Reimagining Informed Consent: From Disclosure to Comprehension

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Half a century ago, the legal doctrine of informed consent was presumably transformed in order to enshrine the ethical goals of ensuring autonomous, voluntary, and informed decision-making in medicine into law. The reasonable patient standard introduced in Canterbury v. Spence *and* Cobbs v. Grant *sought to center the patient by requiring that the physician disclose all information that a reasonable person in the patient's position would consider material to her decision-making. However, those efforts, while laudable, have proven inadequate to achieving the ethical principles they were intended to achieve.*

The legal doctrine of informed consent's focus on the adequacy of physician disclosures—both in documents and conversations—emphasizes ritual over relationships. It has proven to be both needlessly adversarial and backward-looking, leading physicians to assume more disclosure is better for the purposes of preventing liability. In effect, the law's onerous legal requirements necessitate overdisclosure at the expense of patient understanding, rendering it ineffective at actually informing voluntary decision-making. The objective reasonable person standard has proven inadequate in shifting the emphasis from physician disclosure to patient comprehension.

This Article introduces a new element to an informed consent claim: subjective patient understanding of the risks, benefits, and alternatives of the proposed intervention. This proposal transforms the standard for informed consent to emphasize patient comprehension and consent rather than solely focusing on physician disclosure in order to ensure the lofty ethical goals of clinical informed consent.

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INTRODUCTION

The legal doctrine of informed consent developed to serve the ethical goals of ensuring autonomous, voluntary, and informed decision-making in medicine. It represents one of the most widely accepted efforts to encapsulate ethical principles in law. The reasonable patient standard introduced fifty years ago in *Canterbury v. Spence* and *Cobbs v. Grant* sought to center the patient by requiring the physician to

disclose all information that a reasonable person in the patient's position would consider material to her decision making. However, those efforts, while laudable, have proven inadequate to achieve the ethical principles they were intended to realize.

As long as the legal doctrine of informed consent has existed, so, too, have arguments that it is ineffective in protecting patient self-determination. In particular, the doctrine's focus on the legal adequacy of physician disclosures—both in documents and conversations—emphasizes ritual over relationships. Informed consent forms often provide legally mandated information without regard to the usefulness of these forms in increasing patients' understanding.[1] In many circumstances, informed consent forms serve as surrogates for *process*—which ideally includes a discussion of the nature of the decision to be made—as physicians accused of failing to obtain informed consent routinely rely on a signed form to prove they did not breach their duty.

Consequently, the legal doctrine of informed consent is both needlessly adversarial and backward-looking, leading physicians to assume more disclosure is better for the purposes of preventing liability. This results in informed consent becoming a facet of defensive medicine.[2] In effect, the law's onerous legal requirements necessitate overdisclosure at the expense of patient understanding,[3] rendering the legal doctrine ineffective at actually informing voluntary decision-making.[4] The objective reasonable person standard has proven inadequate in shifting the emphasis from physician disclosure to patient comprehension.[5]

This Article introduces a new element to an informed consent claim: subjective patient understanding of the risks, benefits, and alternatives of the proposed intervention. This proposal transforms the standard for informed consent to emphasize patient comprehension and consent, rather than solely focusing on physician disclosure. This approach represents a dramatic change to the common law and medical practice, the latter of which has conformed to the disclosure-focused approach in doctor-patient interactions mandated by the law. While it may be argued that a standard that focuses on consent rather than information is prohibitively inefficient compared to the current approach, this Article's proposal

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1. Yael Y. Schenker, Alicia Fernandez, Rebecca Sudore & Dean Schillinger, *Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: A Systematic Review*, 31 MED. DECISION MAKING 151, 152 (2011).

2. Patients perceive informed consent documents as legal protection for physicians as well. *See* Barrie R. Cassileth, Robert V. Zupkis, Katherine Sutton-Smith & Vicki March, *Informed Consent — Why Are Its Goals Imperfectly Realized?*, 302 NEW ENG. J. MED. 896, 899 (1980).

3. *See, e.g.*, Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 477–79 (2006).

4. For example, a study of over thirty-five hundred clinical decisions found that only 9.0% met criteria for informed decision-making. Clarence H. Braddock III, Kelly A. Edwards, Nicole M. Hasenberg, Tracy L. Laidley & Wendy Levinson, *Informed Decision Making in Outpatient Practice: Time to Get Back to Basics*, 282 JAMA 2313, 2313 (1999).

5. King & Moulton, *supra* note 3, at 446, 451–52 (this lack of uniformity in what patients—even reasonable patients—would want (or need) to know to make medical decisions "challenges the validity of an objective patient-based standard and the notion of the 'reasonable' patient").

will result in legal precedent that more accurately tracks the lofty ethical goals of clinical informed consent.

The Article proceeds in four parts: Part I explores the history and rationale behind the legal doctrine of informed consent to treatment and the introduction of the reasonable person standard. Part II analyzes the failure of the doctrine to achieve those goals. Building on medical and scientific research on patient comprehension and health literacy, Part III argues for a legal doctrine of informed consent that emphasizes comprehension over disclosures in order to realize the ethical promise of informed consent by ensuring that patients' decisions are voluntary and autonomous. Finally, Part IV considers next steps, including contemporary approaches and obstacles to measuring and ensuring comprehension. It explores a legislative approach to including a comprehension element in a claim for informed consent and concludes with a consideration of other levers to ensure patient understanding.

I. INFORMED CONSENT

A. Ethical Goals

Informed consent is considered to be fundamental to medical decision-making. The ethical conception of informed consent evolved to ensure patient self-determination and voluntary decision-making. It is premised on the notion that patients do not relinquish their rights when they enter a hospital or physician's office, and it is intended to foster trust within the physician-patient relationship.

However, informed consent did not always occupy its current position of primacy. Of the three key principles underlying medical ethics—beneficence, respect for persons, and justice[6]—the practice of medicine gave particular weight to beneficence until the middle of the twentieth century.[7] The doctor's decisions were driven by the ethical principle of nonmaleficence—the foundational value often claimed to have been enunciated in the Hippocratic Oath, which required him to "above all, do no harm" to the patient.[8] Doctors knew best, and they often made decisions for their patients without any input from those patients—or even without informing them of what they were doing.[9] Thus, until the middle of the twentieth century, the medical profession was "viewed as a typical example of a patriarchal system."[10]

But over the last century, the doctrine of informed consent has evolved, driven by the principle of respect for persons, as expressed through deference to patient

6. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 13 (7th ed. 2013). Many scholars consider beneficence and its corollary nonmaleficence to be two sides of the same coin. Others have laid out four key principles: beneficence, nonmaleficence, respect for persons, and justice.

7. *Id.*

8. Cedric M. Smith, Special Review/Commentary, *Origin and Uses of* Primum Non Nocere—*Above All, Do No Harm!*, 45 J. CLINICAL PHARMACOLOGY 371, 373, 375 (2005).

9. HOLLY FERNANDEZ LYNCH, CONFLICTS OF CONSCIENCE IN HEALTH CARE: AN INSTITUTIONAL COMPROMISE 21 (2008).

10. Felicity Goodyear-Smith & Stephen Buetow, *Power Issues in the Doctor-Patient Relationship*, 9 HEALTH CARE ANALYSIS 449, 450–51 (2001).

self-determination.[11] Professor Jon Merz nicely lays out four goals of the doctrine of informed consent:

> (1) an ethical goal, in which the law promotes patient autonomy; (2) a decision-making goal, in which the law promotes the ability of patients to make [rational] medical decisions; (3) a regulatory goal, in which the law attempts to control physicians' disclosure practices; and, (4) a compensatory goal, in which the common law functions as a mechanism to provide monetary compensation for injuries.[12]

Specifically, according to the American Medical Association, informed consent is the "process of . . . communication between . . . patient and physician [that] results in the patient's authorization or agreement to undergo a specific medical intervention."[13] The informed consent process intends to ensure autonomous, voluntary, and informed decision-making in medicine.[14]

However, despite the generally accepted notion that the ethical goal of informed consent is to respect and protect patient autonomy,[15] consent may have additional or adjunct purposes and functions. Philosophy Professor Daniel Brudney argues that consent is best thought of as a means of contributing to authentic decision-making.[16] And informed consent may serve other ethical goals, which include (but are not limited to) ensuring patient human being status, avoiding patient fraud or duress, encouraging physicians to make ethical decisions, ensuring patient rational decision-making, involving the public in medicine, and improving patient care.

B. The Legal Doctrine

The *legal* doctrine of informed consent evolved in order to protect and effectuate the goals of ethical medical decision-making. In effect, the law serves Professor Merz's third and fourth goals of informed consent. But because of this, it

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11. Megan S. Wright, *Resuscitating Consent*, 63 B.C. L. REV. 887, 896 (2022) ("[T]he development of the doctrine of *informed* consent is meant to promote patient self-determination.").

12. Jon F. Merz, *On a Decision-Making Paradigm of Medical Informed Consent*, 14 J. LEGAL MED. 231, 231 (1993); *See also* Gopal Sreenivasan, *Does Informed Consent to Research Require Comprehension?*, 362 LANCET 2016, 2016 (2003) ("The doctrine of informed consent is a cornerstone of ethical medicine, both in clinical and in research settings. It consists of two parts: a duty to obtain the voluntary agreement of patients or trial participants before treatment or enrolment; [sic] and a duty to disclose adequate information to the patient or participant before seeking this agreement.").

13. *Code of Medical Ethics Opinion 2.1.1: Informed Consent*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/informed-consent [https://perma.cc/6KRR-SRMN] (last visited Apr. 7. 2024).

14. Merz, *supra* note 12, at 238 ("The doctrine attempts to promote the autonomy interests of a patient, holding that a physician must disclose sufficient information to enable the patient to make decisions regarding the course his or her life is to take. The ethical model represents an attempt to discard the paternalistic approach to patient management, and its advocates are comfortable with using civil law to alter this relic of physician-patient relations.").

15. Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340 (1974).

16. Daniel Brudney, *Choosing for Another: Beyond Autonomy and Best Interests*, 39(2):31-7 HASTINGS CTR. REP. 31 (2009).

poorly—if at all—serves the first (and original) goal of the doctrine of informed consent: the ethical goal of ensuring voluntary informed decision-making in medicine.

1. The Evolution of the Legal Doctrine to Capture the Ethical Goals of Informed Consent

Before the second half of the twentieth century, courts relied upon the traditional intentional tort of battery to resolve cases involving failure to obtain consent in the treatment setting.[17] Patients alleged unauthorized physical contact; in other words, patients had to prove that the physician provided medical intervention without their consent, rather than that they would not have consented to the treatment if they had more complete information.[18] Battery focuses simply on consent; the patient just needs to agree to the procedure itself, but consent needn't be informed. Importantly, the tort of battery does not protect choices that do not involve physical touching.[19] For example, if a patient consented to an amputation of the left leg and the surgeon amputated the right leg by mistake, there is no consent and the surgeon has committed a battery on the patient.[20] Similarly, if a patient specifically told a surgeon not to excise a tumor if one were found during exploratory surgery, a surgeon who did remove the tumor commits a battery.

But in the mid-twentieth century, patients began asserting their autonomy by taking those who failed to disclose the risks, benefits, and alternatives of a proposed medical intervention to court.[21] Beginning in 1957 with *Salgo v. Leland Stanford Jr. University Board of Trustees*,[22] in which the court termed the phrase *informed* consent, the following decades witnessed a proliferation of litigation in which patients claimed that their physicians had an obligation to disclose the nature and risks of an intervention before providing it.[23] In recognizing the autonomy of patients, many courts decided that battery was not an appropriate cause of action for cases involving interventions that were performed with the patient's consent but without adequate disclosure of the risks, benefits, and alternatives to the agreed-upon intervention.[24] This shift from battery to informed consent negligence claims was intended to protect patient self-determination and represented a new standard

17. Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 223–24, 229 (1985).

18. *Id.* at 224–26.

19. Valerie Gutmann Koch, *A Private Right of Action for Informed Consent in Research*, 45 SETON HALL L. REV. 173, 179 (2015). This shift away from medical paternalism and toward patient-driven medicine has been described as "the historical transition from the regime of 'doctor is right' to 'patient has rights.'" *See* Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor Is Right" to "Patient Has Rights*," 50 SYRACUSE L. REV. 1243, 1243 (2000).

20. *See, e.g.*, Mohr v. Williams, 104 N.W. 12, 13 (Minn. 1905) (recognizing battery claim where physician decided to operate on left ear instead of right).

21. *See* Kurtz, *supra* note 19, at 1245.

22. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957).

23. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 778 (D.C. Cir. 1972); Cobbs v. Grant, 502 P.2d 1, 5 (Cal. 1972).

24. Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 319 (2002).

established by judges to address deficiencies in the medical standard of care.[25] The law established that informed consent "meant more than simply accepting or rejecting the doctor's decision; it meant the right for patients to make the decisions themselves."[26]

A claim of lack of informed consent requires the same elements required to establish a traditional negligence claim: (1) a duty of care to provide the plaintiff with adequate disclosure, (2) breach of that duty, (3) harm or injury to the plaintiff, and (4) a causal link between the injury and the breach of duty.[27] To meet the causation element, a plaintiff must show both decision-causation and injury-causation.[28] Importantly, almost every state applies an objective standard for proving causation, whereby the "patient must show that a reasonably prudent person in the patient's medical condition would not have chosen the procedure had he been fully informed."[29] Thus, "[t]he patient must show that (1) the breach of duty would cause a reasonable patient to consent to a medical procedure that he otherwise would have refused, and (2) the medical procedure caused the patient harm."[30]

Under a cause of action for failure to provide informed consent, failure to disclose the risks of a proposed medical intervention or therapy "may allow an individual to recover for harm arising from nondisclosure of information material to the individual's decision to agree to the intervention."[31] Thus, a patient may recover when she consented to the intervention itself but disclosure of the risks was

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25. Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 710–11 (2012) ("When the courts switched to a negligence cause of action, the concept of consent did not fit neatly into the doctrinal framework. For negligence, the plaintiff must prove that the defendant's breach of duty caused the plaintiff's injury. The breach of duty was the physician's failure to disclose sufficient information for the patient to make an informed choice. The only logical place to include some aspect of consent was within the causation element. The courts added this concept by requiring the plaintiff to show that the physician's breach of duty caused the patient to consent to the procedure when he otherwise would have refused. This causation requirement is known as decision-causation.").

26. Morris, *supra* note 24, at 319.

27. *See* JESSICA W. BERG, PAUL S. APPELBAUM, CHARLES W. LIDZ & LISA S. PARKER, INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 132–34 (2d ed. 2001).

28. Tenenbaum, *supra* note 25, at 709–10 (citing Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 562 n.36 (2000); R. Jason Richards, *How We Got Where We Are: A Look at Informed Consent in Colorado – Past, Present, and Future*, 26 N. ILL. U. L. REV. 69, 96 n.163 (2005) ("[There are] two links in the causal chain: first, that nondisclosure caused the patient to agree to a procedure which otherwise she would have declined ('decision causation'); second, that the procedure actually caused the patient's harm ('injury causation').").

29. Tenenbaum, *supra* note 25, at 697. "With *Canterbury*, a broad test for materiality is advanced (reasonable patient) and a narrower objective test for causation (what a reasonable patient would have chosen) preferred." George P. Smith, II., *The Vagaries of Informed Consent*, 1 IND. HEALTH L. REV. 111, 119 (2004).

30. Tenenbaum, *supra* note 25, at 711 (citing Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 562 n.36 (2000)). Moreover, in order to recover for failure to provide informed consent, it must be proven that the patient experienced actual (usually physical) injury. Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 753–74 (1986).

31. Koch, *supra* note 19, at 180.

insufficient.[32] Today, all U.S. jurisdictions have adopted some form of the doctrine of informed consent either by statutory enactment or judicial decision.[33] The last state to adopt the common law doctrine of informed consent was Georgia in 2000.[34]

2. The Reasonable Patient Standard

Until the early 1970s, courts followed the "community standard" of disclosure to resolve cases involving failure to provide informed consent. This standard required disclosure only of what physicians believed patients needed to know.[35] Consent was generally legally adequate as long as the patient had notice of the nature and scope of the proposed medical intervention: what the physician proposed and its probable result.[36] The community standard is one in which the scope of the doctor's duty to provide information is based on the custom of physicians practicing in the same or in a similar community using medical expert testimony.[37] When challenged in court, experts testified as to the appropriate extent of disclosure based

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32. *Id.*

33. *Id.* In general, jurisdictions where the doctrine of informed consent has been introduced by common law decisions have more extensive requirements concerning patient information and participation. *Id.* at 180 n.25. Most informed consent statutes were enacted after 1975 in response to the rise in medical malpractice litigation. *See id.* They bear indications of state medical society lobbying and often state that a signed consent is at least prima facie evidence of an adequately informed consent. *See, e.g.*, FLA. STAT. § 766.103 (2018) ("A consent which is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent."); GA. CODE ANN. § 31-9-6.1 (2012) ("If a consent to a diagnostic or surgical procedure is required to be obtained under this Code section and such consent discloses in general terms the information required in subsection (a) of this Code section, is duly evidenced in writing, and is signed by the patient or other person or persons authorized to consent pursuant to the terms of this chapter, then such consent shall be rebuttably presumed to be a valid consent."); IND. CODE § 34-18-12-2 (1999); LA. STAT. ANN. § 40:1299.40 (2004); ME. STAT. tit. 24, § 2905 (2013) ("A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized persons, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained through fraud, deception or misrepresentation of material fact."); NEV. REV. STAT. § 41A.110 (2017); N.C. GEN. STAT. § 90-21.13 (2018) ("A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception, or misrepresentation of a material fact."); OHIO REV. CODE ANN. § 2317.54 (West 2018) ("Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills all the requirements in divisions (A), (B), and (C) of this section, be presumed to be valid and effective . . . ."); UTAH CODE ANN. § 78B-3-406 (West 2009); WASH. REV. CODE § 7.70.060 (2012); *see also* Weisbard, *supra* note 30, at 752 n.10.

34. Ketchup v. Howard, 543 S.E.2d 371, 373 (Ga. Ct. App. 2000).

35. *See, e.g.*, Cobbs v. Grant, 502 P.2d 1, 10 (Cal. 1972).

36. *See* Jay Katz, *Informed Consent—a Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 146, 152 (1977).

37. *See generally* Charles L. Sprung & Bruce J. Winick, *Informed Consent in Theory and Practice: Legal and Medical Perspectives on the Informed Consent Doctrine and a Proposed Reconceptualization*, 17 CRITICAL CARE MED. 1346, 1347–48 (1989) (discussing the two standards that define a physician's duty to disclose). It has been argued that this standard encourages "disengaged monologues" on the part of the physician. Katz, *supra* note 36, at 146–47.

on professional standards.[38]

This paternalistic standard has been gradually replaced in a number of jurisdictions by a standard requiring disclosure of what the reasonable patient needs to know—thereby imposing a more affirmative disclosure duty on the physician.[39] This shift was demonstrated by the seminal 1972 cases *Canterbury v. Spence*[40] and *Cobbs v. Grant*,[41] which addressed the question of the legal adequacy of a patient's consent to medical treatment. These cases changed the prevailing rules for the duty to disclose, holding that the decision to accept or reject therapy is a personal decision and not a medical decision to be made by a doctor.[42] Thus, under this newer standard, doctors have a duty to disclose all information that is material to a reasoned decision by the patient to accept or reject the offered intervention.[43] Whether the information is "material" is determined by what a "reasonably prudent" person would deem material, including the degree and incidence of the risk of the proposed intervention, the available alternatives to the intervention, and the risks and benefits of no treatment at all.[44] The legal doctrine of informed consent notoriously relies on objective tests to assess both materiality and causation.[45]

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38. Katz, *supra* note 36, at 154.

39. *Id.* at 147–48.

40. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972). The Court of Appeals for the D.C. Circuit addressed the case of a nineteen-year-old patient with chronic back pain who underwent a laminectomy, which had an estimated 1% risk of paralysis. *Id.* at 776, 778. The physician requested phone and then written consent from the patient's mother but did not tell the patient of the risk due to the concern that it might discourage him from undergoing surgery. *Id.* at 777. At trial, the physician argued that he ought to be able to withhold information if it might deter the patient from accepting beneficial therapy, frighten the patient, delay convalescence, or impose a negative placebo effect. *Id.* at 778. When paralysis occurred, the patient sued. *Id.*

41. In *Cobbs*, the Supreme Court of California focused on the relative information disparity between the doctor and patient, stating, "[T]he patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the doctor that transcends arms-length transactions." Cobbs v. Grant, 502 P.2d at 9. In other words, patients need to know the risks because they bear them.

42. *See* Katz, *supra* note 36, at 154–55.

43. *See Canterbury*, 464 F.2d at 786–87 (if a "reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether to forego the proposed therapy" or to submit to it, those risks must be disclosed); *Cobbs*, 502 P.2d at 11. *See also* Marc Tunzi, David J. Satin & Philip G. Day, *The Consent Continuum: A New Model of Consent, Assent, and Nondissent for Primary Care*, 51 HASTINGS CTR. REP. 33, 34 (2021) (citing Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 VIRTUAL MENTOR 563 (2012); Erica S. Spatz, Harlan M. Krumholz & Benjamin W. Moulton, *The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making*, 315 AM. MED. ASS'N 2063 (2016); RUTH R. FADEN, TOM L. BEAUCHAMP & NANCY M.P. KING, A HISTORY AND THEORY OF INFORMED CONSENT (1986)).

44. *Canterbury*, 464 F.2d at 784, 787–88. The court "chooses the objective reasonable person test of causation in order to protect the duty-breaching physician from unwarranted liability. A subjective, 'this patient' test, we are told, would 'place . . . the physician in jeopardy of the patient's hindsight and bitterness." Morris, *supra* note 24, at 331 (citing *Canterbury*, 464 F.2d at 790–91).

45. Richard E. Shugrue & Kathryn Linstromberg, *The Practitioner's Guide to Informed Consent*, 24 CREIGHTON L. REV. 881, 914 (1991) ("[T]he analysis should be undertaken by use of an objective test. That is, the question is not what this particular patient would have done if there had been adequate disclosure, but what a reasonably prudent person in the patient's position would have done if adequately

Today, half of American jurisdictions accept the core point that a patient's need for information in order to effectuate self-determination requires a standard of disclosure established by law (the "reasonable patient" standard) rather than the community standard.[46] Despite the distinctions between the two standards, the basic disclosure requirements are the same regardless of jurisdiction.

II. THE LEGAL DOCTRINE OF INFORMED CONSENT IS FAILING PATIENTS

Since the establishment of the tort of lack of informed consent, scholars and clinicians have recognized its deficiencies. It has been called "a superficial charade rather than an autonomous choice,"[47] "a charade, a symbolic but contentless formality,"[48] and the "*bete noire* of the medical malpractice doctrine."[49] It has been accused of being both needlessly adversarial and backward-looking, resulting in the process of obtaining informed consent to treatment becoming a defensive endeavor.[50] Instead of focusing on informing patients and ensuring patient self-determination—the principles upon which *Canterbury* and other decisions were presumably based—the practice of obtaining informed consent to treatment is preoccupied with physician disclosures, in most cases with the intention of shielding health care professionals from litigation.[51] In other words, it is argued that the informed consent process in the medical context has been coopted by the legal community in an effort to protect health-care providers from liability, and it does not serve the lofty goal of ensuring a robust process to protect patients' decision making by guaranteeing that treatment decisions are voluntary and informed.[52]

Dr. Jay Katz distinguished between "the *legal* doctrine [of informed consent], as promulgated by judges, and the *idea* of informed consent, based on a commitment to individual self-determination."[53] Relying in part on Dr. Katz's work, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (Commission) conducted a study of informed consent, culminating in its 1982 report *Making Health Care Decisions*.[54] The report recognized the deep disconnect between the legal doctrine of informed consent and the presumed goals of the informed consent process.[55] In condemning the

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informed."). *See also* Tenenbaum, *supra* note 25.

46. *See* King & Moulton, *supra* note 3, at 430.

47. George J. Annas, *Informed Consent: Charade or Choice?*, 45 J.L. MED. & ETHICS 10, 11 (2017).

48. Capron, *supra* note 15, at 367.

49. Shugrue & Linstromberg, *supra* note 45, at 881 (emphasis added).

50. Weisbard, *supra* note 30, at 751.

51. *Id.* at 759, 762–63.

52. *Id.* at 762–63.

53. JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT xvi (1984).

54. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. AND BIOMED. AND BEHAV. RSCH., MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 10 (1982) [hereinafter PRESIDENT'S COMM'N], https://repository.library.georgetown.edu/bitstream/handle/10822/559354/making_health_care_decisions.pdf?sequence=1&isAllowed=y [https://perma.cc/BU59-EL4L].

55. *Id.* at 29, 31.

increasing legalism of discussion on informed consent, the Commission recognized that the law cannot be "the primary means of bringing about needed changes in attitudes and practices."[56] The Commission therefore concluded that although informed consent is "essentially an ethical imperative,"[57] actual patient consent bears little resemblance to legal doctrines and descriptions of informed consent.[58] The implication was that, without greater communication between patient and physician, the definition of informed consent would become a doctrine shaped retrospectively by judicial decisions.[59]

The Commission determined that the imposition of legal liability for medical informed consent resulted in the overprovisioning of information for the purpose of avoiding liability[60] and advocated that "[e]thically valid consent is a process of shared decision making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments."[61]

Since the Commission's report and Jay Katz's deep observations of the disconnect between the ethical and legal doctrines of informed consent, "a significant body of research has demonstrated that the ideal of informed consent rarely matches the reality of healthcare decision making."[62] Concerns persist over the legal doctrine of informed consent's ability to increase patient understanding and ensure voluntariness in medicine. Although the modern understanding of the doctrine seeks to dispose of the paternalistic "doctor knows best" approach to patient management and to give patients the right to individual self-determination,[63] scholars such as Professor William Sage opine, "Because of technical complexity, patient vulnerability, and the power of physicians to persuade, it is unclear whether informed consent represents true empowerment or merely the illusion of self-determination."[64] He continues, "[D]isclosure made defensively to gain protection from liability tends to be overly detailed and legalistic, based more on what has survived scrutiny in the past than on what would be useful to recipients."[65] Similarly, Professor Kayte Spector-Bagdady and colleagues express concern about the influence that the threat of liability has on the standard of care, concluding that the "[c]linicians' fear of litigation is a challenge to [the] ethical paradigm" underlying the "complex balance between the principles of beneficence and autonomy."[66] They

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56. Letter from Morris B. Abram to President Ronald Reagan (Oct. 21, 1982), *in* PRESIDENT'S COMM'N.

57. *Id.* at 2.

58. *Id.* at 2, 16–18, 29.

59. *Id.* at 29.

60. *Id.* at 71–72. *See also* Kurtz, *supra* note 19, at 1245. Moreover, as opposed to increasing patient understanding, the doctrine leads to disengaged monologues by physicians. Katz, *supra* note 36, at 139–40.

61. PRESIDENT'S COMM'N, *supra* note 54, at 2.

62. Wright, *supra* note 11, at 900.

63. PRESIDENT'S COMM'N, *supra* note 54, at 17, 36.

64. William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1705 n.8 (1999).

65. *Id.* at 1824.

66. Kayte Spector-Bagdady, Raymond De Vries, Lisa Hope Harris & Lisa Kane Low, *Stemming the Standard-of-Care Sprawl: Clinical Self-Interest and the Case of Electronic Fetal Monitoring*, 47

recognize that "[c]linicians reasonably want to protect themselves against claims of liability, but whether there is an ethical way to do so is unclear."[67]

Others have also studied the apparent disconnect between the doctrine of informed consent in theory and the application of informed consent in practice. Professor Grant Morris has concluded that the law has become "a willing accomplice" to the subversion of informed consent.[68] Professor Peter Schuck surveyed empirical studies and concluded that "most physician-patient discussions appear to be rather perfunctory and reinforce physician control."[69] He observed that physicians avoid interactive, open-ended dialogue and concluded that "informed consent law in action is often ritualistic, formalistic, and hollow."[70] In 1988, Professor Cathy Jones spent six months as an observer in a 900-bed medical center. She concluded that under the status quo, "[p]atients are not protected; physicians are burdened with requirements that mean little; the law and society's principles concerning individual autonomy and decision-making are effectuated in name only."[71] After recognizing the significant shortcomings of the legal doctrine of informed consent, Professor Jones asks, "[D]espite difficulty and cost, do we try to comply in a better, more effective way with not only the technical requirements of the informed consent doctrine, but with the doctrine's spirit as well?"[72]

It is often argued that because the legal doctrine of medical informed consent sets the floor for ethical behavior, physicians may only disclose the minimum that the law requires.[73] The threat of liability may lead physicians to overfocus on avoiding it, resulting in the neglect of the process of medical informed consent to facilitate discussion and understanding.[74] John Lantos has observed that the focus on legal compliance, rather than ensuring medical self-determination for patients, may be demonstrated by the fact that "more articles on informed consent are cross-

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HASTINGS CTR. REP. 16, 16 (2017).

67. *Id.* at 19.

68. Morris, *supra* note 24, at 316.

69. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 932–33 (1994).

70. *Id.* at 933–34.

71. Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 427 (1990).

72. *Id.*

73. Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 245, 273–75 (2000).

74. *Id.* at 273–74. And the actual process of informed consent suffers for it. In a study of the practice of informed consent in clinical medicine, Marc Tunzi and colleagues found it to be "both inconsistent and inadequate." Tunzi et al., *supra* note 43, at 33. In her research, Professor Jones concludes,

> The procedures for informed consent are fraught with difficulties—objective difficulties based on the complexity of the information which should be provided and the patients' intellectual and psychological abilities to comprehend the information, and subjective difficulties based upon physicians' own biases and values. And it may be generally true that patients under the current informed consent system do not understand or remember what they are told, that testing patients' understanding of the information provided is resource intensive, that patients want physicians to make decisions for them, and that physicians can persuade patients to do whatever physicians believe best in any event.

Jones, *supra* note 71, at 427.

referenced under 'risk-management' than under 'patient autonomy' or 'ethics.'"[75]

By emphasizing ritual over relationships, the imposition of legal liability on the informed consent process may, therefore, contribute to the deterioration of the doctor-patient relationship. As Peter Angelos, a surgeon at the University of Chicago, has explained, in the surgical context, "[t]he informed consent process today . . . may . . . not adequately acknowledge the importance of trust in the surgeon that surgical informed consent requires."[76]

A. The Legal Doctrine of Informed Consent Focuses Almost Solely on Disclosures

Despite the ethical goal of securing informed, autonomous decision-making, the legal doctrine of informed consent focuses almost exclusively on physician disclosures at the expense of ensuring that patients actually understand the risks, benefits, and alternatives that are being disclosed to them.[77] Many argue that the law's onerous legal requirements necessitate overdisclosure rather than comprehension and trust in the doctor-patient relationship.[78] As one group of scholars laments, "Current consent processes may strike a less than ideal balance between comprehensiveness and comprehensibility."[79] Generally, doctors assume more disclosure is better for the purposes of preventing liability, but they give little thought to what patients are actually getting out of those disclosures.[80]

As Professor Alan Meisel has explained, "The case law, by and large, stands only for the right to recover for bodily harm occasioned by a doctor's failure to warn about risks,"[81] and not for failure to ensure patient comprehension of those

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75. John Lantos, *Informed Consent: The Whole Truth for Patients?*, 72 CANCER 2811, 2813 (1993).

76. Kinga B. Skowron & Peter Angelos, *Surgical Informed Consent Revisited: Time to Revise the Routine?*, 41 WORLD J. SURGERY 1, 2 (2017).

77. James F. Childress & Marcia Day Childress, *What Does the Evolution from Informed Consent to Shared Decision Making Teach Us About Authority in Health Care?*, 22 AM. MED. ASS'N J. ETHICS 423, 423 (2020) ("[I]nformed consent as a legal doctrine focused almost exclusively on the physician's disclosure of information rather than on the patient's understanding of that information."). This emphasis on disclosures is rooted in the hope that provision of information will lead to patient comprehension of that information. *See* Sreenivasan, *supra* note 12, at 2016. *See also* Matthew E. Falagas, Ioanna P. Korbila, Konstantina P. Giannopoulou, Barbara K. Kondilis & George Peppas, *Informed Consent: How Much and What do Patients Understand?*, 198 AM. J. SURGERY 420, 420 (2009) ("Appropriate information given to a competent individual will promote understanding and, in this regard, sensible decision making without coercion.").

78. King & Moulton, *supra* note 3, at 483.

79. Danya F. Vears, Pascal Borry, Julian Savulescu & Julian J. Koplin, *Old Challenges or New Issues? Genetic Health Professionals' Experiences Obtaining Informed Consent in Diagnostic Genomic Sequencing*, 12 AJOB EMPIRICAL BIOETHICS 12, 19 (2023).

80. In fact, even studies of patient comprehension in informed consent discussions "overwhelmingly focused on patient understanding of risks over other key elements of informed consent, suggesting the prioritization of malpractice risk reduction over enhancement of patient autonomy." Johanna Glaser, Sarah Nouri, Alicia Fernandez, Rebecca Sudore, Dean Schillinger, Michele Klein-Fedyshin & Yael Schenker, *Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review*, 40(2) MED. DECISION MAKING 119, 120 (2020).

81. Alan Meisel, *A 'Dignitary Tort' as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 L., MED. & HEALTH CARE 210, 210 (1988).

risks in order to make an informed decision. In other words, "[c]ourts narrowly focus on the physician duty of disclosure while neglecting to investigate whether the patient understood the disclosure given their health literacy level."[82]

B. Canterbury *Fails*

The reasonable patient standard is inadequate to achieve the ethical principles of the doctrine of informed consent. Since the *Canterbury v. Spence* and *Cobbs v. Grant* decisions fifty years ago, there has been little change to or evolution of the law of informed consent.[83] In both scholarly and clinical analyses of the requirements of informed consent, the reasonable person standard enunciated in *Canterbury* and *Cobbs* has taken primacy. It has been recognized that, for better or worse, the law has shaped medical practice. The most recent draft of the Restatement Third of Torts appreciates "informed consent is an area where law notably has led, rather than followed, professional practice" and had a "pronounced influence . . . on foundational aspects of medical practice."[84] However, despite the fact that the reasonable patient standard sought to center the patient by requiring the physician to disclose all information that a reasonable person in the patient's position would consider material to her decision-making, it has proven inadequate in shifting the emphasis from physician disclosure to patient comprehension.[85]

The reasonable patient standard itself is inherently flawed because there is no uniformity in what patients want to know from their doctors.[86] Scholars have noted the lack of uniformity in what patients—even reasonable patients—would want to know from their physicians, which "challenges the validity of an objective patient-based standard and the notion of the 'reasonable' patient."[87]

The reasonable patient standard was intended to ameliorate many of the problems inherent to the professional standard by considering the needs of actual patients. Thus, many hoped that the new standard would force courts to consider whether patients actually comprehended the relevant medical information to an informed decision.[88] However, this has not been the case. As John Culhane and

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82. Jessica J. Flinn, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 379, 393 (2009).

83. JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 80 (1984) ("The law of informed consent has undergone little analytic development since Canterbury."). And, as discussed in Section II.B, all these changes have effectively been to the disclosure standard.

84. Restatement (Third) of Torts: Medical Malpractice, Reporters' Special Note to §§ 12 & 13 on Ethical Idealism versus Legal Pragmatism in Informed Consent Law (Tent. Drft. No. 1, May 2023).

85. King & Moulton, *supra* note 3, at 446, 451–52. *See also* Spatz et al., *supra* note 43, at 2063 ("Even in those states that apply the reasonable-patient standard, however, the informed consent process is often ill-configured to meet patients' informational needs.").

86. Spatz et al., *supra* note 43, at 2063.

87. King & Moulton, *supra* note 3, at 446.

88. *See* Childress & Childress, *supra* note 77, at 424 ("Critics attacked the virtually exclusive attention to health professionals' duty to disclose information, particularly as interpreted through a professional standard rather than a reasonable person standard or the subjective preferences of particular patients.").

colleagues observe, "[T]he American approach is itself flawed, too often sacrificing patient autonomy to the perceived need for an objective standard that will further both judicial management of the cases and, overall, more just outcomes."[89] The reality of the informed consent process after *Canterbury* and *Cobbs* is that disclosures have become more detailed and extensive. However, this has not resulted in more robust process, understanding, or consent. As Professors Meisel and Loren H. Roth observe,

> [I]nformed consent as envisioned by the courts is a relatively rare phenomenon in the clinical settings that we have examined. Patients receive information; consent forms get signed. But rarely do doctors sit down with patients and provide them with thorough explanations of treatment options and then seek their consent to one or another. Instead, information is often given to patients not to enable them to choose, but to encourage them to cooperate with doctors and to comply with decisions that have already been made, not by patients as law envisions, but by doctors."[90]

This is largely the fault of the legal doctrine of informed consent's prioritization of physician disclosures above all else. The uncertainty regarding the extent of required disclosures may lead physicians to over-provide information to avoid liability.[91] Despite the law's idealistic notions of the goals of informed consent in medicine, the doctrine's mandates focus on the provision of information, rather than process and comprehension. Without accurately gauging patient comprehension, "there may even be a difference between what a provider interprets as consent and what the patient experiences as expressions of doubt, concern, or passive acceptance."[92]

Furthermore, the tort of informed consent is not effective in benefiting patients. Due to its emphasis on disclosures—often to the point of overdisclosure—it does not make patient decision-making easier.[93] When informed consent becomes a defensive endeavor, physicians are inclined to provide any and all information, no matter how unlikely or inconsequential, in order to avoid being liable for failing to disclose those risks.[94]

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89. John G. Culhane, King-Jean Wu, Oluyomi Faparusi & Eric J. Juray, *Toward a Mature Doctrine of Informed Consent: Lessons from a Comparative Law Analysis*, 1 BRIT. J. AM. LEGAL STUD. 551, 579 (2012).

90. Alan Meisel & Loren H. Roth, *Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies*, 25 ARIZ. L. REV. 265, 334 (1983).

91. Sage, *supra* note 64, at 1824.

92. Elizabeth B. Cooper, *Testing for Genetic Traits: The Need for a New Legal Doctrine of Informed Consent*, 58 MD. L. REV. 346, 384–385 (1999) (citing Wilkerson v. Mid-America Cardiology, 908 S.W. 2d 691, 693–95, 700 (Mo. Ct. App. 1995) (noting the factual ambiguity as to whether a patient expressly or impliedly consented to angioplasty).

93. Michael K. Paasche-Orlow, Holly A. Taylor & Frederick L. Brancati, *Readability Standards for Informed-Consent Forms as Compared with Actual Readability*, 348 NEW ENG. J. MED. 721, 722 (2003).

94. Moreover, informed consent claims are difficult for patients to win. *Id.* Even in *Canterbury v. Spence*, 464 F.2d 772 the jury ultimately ruled against Jerry Canterbury.

C. Proposed Solutions Have Exclusively Focused on Disclosures

The medical and legal establishments have long understood that the original requirements of informed consent were not effective. However, efforts to improve the legal doctrine of informed consent have focused exclusively on expanding the content of disclosures. Over the last fifty years, copious amounts of legal decisions and scholarship—both within the legal academy and without—have been devoted to fixing the "disclosure problem." In other words, courts and scholars have continuously attempted to tweak, modify, and/or overhaul what a physician must disclose to a patient in order to ensure the informed consent requirements are adequate.[95]

Some states have attempted to expand the disclosure requirements in order to secure more effective informed consent. In *Arato v. Avedon*, the court addressed the duty of a physician to disclose statistical life expectancy information to a cancer patient and held that an informed consent for therapy need not include a disclosure of the patient's statistical life expectancy with or without therapy. [96] The court distinguished between the materiality of information concerning the mortality and morbidity inherent in the proposed intervention, which is a matter of fact for the jury to decide, and the mortality and morbidity inherent in the patient's disease.[97] The court implied that while life expectancy information may be material to an individual patient, the decision to disclose that information, at least when the patient does not request the information explicitly, is to be decided on the basis of professional community standards.[98] In *Faya v. Almaraz*, the court addressed the duty of an HIV-positive physician to disclose his status to his patients.[99] Based on these and similar cases, Professor Judith Daar has advocated for disclosure of information relevant "to the patient's medical treatment," including physician-specific information.[100]

Other courts have considered expanding disclosure requirements to include personal information about the physician. In *Johnson v. Kokemoor*, the Wisconsin Supreme Court expanded the reasonable patient standard. [101] The Supreme Court of Wisconsin held that evidence could be presented that the surgeon failed: (1) to divulge the extent of his experience in performing this type of operation; (2) to

95. Wright, *supra* note 11, at 891 ("[T]here has been a significant scholarly undertaking to change how providers disclose medical information so that patients can truly understand their healthcare options.").

96. Arato v. Avedon, 858 P.2d 598 (Cal. 1993).

97. *Id.* at 604–05.

98. *Id.* at 606–08.

99. Faya v. Almaraz, 620 A.2d 327, 328 (Md. 1993).

100. Judith F. Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 189 (1995) ("[C]arefully analyzed, these cases do create a strand of uniformity in disclosure requirements: If the physician possesses information which is or may be perceived as relating to the patient's medical treatment, the physician must disclose."). She continues, "[T]aken together, these disparate cases project a theory of informed consent which no longer focuses on the ability of patients to make informed choices about treatment, but rather assesses disclosure based on the nature of medical treatment offered and the characteristics of the physician offering the care." *Id.*

101. Johnson v. Kokemoor, 545 N.W. 2d 495 (1996).

compare the morbidity and mortality rates for this type of surgery among experienced surgeons and inexperienced surgeons like himself; and (3) to refer the plaintiff to a tertiary care center staffed by physicians more experienced in performing the same surgery.[102] In response to this and similar cases, the Wisconsin Hospital Association, the Wisconsin Medical Society, and the Wisconsin chapter of the American College of Emergency Physicians petitioned for a legislative remedy.[103] In 2013, the legislature revised the standard from the objective patient-centered standard back to the reasonable physician standard, so in that state, it reverted to the reasonable physician standard.[104]

In a comprehensive analysis of the expansion of informed consent disclosure requirements beyond purely medical information, Professor Nadia Sawicki explores efforts to require disclosure of information that "reflect modern understandings of how patients make medical decisions."[105] She identifies nonmedical information that may be material to a patient's decision-making, including the cost of treatment; physician-specific information about qualifications, health status, conflicts of interest, the social and ethical implications of various health-care interventions; and the legal consequences associated with diagnosis and treatment.[106]

In 1985, Professor Marjorie Shultz argued for a new tort to replace the doctrine of informed consent that would prioritize the patient's right to informed decision-making.[107] She recommended "the creation of a distinct and independently protected interest in patient autonomy."[108] Professor Shultz proposed that a "duty to disclose would be triggered by the possession of information important and relevant to the patient, rather than by a proposal to touch."[109] This proposal would potentially reduce the damages a plaintiff could recover but would also potentially have a sufficient deterrent effect on physicians who would otherwise withhold important information in the medical decision-making process.

However compelling her proposal was, it did not gain much traction with legislatures or courts.[110] And it notably focused on disclosures rather than comprehension, proposing a rule that would require physicians to disclose information that they possess that is relevant and important to the patient's

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102. *Id.* at 495.

103. 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(1) J. L. MED. ETHICS 51, 57 (2017).

104. WIS. STAT. § 448.30 (2013).

105. Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 UNIV. ILL. L. REV. 821 (2016).

106. *Id.* at 821.

107. Shultz, *supra* note 17, at 283.

108. *Id.* at 220.

109. *Id.* at 283–84.

110. Morris, *supra* note 24, at 343 ("Although Marjorie Shultz entitled her article: *From Informed Consent to Patient Choice: A New Protected Interest*, her prophesied development did not materialize. To the contrary, the law has not merely stagnated, it has regressed . . . . [T]he move has not been from informed consent to patient choice, but rather, from informed consent to uninformed acquiescence.").

decision.[111] Others have also proposed the establishment of a new dignitary tort that would address harms are "caused by conduct that overrides patients' autonomy, treats them as less than human, and denigrates them as human beings."[112] While proposals that emphasize patient autonomy have been powerful,[113] they still center around physician disclosure.

These proposed modifications to the disclosure requirements are intended to give patients more information that is presumably relevant to the patient's medical decision-making. However, they have not been effective at improving patient comprehension (nor are they necessarily intended to).[114] Despite efforts to expand and modify the categories of required disclosures during the informed consent process, in 1985 Professor Daar concluded that "[w]hether this expanded plate of information will actually enable patients to reach a more informed choice remains to be seen."[115] Almost 30 years later, it is clear that informed consent, with its ever-expanding disclosure requirements, has become overly formulaic and ineffective at achieving the ethical goals with which it is associated.

D. Emphasizing Disclosures Instead of Comprehension Undermines the Ethical Goals of Informed Consent

The primacy of disclosures in the law of informed consent undermines efforts to achieve the ethical goal of ensuring autonomous, informed medical decision-making. Prioritizing disclosure over comprehension results in emphasizing form over substance. Professor Megan Wright observes, "The scholarly focus on the 'informed' element of informed consent may elide failures with the legal requirement to obtain patient consent to medical treatment."[116] Informed consent has been characterized as "information dumping," which "[o]verload[s] the patient with information, thereby complying with the letter of the law but undermin[es] the

111. Shultz, *supra* note 17, at 284.

112. Dena S. Davis, *The Ambiguous Effects of Tort Law on Bioethics: The Case of Doctor-Patient Communications*, 21 J. CLINICAL ETHICS 264, 265 (2010). Similarly, despite frequent calls for the recognition of negligence claims allowing recovery for dignitary harms, American courts have generally been reluctant to allow such claims.

113. Professor E. Haavi Morreim notes, "Because standard informed consent doctrine usually limits recovery to cases featuring a physical or other separate injury, it can fail to honor human autonomy in cases where someone's right to choose has been abused without demonstrable physical damage." E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 73–74 (2003) (citing Joseph Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683, 691 (1975); Joan Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 265–66 (1999)); Nancy Levit, *Ethereal Torts*, 61 GEO. WASH. L. REV. 136, 150–151 (Shultz, *supra* note 17, at 291–92; Meisel, *supra* note 81, at 210–18; Morris, *supra* note 24, at 369; Weisbard, *supra* note 30, at 763.

114. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647 (2011).

115. Judith F. Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 208–09 (1995).

116. Wright, *supra* note 11, at 906.

idea of informed consent."[117]

The mandated disclosure requirements of the legal doctrine of informed consent do not serve the ethical goals underlying informed consent because (1) "doctors do not give patients the information that they would need to make educated decisions," (2) "good ways to communicate information have proved elusive. Forms used to provide information frequently exceed readability standards," (3) "even when doctors lavish information on patients, most patients neither understand nor remember it," and (4) "patients regularly make life-and-death decisions without even the most basic information and with many misconceptions."[118]

Scholars have analogized the informed consent process to the act of giving Miranda warnings in criminal procedure.[119] Professor Meisel has called informed consent a "medical *Miranda* warning in which risk disclosure substitutes for conversation."[120] Professors Meisel and Mark Kuczewski posit that these medical Miranda warnings diminish some patients' reliance on consent forms for medical disclosures and decision-making.[121] Physicians wrongly believe that a patient's signature satisfies the legal requirement of informed consent in the same way law enforcement agents only need to advise suspects of their constitutional rights to avoid lawsuits. Thus, the question of whether someone "consent[ed] the patient" is heard frequently in the medical setting, implying that "'consent' is something that is done to the patient, not something that the patient does."[122] In turn, the threat of legal liability for failure to ensure voluntary, informed consent has covered the physician-patient relationship with "bureaucratic red tape."

It is argued that "[l]ike warning labels generally, 'overdisclosure' makes it difficult for patients to distinguish meaningful risks from trivial ones," resulting in less comprehension.[123] The informed consent process is further diminished when physicians focus on documentation of disclosures via informed consent forms. Informed consent forms are notoriously unreadable, often providing information required under the law without considering the usefulness of these forms in

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117. Alan Meisel, *From Tragedy to Catastrophe: Lawyers and the Bureaucratization of Informed Consent*, 6 YALE J. HEALTH POL'Y L. & ETHICS 479, 482 (2006).

118. Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 667–68 (2011) (defining mandated disclosure as a "regulatory technique" that is expected to "improve decisions people make in their economic and social relationships and particularly to protect the naïve from the sophisticated").

119. Meisel, *supra* note 81, at 210–18 (1988) (addressing how courts have trivialized informed consent, "reducing it to little more than a medical *Miranda*-warning").

120. Meisel, *supra* note 117, at 482. He continues, "This converts an affirmative duty of doctors into a defense of assumption of risk against patients." *Id.*

121. Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 ARCHIVES INTERNAL MED. 2521, 2522 (1996); Victor Ali, Note, *Consent Forms as Part of the Informed Consent Process: Moving Away from "Medical Miranda"*, 54 HASTINGS L.J. 1575, 1578 (2003).

122. Scott, *supra* note 73, at 274.

123. Robin Fretwell Wilson, *The Promise of Informed Consent*, *in* THE OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 229 (I. Glenn Cohen, Allison K. Hoffman & William M. Sage eds., 2017).

increasing patients' comprehension.[124] In overproviding the risks and other information in an effort to meet legal disclosure requirements, informed consent forms may be poorly drafted, overly complicated, and inundated with detail.[125] Thus, the legal doctrine of informed consent may contribute to diminishing patient understanding, replacing the process of physician-patient dialogue with the ritual signing of a form that patients may not even trust or understand.[126]

As Professor Meisel explains, "[I]nstead of focusing on the goals that the requirement of obtaining informed consent sought to promote—patient self-determination, informed decision-making, and protection from harm chief among them—lawyers instead focused on *documenting* whether information had been disclosed, even if in fact it had not been."[127] Regardless of mandated disclosures, patients "are largely ignorant about the treatments they choose, along with the attendant risks and benefits."[128]

Likewise, Professor Wright observes,

> [T]he scholarly focus on autonomy and healthcare decision making largely has been on *information about* medical treatment, and much less about the issue of *consent* to medical treatment. Indeed, there is an assumption in the law, bioethics, and clinical literature that if a patient has complete information and understanding about a proposed medical intervention then the patient will choose the treatment their physician thinks in in their best interests.[129]

In effect, the act of physician disclosure coupled with a patient's signature on an informed consent form "does not assure genuine informed consent."[130] Professor Cathy Jones argues that the law has been unwilling to require that physicians give patients the opportunity to comprehend the information on which their decisions are based, resulting in a self-fulfilling prophecy that patients are not ultimately responsible for their medical decisions.[131] In the absence of comprehension, "[a]lthough the patient is likely to sign the form, one must question the nature and quality of her consent."[132]

Thus, in its current incarnation, the legal doctrine of informed consent fails to

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124. Schenker et al., *supra* note 1, at 152.

125. Paasche-Orlow et al., *supra* note 93, at 722.

126. Anne Sherlock & Sonya Brownie, *Patients' Recollection and Understanding of Informed Consent: A Literature Review*, 84 ANZ J. SURGERY 207, 209 (2014) ("A patient who signs a consent form without fully comprehending the intended procedure, complications and outcomes has not given an informed consent.").

127. Meisel, *supra* note 117, at 482, 483 (emphasis in original).

128. Wright, *supra* note 11, at 890.

129. *Id.* at 891 (emphasis in original) (citing BERG et al., *supra* note 27, at 227 ("[T]he term informed consent itself suggests that patients are expected to agree to be treated rather than to decline treatment.").

130. Scott Burris & Lawrence O. Gostin, *Genetic Screening from a Public Health Perspective: Some Lessons from the HIV Experience*, *in* GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 137, 140 (Mark A. Rothstein ed., 1997).

131. Jones, *supra* note 71.

132. Cooper, *supra* note 92, at 385.

ensure patient comprehension. Evidence indicates that pretherapeutic comprehension is already quite low.[133] Even when information is shared, recall is not very good.[134] In a study of almost one hundred patients scheduled for elective orthopedic surgery, researchers found that "[p]atient comprehension and recall immediately following a thorough discussion of the consent form was unexpectedly low."[135] Another study showed patients' recall of risks to be 26.5% twenty minutes after the informed consent process.[136] And in a third study, investigators found that the average patient only recalled 18% of disclosed risks of a particular intervention.[137] In a study on informed consent for cataract surgery, despite preoperative discussions and written information, 61% of patients did not know what a cataract was, yet they had consented to surgery and 43% misunderstood that surgery was completely risk-free.[138]

Moreover, there is evidence that patient recall and comprehension deteriorates from the time of consent to post-surgical visits, indicating that comprehension at the time of injury may not reflect the patient's comprehension when she consented to the intervention.[139] In a study of informed consent with patients admitted to a hospital for total joint replacement, the investigators concluded that "after an operation, patients' recollection are not reliable about the risks and benefits of the operation, despite preoperative instruction and tutoring."[140]

III. TOWARD A LEGAL DOCTRINE OF INFORMED CONSENT THAT EMPHASIZES COMPREHENSION

Fifty years after the courts laid out the reasonable patient standard for

133. Allison E. Crepeau, Bart I. McKinney, Maya Fox-Ryvicker, Jennifer Castelli, James Penna & Edward Wang, *Prospective Evaluation of Patient Comprehension of Informed Consent*, 93(19) J. BONE & JOINT SURGERY e114, e114(4)–e114(6) (2011).

134. Daniel E. Hall, Allan V. Prochazka & Aaron S. Fink, *Informed Consent for Clinical Treatment*, 184(5) CAN. MED. ASS'N J. 533, 534 (2012) ("Data repeatedly show that patients remember little of the information disclosed during the informed consent process and that their level of comprehension is often overestimated.").

135. Crepeau et al., *supra* note 133, at e114(1).

136. Mark Fleishman & Carlos Garcia, *Informed Consent in Dermatologic Surgery*, 29(9) DERMATOLOGICAL SURGERY 952, 953 (2003).

137. Wolfgang Krupp, Oliver Spanehl, Wilfried Laubach & V. Seifert, *Informed Consent in Neurosurgery: Patients' Recall of Preoperative Discussion*, 142 ACTA NEUROCHIRURGICA 233, 235 (2000).

138. Dennis Cheung & Soupramanien Sandramouli, *The Consent and Counselling of Patients for Cataract Surgery*, 19(9) EYE (LOND) 963, 969 (2005).

139. Crepeau et al., *supra* note 133, at e114(1) ("[P]oor recall deteriorated further between the preoperative visit and the first postoperative visit (a period of no more than two weeks)."). The authors conclude, "The perfect informed consent would require perfect comprehension at the time of signing. Furthermore, this comprehension would need to remain constant into the postoperative period." *Id.* at e114(7). *See also* George Robinson & Avraham Merav, *Informed Consent: Recall by Patients Tested Postoperatively*, 22(3) ANN. THORACIC SURG. 209 (1976) ("When tested for recall between 4 and 6 months following operation, 20 patients failed to remember accurately major portions of their informed consent interview.").

140. Melinda McDaniel Hutson & J. David Blaha, *Patients' Recall of Preoperative Instruction for Informed Consent for an Operation*, 73-A(2) J. BONE & JOINT SURGERY 160, 162 (1991).

informed consent in *Canterbury* and *Cobbs*, it is clear that the mandated disclosure framework of the legal doctrine of informed consent does not serve the intended purpose of respecting individual self-determination.[141] The inadequacy of the doctrine of informed consent to safeguard the very principle it is intended to protect supports arguments in favor of moving away from the doctrine toward a new approach.[142] As Professor Ellen Wright Clayton observes, "It is time to think more clearly about what we hope to achieve with informed consent."[143] However, despite repeated claims that patients should give "true" consent,[144] recommendations for how the law can ensure that consent is, in fact, "true" have been few and far between.

In effect, the law's onerous legal requirements necessitate overdisclosure at the expense of patient understanding, rendering the legal doctrine of informed consent ineffective at actually informing voluntary decision-making. Even though the legal doctrine of informed consent is one of the most widely accepted efforts to encapsulate ethical principles in law, studies have consistently shown that the results of efforts to increase patient understanding and self-determination are disappointing.[145]

Consequently, this Article does not attempt to reassess *what* should be disclosed; as explained in Part II, this has been the sole focus of (ineffective) efforts to fix the legal doctrine of informed consent. Rather, it proposes a shift away from the exclusive focus on physician disclosures and a shift toward a standard that emphasizes patient comprehension, in order to realize the ethical promise of informed consent by ensuring that patients' decisions are voluntary and autonomous.[146] The ethical practice of informed consent emphasizes

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141. While the goal of mandated disclosures is to assure comprehension, it is not effective in achieving that goal. *See* Sreenivasan, *supra* note 12, at 2017 ("Obviously, the point of disclosing information is to impart a certain grasp of the procedure or protocol in question. An aspiration to produce adequate comprehension is therefore inseparable from the requirement of disclosure. It does not follow, however, that success in producing comprehension is likewise required. The standard view confuses an ethical aspiration with a minimum ethical standard.").

142. In previous scholarship, I have explored an alternative approach to addressing the fact that the legal doctrine of informed consent does not serve its intended ethical goals: eliminating liability for informed consent to medical treatment. Valerie Gutmann Koch, *Eliminating Legal Liability for Informed Consent to Medical Treatment*, 53 U. RICH. L. REV. 1211 (2019). There, I evaluate the rationale and procedure for abolishing a common law private right of action for lack of informed consent, as well as potential alternatives to tort liability for failure of informed consent to medical treatment. The article concludes that the time has not come for a wholesale elimination of the private right of action for lack of informed consent to treatment. Abolishing liability for lack of informed consent in treatment would not only eliminate the deterrent effect for potential bad actors but would also remove recourse for those who have suffered harm due to a failure of informed consent.

143. Ellen Wright Clayton, *The Unbearable Requirement of Informed Consent*, 19 AM. J. BIOETHICS 19, 19 (2019).

144. *See, e.g.*, Cooper, *supra* note 92, at 382, 412.

145. Hall et al., *supra* note 134, at 536 & nn.50–54.

146. This idea originated with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which stated that "[e]thically valid consent is a process of shared decision making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments." PRESIDENT'S COMM'N, *supra* note 54.

comprehension over the duty to inform, and thus we should craft a right of action that underscores the duty to obtain consent to treatment. This proposal shifts the emphasis away from mandated disclosures to a system of disclosures *and* comprehension. Thus, a standard for informed consent that requires patient understanding must assess whether the patient, in fact, comprehended the risks, benefits, and alternatives of the intervention to which they agreed. In other words, if the plaintiff herself did not comprehend the risks, benefits, and alternatives of the proposed intervention, then the physician has breached her duty.

Importantly, this proposal would not eliminate physicians' duty to ensure that patients receive all information material to a voluntary decision. Instead, it argues that legal rules should reject the singular focus on the clinician's affirmative duty to disclose.

This new rule for informed consent does two things. First, it adds a subjective assessment of patient comprehension to the elements of an informed consent claim. Second, it calls for the establishment of standards for comprehension to ensure informed consent obligations have been met.

Scholars in the medical and medical ethics fields have long advocated for an approach to clinical informed consent that emphasizes comprehension, in order to embody the ethical principles and goals of informed consent.[147] While this analysis relies on that scholarship addressing how to assure and measure patient understanding, it is the first to offer a concrete legal proposal to incorporate comprehension assessments into the standard for informed consent.[148] It therefore represents a dramatic shift away from common law and the accepted doctrine of informed consent.

A. A New Rule

The new standard for informed consent would assure that informed consent is a process that treats the patient as an active participant in her medical decision-making, rather than a moment in time that treats the patient as an object to be

147. *See, e.g.*, Tomasz Pietrzykowski & Katarzyna Smilowska, *The Reality of Informed Consent: Empirical Studies on Patient Comprehension—Systematic Review*, 22 TRIALS 57 (2021) ("[T]he extent to which patients can comprehend the consent they grant is essential to the ethical viability of medicine as it is pursued today. However, research on patients' comprehension of an informed consent's basic components shows that their level of understanding is limited."); Sreenivasan, *supra* note 12, at 2017 ("[T]he validity of an individual's consent depends on him or her actually comprehending the information disclosed."); James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292(13) J. AM. MED. ASSOC. 1593 (2004) ("[E]thically valid informed consent requires more than just disclosure. Research participants should also understand the essential disclosed information."); Hall et al., *supra* note 134, at 537 (advocating to "encourage and check patient comprehension" in the informed consent process).

148. In the U.K., at least one scholar has proffered that there should be "actionable negligence for a doctor to present information in a manner or in circumstances where it is foreseeably likely that the patient will not understand." Kevin Williams, *Comprehending Disclosure: Must Patients Understand the Risks They Run?*, 4 MED. L. INT'L 97, 97 (2000). Williams argues that "recent professional guidelines and the law of negligence now take matters further by requiring doctors to take reasonable steps in an attempt to ensure that patients understand the risks they are being invited to run." *Id.* at 97 ("[U]nless patients understand the information they are given, arguably they will be no better off and disclosure will have become an empty exercise, a 'rite' rather than a 'right.'").

"consented." As discussed in Section II.D., relying exclusively on the objective disclosure standard articulated in *Canterbury* and *Cobbs* does not ensure that patients are able to make informed and autonomous medical decisions. Rather, informed consent should work to ensure patient comprehension to serve the ethical goals of the doctrine. In other words, consent must continue to be informed, but disclosed information must also be understood in order that patients can exercise true self-determination in medical decision-making. In the absence of understanding, "informed" consent does not mean much—it continues to focus on just disclosures, regardless of comprehension.

1. Against Abandoning Objective Disclosure Requirements

Importantly, this proposal does not call for a wholesale elimination of the disclosure requirements in the physician-patient interaction. Rather, disclosure alone will not solve the problem. Thus, this proposal would maintain the objective standard for what a reasonable patient would find material to a decision to accept or reject a proposed therapy, as it is measurable and commensurate with negligence cases more generally. Mandated disclosures are still necessary and important—doctors must continue to tell patients what they need to know.

In all jurisdictions, disclosure is based on an objective approach—it looks not to the individual patient's subjective informational needs but to the reasonable patient's informational needs. The reasonable patient standard, which establishes an objective rule for disclosure, has persevered. This is because it is much more efficient and straightforward to determine whether a reasonable patient has received enough information to make a meaningful decision than it is to determine whether a particular patient has received information relevant to her own personal decision. In other words, it is far simpler to identify an adequate (or inadequate) level of objective disclosure than it is to measure individual patient comprehension. The current rule that focuses solely on an objective standard for disclosures is relatively easy to measure. But this efficiency belies the law's ability to facilitate better decisions and results in overdisclosure of information in efforts to avoid liability (which in turn leads to less comprehension as patients are overwhelmed with information).

Further, this proposal does not necessarily advocate, as other scholars have, for the abandonment of objective causation and its replacement with a subjective standard.[149] Under current rules, decision-causation (like disclosure) is judged

149. Tenenbaum, *supra* note 25, at 697. The proposal contained in this Article is distinct from those offered by other scholars, who argue for a subjective materiality or causation standard for disclosures. Such a standard would force physicians to ask their patients what is important and to involve them more fully in the decision-making process, thereby necessitating that disclosures be specific to the particular patient and may require disclosure of facts beyond the medical risks, benefits, and alternatives of the proposed intervention. Merz, *supra* note 12, at 244 ("Several courts and commentators, however, have concluded that the causation issue should be resolved on a subjective level: would the patient have agreed to the proffered procedure if informed of the reasonably 'material' information?"). Calls for a subjective causation standard would require determining that a particular patient would not have chosen the procedure had he been fully informed; rather than focusing on

objectively. In other words, juries are asked to determine whether a reasonable patient would have consented to the intervention had she had full information. But it is not enough that the *Canterbury* materiality standard looks to whether the reasonable patient would have not consented had she had the necessary information. The determination of "materiality" of information arguably cannot be made without actually engaging in the decision-making process.[150] When we measure whether a patient would agree to a particular intervention, we need to know what the patient understood. The court in *Canterbury* held that "true consent to what happens to one's self is the informed exercise of a choice, and that entails the opportunity to evaluate knowledgeably the options available and the risks attendant upon each."[151] If we believe this to be true—or at least an aspiration of what informed consent can and should be—then we need to ensure that patients actually make a choice, which they can only do if they understand the implications and weight of those choices. Disclosures alone cannot ensure that medical decision-making is a true expression of self-determination.

2. Introducing a Subjective Standard for Comprehension

This proposal adds a new element to an informed consent claim: subjective patient understanding of the risks, benefits, and alternatives of the proposed intervention. Medicine and ethics scholars have advocated for a new comprehension-based standard that better reflects the ethical principles and goals of informed consent.[152] They have consistently emphasized that informed consent "relies on patients understanding the information they are given to inform their decision."[153] However, this shift could be feasible from a legal perspective. Establishing a subjective rule for comprehension that looks to the individual patient's understanding respects the fact that patient preferences are personal and may be idiosyncratic. No matter what the outcome, it is the patient who will bear

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whether the individual patient, in fact, understood the decision she was making, it attempts to address the deficiencies in informed consent by changing the disclosure requirements. Scholars have argued that the objective reasonable person standard for disclosures "show[s] disrespect, not only for the individual patient's rights to autonomous medical decision making, but also for the jurors who are called upon to determine whether a break of the disclosure duty occurred and whether it caused injury." Morris, *supra* note 24, at 333.

However, this proposal is not just focused on physician disclosures; rather, it is focused on whether the patient *understands/comprehends*. Has the patient, in fact, consented? Under the existing legal doctrine of informed consent, juries are not asked to assess what patients understood. They only consider whether, had they been given certain information, they would have undergone the intervention. So, a subjective disclosure standard is not going to change that.

150. Merz, *supra* note 12, at 250.

151. Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972).

152. *See, e.g.*, Pietrzykowski & Smilowska, *supra* note 147 ("[T]he extent to which patients can comprehend the consent they grant is essential to the ethical viability of medicine as it is pursued today. However, research on patients' comprehension of an informed consent's basic components shows that their level of understanding is limited.").

153. Victoria Richardson, *Patient Comprehension of Informed Consent*, 23 J. PHARMACY & PHARMACOLOGY 26, 26 (2013).

the burden. Thus, in addition to mandated disclosures, the physician's duty to the patient must include assurance of patient comprehension of the risks, benefits, and alternatives of the proposed intervention.[154]

Under the new standard, those responsible for obtaining informed consent to treatment should be required to gauge and document that the patient has understood the information disclosed to her at the time of consent.[155] Comprehension should be assessed at the time of each decision so that if the patient is harmed, she cannot claim she did not understand the intervention to which she was agreeing.[156] A standard for informed consent that requires patient comprehension must assess whether the patient understood the risks, benefits, and alternatives of the intervention to which she agreed.

If, instead of applying a subjective standard to this analysis, we were to assess this element objectively—by asking what the reasonable patient would understand, in light of the physician's chosen disclosures[157]—this proposal would simply reinforce existing obligations under the legal doctrine of informed consent. Tying the disclosures that a reasonable patient would need to know to whether the reasonable patient would understand those disclosures would do little to ensure that patients are, in fact, making voluntary decisions based on actual comprehension of the risks, benefits, and alternatives of the proposed medical intervention. And, of course, a purely objective standard would suffer from the same problems that have been associated with the reasonable person (or, historically, the "reasonable man") standard since its introduction in tort law.[158]

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154. However, this proposal might be conceptualized in two ways. The first would look to whether the patient themselves comprehended the disclosures provided to them. The second would look to whether the physician ensured that the patient comprehended the disclosures provided to them. The former has advantages over the latter, in that it is less likely to be conflated with the disclosure requirement. Further, the latter approach would require an additional step because it would require that the court determine *both* whether the patient understood the disclosure *and* that the physician ensure that understanding.

155. Importantly, however, "complete knowledge of all the information deemed important for disclosure is not necessary to give valid consent." Laura M. Beskow & Kevin P. Weinfurt, *Exploring Understanding of "Understanding:" The Paradigm Case of Biobank Consent Comprehension*, 19(5) AM. J. BIOETHICS 6, 6 (2019) (citing Paul S. Appelbaum, *Understanding "Understanding": An Important Step Toward Improving Informed Consent to Research*, 1(2) AM. J. BIOETHICS PRIM. RES. 1 (2010); David S. Wendler, *Can We Ensure that All Research Subjects Give Valid Consent?*, 164(20) ARCHIVES INTERNAL MED. 2201 (2004); David S. Wendler & Christine Grady, *What Should Research Participants Understand to Understand They Are Participants in Research?*, 22(4) BIOETHICS 203 (2008)).

156. Crepeau et al., *supra* note 133.

157. The "reasonable person" or "reasonably prudent person" standard looks to the "care that a reasonable person would exercise under the same or similar circumstances." ALEX B. LONG & TERI DOBBINS BAXTER, TORTS: A MODERN APPROACH, 97 (Carolina Acad. Press, 2020). As Justice Holmes stated, "The law takes no account of the infinite varieties of temperament, intellect, and education which make the internal character of a given act so different in different men." O.W. HOLMES, JR., THE COMMON LAW 108 (Bos., Little, Brown & Co. 1881).

158. *See, e.g.*, Warren A. Seavey, *Negligence – Subjective or Objective*, 41 HARV. L. REV. 1 (1927); Leon Green, *The Negligence Issue*, 37 YALE L.J. 1029 (1928); Omri Ben-Shahar & Ariel Porat, *Personalizing Negligence Law*, 91 N.Y.U. L. REV. 627 (2016); Dolores A. Donovan, *Is the Reasonable Man Obsolete: A Critical Perspective on Self-Defense and Provocation*, 14 LOY. L.A. L. REV. 435 (1981);

At least in the scholarly literature, a commonly accepted trope is that informed consent does not require that consent be rational.[159] This is a feature (rather than a bug) of the current disclosure-focused rule. So long as doctors have fulfilled their legal disclosure requirements, the patient's consent is sufficient. This may result in irrational and illogical agreements to an intervention. The current rule is often justified by reliance on the autonomy principle: patients are allowed to make whatever decision they choose, regardless of whether it is medically justified.

However, in making these arguments, we miss the point. If we knew that the patient *understood* what the risks, benefits, and alternatives of a proposed intervention were, perhaps we could reduce irrational decision-making (at least to some extent),[160] all while maintaining patient autonomy where it matters. In other words, if we do not know that the patient actually understood the facts upon which they are basing their decision to accept or reject a proposed intervention, then we cannot know whether the patient's decision was "irrational" or whether the patient simply did not fully understand the decision they were making. But if we know that patients really comprehend the decision that they are making, we may see more patients choosing the "rational" approach because their decision is based on more complete comprehension. Holding and acting on rational beliefs may also promote autonomy.[161] Patients' ability to make decisions after they understand the disclosed information may therefore lead to more accord between physician and patient.[162] Therefore, shifting the focus of our informed consent rule to comprehension could more truly respect individual patient autonomy than the existing rule.[163]

Mayo Moran, *The Reasonable Person: A Conceptual Biography in Comparative Perspective*, 14 LEWIS & CLARK L. REV. 1233, 1271 (2010); R. George Wright, *Objective and Subjective Tests in the Law*, 16 U.N.H. L. REV. 121, 144 (2017).

159. Jon F. Merz & Baruch Fischhoff, *Informed Consent Does Not Mean Rational Consent*, 11 J. LEG. MED. 321 (2009). *See also* Julian Savulescu & Richard W. Momeyer, *Should Informed Consent be Based on Rational Beliefs?*, 23(5) J. MED. ETHICS 282 (1997) ("Medical ethics places great emphasis on physicians respecting patient autonomy. It encourages tolerance even towards harmful choices patients make on the basis of their own values."). While this is true on paper, in reality, this is often only true if the plaintiff agrees with the physician's recommended course of treatment. When patients disagree with the physician's recommendation, the patient's capacity to consent will be questioned.

160. *See* Cathy Charles, Amiram Gafni & Tim Whelan, *Decision-Making in the Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model*, 49 SOC. SCI. & MED. 651, 658 (1999) ("Underlying the evidence-based approach is an assumption that whatever treatment is shown by the evidence to be the most effective is the best treatment and the 'rational' choice to implement.").

161. Julian Savulescu & Richard W. Momeyer, *Should Informed Consent be Based on Rational Beliefs?*, 23(5) J. MED. ETHICS 282 (1997).

162. Merz & Fischhoff, *supra* note 159. *See also* Floyd J. Fowler Jr., Patricia M. Gallagher, Keith M. Drake & Karen R. Sepucha, *Decision Dissonance: Evaluating an Approach to Measuring the Quality of Surgical Decision Making*, 39(3) JOINT COMM. J. QUAL. PATIENT SAFETY 136, 142 (2013) ("Hypothesis 1 stated that more-informed patients would make less dissonant decisions. When the results are averaged across all the procedures, higher knowledge had a statistically significant ($p < .001$) association with a lower Decision Dissonance Score.").

163. Further, there are two additional possible advantages of this proposal to incorporate a comprehension element to the legal doctrine of informed consent. The first is the possibility of fewer lawsuits. *See* Richardson, *supra* note 153, at 27 ("Poor comprehension however, can lead to patient dissatisfaction through unrealistic expectations caused by lack of suitable information. This can result

A proposal to require a subjective assessment of patient comprehension of the risks, benefits, and alternatives of a proposed intervention would still allow for supported[164] and surrogate decision-making. Thus, this rule would not exclude patients who lack consent capacity and could, in fact, be more friendly to those with decisional disabilities because the standard focuses on individuals' needs rather than "objectivity" and "reasonableness," which may be inherently ablest.[165]

Finally, what of the patient who wishes to waive the comprehension requirement? Scholarship has demonstrated that, when it comes to disclosures, some patients just do not want to know the risks, benefits, and alternatives of the proposed intervention. They are content to have physicians make decisions for them. In such circumstances, ex-ante waiver of the comprehension requirement of informed consent would allow patients to agree to a medical intervention without any evidence of their understanding of the implications of their decision.[166]

IV. AN INITIAL FRAMEWORK FOR ENSURING COMPREHENSION IN THE LEGAL DOCTRINE OF INFORMED CONSENT

A. Ensuring Comprehension in the Informed Consent Process

We are just beginning to understand how patients process risk information and to develop validated ways to measure patient comprehension. While ensuring patient comprehension is ideal, obstacles remain. Despite these obstacles, the proposal contained in this Article represents the first steps in building a system that can ensure a more robust and successful informed consent process. The following analysis represents a first step in the legal literature, based on contemporary empirical social science research about patient understanding. Research and education surrounding these issues is still in its infancy, and our current ability to assess understanding is still developing. In other words, "no generalized agreement dictates how to measure understanding, despite some attempts to devise assessment tools."[167]

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in legal action and it has been reported that 20–30% of surgical claims have an element within them relating to consent or failure to warn."). Second, there is evidence that better informed patients make patients make less extreme medical decisions, resulting in monetary savings.

164. Wright, *supra* note 11, at 898.

165. For example, under current rules, providers may provide nonconsensual treatment after informal capacity assessments (deeming the patient unable to make own decisions). Marshall B. Kapp & Bernard Lo, *Legal Perceptions and Medical Decision Making*, 64 MILBANK Q. (SUPP. II) 163, 191–92 (1986).

166. *See* Wright, *supra* note 11, at 902; Sawicki, *supra* note 105.

167. Laura B. Dunn & Dilip V. Jeste, *Enhancing Informed Consent for Research and Treatment*, 24(6) NEUROPSYCHOPHARMACOLOGY 595, 596 (2001) (citing Cheryl K. Miller, Dannielle C. O'Donnell, Russell H. Searight & Rick A. Barbarash, *The Deaconess Informed Consent Comprehension Test: An Assessment Tool for Clinical Research Subjects*, 16(5) PHARMACOTHERAPY 872 (1996); THOMAS GRISSO & PAUL S. APPELBAUM, ASSESSING COMPETENCE TO CONSENT TO TREATMENT: A GUIDE FOR PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS (Oxford University Press, 1998)). Further, while there is no generally agreed-upon definition of understanding, it has been argued that "[a] person understands 'if they have acquired pertinent information and have relevant beliefs about the nature and consequences of their actions.'" Flinn, *supra* note 82, at 391 (quoting TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 127 (6th ed. 2009)).

While creating a useful comprehension test across all medical settings and all types of medical decisions is not possible (or advised), we can begin to look to approaches adopted in empirical studies of comprehension to develop validated comprehension tools. For example, scholars analyzing the benefits of utilizing patient decision aids during the informed consent process looked to the "decisional conflict scale,"[168] which measures five dimensions of decision-making.[169] These dimensions include "modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making."[170]

Another approach is to calculate a "Decision Dissonance" score to measure the extent to which patient ratings of goals run counter to the decision made and the treatment received.[171] In a study of patients one year after undergoing one of three procedures (coronary artery bypass graft (CABG), a lumpectomy or a mastectomy for breast cancer, or surgery for prostate cancer), researchers found that Decision Dissonance appears to be a promising approach to validly measuring decision quality.[172] However, this may not be the most useful tool for assessing the quality of decision-making at the time of consent, as decision dissonance needs to be calculated sometime after the treatment rather than at the time of the patient's decision.[173]

Those who seek to measure and improve comprehension in the clinical context may look to more rapidly evolving endeavors in the context of research consent. Thus far, efforts to ensure understanding may be more successful due to the clear enunciation of understanding as a required component of the Basic Elements of Informed Consent in the Common Rule, the regulations that govern a

168. Dawn Stacey, France Legere & Krystina B. Lewis, *Patient Decision Aids to Engage Adults in Treatment or Screening Decisions*, 318(7) J. AM. MED. ASS'N 657, 657 (2017) (finding that "[p]atient decision aids were associated with improved decision-making processes").

169. Mirjam M. Garvelink, Laura Boland, Krystal Klein, Don Vu Nguyen, Matthew Menear, Hilary L. Bekker, Karen B. Eden, Annie LeBlanc, Annette M. O'Connor, Dawn Stacey & France Legere, *Decisional Conflict Scale Use over 20 Years: The Anniversary Review*, 39(4) MED. DECISION MAKING 301 (2019).

170. OTTAWA HOSPITAL, *Decisional Conflict Scale*, https://decisionaid.ohri.ca/eval_dcs.html#:~:text='The%20decisional%20conflict%20scale%20(DCS,unsupported%20in%20decision%20making%3B%20and [https://perma.cc/36HA-N5L3] (last visited Apr. 7, 2024).

171. Fowler et al., *supra* note 162.

172. *Id.* at 137.

173. Tools to measure and assure understanding are being developed for informed consent to human subjects research at a rate that seems higher than in the clinical context. *See, e.g.*, Steven Joffe, E. Francis Cook, Paul D. Cleary, Jeffrey W. Clark & Jane C. Weeks, *Quality of Informed Consent: A New Measure of Understanding Among Research Subjects*, 93(2) J. NAT'L CANCER INST. 139 (2001) (designing a brief questionnaire, the Quality of Informed Consent, to measure subjects' actual (objective) and perceived (subjective) understanding of cancer clinical trials, in order to standardize the assessment of the outcome of the informed consent process); Cheryl K. Miller, Dannielle C. O'Donnell, H. Russell Searight & Rick A. Barbarash, *The Deaconess Informed Consent Comprehension Test: An Assessment Tool for Clinical Research Subjects*, 16(5) PHARMACOTHERAPY 872 (1996) (creating a questionnaire and scoring criteria that are used to assess patients' understanding of the information); Jaime Fons-Martinez, Cristina Ferrer-Albero & Javier Diez-Domingo, *Keys to Improving the Informed Consent Process in Research: Highlights of the i-CONSENT Project*, HEALTH EXPECTATIONS 1183, 1884–85 (2022). Whether these tools and methods can be utilized in the clinical setting remains unclear but provides hope for the development of a validated tool for assessing comprehension for patients.

majority of human subjects research in the United States.[174] For example, researchers have developed an instrument called the uConsent scale, a "validated, rigorously derived, and generalizable measure of understanding" for research consent based on educational theory.[175] The authors explain,

> The goal of the uConsent scale and the evaluation strategy used here is not simply to measure a participant's ability to restate facts from a consent form but, rather, to rigorously measure a research participant's understanding of both the required elements of informed consent as well as concepts deemed critical to making a truly informed decision about their participation in a study.[176]

Currently, measures of comprehension—in both the clinical and research contexts—remain inadequate, and at this moment proxies are relied upon to measure understanding. For example, most studies of understanding in informed consent discussions rely on patient recall of information as a proxy, under the assumption that a patient remembering information is a prerequisite for them understanding it.[177] Confusion between recall and comprehension confounds much research related to assessments of understanding of medical risk disclosures.[178] Thus, legal standards for assessing patient comprehension during the informed consent process will need to constantly evolve to reflect progress in the development of tools based on empirical research.

1. "Direct Human Contact"

Ultimately, "direct human contact tends to be more successful in improving

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174. 2018 Final Rule (45 C.F.R. 46.116(a)(5)(i–ii)).

175. Richard F. Ittenbach, J. William Gaynor, Jenny M. Dorich, Nancy B. Burnham, Guixia Huang, Madisen T. Harvey & Jeremy J. Corsmo, *uConsent: Addressing the Gap in Measuring Understanding of Informed Consent in Clinical Research*, CLINICAL & TRANSLATIONAL SCI. 1, 1 (2023).

176. *Id.* at 11.

177. Stuart M. White & Joanne Seery, *Consent: The Law and Ethical Considerations*, 10(3) ANAESTHESIA & INTENSIVE CARE MED. 111, 112–13 (2009). *See also* Ittenbach et al., *supra* note 175, at 10:

> To date, any attempts at evaluating participants' understanding of informed consent have provided only passing attention to scale development and rigorous applications of learning theory needed for this important prerequisite of a clinical research study. Strategies thus far have generally relied upon a single subjective question such as "Do you understand . . . ?" or "Do you have any questions about . . . ?" or coordinators asking potential participants to restate what they have heard (c.f., Teach-Back method). Although good in principle, these strategies are often ad hoc, with evaluation left to staff who are generally not trained in assessment or knowledge acquisition of complex material. Finally, self-generated quizzes are frequently used, which may appear to represent good instructional practice, but are likely to lack any basis in assessment-related theory or practice. These quizzes most often emphasize recall of facts rather than more difficult and discriminating components of a consenting process, often lack any systematic coverage of key regulatory components, and are not likely to be targeted to the needs of a specific population. Quizzes created by research staff are not likely to deliver on their intended purpose—to distinguish those who "understand" from those who do not.

Ittenbach et al., *supra* note 175, at 10.

178. Sherlock & Brownie, *supra* note 126, at 604.

understanding than relying on tools like consent forms and multimedia interventions."[179] Significantly, total consent time is the strongest predictor of patient comprehension. A systematic review of interventions to improve patient comprehension in the informed consent process concluded that "interactive informed consent interventions (i.e., those that intentionally promote active patient involvement and bidirectional communication), may be superior to noninteractive interventions."[180]

However, currently, providers spend "less than 5 percent of a typical medical encounter . . . providing information to patients."[181] Assuring and assessing understanding will necessarily require more time. It will require constant assessment and documentation.[182] Thus, "[a]ffording adequate time for informed consent discussions and using informed consent adjuncts . . . may enhance comprehension in such individuals."[183]

Of course, requiring a subjective assessment of patient comprehension is likely to be burdensome, particularly in today's circumstances where physicians are under- or uncompensated for informed consent discussions, and time is already short.[184] If

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179. James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292(13) J. AM. MED. ASSOC. 1593, 1599 (2004) (addressing comprehension in informed consent to research). *See also* Adam Nishimura, Jantey Carey, Patricia J. Erwin, Jon C. Tilburt, M. Hassan Murad & Jennifer B. McCormick, *Improving Understanding in the Research Informed Consent Process: A Systematic Review of 54 Interventions Tested in Randomized Control Trials*, 14(28) BMC MED. ETHICS 1, 10 (2013) ("The approach of using extended discussion was associated with significant increase in understanding scores compared with control consent approach.").

180. Glaser et al., *supra* note 80, at 138–39.

181. BERG et al., *supra* note 27, at 184 (citing Howard Waitzkin, *Doctor-Patient Communication: Clinical Implications of Social Scientific Research*, 252 J. AM. MED. ASSOC. 2441, 2442 (1984)); Elizabeth C. Thomas, Sarah Bauerle Bass & Laura A. Siminoff, *Beyond Rationality: Expanding the Practice of Shared Decision Making in Modern Medicine*, 277 SOC. SCI. & MED. 1, 3 (2021). The average fifteen minute physician visit in the United States does now allow for sufficient time for doctor-patient discussions of the risks, benefits, and alternatives of a proposed intervention. Michael R. Ulrich, *Why Money is Well Spent on Time*, 24(12) AM. MED. ASSOC. J. ETHICS E 1155, 1155–58 (Dec. 2022) (citing Bruce Y. Lee, *Time to Change the 15-Minute Limit for Doctor Visits*, FORBES (Sept. 10, 2016), https://www.forbes.com/sites/brucelee/2016/09/10/time-to-change-the-15-minute-limit-for-doctor-visits/) [https://perma.cc/4J2R-62YT].

182. Presentation of Michael Paasche-Orlow, IOM (Institute of Medicine), *Informed Consent and Health Literacy: Workshop Summary*, Washington D.C. at 88 (2015).

183. Aaron S. Fink, Allan V. Prochazka, William G. Henderson, Debra Batenfeld, Carsie Nyiernda, Alexandra Webb, David H. Berger, Kamal Itani, Thomas Whitehall, James Edwards, Mark Wilson, Cynthia Karsonovich & Patricia Parmelee, *Predictors of Comprehension During Surgical Informed Consent*, 210(6) J. AM. COLL. SURGEONS 919, 919 (2010).

184. Floyd Fowler and colleagues considered the counterarguments to incorporating patient decision aids into the informed consent process. One of these counterarguments is that "[u]sing decision aids takes too much time." Floyd J. Fowler, Michael J. Barry, Karen R. Sepucha & Benjamin W. Moulton, *Let's Require Patients to Review a High-Quality Decision Aid Before Receiving Important Tests and Treatments*, 59(1) MED. CARE 1, 3 (2001). They expound on the argument that "[p]hysicians have only limited amounts of time to spend with patients. Insurance paperwork, electronic medical record systems, and other nonmedical demands on their scarce time mean that adding another responsibility feels unreasonable." George Annas has observed, "business models . . . see genuine doctor-patient conversations as inefficient (and a waste of time)." Annas, *supra* note 47, at 10.

we expect physicians to be responsible for engaging in meaningful informed consent discussions, financial incentives are necessary to allow clinicians to allocate adequate time for the process.[185]

2. Approaches to Assuring Comprehension

Without clear guidance about what it means to comprehend information and consent to a proposed intervention based on that comprehension, changing the existing standard for informed consent will only cause more chaos and confusion. Thus, we must look to how to ensure understanding. Although medical and ethics scholars have been calling for increased patient comprehension in the informed consent process for decades, empirical research is now confirming the tools that may be most effective in assuring understanding.

A new rule would require an intensification of the process of informed consent to improve comprehension, relying on the most validated tools and techniques. A tool would be "valid, reliable, inexpensive to use, easy to administer and to score."[186] Scholars have engaged in the process of analyzing and implementing such tools in the movement toward shared decision making in clinical medicine.[187]

Under the shared decision-making model, physicians and patients participate jointly in a process to increase patient understanding and allow patients to engage in decision making that reflects their values and preferences. Physicians are expected to ask patients early in the treatment relationship (or at its onset) about their values and preferences and how much they want to participate in the decision-making process; they are expected to continue these discussions throughout the relationship. This approach is much less focused on physician disclosures and much more on the individual patient's needs in the decision-making process.

Once we better know how to assess comprehension, then we can look at the patient to determine whether she has comprehended, based on the disclosures provided. Unfortunately, comprehension is not a constant. This approach necessitates improvement in patient literacy in order to enable more informed—and perhaps consistent—decision-making.[188] As Jessica Flinn observed, "[I]nadequate patient health literacy [is] a barrier to obtaining genuine informed

185. Ulrich, *supra* note 181, at 1155. ("To improve patient trust, cooperation, and health outcomes, the health care system should better incentivize time spent between patient and clinician to enable a deeper, more meaningful collaborative relationship."). We can look to end-of-life care as a model for compensating physicians for the time expended counseling patients in difficult decisions.

186. Steven Joffe, E. Francis Cook, Paul D. Cleary, Jeffrey W. Clark & Jane C. Weeks, *Quality of Informed Consent: A New Measure of Understanding Among Research Subjects*, 93(2) J. NAT'L CANCER INST. 139, 140 (2001).

187. *See* Robert M. Kaplan, *Shared Medical Decision Making: A New Tool for Preventive Medicine*, 26(1) AM. J. PREVENTIVE MED. 81, 81–82 (2004).

188. F.J. Ingelfinger, *Informed (but Uneducated) Consent*, 287(9) NEW ENGL. J. MED. 465, 466. (1972); Alicia Fernandez, *Improving the Quality of Informed Consent: It's Not All About the Risks*, 153(3) ANNALS INTERNAL MED. 342, 342 (2010).

consent that is not adequately taken into account by the legal system."[189] Thus, despite the fact that informed consent is a process, health literacy may still be improved through the redesign and simplification of it informed consent forms.[190] However, modification of informed consent forms is not sufficient to achieving patient comprehension.

a. Physician Decision Aids

Patient decision aids—evidence-based informational documents, videos,[191] or interactive web-based tools designed to help patients make decisions about treatment options[192]—have been demonstrated to help "bridge the gap between the

189. Flinn, *supra* note 82, at 380.

190. Presentation of Christopher Trudeau, IOM (Institute of Medicine), *Informed Consent and Health Literacy: Workshop Summary*, Washington D.C. at 62–63 (2015).

191. Richard A. Deyo, Daniel C. Cherkin, James Weinstein, John Howe, Marcia Ciol & Albert G. Mulle, Jr., *Involving Patients in Clinical Decisions: Impact of an Interactive Video Program on Use of Back Surgery*, 38(9) MED. CARE 959, 966–68 (2000); Julie Weston, Mary Hannah & Julia Downes, *Evaluating the Benefits of a Patient Information Video During the Informed Consent Process*, 30(3) PATIENT EDU. & COUNSELING 239, 239 (1997).

192. Natalie Evans, Suzanne Metselaar, Carla van El, Nina Hallowell & Guy Widdershoven, *How Should Decision Aids be Used During Counseling to Help Patients who are "Genetically at Risk"?*, 21 AM. MED. ASS'N J. ETHICS 865, 866–67 (2019). For an in-depth analysis of legal mechanisms for ensuring the quality of decision aids, *see* Nadia N. Sawicki, *Patient Protection and Decision Aid Quality: Regulatory and Tort Law Approaches*, 54 ARIZ. L. REV. 621 (2012). *See also* Spatz et al., *supra* note 43, at 2063 ("Patient decision aids can provide balanced, evidence-based information about treatment options and usually are easy to read, often with pictures and figures; some may include patient testimonials about different pathways."); Charles et al., *supra* note 160, at 655 ("[t]hese aids range from high technology interactive videos [Michael J. Barry, Floyd J. Fowler, Albert G. Mulley, Joseph V. Henderson & John E. Wennberg, *Patient Reactions to a Program Designed to Facilitate Patient Participation in Treatment Decisions for Benign Prostatic Hyperplasia*, 33 MED. CARE 771 (1995); Raisa B. Deber, *Shared Decision-Making in the Real World*, 11 J. GEN. INTERNAL MED. 377 (1996); Ann Barry Flood, John E. Wennberg, Robert F. Nease, Floyd J. Fowler, Jiao Ding & Lynda M. Hynes, *The Importance of Patient Preference in the Decision to Screen for Prostate Cancer*, 11. J. GEN. INTERNAL MED. 342 (1996); Lawrence Liao, James G. Jollis, Elizabeth R. DeLong, Eric D. Peterson, Kenneth G. Morris & Daniel B. Mark, *Impact of an Interactive Video on Ischemic Heart Disease Patient Decision Making*, 11 J. GEN. INTERNAL MED. 373 (1996)] to low technology flip charts with audio tapes. [Annette M. O'Connor, Peter Tugwell, George Wells, Tom Elmsie, Elaine Jolly, Gary Hollingworth, Ruth Mcpherson, Elizabeth Ruth Drake, Wilma Hopman & Thomas Mackenzie, *Testing a Portable, Self-Administered, Decision Aid for Post-Menopausal Women Considering Long-Term Hormone Replacement Therapy (HRT) to Prevent Osteoporosis and Hearth Disease*, 14 MED. DECISION MAKING 438 (1994)]. Decision boards are another form of communication aid that lie between the high and low technology options [Mark N. Levine, Amiram Gafni, Barbara Markham & Dawn MacFarlane, *A Bedside Decision Instrument to Elicit a Patient's Preference Concerning Adjuvant Chemotherapy for Breast Cancer*, 117 ANNALS INTERNAL MED. 53 (1992); Sebban, George Browman, Amiram Gafni, G. Norman, Mark Levine, D. Assouline & D. Fiere, *Design and Validation of a Bedside Decision Instrument to Elicit a Patient's Preference Concerning Allogenic Bone Marrow Transplantation in Chronic Myeloid Leukemia*, 48 AM. J. HEMATOLOGY 221 (1995); Timothy J. Whelan, Mark Levine, Amiram Gafni, Himu Lukka, E.A. Mohide, Malti Patel & David L. Streiner, *Breast Irradiation Postlumpectomy: Development and Evaluation of a Decision Instrument*, 13 J. CLIN. ONCOLOGY 847 (1995); Laurie M. Elit, Mark N. Levine, Amiram Gafni, Timothy J. Whelan, Gordon Doig, David L. Streiner & Barry Rosen, *Patients' Preferences for Therapy in Advanced Epithelial Ovarian Cancer: Development Testing and Application of a Bedside Decision Instrument*, 62 GYNECOLOGIC ONCOLOGY J. 329 (1996)]).

theory and practice of informed consent."[193] Decision aids may provide risk information that would not otherwise be accepted by patients.[194] In a study of 105 randomized clinical trials, utilization of patient decision aids was found to improve both decision quality and decision-making processes.[195] These aids, "when used as adjuncts to counseling, improve decision quality and reduce the overuse of surgical treatments by 25 percent."[196] Specifically, the use of interactive multimedia tools during the informed consent process have been found to improve patient understanding.[197] In one systematic review of interventions to improve patient comprehension in clinical informed consent, researchers found that most digital interventions resulted in improved understanding compared with standard informed consent.[198] Interactive tools "can create information tailored to specific patients' learning styles and preferences."[199]

Based on current knowledge, concrete examples satisfying the comprehension requirement include relying on the answers to questions in decision aids as evidence that the patient understood the risks and alternatives of the proposed intervention. Alternatively, in order to consent to invasive surgical interventions, patients may be required to review a decision aid and respond to questions designed to assess understanding.

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193. Thaddeus Mason Pope, *Patient Decision Aids Improve Patient Safety and Reduce Medical Liability Risk*, 74 ME. L. REV. 73, 74 (2022). *See also* Fowler et al., *supra* note 162, at 1 ("[A] preponderance of evidence suggests informed consent as currently practiced does not ensure patients are informed and involved in medical decisions. Routinely viewing decision aids could help elevate the level of informed consent.").

194. Laura D. Scherer, Peter A. Ubel, Jennifer McClure, Sarah M. Greene, Sharon Hensley Alford, Lisa Holtzman, Nicole Exe & Angela Fagerlin, *Belief in Numbers: When and Why Women Disbelieve Tailored Breast Cancer Risk Statistics*, 92 PATIENT EDU. & COUNSELING 253, 253 (2013).

195. Stacey et al., *supra* note 168; Dawn Stacey, France Legere, Krystina B. Lewis, Michael J. Barry, Carol L. Bennett, Karen B. Eden, Margaret Holmes-Rovner, Hilary Llewellyn-Thomas, Anne Lyddiatt, Richard Thomson & Lyndal Trevena, *Decision Aids for People Facing Health Treatment or Screening Decisions (Review)*, 4(4) COCHRANE DATABASE SYS. REV. 1, 28 (2017) ("[T]here is high-quality evidence that compared to usual care, decision aids improve people's knowledge regarding options and reduce the decisional conflict stemming from feeling uninformed and unclear about their personal values. There is moderate-quality evidence that decision aids stimulate people to take a more active role in decision making and increase the accuracy of their risk perceptions.").

196. Annette M. O'Connor, John E. Wennberg, France Légaré, Hilary A. Llewellyn-Thomas, Benjamin W. Moulton, Karen R. Sepucha, Andrea G. Sodano & Jaime S. King, *Toward the 'Tipping Point': Decision Aids and Informed Patient Choice*, 26 HEALTH AFF. 716, 717 (2007).

197. Sherlock & Brownie, *supra* note 126, at 209 ("[T]he use of interactive multimedia and written material that are easy-to-read and comprehend, and prepared for individual patients has been shown to increase patient awareness, recollection and understanding of the consenting procedure.").

198. Glaser et al., *supra* note 80, at 136 (Of the thirteen interactive digital interventions evaluated, six used computer-based programs, four used tablet applications, two used web modules, and one used a mobile phone application. 86% (6/7) of interactive digital intervention trials with some bias risk resulted in improved patient comprehension compared with 83% (5/6) of those with high bias risk. Nine were provided in addition to standard informed consent, of which seven (78%) resulted in improved patient comprehension; two were provided in place of standard informed consent, both of which resulted in improved patient comprehension, and one study did not specify. All of the interactive digital interventions contained interactive features, and five included a test/feedback component.).

199. Dunn & Jeste, *supra* note 167, at 604.

b. Incorporating Technology into the Informed Consent Process

Professor Linda Aldoory and colleagues conducted a comprehensive literature review of trends in informed consent and health literacy for the Institute of Medicine of the National Academies (IOM).[200] They identified multimedia and online approaches as having "mixed" effectiveness in improving informed consent.[201] Likewise, although it focused on informed consent to clinical trial research rather than medical care, a systematic study found that "multimedia and enhanced consent form interventions do not consistently improve research participants' understanding."[202] During Professor Aldoory's presentation to the IOM, she explained that "research on low health literacy has not yet found solid evidence that alternative formats beyond verbal and written communications have been effective and that, furthermore, the effectiveness of these alternative formats depends on education level, age, and computer experience."[203]

c. "Repeat-back" Techniques

"Repeat-back" or "teach-back" techniques, whereby patients recount what they have learned about the risks, benefits, and alternatives of the proposed intervention during the informed consent process,[204] have been shown to improve informed consent comprehension from 53% of patients to 70%.[205] The improvement was particularly notable with regard to understanding risks and alternatives.[206] In a study of eight hospitals' approaches to informed consent, Jennifer Matiasek and Dr. Matthew Wynia found that "repeat-back" was "one of very few interventions that have been quantitatively shown to improve patient comprehension and recollection of health care information."[207] Repeat-back tools can also aid physicians in assessing whether patients have comprehended the informed consent disclosures. At least one organization already includes teach-back recommendations in its quality guidelines for clinical informed consent.[208]

200. INST. MED., INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY 10–15 (2015).

201. *Id.* at 12.

202. Flory & Emanuel, *supra* note 147, at 1598.

203. INST. MED., INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY 12 (2015).

204. Fink et al., *supra* note 183.

205. *Id.* at 919. *See also* Aaron S. Fink, Allan V. Prochazka, William G. Henderson, Debra Batenfeld, Carsie Nyiernda, Alexandra Webb, David H. Berger, Kamal Itani, Thomas Whitehall, James Edwards, Cynthia Karsonovich & Patricia Parmelee, *Enhancement of Surgical Informed Consent by Addition of Repeat Back: A Multicenter, Randomized Controlled Clinical Trial*, 252(1) ANNALS SURGERY 27, 31 (2010) (concluding that repeat-back implemented within an electronic informed consent system improved patient comprehension).

206. *Id.* at 31.

207. Jennifer Matiasek & Matthew K. Wynia, *Reconceptualizing the Informed Consent Process at Eight Innovation Hospitals*, 34(3) JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 127, 134 (2008).

208. *See* NATL. QUALITY F., *Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals*, 1, 11 (2005).

d. The "Best case/Worst case" Approach

Dr. Gretchen Schwarze and colleagues offer an approach in which physicians "provide information about possible interventions in a way that contextualizes the medical decision into a larger personal framework."[209] Such a decision support tool would offer patients the best case scenario, the worst case scenario, and the most likely case scenario for an individual patient, which will "allow patients to contextualize the possibilities and attach preferences or state valid fears about specific outcomes."[210] Schwarze and colleagues have noted the advantages of their best-case-worst-case approach, comparing it to patient decision aids: "While decision aids have proven effectiveness for achieving preference-sensitive decisions, these aids have limited availability for many clinical situations and lack flexibility for in-the-moment decision making."[211] Likewise, Dr. Yael Schenker, in her presentation to the IOM, described her belief "that it is possible to improve the process of informed consent" in order to achieve adequate patient understanding in the effort to achieve the ethical goals of informed consent.[212] She advocated for a shift in the focus of the informed consent process from the risks of the proposed intervention to the potential outcomes of the procedure.[213]

B. Continuing Obstacles to Patient Comprehension

Despite their promise, our tools for measuring and ensuring patient comprehension during the informed consent process are still developing. Policy and lawmakers, as well as legal and ethics scholars, have a critical opportunity to work with empirical social science researchers to build verified tools to measure patient understanding and assessments of how much comprehension is necessary to meet ethical and legal requirements for informed consent.

The proposal to add a subjective patient comprehension requirement to the legal doctrine of informed consent necessitates additional foresight on behalf of physicians, such that they must be able to recognize, at each juncture in medical decision-making, that the parties need to stop, measure, and document comprehension to avoid potential future liability. This means that a new standard that focuses on comprehension (and that requires assessment at each decision point to avoid the hindsight problem) could become even more of a defensive endeavor than the current disclosure-focused rules. It might lead to required patient signatures at each decision point, claiming that they understand the risks, benefits, and alternatives of the intervention to which they have consented.[214]

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209. Margaret L. Schwarze, Jacqueline M. Kehler & Toby C. Campbell, *Navigating High Risk Procedures with More than Just a Street Map*, 16(10) J. PALLIATIVE CARE 1169, 1169. (2013).

210. *Id.* at 1170.

211. *Id.* at 1169.

212. INST. MED., INFORMED CONSENT AND HEALTH LITERACY: WORKSHOP SUMMARY 35 (2015).

213. *Id.* at 38.

214. And these signatures might not have much weight, or similar weight to signatures on current informed consent forms. Signed documents claiming understanding might be presumptive

Significantly, while perfect comprehension is ideal, it unfortunately cannot be expected in all circumstances. Since investigators began analyzing the sufficiency of informed consent, they have recognized that education, race, and age are associated with the degree of comprehension.[215] We continue to see inconsistent health

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evidence of comprehension but should not be nonrebuttable evidence. In response, patients might claim they did not understand the form they signed attesting to their understanding. While this Article argues for an expansive new approach to informed consent that includes comprehension of the intervention to which each individual is consenting, a more limited approach is also possible. In order to address the concern that applying a subjective standard for assessment of comprehension may prove to be less efficient (and therefore less practicable) than the current rule, one may consider moderating this new standard in order to avoid overburdening practitioners and the health care system while simultaneously encouraging efforts to employ tools that will improve patient understanding. For example, there are efforts to establish uniform certification standards for decision aids currently underway. Floyd J. Fowler, Michael J. Barry, Karen R. Sepucha & Benjamin W. Moulton, *Let's Require Patients to Review a High-Quality Decision Aid Before Receiving Important Tests and Treatments*, 59(1) MED. CARE 1, 3 (2001) (calling for an independent organization to be set up and funded to certify the quality of decision aids). Often, these calls for certification are coupled with proposals to make certification a requirement for using it to qualify for (additional) payment. While these proposals are generally focused on the quality of the patient decision aids (e.g., with regard to their clarity, balance, and evidentiary support) it is not a far stretch to suggest that they also be tested to determine whether they support patient comprehension in a meaningful way. If a decision aid has been rigorously tested to result in comprehension by a significant percentage of patients, it could, perhaps, establish a rebuttable presumption that the patient did, in fact, understand the risks of the medical intervention they chose. However, in cases where a physician was aware that her patient had unique circumstances that would render their ability to comprehend the risks of the proposed intervention particularly unlikely—even with the certified patient decision aid—the physician would not be freed from liability for failure to assure comprehension. Spatz et al., *supra* note 43, at 2063 ("High-quality decision aids are developed and tested with patients; thus, they are intended to conform to the standards of a reasonable patient."). This approach may ameliorate some of the concerns associated with efficiency of the overall proposal to incorporate a new element into the legal doctrine of informed consent, without entirely undermining its goal of ensuring individual subjective patient comprehension.

Washington State's law can serve as a model for this proposal. In 2007, Washington became the first state to pass legislation establishing increased legal protection to physicians who clearly document that decision aids were used during the informed consent process. WASH REV. CODE ANN. § 7.70.060 (West 2007). In August 2012 the state of Massachusetts passed legislation to foster the routine use of decision aids. Commonwealth of Massachusetts. Session Laws: Chapter 224 of the Acts of 2012. Further, Section 3506 of the Patient Protection and Affordable Care Act calls for programs to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients and to award grants for the establishment and support of Shared Decisionmaking Resource Centers and for the establishment of criteria for the certification of decision aids. The Patient Protection and Affordable Care Act (PPACA) of 2010, Pub. L. No. 111–148. In doing so, it initiated the first decision aid certification program in the country. The criteria for certification are available online. *See* Washington State Health Care Authority, *Patient Decision Aid Certification Criteria*, available at https://www.hca.wa.gov/assets/program/washington-state-pda-certification-criteria.pdf [https://perma.cc/W9BY-NP9W] (last visited Apr. 7, 2024). *See also* Fowler et al., *supra* note 162, at 3 ("The National Quality Forum has also published a set of guidelines for evaluating decision aids, using Washington State as a model. Both of those efforts built on the work of the International Patient Decision Aids Standards group. So the work of establishing quality criteria is well along. The critical needed step is to have an organization that systematically applies them.").

This approach would require continued effectiveness research to ensure that any decision aids being used to help protect physicians from liability are validated to measure and assure patient comprehension of the risks, benefits, and alternatives of the medical intervention to which they are consenting.

215. *See, e.g.*, Jan M. Howard & David DeMets, *How Informed is Informed Consent?: The BHAT*

literacy, language barriers, and racial inequities in the medical system.[216] It remains a reality that poor informed consent disparately impacts certain populations, such as those with limited English proficiency, poor health, and poor medical literacy. Conversely, certain communities—those with greater resources—will have the privilege of subjective understanding. Perhaps the proposal contained in this Article can help to achieve some greater level of understanding and shift the emphasis from disclosures alone to disclosure and comprehension in order to align the ethical goals of informed consent with the legal rules that govern it.[217] Perhaps by shifting to a more subjective approach, we can begin to not only align the law with ethics but also to ameliorate some of the inequities that are endemic to the informed consent process.

C. Legislating a Subjective Standard

It is unlikely that the common law will begin to require that patients comprehended the risks of the intervention to which they consented. This proposal is not a natural extension of organic developments in informed consent law because informed consent law has focused almost exclusively on improving or expanding physician disclosures.[218] Thus, as methods for assessing and ensuring patient comprehension during the informed consent process become more effective, state legislatures should amend their rules for determining whether a patient has a valid claim for failure of informed consent to medical treatment.[219]

Applying a subjective standard for assessment of comprehension may prove to be less efficient (and therefore less practicable) than the current rule. However, although in traditional negligence actions the conduct of both the defendant and plaintiff are judged by the reasonable person standard, subjective standards are not new to tort law. For example, when one of the litigants is a minor[220] or lacks mental capacity,[221] courts will apply a subjective standard or at least take into account

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Experience, 2 CONTROLLED CLIN. TRIALS 287, 299–301 (1981); Crepeau et al., *supra* note 133, at e114(1); Dunn & Jeste, *supra* note 167, at 604 ("Older patients with less education seemed to be more vulnerable to poor understanding.").

216. Rebecca L. Sudore, C. Seth Landefeld, Brie A. Williams, Deborah E. Barnes, Karla Lindquist & Dean Schillinger, *Use of a Modified Informed Consent Process Among Vulnerable Patients*, 21 J. GEN. INTERNAL MED. 867, 867 (2006) (finding that minority status is an important determinant of understanding consent information).

217. Or, we may see physicians cherry-pick patients based on their medical literacy levels in order to avoid liability under the new standard. Further, incentives must be considered to avoid the possibility that patients with fewer resources will say that they comprehend the risks, benefits, and alternatives of the proposed intervention in order to get the treatment they seek where they have coverage.

218. *See* Section II.A.

219. Rather than trying to force a sea-change across jurisdictions, this proposal may be better effected by attempting to convince a jurisdiction to adopt a demonstration project, similar to the Washington State shared decision-making demonstration project. WASH REV. CODE ANN. § 7.70.060 (West 2007).

220. *See* Schomp v. Wilkens by Leen, 501 A.2d 1036, 1038 (N.J. Super. Ct. 1985). *See also* William Binchy, *The Adult Activities Doctrine in Negligence Law*, 11 WM. MITCHELL L. REV. 733, 736 (1985).

221. Elizabeth J. Goldstein, *Asking the Impossible: The Negligence Liability of the Mentally Ill*, 12 J. CONTEMP. HEALTH L. & POL'Y 67, 79–84 (1995).

special characteristics of the actor.[222]

Further, the subjective standard called for in this Article can be distinguished from those often found in tort law, making it less likely to be adopted as a natural progression in the law of informed consent. When we talk about subjective standards in tort law, we often look at whether the litigant's conduct should be judged by a standard "requiring that she act in a way that is reasonable (optimal for the economically oriented), given her actual ability to take care, and when should it be judged by some objective standard that is uniformly applicable to all persons without regard to each one's ability to take care."[223] In contrast, this proposal calls for application of a subjective standard to ascertain the effect the conduct had on the plaintiff. It does not look at the conduct of either party but instead focuses on the impact of the conduct.[224] Thus, a rule that emphasizes comprehension necessitates a more drastic legislative approach. Legislative action to incorporate a subjective standard for patient comprehension in the law of informed consent may require "a major cultural change."[225]

D. Additional Levers to Ensuring Comprehension

1. Delegation of Informed Consent

In order to ensure that patients are afforded the appropriate time and resources to ensure comprehension of the risks of a proposed intervention, this proposal may also require a reexamination of other existing rules related to the informed consent process. For example, courts have clearly required that only the treating physician obtain informed consent from their patients. This policy of nondelegation was upheld by the Pennsylvania Supreme Court in *Shinal v. Toms* in

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222. LONG & BAXTER, TORTS: A MODERN APPROACH, 128–29 (discussing circumstances where special characteristics of the actor will be considered, including individuals' special skills or knowledge beyond those possessed by most people, superior mental or physical abilities, involuntary intoxication, and physical impairments).

223. Warren F. Schwartz, *Objective and Subjective Standards of Negligence: Defining the Reasonable Person to Induce Optimal Care and Optimal Populations of Injurers and Victims*, 78 GEO. L. J. 241, 241 (1989).

224. This might be better analogized to the eggshell skull rule, which provides that "[t]he negligent actor is subject to liability for harm to another although a physical condition of the other . . . makes the injury greater than that which the actor as a reasonable man should have foreseen as a probable result of his conduct." Restatement (Second) of Torts § 461 (1965). However, the eggshell skull rule focuses on the harm the plaintiff experiences, while the proposal in this Article focuses, in some ways, on the duty owed to the patient to ensure comprehension. In other circumstances in tort law, courts apply an objective standard to determine the effect a defendant's conduct has on the plaintiff. For example, for the intentional tort of battery, harmful or offensive contact "includes all physical contacts that the individual either expressly communicates are unwanted, or those contacts to which *no reasonable person would consent*." Wagner v. State, 122 P.3d 599, 609 (Utah 2005) (emphasis added). However, the Restatement (Third) of Torts § 105 cmt. D Tent. Draft (2015) takes the position that it is enough that the plaintiff—however unreasonably—subjectively apprehends an imminent contact.

225. Presentation of Michael Paasche-Orlow, *supra* note 182, at 81–82. Such legislation must flesh out the additional element to the informed consent claim looks like vis-à-vis duty, causation, and injury. However, this concern is outside the scope of the present Article.

2017.[226] Like the doctrine of informed consent,[227] the court's decision was premised on the primacy of the principles of bodily integrity and autonomy.[228] It held that physicians may not delegate any aspect of the informed consent process to physician assistants, nurses, or anyone else qualified to act as an assistant to the physician. The court emphasized the necessity of this holding to secure the crucial trust of the physician-patient relationship. Despite this lofty goal, the decision is problematic because it deemphasizes the importance of process in obtaining informed consent, underscores physician disclosure at the peril of patient comprehension, and fails to recognize the evolving nature of health care delivery and the physician-patient relationship. In particular, the court's reasoning highlights a concern about the legal doctrine of informed consent generally: it focuses primarily on the duty of the physician to disclose information to the patient, and secondarily on the patient's consent.[229]

Thus, the physician may not always be the best individual to assess patient understanding.[230] It is worth considering potential approaches to streamlining the informed consent process for complex medical or surgical interventions. Such proposals include an official designation of a single individual (an "informed consent ombudsman"[231]) or committee to whom the patient can go whenever a question or concern arises. The patient's physician themself may not be the ideal individual to exclusively carry the additional duty of assessing comprehension during the informed consent process.

2. Non-Tort Approaches to Ensuring Comprehension

While this Article emphasizes tort solutions to the failures of the legal doctrine of informed consent, it is worth noting other approaches to fostering the type of physician-patient relationship that can support better communication and more robust informed consent discussions. These solutions may not be stand-alone but may be considered in conjunction with the proposal for a revised common law claim for informed consent.

As has been argued time and time again,[232] resources must be devoted to the informed consent process. Allowing access to and discussing information in decision aids is one approach to improving patient understanding and involvement

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226. Shinal v. Toms, 162 A.3d 429, 454 (2017).

227. Sawicki, *supra* note 105, at 827 ("The doctrine of informed consent is grounded in the ethical principle of patient autonomy.").

228. *Shinal*, 162 A.3d at 454 ("Were the law to permit physicians to delegate the provision of critical information to staff, it would undermine patient autonomy and bodily integrity by depriving the patient of the opportunity to engage in a dialogue with his or her chosen health care provider.").

229. BERG et al., *supra* note 27, at 141.

230. *See, e.g.*, Alan R. Tait, Terri Voepel-Lewis & Shobha Malviya, *Do They Understand? (Part 1): Parental Consent for Children Participating in Clinical Anesthesia and Surgery Research*, 98(3) ANESTHESIOLOGY 603, 607 (2023) ("It was interesting to note that understanding was significantly better when a nonphysician investigator provided information . . . . The reason for this is unclear, although one may speculate that the physicians present the information at a level above that of a layperson.").

231. Valerie Gutmann Koch, *Delegating Informed Consent*, 47(5) HASTINGS CTR. REP. 5, 6 (2017).

232. Annas, *supra* note 47, at 10–11.

in the decision-making process. But, in most circumstances, there are insufficient incentives to encourage physicians to provide such tools. Thus, it has been argued that "physicians should be paid for providing decision aids to their patients and payers should require that patients review these decision aids as a prerequisite for paying providers when these services are rendered."[233]

Resources should also be devoted to educating medical professionals and patients about the benefits of eliciting patient values and preferences during a process of shared decision-making. Educating physicians about the benefits of gauging their patients' understanding of the risks of proposed interventions will not only improve the doctor-patient relationship but also potentially result in the avoidance of more low-value or no-value care.

Relatedly, rather than compensating physicians for the informed consent conversations, another option would be to tie physician reimbursement to the informed consent process, thereby creating a more tangible incentive for physicians to explore patients' values and preferences and confirm patient understanding of the risks of the intervention to which they are agreeing. Thus, physicians' pay would be effectively docked if they failed to at least assess patient comprehension. In a similar vein, tying physicians' licensure to their informed consent obligations may deter at least the most egregious violations.

CONCLUSION

By considering the intersection between contemporary empirical social science research about patient understanding and ethics scholarship on the role of informed consent in medical decision making, this Article proposes practical changes to existing legal rules to adopt a subjective standard for assessing understanding and agreement. Building a comprehension element into the question of whether the physician satisfied their duty of care will allow the law to better reflect the ethical values of the doctrine of informed consent and the shared decision-making model. The existing legal doctrine of informed consent that focuses on disclosures at the expense of patient comprehension is premised on the goal of liability protection, "but informed consent should have the goals of serving an ethical duty, empowering patients, and strengthening trust between patient and physician."[234] As Professor Charity Scott observed,

> "When we focus on the law, we tend to lose sight of the ethical underpinnings for it. In trying to focus on the 'letter of the law,' we often lose sight of its 'spirit.' When law becomes pervasive, we often forget about the original ethical questions that prompted the legal resolutions."[235]

With this proposal, the law can better reflect the ethical goals that underpin

233. Fowler et al., *supra* note 162, at 1.
234. Presentation of Michael Paasche-Orlow, *supra* note 182, at 81–82.
235. Scott, *supra* note 73, at 262.

the doctrine of informed consent. And while legislative action to incorporate a subjective standard for patient comprehension in the law of informed consent may require "a major cultural change,"[236] it will better encourage information exchange and deliberation in the medical decision-making process, while continuing to reflect patient autonomy and uphold patient dignity.

236. Presentation of Michael Paasche-Orlow, *supra* note 182, at 81–82.