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REFORMING INFORMED CONSENT TO INCLUDE
COMPREHENSION:
A PROPOSAL TO PROMOTE EQUITY IN MEDICAL
DECISION-MAKING

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INTRODUCTION

The ethical goals of the legal doctrine of informed consent are lofty. The law requires that clinicians explain the risks, benefits, and alternatives of proposed treatments to patients, and to respect patient autonomy through voluntary, informed medical decisions aligned with individual values and preferences. Yet in practice, patients often struggle to comprehend the risks and alternatives of a proposed medical intervention.¹ Since investigators began analyzing the sufficiency of informed consent, it has been recognized that the current rules, which focus solely on clinical disclosures, are inadequate in addressing disparities associated with education, race/ethnicity, and age.²

Health literacy gaps and power differentials between doctors and patients make true comprehension of health information elusive for vulnerable groups.³ Consent documents laden with dense technical and numerical data are often indecipherable.⁴ Negative healthcare encounters, cultural factors, and individual and community experiences of exploitation and racism create distrust among marginalized groups who

¹ Kevin J. O’Leary, Nita Kulkarni, Matthew P. Landler, Jiyeon Jeon, Katherine J. Hahn, Katherine M. Englert & Mark V. Williams, *Hospitalized Patients’ Understanding of Their Plan of Care*, 85 MAYO CLINIC PROC. 47, 47 (2010).

² Johanna Glaser, Sarah Nouri, Alicia Fernandez, Rebecca L. 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 MED. DECISION MAKING 119, 137–38 (2020) (“Some studies conducted subanalyses on the basis of sociodemographic data, most commonly examining education (19 studies), age (16 studies), and gender (12 studies). Lower education (10/19 studies), older age (6/16 studies), and limited health literacy (3/4 studies) were associated with lower patient comprehension scores; however, these studies did not clearly specify whether interventions were differentially effective based on these factors. Only 4 studies examined effects according to health literacy, of which 1 reported a statistically significant improvement in comprehension scores among participants with limited health literacy receiving the intervention. The reading level of intervention materials was reported in 7 studies and ranged from second to eighth grade. One study assessed the efficacy of an informed consent intervention for patients with language barriers, finding that nonnative speakers of the study language showed decreased comprehension compared with native speakers in both the control and intervention groups.”).

³ *Id.* at 137. Moreover, “[n]early half of all American adults (47 percent)—90 million people—have limited health literacy, which restricts their capacity to obtain, process, and understand the basic health information and services that are needed to make appropriate health decisions.” NAT’L QUALITY F., IMPLEMENTING A NATIONAL VOLUNTARY CONSENSUS STANDARD FOR INFORMED CONSENT: A USER’S GUIDE FOR HEALTHCARE PROFESSIONALS 1, 1 (2005).

⁴ Michael Jefford & Rosemary Moore, *Improvement of Informed Consent and the Quality of Consent Documents*, 9 THE LANCET 485, 487 (2008).

have been systemically denied access to medical decision-making and medical education.⁵

Consequently, despite technically “adequate” disclosures under the legal doctrine of informed consent, patients may consent to major procedures with little substantive grasp of the risks. This undermines decision-making autonomy, reduces consent to a hollow formality, and fails to facilitate truly educated, empowered choices.

I. REFORMING INFORMED CONSENT LAW TO INCLUDE A COMPREHENSION ELEMENT

Shifting the law’s emphasis from disclosures alone to disclosure and comprehension will better align the ethical goals of informed consent with the legal rules that govern it.⁶ Scholars in the medical and ethics fields have consistently advocated for a new comprehension-based standard that better reflects the ethical principles and goals of informed consent⁷—namely, recognizing that informed consent “relies on patients understanding the information they are given to inform their decision.”⁸ Significantly, the law could be reformed to reflect this standard. To address inequalities in the informed consent process, the law should reduce emphasis on technical disclosure requirements and strengthen focus on patient comprehension. 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.⁹

In other words, when we assess whether a patient agreed to a particular intervention, we need to know what the patient understood. The

⁵ See, e.g., Melissa Creary & Lynette Hammond Gerido, *The Public Performativity of Trust*, 52 THE HASTINGS CTR. REP. S76, S76–77 (2023).

⁶ For a more thorough proposal in favor of revising the legal doctrine of informed consent to include a comprehension element, see generally Valerie Gutmann Koch, *Reimagining Informed Consent: From Disclosure to Comprehension*, 14 U.C. IRVINE L. REV. (forthcoming May 2024).

⁷ See, e.g., Tomasz Pietrzykowski & Katarzyna Smilowska, *The Reality of Informed Consent: Empirical Studies on Patient Comprehension—Systematic Review*, TRIALS, Jan. 2021, at 1 (“[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.”).

⁸ Victoria Richardson, *Patient Comprehension of Informed Consent*, 23 J. PERIOPERATIVE PRAC. 26, 26 (2013).

⁹ 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.

court in the seminal 1972 decision *Canterbury v. Spence* held that “[t]rue 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.”¹⁰ Choice cannot be effectuated in the absence of understanding of the implications and weight of those choices. Thus, disclosures alone cannot ensure that medical decision making is a true expression of self-determination.

Adopting a new rule for clinical informed consent would incentivize clinicians to take greater care, confirming patient understanding by using validated strategies such as physician decision aids,¹¹ increasing the use of technology in the informed consent process,¹² “repeat back”/“teach back” techniques,¹³ and the “best case/worst case” approach.¹⁴ Admittedly, comprehension can be complex to reliably measure. But the current legal rule’s efficiency belies the law’s ability to facilitate better decisions and results in over-disclosure of information in efforts to avoid liability (which in turn can lead to less comprehension as patients are overwhelmed with information). Although incorporating a comprehension element in the legal doctrine of informed consent involves challenges, doing so reflects a commitment to patient-centric reform where empowerment through understanding takes priority over administrative efficiency.¹⁵ If informed consent is to be more than an empty formality, prioritizing comprehension is essential. Emerging empirical research on measuring understanding can help develop flexible legal standards for adequate comprehension.

¹⁰ *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972).

¹¹ See generally Dawn Stacey, France Légaré, Krystina 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)*, COCHRANE DATABASE SYSTEMATIC REVIEWS, Apr. 12, 2017, at 2 (finding that “people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices.”).

¹² See INST. OF MED., *Informed Consent and Health Literacy: Workshop Summary* 10, 39, 75–82 (2015).

¹³ See Aaron S. Fink, Allan V. Prochazka, William G. Henderson, Debra Bartenfeld, Carsie Nyirenda, Alexandra Webb, David H. Berger, Kamal Itani, Thomas Whitehill, James Edwards, Mark Wilson, Cynthia Karsonovich & Patricia Parmelee, *Predictors of Comprehension During Surgical Informed Consent*, 210 J. AM. COLL. SURGEONS 919, 920 (2010); see also Jennifer Matiassek & Matthew K. Wynia, *Reconceptualizing the Informed Consent Process at Eight Innovation Hospitals*, 34 JOINT COMM’N J. QUALITY & PATIENT SAFETY 127, 128 (2008).

¹⁴ See Margaret L. Schwarze, Jacqueline M. Kehler & Toby C. Campbell, *Navigating High Risk Procedures with More than Just a Street Map*, 16 J. PALLIATIVE MED. 1169, 1169–70 (2013).

¹⁵ See generally Koch, *supra* note 6 (proposing the addition of a new element to an informed consent claim: subjective patient understanding of the risks, benefits, and alternatives of the proposed intervention).

Moreover, establishing a 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 its burden.

II. THE POTENTIAL TO REDUCE HEALTH DISPARITIES

This proposal has the primary goal of improving informed consent writ large, but has the important potential benefit of mitigating disparities in medical care. Effective physician-patient communication is linked with improved patient health outcomes.¹⁶ But deficiencies in physician-patient communication may contribute to health care disparities.¹⁷ As a result of discrepancies in health care literacy and education status,¹⁸ communication barriers,¹⁹ bias,²⁰ and distrust,²¹ physician-patient communications among historically marginalized populations have suffered. For example, Black patients rate visits with physicians as significantly less participatory than whites, particularly where there is not racial/ethnic concordance.²²

Requiring clinicians to assess patient comprehension during the informed consent process addresses these systemic disadvantages

¹⁶ Moira A. Stewart, *Effective Physician-Patient Communication and Health Outcomes: A Review*, 152 CANADIAN MED. ASS'N J. 1423, 1429 (1995); Thomas O. Straiger, Jeffrey G. Jarvik, Richard A. Deyo, Brook Martin & Clarence H. Braddock III, *Brief Report: Patient-Physician Agreement as a Predictor of Outcomes*, 20 J. GEN. INTERNAL MED. 935, 936 (2005).

¹⁷ Rachel L. Johnson, Debra Roter, Neil R. Powe & Lisa A. Cooper, *Patient Race/Ethnicity and Quality of Patient-Physician Communication During Medical Visits*, 94 AM. J. PUB. HEALTH 2084, 2084 (2004).

¹⁸ Jaime S. King, Mark H. Eckman & Benjamin W. Moulton, *The Potential of Shared Decision Making to Reduce Health Disparities*, 39 J.L. MED. & ETHICS 30, 31 (2011).

¹⁹ See generally Lisa A. Cooper, Debra L. Roter, Kathryn A. Carson, Mary Catherine Beach, Janice A. Sabin, Anthony G. Greenwald & Thomas S. Inui, *The Associations of Clinicians' Implicit Attitudes About Race with Medical Visit Communication and Patient Ratings of Interpersonal Care*, 102 AM. J. PUBLIC HEALTH 979 (2012) (concluding that clinician implicit bias and race, as well as compliance stereotyping, are associated with poor visit communication and poor ratings of care).

²⁰ See generally Kevin A. Schulman, Jesse A. Berlin, William Harless, Jon F. Kerner, Shyrl Sistrunk, Bernard J. Gersh, Ross Dubé, Christopher K. Taleghani, Jennifer E. Burke, Sankey Williams, John M. Eisenberg, William Ayers & José J. Escarce, *The Effect of Race and Sex on Physicians' Recommendations for Cardiac Catheterization*, 340 NEW ENG. J. MED. 618 (1999) (finding that race and sex of the patient can influence physicians' recommendations, suggesting physician bias independent of other factors).

²¹ Laura Specker Sullivan, *Trust, Risk, and Race in American Medicine*, HASTINGS CTR. REP. Jan.-Feb. 2020, at 18 (responding to evidence that patient mistrust toward the American medical system is to some extent associated with communal and individual experiences of racism).

²² Lisa Cooper-Patrick, Joseph J. Gallo, Junius J. Gonzales, Hong Thi Vu, Neil R. Powe, Christine Nelson & Daniel E. Ford, *Race, Gender, and Partnership in the Patient-Physician Relationship*, 282 JAMA 583, 583 (1999).

directly. It provides underserved communities targeted support in comprehending risks and weighing alternatives to make choices aligned with their values and preferences. Alongside broader equity efforts, informed consent discussions that emphasize comprehension further patient autonomy by empowering patients with the knowledge needed for informed decision-making. Maintaining formulaic consent rituals that fail the disadvantaged seems ethically untenable. Introducing a comprehension element in the informed consent process is a step toward fixing a system that enables inequities cloaked in hollow disclosure rituals. Shifting the legal requirements for informed consent to add a comprehension element also complements broader initiatives to promote health equity through greater community empowerment, culturally responsive practices, improved health literacy, and increased provider diversity.

III. COMPREHENSION, PATIENT CHOICE, AND CLINICIAN AGREEMENT

It has been recognized that patient involvement in their care “via negotiation and consensus-seeking” improves patient outcomes.²³ When there is conflict between a clinician’s preferred course of treatment and a patient’s choice, quality of care and medical outcomes can suffer. Moreover, physicians are more likely to presume lack of decision-making capacity when patients go against medical advice.²⁴ In other words, while medical ethics “encourages tolerance even towards harmful choices patients make on the basis of their own values,”²⁵ in practice this is often only true if the plaintiff agrees with the physician’s recommended course of treatment.²⁶ When patients disagree with the physician’s recommendation, the patient’s capacity to consent will be questioned. And, in many cases, patient disagreement with clinical recommendations is more prevalent amongst patients with low literacy levels and patients from minority communities in race/ethnicity discordant physician-patient relationships.²⁷ Oftentimes, such disagreements arise from lack of patient

²³ *Id.* at 584.

²⁴ Linda Ganzini, Ladislav Volicer, William A. Nelson, Ellen Fox & Arthur R. Derse, *Ten Myths About Decision-Making Capacity*, 5 J. AM. MED. DRG. ASS’N. 263, 264 (2005).

²⁵ Julian Savulescu & Richard W. Momeyer, *Should Informed Consent be Based on Rational Beliefs?*, 23 J. MED. ETHICS 282, 282 (1997).

²⁶ Bernard Lo, *Assessing Decision-Making Capacity*, 18 L. MED. & HEALTH CARE 193, 194 (1990); Edward Etchells, Peteris Darzins, Michael Silberfeld, Peter A. Singer, Julia McKenny, Gary Naglie, Mark Katz, Gordon H. Guyatt, D. William Molloy & David Strang, *Assessment of Patient Capacity to Consent to Treatment*, 14 J. GEN. INTERNAL MED. 27, 30 (1999).

²⁷ Ana H. Traylor, Julie A. Schmittdiel, Connie S. Uratsu, Carol M. Mangione & Usha Subramanian, *Adherence to Cardiovascular Disease Medications: Does Patient-Provider Race/Ethnicity and Language Concordance Matter?*, 25 J. GEN. INTERNAL MED. 1172, 1173

understanding of the risks, benefits, and alternatives of the proposed intervention.²⁸ Thus, comprehension can play a key role when patients make choices that contradict physician recommendations and result in less than favorable outcomes.

At least in scholarly literature, a commonly accepted trope is that informed consent does not require that consent be rational.²⁹ This is a feature, and not a bug, of the current disclosure-focused rule. So long as doctors have fulfilled their legal disclosure requirements, the patient's consent is sufficient.³⁰ This may result in irrational and illogical agreements (or disagreements) to an intervention. The current legal 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.³¹

However, these arguments 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 dissenting decision-making (at least to some extent).³² 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," whether the patient simply did not fully understand the decision they were making, or whether the patient's decision was based on values and preferences that do not align with clinical medical advice.³³ But if we know that patients

(2010); Stephen M. Strakowski, John M. Hawkins, Paul E. Keck, Jr., Susan L. McElroy, Scott A. West, Michelle L. Bourne, Kenji W. Sax & Karen C. Tugrul, *The Effects of Race and Information Variance on Disagreement Between Psychiatric Emergency Service and Research Diagnoses in First-Episode Psychosis*, 58 J. CLINICAL PSYCH. 457, 461 (1997).

²⁸ Rozemarijn Lidewij van Bruchem-Visser, Inez Duconia de Beaufort, Francesco Umberto Salvatore Mattace-Raso & Ernst Johan Kuipers, *What to do When Patients and Physicians Disagree? Qualitative Research Among Physicians with Different Working Experiences*, 11 EUR. GERIATRIC MED. 659, 664–65 (2019).

²⁹ Jon F. Merz & Baruch Fischhoff, *Informed Consent Does Not Mean Rational Consent: Cognitive Limitations on Decision-Making*, 11 J. LEGAL MED. 321, 343 (1990) ("From a legal viewpoint, as long as patients make a choice and can explain some rationale for their decision, then further inquiry is not made into the rationality or appropriateness of the decision.").

³⁰ *See id.*

³¹ RUTH R. FADEN, TOM L. BEAUCHAMP & NANCY M.P. KING, *A HISTORY AND THEORY OF INFORMED CONSENT* 7–9 (Oxford Univ. Press 1986); JESSICA W. BERG, PAUL S. APPELBAUM, CHARLES W. LIDZ, LISA S. PARKER, *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 24 (Oxford Univ. Press 2d ed. 2001).

³² *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."); Gutmann Koch, *supra* note 6.

³³ Edward Jacobs argues that, along with supporting autonomous authorization, the other primary role of understanding in informed consent is to enable "values-aligned decision-making,"

truly comprehend the decision that they are making, we can put more faith in their decisions (even when they are contrary to clinical advice). Further, with increased comprehension of the risks, benefits, and alternatives of a proposed course of treatment, we may even see more patients agreeing with physician recommendations.³⁴ Patients' ability to make decisions after they understand the disclosed information may therefore lead to more accord between physician and patient.³⁵

Shifting the focus of our informed consent rule to comprehension could more truly respect individual patient autonomy than the existing rule. Enhancing comprehension lays the groundwork for more informed patient decisions. Holding and acting on rational beliefs may promote autonomy.³⁶ Even if those decisions ultimately still oppose medical advice, they will at least be grounded in a substantive comprehension of the risks and benefits of the proposed intervention. Emphasizing comprehension upholds the ethical goals of informed consent while promoting high-quality, ethical care for diverse populations.

CONCLUSION

Informed consent cannot fulfill its ethical goals if patients are unable to comprehend the risks, benefits, and alternatives of the proposed intervention when they are disclosed. Whereas unilateral disclosures fulfill the current legal requirements of the doctrine of informed consent, emphasizing comprehension enables patients to evaluate risks and benefits based on their own personal values and preferences. This, in turn,

with an eye toward the rational weighing of options. Edward Jacobs, *Transformative Experience and Informed Consent to Psychedelic-Assisted Psychotherapy*, 14 FRONTIERS IN PSYCH., May 26, 2023, at 1; see also Daniel Villiger, *Informed Consent Under Ignorance*, AM. J. BIOETHICS, Jan. 5, 2024, at 8 (explaining that, according to Jacobs, "ignorance caused by a treatment's transformative nature poses a big problem to understanding as it blocks rational decision-making . . .").

³⁴ For example, one study of medication adherence in hypertensive Black patients concluded that collaborative patient-provider communication may play an influential role in those patients' adherence behaviors when receiving care from white providers. Antoinette Schoenthaler, John P. Allegrante, William Chaplin & Gbenga Ogedegbe, *The Effect of Patient-Provider Communication on Medication Adherence in Hypertensive Black Patients: Does Race Concordance Matter?*, 43 ANNALS BEHAV. MED. 372 (2012).

³⁵ See generally Merz & Fischhoff, *supra* note 29, at 323 (addressing the question of "what should be done when individuals make poor choices because they lack either critical information or the intellectual skills needed to use that information effectively when identifying courses of action"); 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 JOINT COMM'N J. QUALITY & PATIENT SAFETY 136, 140 (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.").

³⁶ Savulescu & Momeyer, *supra* note 25, at 282.

may empower patients and align the law of informed consent with the ethical values of ensuring voluntary, informed decision-making. Beyond being technically told the risks, patients gain the opportunity to meaningfully discuss them with clinicians, thereby reducing historically entrenched power asymmetries. Ensuring patient comprehension in the informed consent process empowers patients to be more collaborative partners in medical decision-making. Ensuring comprehension in consent conversations enhances trust and humanizes patients as partners in their own care, rather than passive recipients of technical disclosures. Reform centered on understanding, rather than rituals, brings informed consent's realities closer to its ethical aspirations. In doing so, it upholds consent's role in advancing equitable, patient-focused healthcare.

Centering comprehension in consent laws is a pragmatic, incremental strategy to promote equity. Thus, ensuring patient comprehension in the informed consent process is a first step in establishing more culturally responsive practices, potentially improving patient trust and empowering medical decision-making for historically and systemically marginalized communities.