Surgery: Alleged Injury Mechanisms and Outcomes*, 34 J. CARDIAC SURGERY 323, 324 (2019).

87. DARRELL RANUM ET AL., THE DR.’S CO., PLASTIC SURGERY CLOSED CLAIMS STUDY (2019).

88. Michelle V. Lee et al., *Breast Cancer Malpractice Litigation: A 10-year Analysis and Update in Trends*, 60 CLINICAL IMAGING 26, 28 (2020); see also Brittany L. Murphy et al., *Breast Cancer Litigation in the 21st Century*, 25 ANNALS SURGICAL ONCOLOGY 2939, 2943 (2018) (2.3% of claims); *id.* at 2945 (“Improved informed consent for the procedure performed and potential complications remain an opportunity for improved patient education and decreased litigation . . .”).

89. SANDRA LEVY & LESLIE KANE, MEDSCAPE OB/GYN MALPRACTICE REPORT 2017 7 (2017).

90. Thomas B. Scheffey, *Parents Robbed of Tough Choice*, CONN. L. TRIB. (Nov. 21, 2005), <https://www.law.com/ctlawtribune/almID/900005441652/> [<https://perma.cc/7FXZ-8XTJ>]. A second Connecticut case also resulted in a jury verdict for plaintiff. Christian Nolan, *Court Upholds \$5 Million Malpractice Verdict*, CONN. L. TRIB., (Aug. 20, 2012), [https://www.law.com/ctlawtribune/almID/1202567905463&Court\\_Upholds\\_5\\_Million\\_Malpractice\\_Verdict/?slretum=20211104154617](https://www.law.com/ctlawtribune/almID/1202567905463&Court_Upholds_5_Million_Malpractice_Verdict/?slretum=20211104154617) [<https://perma.cc/3FF2-KWLX>].

91. *Shapira v. Christiana Care Health Servs., Inc.*, 99 A.3d 217, 220 (Del. 2014).

92. Lauren Weber, *University of Missouri Pays \$16 Million to Settle Lawsuits over Knee Surgeries*, ST. LOUIS POST DISPATCH (Mar. 12, 2021), [https://www.stltoday.com/news/local/education/university-of-missouri-pays-16-million-to-settle-lawsuits-over-knee-surgeries/article\\_4d41e10b-0f8e-5b3b-af36-e9cf8013555d.html](https://www.stltoday.com/news/local/education/university-of-missouri-pays-16-million-to-settle-lawsuits-over-knee-surgeries/article_4d41e10b-0f8e-5b3b-af36-e9cf8013555d.html) [<https://perma.cc/H9NE-DHN3>].

93. Cary Spivak, *Jury Awards Milwaukee Woman \$25.3 Million in Medical Malpractice Case*, JOURNAL-SENTINEL (July 7, 2014), <https://archive.jsonline.com/business/jury-awards-milwaukee-woman-253-million-in-medical-malpractice-case-b99304583z1-266106991.html/> [<https://perma.cc/X7RT-RVTZ>]. A second Wisconsin case also resulted in a jury verdict for plaintiff. David Wahlberg, *Jury Awards Oregon Couple \$435,000 in UW Malpractice, Informed Consent Case*, WIS. STATE J. (June 8, 2019), [https://madison.com/wsj/news/local/health-med-fit/jury-awards-oregon-couple-435-000-in-uw-malpractice-informed-consent-case/article\\_84de5548-af00-561d-8b08-0ee17a16961f.html](https://madison.com/wsj/news/local/health-med-fit/jury-awards-oregon-couple-435-000-in-uw-malpractice-informed-consent-case/article_84de5548-af00-561d-8b08-0ee17a16961f.html) [<https://perma.cc/RJ6L-G46G>].

they can reduce the risk of liability on asserted claims. Even dropped, dismissed, and withdrawn claims still cost money. Moreover, the resources required to resolve these complaints far exceed the collective value of the nondisclosure complaints themselves.

Although negligent nondisclosure claims represent only half of all complaints, they “disproportionately absorb[] two-thirds of staff time devoted to complaint resolution.”<sup>94</sup> In one study, researchers measured the resources used during internal resolution of complaints by document complexity, document length, document counts, and staff involvement.<sup>95</sup>

For example, physician and nonphysician staff time involved in producing required documents included at least these separate tasks:

- “Electronic file notes (nonphysician staff): 15 minutes per short note, 30 minutes per intermediate note, 1 hour per extensive note.”<sup>96</sup>
- “Response letter to patient (nonphysician staff): 30 minutes per short letter, 1 hour per long letter, 2 hours per very long and complex letter.”<sup>97</sup>
- “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.”<sup>98</sup>

By offering shields, avoiding swords, and improving documentation, 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.

In sum, while negligent nondisclosure may not be at the very top of the list of medical liability drivers, it does present significant risk. There is room for improvement. Medical professional liability carriers have considerable opportunity for significant risk reduction.

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

If the scope of liability risk for negligent nondisclosure is significant, using PDAs can reduce it in three ways, by: (1) offering shields, (2) avoiding swords, and (3) achieving better documentation. In this Section, I describe how PDAs offer a shield. I describe other liability-reducing benefits later in this Article.

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94. 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 J. HEALTHCARE RISK MGMT. 38, 38 (2015).

95. *Id.*

96. *Id.* at 40.

97. *Id.*

98. *Id.*

Liability law can guide conduct by serving as a “shield.”<sup>99</sup> A shield serves as a positive incentive (a carrot) by offering protection for specified conduct.<sup>100</sup> There are two ways in which PDAs serve as shields. First, there is *de jure* safe harbor legal immunity.<sup>101</sup> Some states expressly provide statutory protection to clinicians using PDAs. Second, there is *de facto* safe harbor legal immunity.<sup>102</sup> In those cases, PDAs serve a “protective” function even without express statutory terms because jurors overwhelmingly conclude that clinicians who use PDAs have satisfied their disclosure duties.

### 1. *De Jure Safe Harbor Legal Immunity*

Washington State offers the most concrete example of how using PDAs can reduce liability risk from negligent nondisclosure. 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.<sup>103</sup>

The Washington statute provides that “if a patient . . . signs an acknowledgment of shared decision making” with a PDA, “such acknowledgment shall constitute prima facie evidence that the patient gave his or her informed consent to the treatment administered.”<sup>104</sup> Moreover, the statute requires patients to overcome this presumption with “clear and convincing evidence.”<sup>105</sup>

This is significantly more demanding than the plaintiff’s typical burden, “preponderance of the evidence.” Under Washington law, a “regular” signed consent form “constitute[s] prima facie evidence that the patient gave his or her informed consent to the treatment administered.”<sup>106</sup> “[T]he patient has the burden of rebutting this presumption by a preponderance of the evidence”<sup>107</sup> (showing it is greater than 50% likely that her consent was not informed).

In contrast, a patient’s signed “acknowledgment” of shared decision making with a PDA also “constitute[s] prima facie evidence that the patient gave his or her informed consent to the treatment administered.”<sup>108</sup> But now the patient has the much heavier burden of rebutting this presumption by “clear and convincing evidence.”<sup>109</sup>

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99. See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 695-708 (2001).

100. See generally Thaddeus M. Pope, *Physicians and Safe Harbor Legal Immunity*, 21 ANNALS HEALTH L. 121 (2012) (describing the methods and benefits of safe harbor legal immunity “shields” for physicians).

101. See *infra* Section III.B.1.

102. See *infra* Section III.B.2.

103. WASH. REV. CODE § 7.70.060 (effective until Jan. 1, 2022).

104. *Id.* § 7.70.060(2).

105. *Id.*

106. *Id.* § 7.70.060(1).

107. *Id.*

108. *Id.* § 7.70.060(2).

109. *Id.* The logic is that PDAs ensure not only that disclosure is made but also that it is effective, accurate, and complete.

In short, using 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 (greater than 50%) not informed, a patient must instead more convincingly establish that there was a high probability (greater than 75%) that her consent was not informed.<sup>110</sup>

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. However, the statute links protection to the use of "certified" PDAs, those that an independent expert entity confirms to be accurate, balanced, effective, and free from bias.<sup>111</sup> Washington did not start certifying PDAs until 2016.<sup>112</sup> Consequently, it may be a few years before there is a track record showing how the incentive works.

## 2. *De Facto Safe Harbor Legal Immunity*

Only Washington State clinicians can earn *de jure* safe harbor liability protection. However, clinicians in other states can earn similar liability protection by using a PDA because using a PDA effectively immunizes them from liability for negligent nondisclosure claims.<sup>113</sup> We can call this *de facto* safe harbor liability protection.

Two instructive studies with prospective mock jurors found that using a PDA provides greater protection against a determination of malpractice than either the clinician's word or a medical record note about provision of information. The first study, published in 2008, presented potential jurors with a hypothetical malpractice suit alleging failure to perform a prostate-specific antigen screening test for prostate cancer.<sup>114</sup> The jurors overwhelmingly found that clinicians followed the standard of care when care decisions emerged from the use of PDAs.<sup>115</sup>

Presenting a PDA to mock jurors seemed to accomplish three things. First, it educated them about the complexity of the situation.<sup>116</sup> Second, it visually

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110. This is my own ballpark estimate. The law does not assign specific percentage values to various burdens of persuasion. See generally J.P. McBaine, *Burden of Proof: Degrees of Belief*, 32 CAL. L. REV. 242 (1944) (explaining how to operationalize and apply the "clear and convincing" evidentiary standard). However, in one survey of judges, most selected 75% as the appropriate percentage value for "clear and convincing evidence." Marvin B. Steinberg, *Burdens of Persuasion: Burdened by Too Many Burdens*, 23 UNIV. BALT. L.F. 3, 6 (1992).

111. Pope, *supra* note 5, at 25-26.

112. *Patient Decision Aids (PDAs)*, WASH. STATE HEALTH CARE AUTH., <https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas> [<https://perma.cc/CVJ6-2QNB>] (last visited Dec. 23, 2021).

113. Cf. Timothy Bhattacharyya et al., *The Medical-Legal Aspects of Informed Consent in Orthopaedic Surgery*, 87 J. BONE JOINT SURGERY 2395, 2399 (2005) (finding that surgeons who obtained informed consent in the office instead of the preoperative area "were associated with a significantly decreased indemnity risk").

114. 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).

115. *Id.*

116. *Id.*

documented content that had been presented to the “patient.”<sup>117</sup> Third, it demonstrated that the “physician” had taken great care to support the patient’s knowledge and decision-making.<sup>118</sup> Moreover, using the PDA prevented 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.<sup>119</sup>

Ten years later, the same group of researchers published a similar study using a hypothetical bad outcome after a trial of labor following a prior cesarean birth.<sup>120</sup> The study again demonstrated that using a PDA resulted in a nearly ironclad level of liability protection. Specifically, when a “PDA . . . was provided to the patient and a patient-clinician discussion [was] documented in the medical record, 98% of the [jurors] voted that the defendant met the standard of care.”<sup>121</sup> In contrast, only 70% of the jurors thought the standard of care was met when just a note was included in the medical record stating that the patient and provider discussed the options.<sup>122</sup>

In sum, while using a PDA has a formal legal status only in Washington State, using a PDA is powerful evidence that the clinician has fulfilled her duties of informed consent.<sup>123</sup> It is nearly impossible to establish liability for negligent nondisclosure when the clinician has properly used a legitimate PDA.

### *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 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 twenty states that follow the reasonable patient material risk standard to measure informed consent disclosure duties.

#### *1. Disclosure Mandates and Presumptions of Negligence*

In 1977, the Texas legislature created the Texas Medical Disclosure Panel (TMDP).<sup>124</sup> The TMDP is a panel appointed by the Commissioner of Health that

117. *Id.*

118. *Id.*

119. Cf. Neil H. Ekblom, *Limit Lawsuits by Mitigating Risk*, OPTHALMOLOGY MGMT. (Apr. 1, 2017), <https://www.ophtalmologymanagement.com/issues/2017/april-2017/limit-lawsuits-by-mitigating-risk> [<https://perma.cc/9N2S-5RW8>] (noting that clear documentation deters claims); ROSS, *supra* note 82, at 9 (finding “[i]nsufficient or lack of documentation” in 14% of claims).

120. Suzanne Brodney et al., *A Decision Aid May Offer Liability Protection for a Bad Obstetrical Outcome: Results of Mock Trials*, 46 J.L. MED. & ETHICS 967, 967 (2018).

121. *Id.* at 972.

122. *Id.*

123. However, the protective value of a PDA might be less if it fails to satisfy generally accepted criteria for validity, such as the International Patient Decision Aid Standards (IPDAS). See Pope, *supra* note 5, at 25-29; Faisal M. Merchant et al., *Mandatory Shared Decision Making by the Centers for Medicare & Medicaid Services for Cardiovascular Procedures and Other Tests*, 320 JAMA 641 (2018).

124. *Texas Medical Disclosure Panel*, TEX. HEALTH & HUM. SERVS., <https://hhs.texas.gov/doing-business-hhs/provider-portals/health-care-facilities-regulation/texas-medical-disclosure-panel> [<https://perma.cc/299V-FT9J>] (last visited Dec. 23, 2021).

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 patients). The TMDP is also charged with establishing the general form and substance of such disclosure.<sup>125</sup>

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.<sup>126</sup> 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 both “in the form and to the degree required by” the TMDP.<sup>127</sup> Therefore, in obtaining consent for a specified procedure, the provider should both disclose the risks identified by the TMDP for that procedure and use the TMDP consent form.

In a health care liability claim by a patient against a Texas provider alleging negligent failure to disclose the risks of a medical treatment, if the provider disclosed the risks identified by the TMDP, then there is a rebuttable presumption that the provider was not negligent.<sup>128</sup> The patient then has the heavy burden of presenting 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.<sup>129</sup>

This rule looks like the Washington State presumption of compliance. But there is an important difference. Washington offers a shield but no sword. The Washington statute provides: “[f]ailure 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.”<sup>130</sup>

In contrast, Texas adds a sword. If a Texas provider either fails to disclose the specific risks and hazards identified by the TMDP or fails to use the TMDP 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.<sup>131</sup>

While the TMDP disclosure forms are now dense text documents, the TMDP may replace its current requirements with PDAs.<sup>132</sup> At that point, failure to use a PDA will increase the Texas clinician’s risk of liability for negligent nondisclosure. Furthermore, PDA mandates will extend beyond Texas because other states also have mandated disclosures. Those states may also evolve to require PDAs instead of standardized written information.<sup>133</sup>

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125. TEX. CIV. PRAC. & REM. CODE §§ 74.101-74.107 (West 2021); 25 TEX. ADMIN. CODE §§ 601.1-601.8 (2021).

126. TEX. CIV. PRAC. & REM. CODE ANN. § 74.106 (West 2021).

127. *Id.* § 74.105.

128. *Id.* § 74.106.

129. *Id.* § 74.106(a)(1)-(2).

130. WASH. REV. CODE § 7.70.060(5) (2021) (emphasis added).

131. TEX. CIV. PRAC. & REM. CODE ANN. § 74.106(a)(1)-(2) (West 2021).

132. The TDMP has been developing, updating, and publishing more forms. 44 Tex. Reg. 3129 (June 21, 2019) (amending 25 TEX. ADMIN. CODE §§ 601.4, 601.8).

133. See Pope, *supra* note 5, at 24-25.

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

While Texas may establish presumptive negligence for failing to use a PDA, such failure may be negligent in dozens of other states even without explicit statutory rules. The yardstick with which courts measure the scope and extent of informed consent duties varies from state to state. Most states follow either of two dominant disclosure standards.<sup>134</sup> Approximately twenty-five states follow the malpractice (aka “physician-based,” “professional,” or “custom-based”) standard.<sup>135</sup> The other twenty-five states follow the material risk (aka “patient-based” or “lay”) standard.<sup>136</sup> There is likely now a duty to use PDAs 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 sets the standard.<sup>137</sup> While a minority of states set geographic limitations, in most states, a physician must disclose the same information that a reasonable physician in the United States would disclose under the same circumstances.<sup>138</sup> Because most physicians do not use PDAs with their patients, there is no duty to do so.<sup>139</sup> The absence of a custom and practice means the absence of a legal duty.

**Material Risk Standard.** But the analysis is very different in the other half of the states. While the malpractice standard is physician-defined, the material risk standard is patient-defined. It requires physicians to provide all of the information that a hypothetical reasonable patient would consider important or significant in making a treatment decision.<sup>140</sup> This disclosure duty is broader than the malpractice standard and increases the burden on physicians.<sup>141</sup>

After all, a reasonable patient may deem information material even if the medical profession does not customarily discuss that information. For example,

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134. FAY A. ROZOVSKY, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* § 2.02 (5th ed. 2020); Pope, *supra* note 5, at 15.

135. Jaime S. King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 430 (2006) (including an appendix of state informed consent laws); see also David M. Studdert et al., *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks*, 4 J. EMPIRICAL LEGAL STUD. 103 (2007); W.G. Cobb, *Defending the Informed Consent Case*, 72 DEF. COUNS. J. 330 (2005).

136. King & Moulton, *supra* note 135, at 430.

137. Arthur R. Derse, *Flying Too Close to the Sun: Lessons Learned from the Judicial Expansion of the Objective Patient Standard for Informed Consent in Wisconsin*, 45 J.L. MED. ETHICS 51, 57 (2017).

138. Michelle Huckaby Lewis et al., *The Locality Rule and the Physician's Dilemma Local Medical Practices vs the National Standard of Care*, 297 JAMA 2633, 2634 (2007); Marc D. Ginsberg, *The Locality Rule Lives! Why? Using Modern Medicine to Eradicate an Unhealthy Law*, 61 DRAKE L. REV. 321, 323-24 (2013).

139. See *infra* Section I.C (showing limited uptake of PDAs). This could change if the incentive works. For example, Washington follows a statewide standard of care. If enough Washington clinicians follow the incentives in the law, the standard of care could evolve to impose a duty on clinicians not directly affected by the statute.

140. See Pope, *supra* note 5, at 15.

141. See *Canterbury v. Spence*, 464 F.2d. 772, 782-83 (D.C. Cir. 1972) (rejecting the malpractice standard as too protective of physicians and not sufficiently protective of patients); WIS. MED. EXAMINING BD., CR 14-040, ORDER OF THE MEDICAL BOARD ADOPTING RULES (2015) (observing that the malpractice standard is “not as broad as” the reasonable patient standard and “lessens the burden on physicians”).

physicians do not ordinarily disclose the limits of their experience. But a reasonable patient may find such information important.<sup>142</sup> Given the compelling evidence on PDA effectiveness, it is likely that a reasonable patient would want to know about such an educational tool. Consequently, there may be a duty to use it.<sup>143</sup>

#### *D. Lower Risk through Better Documentation*

In addition to the liability-reducing benefits of obtaining shields and avoiding swords, PDAs offer yet another liability-reducing benefit: better documentation. Documenting informed consent using paper forms exposes providers to the risk of missing forms, improper documentation, and associated liabilities. One study found missing consent forms in 66% of procedures.<sup>144</sup> The lack of contemporaneous documentation materially increases the risk of liability.<sup>145</sup>

PDAs improve documentation because potential plaintiffs and jurors can see not only *what* information was presented to the patient but also *how* it was presented.<sup>146</sup> Moreover, some online PDAs track user behavior so that there is a detailed record of what time the patient logged on, how long she spent in the site, and where she clicked.<sup>147</sup>

In sum, PDAs help establish that the clinician satisfied the basic requirement of informed consent: disclosure of key risks, benefits, and alternatives. Indeed, the evidence supports an even stronger conclusion. PDAs serve as compelling (and often nearly dispositive) evidence that a clinician satisfied her duties of informed consent. But that is only one liability-reducing benefit. PDAs also reduce liability risk from other types of medical malpractice claims.

#### IV. PDAS ALSO REDUCE LIABILITY RISK FROM OTHER TYPES OF MEDICAL MALPRACTICE CLAIMS

While PDAs can most obviously mitigate liability from negligent nondisclosure, they can also mitigate liability from most other types of medical malpractice claims—from misdiagnosis to administration of incorrect medications. They do this in two ways. First, PDAs result in better outcomes, and patients with better outcomes

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142. Thaddeus Mason Pope, *Full Disclosure: What Oncologists Must Tell Patients about Their Experience and Training*, ASCO POST (Apr. 10, 2019), <https://ascopost.com/issues/april-10-2019/full-disclosure-what-oncologists-must-tell-patients-about-their-experience-and-training/> [<https://perma.cc/2HZE-FPY3>].

143. Admittedly, the focus of informed consent litigation is typically on the content rather than on how effectively it is conveyed. *But cf.* *Mordel v. Royal Berkshire NHS Found. Tr.*, [2019] EWHC 2591 (QB) (85, 87) (requiring clinicians to present information in a way the patient can understand).

144. Jacqueline M. Garonzik-Wang et al., *Missing Consent Forms in the Preoperative Area: A Single-Center Assessment of the Scope of the Problem and Its Downstream Effects*, 148 JAMA SURGERY 886, 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 Gynecologists*, 24 J. MINIMALLY INVASIVE GYNECOLOGY 727 (2017).

145. See Brodney, *supra* note 120, at 969-70.

146. See, e.g., *Emmi Patient Engagement*, WOLTERS KLUWER, <https://www.wolterskluwer.com/en/solutions/emmi> [<https://perma.cc/TCJ3-Y7GE>]. This was key in the two mock juror studies described above. See *supra* notes 114-123 and accompanying text.

147. See, e.g., *Emmi Patient Engagement*, *supra* note 146.



bring fewer claims.<sup>148</sup> Second, PDAs result in more satisfied patients, and satisfied patients bring fewer claims.<sup>149</sup> This is important because medical liability insurers face significant liability risk from medical malpractice claims.

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

The national cost of the medical liability system is almost \$56 billion annually.<sup>150</sup> Much of this is borne by medical malpractice insurers, including \$5.7 billion in indemnity payments, \$1.1 billion in defense costs, and \$1.1 billion in risk management.<sup>151</sup> These costs have been dropping over the past few years.<sup>152</sup> But they are still enormous, and there is significant room for improvement.

#### *B. PDAs Result in Better Outcomes and Fewer Claims*

The most notable liability-mitigating benefit of PDAs is the fact that they can prevent patients from getting injured in the first place. Expectedly, patients with good outcomes do not file claims. PDAs produce better outcomes for two reasons. First, they increase the rate of patient adherence and compliance.<sup>153</sup> Second, they lead patients to less aggressive interventions with fewer risks and complications.<sup>154</sup>

##### *1. Greater Adherence Leads to Better Outcomes*

Patient nonadherence to prescribed regimens is a common problem encountered by physicians in all specialties.<sup>155</sup> Nonadherence adversely impacts the effectiveness of the treatment and materially increases the chance of a bad outcome.<sup>156</sup> Indeed, “[i]n some disease conditions, more than 40% of patients sustain significant risks by misunderstanding, forgetting, or ignoring healthcare advice.”<sup>157</sup>

148. See *infra* Section V.B.

149. See *infra* Section V.C.

150. Michelle M. Mello et al., *National Costs of the Medical Liability System*, 29 HEALTH AFFS. 1569, 1569 (2010).

151. *Id.* at 1570-71.

152. ROBERT LOWES, MALPRACTICE PREMIUM TRENDS BELIE MALPRACTICE CRISIS 7 (2017) (reporting annual premium survey by Medical Liability Monitor); Philip G. Peters Jr., *On the Cusp of the Next Medical Malpractice Insurance Crisis* (U. Mo. Sch. L. Legal Stud., Research Paper No. 2021-07, 2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3842533](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3842533) [<https://perma.cc/SV9L-BVGW>].

153. See *infra* Section V.B.1.

154. See *infra* Section V.B.2.

155. See generally EDUARDO SABATÉ, WORLD HEALTH ORG., ADHERENCE TO LONG-TERM THERAPIES: EVIDENCE FOR ACTION (2003); Laura J. Anderson et al., *A Systematic Overview of Systematic Reviews Evaluating Medication Adherence Interventions*, 77 AM. J. HEALTH SYS. PHARMACY 138 (2020).

156. See generally Meaghann S. Weaver et al., *A Practical Approach to Reporting Treatment Abandonment in Pediatric Chronic Conditions*, 62 PEDIATRIC BLOOD CANCER 565 (2015) (finding that treatment abandonment—the failure to complete therapy that is required for definitive disease control—frequently causes treatment failure).

157. Leslie R. Martin et al., *The Challenge of Patient Adherence*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 189, 189 (2005); see also Meera Viswanathan et al., *Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review*, 157 ANNALS INTERNAL MED. 785, 785 (2012) (estimating that medication nonadherence causes 125,000 deaths annually).

For example, clinicians treating patients with epilepsy note that non-adherent patients report more difficulty in attaining seizure control compared to adherent patients.<sup>158</sup> These “[u]ncontrolled seizures lead to major morbidity and mortality, including not only physical injury, such as head trauma, fractures and burns, but also psychosocial problems, such as depression, anxiety disorders, decreased quality of life, and sudden unexpected death.”<sup>159</sup>

Patients must understand what they are supposed to do before they can follow medical recommendations. Growing evidence shows that PDAs can help.<sup>160</sup> For example, in a Mayo Clinic study, diabetes patients who were offered a PDA called Statin Choice were better informed and were more likely to adhere to their drug regimens.<sup>161</sup> The PDA improved the accuracy of patients’ estimates of cardiovascular risk without statin therapy.<sup>162</sup> It improved their knowledge about statins and the potential relative merits of statin therapy. The PDA improved the accuracy of patients’ estimates of absolute cardiovascular risk reduction with statin therapy.<sup>163</sup> Because these patients better understood the importance of compliance, they were more adherent.

Recognizing the advantages of PDAs, some leading liability insurers now advise that doctors give their patients supplemental materials. For example, one company advises that “[w]ritten and audiovisual materials for the patient to take home are a useful supplement to the informed consent discussion.”<sup>164</sup> This malpractice carrier explains that supplemental materials “are helpful because many patients cannot remember or explain to their families what they were told by their doctors.”<sup>165</sup> Indeed, some insurers include this at the top of their list of risk mitigation strategies.<sup>166</sup>

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158. Carla Maria Maluf Ferrari et al., *Factors Associated with Treatment Non-adherence in Patients with Epilepsy in Brazil*, 22 SEIZURE 384, 384 (2013).

159. *Id.*

160. See generally Carissa Bonner et al., *Online Decision Aids for Primary Cardiovascular Disease Prevention: Systematic Search, Evaluation of Quality and Suitability for Low Health Literacy Patients*, 9 BMJ OPEN 1, 2 (2019) (“Patient decision aids for CVD prevention have been shown to improve uptake and self-reported adherence to preventive interventions.”); Michael S. Blaiss et al., *Shared Decision Making for the Allergist*, 122 ANNALS ALLERGY, ASTHMA & IMMUNOLOGY 463 (2019); Amber E. Hoek et al., *Patient Discharge Instructions in the Emergency Department and Their Effects on Comprehension and Recall of Discharge Instructions: A Systematic Review and Meta-Analysis*, 75 ANNALS EMERGENCY MED. 435 (2019); cf. Martin et al., *supra* note 157, at 193; Tammy Hoffman et al., ‘What Happens if I do Nothing?’ A Systematic Review of the Inclusion and Quantitative Description of a ‘No Active Intervention’ Option in Patient Decision Aids, J. OF GEN. INTERNAL MED., Feb. 2, 2021.

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

162. *Id.* at 1080.

163. *Id.* (finding a nearly seven-fold better understanding).

164. THE DR.’S CO., WELCOME TO THE DOCTOR’S COMPANY: A SERVICE AND PATIENT SAFETY/RISK MANAGEMENT GUIDE FOR NEW MEMBERS 14 (2017).

165. *Id.*

166. See, e.g., *Medical Risk Management Tips for Physicians & Hospitals: Tip #9: Effective Communication with Patients*, MLMIC, <https://www.mlmic.com/why-mlmic/services-resources/risk-management-tips> [https://perma.cc/33L7-227D] (last visited Dec. 23, 2021).

In sum, PDAs increase patient adherence and compliance, in turn, decreasing the risk of bad outcomes. Fewer bad outcomes mean fewer claims. PDAs reduce medical malpractice liability because they improve patient safety.

## *2. Less Aggressive Interventions Pose Fewer Risks*

Better adherence is not the only reason that using PDAs results in better outcomes. Many patients choose aggressive procedures that have significant risks and side effects. PDAs show patients that these procedures often offer limited benefits to outweigh these risks and side effects. Consequently, patients using PDAs often elect to be treated with less aggressive interventions that pose fewer risks.<sup>167</sup>

PDAs deter patients from electing low benefit interventions like some surgeries. They may even deter patients from electing moderate benefit interventions when those patients judge the risks to be unacceptable. Because the alternative treatment pathway for these patients (like watch and wait) usually entails fewer risks, these patients are less likely to suffer injuries that would prompt a claim.

### *C. PDAs Result in More Satisfied Patients Who Are Less Likely to Make Malpractice Claims*

While prevention is the best medicine, sometimes patients will suffer iatrogenic injuries. It is widely understood that only a small subset of negligently injured patients file claims.<sup>168</sup> Still, that volume of claims presents significant risk to healthcare malpractice carriers. But even here, PDAs can reduce liability risk by

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167. See David Arterburn et al., *Introducing Decision Aids at Group Health Was Linked to Sharply Lower Hip and Knee Surgery Rates and Costs*, 31 HEALTH AFFS. 2094 (2012); Andrew D. M. Kennedy et al., *Effects of Decision Aids for Menorrhagia on Treatment Choices, Health Outcomes, and Costs: A Randomized Controlled Trial*, 288 JAMA 2701 (2002); David Veroff et al., *Enhanced Support for Shared Decision Making Reduced Costs of Care for Patients with Preference-Sensitive Conditions*, 32 HEALTH AFFS. 285 (2013); Angelo E. Volandes et al., *Randomized Controlled Trial of a Video Decision Support Tool for Cardiopulmonary Resuscitation Decision Making in Advanced Cancer*, 31 J. CLINICAL ONCOLOGY 380 (2013); Angelo E. Volandes et al., *A Randomized Controlled Trial of a Goals-of-Care Video for Elderly Patients Admitted to Skilled Nursing Facilities*, 15 J. PALLIATIVE MED. 805 (2012); Jessica B. McCannon et al., *Augmenting Communication and Decision Making in the Intensive Care Unit with a Cardiopulmonary Resuscitation Video Decision Support Tool: A Temporal Intervention Study*, 15 J. PALLIATIVE MED. 1382 (2012); Areej El-Jawahri et al., *Use of Video to Facilitate End-of-Life Discussions with Patients with Cancer: A Randomized Controlled Trial*, 28 J. CLINICAL ONCOLOGY 305 (2010).

168. See *infra* notes 180-82. See generally Howard H. Hiatt et al., *A Study of Medical Injury and Medical Malpractice*, 321 NEW ENG. J. MED. 480 (1989); Wendy Levinson et al., *Physician-Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons*, 277 JAMA 553 (1997); Tamara Relis, *"It's Not About the Money!": A Theory on Misconceptions of Plaintiff's Litigation Aims*, 68 U. PITT. L. REV. 701 (2007); Charles Vincent et al., *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 LANCET 1609 (1994).

mitigating key factors that motivate claims.<sup>169</sup> PDAs can reduce claims both by setting realistic expectations and by minimizing surprise.<sup>170</sup>

Most patients who are injured from medical care do not make a claim.<sup>171</sup> Not even most injured patients who can prove negligence make a claim.<sup>172</sup> Only a very small percentage of negligent medical errors result in claims even when those errors cause injuries.<sup>173</sup> In just one of the many studies confirming this statistic, Harvard researchers used a sample of hospitalizations in New York to compare medical records to claims files.<sup>174</sup> This study suggested that only 1 in 7.6 hospital-based medical errors result in a malpractice claim.<sup>175</sup> Researchers made similar findings in Colorado and Utah.<sup>176</sup>

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*.<sup>177</sup> Commentators have long recognized communication failures as “an important source of malpractice litigation.”<sup>178</sup> After

169. See Rachel A. Lindor et al., *Liability and Informed Consent in the Context of Shared Decision Making*, 23 ACAD. EMERGENCY MED. 1428, 1432 (2016). *Contra* Marie-Anne Durand et al., *Can Shared Decision-Making Reduce Medical Malpractice Litigation? A Systematic Review*, 15 BIOMED CENT. HEALTH SERVS. RSCH. 167 (2015).

170. See Elizabeth M. Schoenfeld et al., *The Effect of Shared Decisionmaking on Patients' Likelihood of Filing a Complaint or Lawsuit: A Simulation Study*, 74 ANNALS EMERGENCY MED. 126 (2019) (finding that in the setting of an adverse outcome from a missed diagnosis, PDAs may affect patients' perceptions of fault and liability); *see also* Blaiss, *supra* note 160, at 465-66; Karina Dahl Steffensen, *The Promise of Shared Decision Making in Healthcare*, 9 AMS REV. 105, 106-07 (2019); *cf.* LESLIE KANE & DEBRA A. SHUTE, MEDSCAPE MALPRACTICE REPORT 2019 13 (2019) (emphasis added) (one of the top reasons doctors gave as to why they think malpractice lawsuits occur is that “[p]atients blame outcomes on doctors because they *don't understand* medical risks.”); Ziai et al., *supra* note 83, at 420 (“The low recall of procedural complications by patients is another potential risk that may place physicians in the harm of probable litigation.”).

171. *See generally* David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 254-55 (2000).

172. *Id.*

173. *Id.*

174. HARV. MED. PRAC. STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990).

175. A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, 325 NEW ENG. J. MED. 245, 248 (1991).

176. David M. 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, 1664 (2000).

177. *Cf.* Thomas McIlraith, *Cognitive, Emotional Memory Disconnect Impacts Patient Satisfaction*, HOSPITALIST (Sept. 2015), <https://www.the-hospitalist.org/hospitalist/article/122189/cognitive-emotional-memory-disconnect-impacts-patient-satisfaction?print=1> [<https://perma.cc/327P-4MQD>]; *see* FRANCIS A. FULLAM, THE LINK BETWEEN PATIENT SATISFACTION AND MALPRACTICE RISK (2009); Jill Wieber Lens, *Medical Paternalism, Stillbirth, & Blindsided Mothers*, 106 IOWA L. REV. 665, 715 (2021) (“[A] patient who is not blindsided may feel less urge to blame the doctor in the first place.”); *cf.* *Montgomery v. Lanarkshire Health Bd.* [2015] UKSC 11 [93] (noting that informed patients “may be less likely to encourage recriminations and litigation, in the event of an adverse outcome”); Elizabeth Kukura, *Obstetric Violence*, 106 GEO. L.J. 721, 772 (2018).

178. Anupam B. Jena, Editorial Commentary on Marc Colaco et al., *Influencing Factors Leading to Malpractice Litigation in Radical Prostatectomy*, 191 J. UROLOGY 1770, 1776 (2014); *see also* Beth Huntington & Nettie Kuhn, *Communication Gaffes: A Root Cause of Malpractice Claims*, 16 BAYLOR U. MED. CTR. PROC. 157, 157 (2003). Policymakers have devoted substantial attention to after injury

an adverse event, patients are more likely to sue when the reaction is: “how the hell could that happen?” They are less likely to sue when the reaction is: “things did not turn out as I had hoped, but I knew that was a risk.”

One notable study examined the factors that prompted families to file medical malpractice claims following perinatal injuries.<sup>179</sup> Half of the responding families reported that physicians attempted to mislead them.<sup>180</sup> Nearly 70% reported that physicians did not warn them about long-term neurodevelopmental problems.<sup>181</sup> Another study found that cancer patients may be *more* harmed by the divergence between pretreatment expectations and the toxicity of radiation than by the absolute severity of adverse effects.<sup>182</sup>

PDAs can mitigate the bad feelings that motivate claims because PDAs improve the quality of physician-patient communication.<sup>183</sup> If patients are well-informed of potential risks, then they are less surprised (or angry) when those risks later materialize.<sup>184</sup> PDAs “help to establish realistic expectations . . . and satisfied patients.”<sup>185</sup> Patients using PDAs have less decisional regret and take more ownership of their own decisions.<sup>186</sup> In short, better communication means lower liability exposure.<sup>187</sup>

At least one study has measured this directly.<sup>188</sup> As discussed, previous research findings consistently determine that poor communication about medical procedures

communication like “I’m Sorry” programs. See, e.g., Benjamin J. McMichael et al., *‘Sorry’ Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk*, 71 STAN. L. REV. 341 (2019). In contrast, PDAs improve communication before treatment.

179. Gerald B. Hickson et al., *Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267 JAMA 1359, 1361 (1992).

180. *Id.*

181. *Id.*

182. Narek Shaverdian et al., *Nationwide Survey of Patients’ Perspectives Regarding Their Radiation and Multidisciplinary Cancer Treatment Experiences*, 15 J. ONCOLOGY PRAC. 654, 657 (2020) (finding that “how actual adverse effects compare with expectations may be of greater impact to patients than the absolute severity of adverse effects”).

183. Cf. Philip J. Moore et al., *Medical Malpractice: The Effect of Doctor-Patient Relations on Medical Patient Perceptions and Malpractice Intentions*, 173 W.J. MED. 244 (2000); Evelyn M. Tenenbaum, *Using Informed Consent to Reduce Preventable Medical Errors*, 21 ANNALS HEALTH L. 11 (2012); Jody Lynée Madeira, *Terminating the Paper Trail: Evaluating the Efficacy of a Multimedia Informed Consent Application in Reproductive Medicine*, PETRIE-FLOM CTR. FOR HEALTH L. POL’Y, BIOTECHNOLOGY, & BIOETHICS HARV. L. SCH., [https://petrieflom.law.harvard.edu/assets/publications/Madeira\\_Terminating\\_Paper\\_Trail.pdf](https://petrieflom.law.harvard.edu/assets/publications/Madeira_Terminating_Paper_Trail.pdf) [<https://perma.cc/9JBP-7VDC>] (last visited Dec. 23, 2021).

184. See Ekblom, *supra* note 119 (“[P]oor communication, unrealistic expectations and lack of one-on-one risk discussions are common patterns for cases in suit.”). One leading insurer advises the following as a risk mitigation strategy: “[h]elp patients set reasonable expectations about outcomes by discussing the possibility of less-than-optimal results and complications that could delay recovery and affect appearance.” RANUM, *supra* note 87, at 14.

185. Murphy, *supra* note 88, at 2945.

186. See Dawn Stacey et al., *Implementation of a Patient Decision Aid for Men with Localized Prostate Cancer: Evaluation of Patient Outcomes and Practice Variation*, IMPLEMENTATION SCI., July 2, 2016 (explaining that PDAs help empower individuals and resolve decisional conflict).

187. Spiegel & Kavalier, *supra* note 82.

188. Søren Birkeland et al., *Does Greater Patient Involvement in Healthcare Decision-making Affect Malpractice Complaints? A Large Case Vignette Survey*, PLOS ONE (July 2, 2021), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0254052> [<https://perma.cc/D8DT-JMZ4>].

is a key predictor of patient complaints, compensation claims, and malpractice lawsuits. So, these researchers conducted an experimental case vignette survey to assess whether greater patient involvement would affect the inclination to complain.<sup>189</sup> They found that using PDAs reduced medical malpractice risk, concluding that “greater patient involvement in health care decision-making may indeed provide some protection against complaints, even when the outcome is poor.”<sup>190</sup>

In sum, there are three reasons that using PDAs should lower medical liability risk from claims other than negligent nondisclosure. First, patients will have better outcomes because PDAs help them be more compliant and adherent to the treatment plan. Second, patients will have better outcomes because they will choose less risky treatment options. Third, even when patients have adverse outcomes, they are less likely to have the surprise and anger that motivates claims.

#### CONCLUSION

Overwhelming evidence shows that PDAs hold enormous promise for improving the quality of informed consent. PDAs can reduce unwanted medical treatment and can help assure that care is value congruent, but too few clinicians use PDAs with their patients. To push clinicians to use PDAs, medical malpractice insurers should offer premium discount incentives. At least, they should pilot premium discounts where the potential is greatest. They should start with high-risk specialties like surgery, urology, and OB/GYN, and with procedures where quality (or even certified) PDAs are already available. These discounts will more than pay for themselves because PDAs materially reduce the risk of liability both from negligent nondisclosure claims and from other types of medical malpractice claims.

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189. *Id.*

190. *Id.*