Rethinking Valid Informed Consent: Requiring Disclosure of Controversies and Standard of Care

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ABSTRACT

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Purpose: This paper offers a normative argument for amending current informed consent standards to mandate disclosure of the standard of care and to require explanation of any controversial aspects of a recommended intervention.

Discussion: Healthcare providers have a common law duty to inform patients of the benefits and drawbacks of the medical interventions they recommend as well as their alternatives. However, the materiality of informed consent, the actual substantive content of the discussions, though regulated by State law, is largely left up to individual providers' judgments and expertise. This paper argues that whenever an intervention is controversial, patients have the right to understand opposing views. Explaining the disagreement between experts in the field conveys uncertainties about the interventions' outcomes and supporting data. Conversely, explaining when an intervention is standard of care conveys experts' confidence in the intervention and its outcomes. Discussing controversies and the standard of care helps patients hold more realistic expectations and furthers patient autonomy, trust, and beneficence. Moreover, by forthrightly sharing this information health care providers more accurately convey the state of the field as opposed to an individual provider's beliefs.

Conclusion: Discussing controversies and the standard of care during informed consent discussion furthers the goals of informed consent and should be adapted in clinical practice.

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I. Introduction:

Informed consent in clinical and research settings co-evolved and spread during the 20th century. The doctrine of informed consent furthers many goods—trust, self-ownership, integrity, etc. However, it is most-often viewed as a safeguard for patient autonomy.[1,2] The ethical framework for informed consent requirements stems from both the Kantian deontological value that personal autonomy ought to be protected as a good in and of itself, as well as the consequentialist belief that protecting patients' autonomous decision-making rights promotes patients' general welfare, even if patients are allowed to make autonomous decisions that lead to worse clinical outcomes.[1-5] A patient's right to autonomous decision-making is both a negative and a positive right. The negative right protects patients from having their decisions undermined by others, while the positive right ensures that patients have access to enough information to make an autonomous decision.[3] The requirement to obtain informed consent aims to ensure that patients do not undergo medical interventions without prior permission, addressing the negative right. The topic of the materiality of informed consent examines what kind of information patients need to understand in order to make informed, autonomous decisions, addressing the positive right.

The legal right to informed consent originated with the key 1914 ruling recognizing patient autonomy, during which Justice Cardozo famously wrote that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[6] The idea that autonomy was worthy of protection spread during the mid-20th century, with the publicization of human rights abuses in medical research. In 1947, the Nuremberg Medical Tribunal spotlighted atrocities committed during human experimentation throughout the holocaust, underscoring the need for a regulated informed consent process.[7] In 1964, the World Medical Association issued the Declaration of Helsinski, outlining ethical standards for informed consent in research.[8] The Tuskegee Syphilis Study, conducted from 1932 to 1972, similarly sparked outrage about the rights of human subjects to receive fully informed consent and led to the creation of the National Commission, responsible for federal policy protecting human subjects.[9]

By the 1960s, as dissatisfaction with physician paternalism grew, the importance of protecting patients' autonomy in clinical practice began to spread and, over the proceeding decades, informed consent practices became increasingly common.[10] By the 1970s, most courts

recognized failure to obtain informed consent as a form of malpractice liability, first as a form of battery then as a form of negligence. [11]

The materiality of informed consent, the information providers must necessarily provide patients during informed consent discussions, remained poorly defined. Perhaps the most influential ethical criteria for the materiality of informed consent come from Beauchamp and Childress's *Principles of Biomedical Ethics*, which offers five requirements for informed consent discussions:

> "(1) those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research, (2) information the professional believes to be material, (3) the professional's recommendation, (4) the purpose of seeking consent, and (5) the nature and limits of consent as an act of authorization." [3]

The common law standard adopted by the courts and, therefore, hospital policies and physician groups required that providers disclose the benefits and risks of the recommended medical intervention and its alternatives (including non-treatment). [11] However, deciding which benefits and risks are necessary and relevant to informed decision making has been largely left to individual providers' judgments. [11] This led to wide variation in the substantive content of informed consent discussions, which cannot be explained by patient preferences.

State informed consent tort laws aim to better define providers' duties to disclose by adopting one of two standards.[12] States either adopted the physician-based standard, currently used by 25 States, meaning that providers have the duty to disclose the benefits, risks, and alternatives of a medical intervention to the same degree as a "reasonable medical practitioner would under the same or similar circumstances" [13] in that State.[14-17] Alternatively, States may have adopted the patient-based standard, currently used by 23 States and the District of Columbia, meaning providers have the duty to disclose the benefits, risks, and alternatives of a medical intervention that a reasonable person in the patient's position would likely find material to decision making.[18, 19] Both standards have been extensively scrutinized.[12,20] Critics of the physician-based standard point out that using other physicians as a standard for consent practices could be used to justify very little disclosure so long as that was the norm among doctors in that region. In fact, as long

as providers maintained a culture of minimal consent, they would be relatively immune from liability under that standard.[20] Moreover, existing evidence suggests that providers often disagree about the information patients find material to decision-making so a "reasonable practitioner" may be doubly a poor standard and difficult to define.[21] While the patient-based standard has been seen as an improvement, it has been criticized because it uses one "reasonable person" as a standard for all patients instead of recognizing that different patients hold different values. It also assumes providers understand what a typical patient may find important, which has been empirically challenged.[20] In short, which facts or descriptions patients or professionals find material for making autonomous decisions remains "unsettled." [11]

With recognition that both the physician-based and patient-based standards are imperfect for ensuring that the relevant and necessary content is discussed during informed consent, a third standard has been gaining a lot of support in legal, medical, and ethics literature on informed consent—the shared decision making model.[20,22] While it is not recognized in State tort law, shared decision making has been included among the goals of the Center for Medicare and Medicaid Innovation under the Affordable Care Act (ACA) and Health Care and Education Reconciliation Act of 2010. [23] It has also been adopted in many clinical practices with reported success.[24] The model states that providers should explain all of the relevant benefits, risks, and alternatives of a recommended intervention, often with the help of decision aids, then illicit their patients' relevant beliefs and values before arriving at a joint decision.[25] The decision aids, when available, provide patients with relatively unbiased updated information on specific medical decisions and have been shown to effectively increase patient decision-making. However, they have been criticized for being labor intensive to produce and update and, therefore, cannot be available for most medical decisions.[20] Neither current State regulations nor the shared decision-making model offer providers concrete guidance on distinguishing material from non-material medical information, leaving providers to use their own judgments.

Available literature on medical materiality is limited; several works describe the benefits of disclosing uncertainties in medicine but offer little guidance on how to do so.[26,27] Other scholarship on materiality has aimed to expand the scope of a provider's duties of disclosure beyond just clinical facts. Nadia Sawicki argued that disclosure duties ought to encompass any

provider-specific factors that may affect a patient's outcomes, including non-medical information such as a provider's biases, values, or personal health issues. [28] Similarly, with the rise of managed care and the ruling in Moore v. University of California,[29] many have argued for mandatory disclosure of financial relationships that may affect providers' clinical recommendations. [30-33] After another publicized lawsuit, Johnson v. Kokemoor,[34] some called for disclosure of providers' experience and qualifications.[35] During the peak of the AIDS epidemic, courts, national medical organizations, and ethicists grappled with whether providers, especially surgeons, must disclose their HIV serostatus.[36-38] Most recently, with growing awareness of the costs of healthcare, support has grown for disclosure of the costs of treatment as if it were a "side effect" during informed consent. [39-41]

This paper furthers the literature on informed consent by proposing two additional disclosure requirements for medical materiality. First, it argues that, during fully informed consent discussions, patients have the right to know if any of the options offered to them are controversial among experts in the field. Second, it argues that whenever there is an effective medical intervention that most medical experts agree will result in the best outcomes for most patients, then patients have the right to know what that standard of care is and whether their providers' recommendations deviate from it. Adding both as requirements for valid consent would further the goals of informed consent by increasing autonomy, beneficence, and trust and would help providers more effectively communicate the present state of the medical field.

II. Student Role

The student generated the thesis for this paper and developed, with the benefit of innumerable conversations with mentors, the arguments presented here.

III. Controversy

Defining controversy

This paper defines a medical decision as controversial when experts form two or more major camps of beliefs about which intervention results in the best outcome for most patients because of competing interpretations of existing medical data. This paper's usage of "controversy" is distinct from several other usages of the word. Controversies in this paper refer only to disagreements among experts in their fields, not layperson disagreements. For example, while laypeople debate whether certain vaccines are associated with autism, most experts agree that no association exists.

This paper uses controversy specifically to refer to disagreements over the conclusions of data, not disagreements that stem from differences in values. For example, when patients should undergo cancer screening (e.g., mammography, colonoscopy, lung cancer screening, etc.) has been debated because some patients value the benefit of earlier diagnosis versus the risk of cancer over detection differently than others[42] and, consequently, may want screening earlier or more frequently than others. Such value disagreements are not the subject of this paper because they can be addressed with the existing informed consent model. When patients are adequately informed of the benefits and drawbacks of an intervention, they can decide whether or not they want to undergo it. However, current informed consent standards leave patients unprotected when experts disagree about the conclusions of medical data. For example, emergency physicians disagree on whether existing evidence justifies the use of tissue plasminogen activator (tPA) for acute stroke with up to half of emergency physicians questioning its efficacy in some surveys.[43-45] Since current informed consent standards leave individual providers to counsel patients using their judgment and expertise, the content of providers' informed consent discussions may vary with their stance. One of the most publicized consequences of informed consent variability occurred in 2013, when anesthesiologist Amy Reed had a hysterectomy causing an unsuspected uterine cancer to disseminate within her abdominal cavity, worsening her prognosis from a 63 percent survival at 5-years to 14 percent.[46] A year prior, data began to suggest that uterine power morcellators may disseminate tumor cells during laparoscopic

surgeries more frequently than believed.[47] The widely accepted 1 in 10,000 risk was challenged by estimates as high as 1 in 350.[48]

Gynecologists skeptical of the new data did not discuss the increased risks with their patients. After all, why would beneficent gynecologists counsel their patients on data they disagree with? After significant media attention and prominent lawsuits, however, many hospitals and even the Food and Drug Administration advised all providers to counsel their patients on the revised risks of morcellation.[48] Since the true risk of morcellation remains contended, [49] many providers felt this was an "overstep." [50] Though most real controversies have elements of disagreement about both values and data, this paper focuses on disagreements over data and argues that patients have the right to know whenever providers interpret medical data in conflicting ways.

Disclosing Controversy

Informed consent should strive to convey medicine's best estimate of an intervention's outcomes. When new data questioned the accepted cancer rates after morcellation, the confidence intervals around medicine's best estimate of morcellators' risks widened. A balanced explanation of opposing views would facilitate conveying an outcome's uncertainty, helping patients hold more realistic expectations. Furthermore, understanding that morcellators' risks are controversial means that they are not just uncertain because of absence of data but are actually backed by sufficient evidence to convince many experts that they are life-threatening.

When experts interpret data in competing ways, at least one camp of experts will eventually be disproven. While a provider may feel that explaining opposing views decreases beneficence, a miscalibration bias may increase providers' tendencies to be overly confident in their own knowledge and may decrease the likelihood of experts recognizing opposing interpretations as valid.[51.52] Mandating balanced explanations of opposing views decreases the risk of misleading patients and, by serving as a counterbalance to miscalibration bias, increases beneficence over a provider's career. Historically, the ethics literature balanced beneficence and autonomy on opposite sides of a scale, believing that gaining one sacrificed the other.[3] However, by checking

the influence of individual providers' biases over patients' decisions, mandating balanced explanations of opposing views furthers autonomy as well.

Admittedly, a new awareness of the disagreements and uncertainties in medicine may lessen short-term trust. However, trust should never be founded on misrepresenting uncertainties. In the long-term, many patients may trust a field more deeply knowing it were more transparent. When patients first learn of the uncertain risks of their hysterectomy from articles entitled "Deadly Medical Device?"[53] or "Deadly Medicine" [50] rather than from their gynecologists, the trust loss is profound. Moreover, when providers explicitly identify the uncertainties, perhaps patients would trust more in the certainties—vaccines, anti-hypertensive drugs, etc.

Different medical interventions require different degrees of informed consent with many factors influencing the extent of discussion necessary (e.g., the invasiveness of a procedure or the magnitude, frequency, timing, or permanence of its risks). During controversies, experts may have diverging intuitions on the extent of consent appropriate, depending on their beliefs. In the case of morcellation, a gynecologist believing the risk of cancer to be 1 in 10,000 may hardly mention it. Since morcellation is just one technical aspect of a surgery, which patients often consider immaterial for making informed decisions, [54] that gynecologist may not have even explained it during the consent. However, the same gynecologist, now wanting to provide a balanced discussion of opposing views should discuss the risks of morcellation. In a controversy where experts disagree over the likelihood of a risk, even one camp of experts believing an intervention's risks are impactful enough to warrant fully informed consent should trigger all camps to provide fully informed consent.

IV. Standard of Care

Defining the Standard of Care

This paper defines standard of care as the intervention (or lack thereof) most experts agree will result in the best outcomes for most patients in a defined clinical situation. This paper distinguishes between a standard of care and published guidelines. Though many academic

societies publish guidelines that they believe should be accepted by most experts in their field, they only represent agreement within a small committee that may not be representative of most experts' beliefs. In fact, different societies may publish competing guidelines and guidelines may themselves be controversial. [55,56] Standards of care may also vary regionally (e.g., antibiotic regimens). Lastly, more than one intervention may be considered standard of care whenever they have comparable outcomes (e.g., different approaches to hernia repair). Conversely, non-standard medical interventions are defined here as those that may be pursued instead of the standard of care or those that most experts agree do not result in the best outcomes for most patients (e.g., routine electrocardiograms for cardiovascular disease screening in asymptomatic adults, withholding measles vaccines, etc.). Practical issues on defining the standard of care are discussed further, under "Implementation."

Disclosing the Standard of Care

Communicating expert agreement is as important as communicating disagreements. Whenever experts agree on a standard of care, patients have the right to know what it is and whether their provider's recommendation deviates from it.

Patients often have good reason to trust a standard of care over opposing, non-standard recommendations. Firstly, a scientific community can synthesize all available data more ably than most individuals can alone, leading to the most accurate interpretation of medical information. Secondly, when experts arrive at a consensus independently, even if it is based on insufficient evidence or aligning intuitions, as long as the probability that each expert accurately interprets the available data is higher than random chance, the majority has a higher likelihood of drawing the soundest conclusions—this is the so-called Condorcet Theorem that is often cited in favor of majority rule in defenses of democracy.[57] Therefore, whether through teamwork or democracy, if experts agree that an intervention leads to the best outcomes for most patients, it more likely does.

A standard of care correlates with the medical field's confidence in the outcomes patients are told to expect. Communicating the field's confidence helps patients hold more realistic

expectations. While this paper defines the standard of care in terms of expert agreement on choosing one intervention over another, not in terms of the certainty of supporting evidence, the two often correlate. Explaining clinical uncertainties during informed consent discussions can be tedious and overwhelming for both patient and provider. Conversely, explaining that experts agree on a standard of care relays information about uncertainty without discussing technical details.

While the standard of care is not appropriate for everybody, patients may arguably lose trust when they hear that their provider's recommendation is non-standard. However, since most adults research their health on the Internet, [58] being forthcoming about non-standard recommendations may also preserve trust. When patient factors require deviations from standards of care, explanations help patients realize how much thought goes into personalizing their treatment plans.

V. The Present State of the Medical Field

The above sections describe unique reasons for disclosing controversies and the standard of care. The common reason for disclosing both is that each helps patients better understand the present state of the medical field, which, ultimately, is what most patients want from informed consent discussions.

Much of medicine's variability is increasingly recognized as unscientific and driven by providers' rather than patients' preferences, resulting in variable outcomes and unnecessary costs.[59-61] According to data found in the Dartmouth atlas, the percent of patients prescribed a beta blocker after suffering a heart attack ranged from 83 to 40 percent of ideal candidates in various regions, despite their well-established mortality benefit. [60] If a provider's recommendation is controversial or deviates from the standard of care, the patient has the right to know why. Provider-specific factors driving variability include biases, values, and conflicts of interest. Empirically, providers have been shown to discuss reasons for undergoing their

recommended intervention more thoroughly than the reasons patients might not want to. [62] Justifying why a recommendation is controversial or deviates from the standard of care requires a more thorough explanation than why it is preferable to alternatives and may ensure a more thorough discussion of alternatives. In many situations, this would help patients identify the provider-specific factors that influence clinical recommendations and balance the patient-provider knowledge asymmetry, increasing both beneficence and autonomy.

Some patients may not want to know about controversies or standards of care. They may find the additional information too distressful, confusing, or overwhelming. Patients may also specifically seek providers for their non-standard views. Some may seek the unique perspective of an expert at the forefront of the field. Others may seek providers who take patients' non-medical values into clinical consideration. But all patients have the right to know, unless they specify otherwise, when providers incorporate controversial or dissenting views into their clinical recommendations. They may want to know where world experts' expertise ends and when providers' values diverge from their own.

Most patients do not seek individual providers for their unique views but rather seek information on the present state of the medical field. Outcomes data for most providers are not publically available and patients do not usually know what personal factors affect providers' recommendations. Limited by geography, socioeconomic status, or insurance restrictions, many patients cannot freely choose the provider they see. Thus, most patients neither have the necessary information nor the opportunity to cherry pick providers. They want to be treated according to the most current medical standards and counseled with information that conveys the present state of the medical field. Patients view their providers as a representative of the medical field and their trust in their provider is usually predicated on their trust of the medical field. The growing business of "second opinions," especially for serious diagnoses and impactful interventions, underscores, in part, patients' concern about provider variability.[63-65] Disclosing medical experts' disagreements and consensuses (i.e., controversies and standards of care) within informed consent discussions summarizes the present state of the field without overwhelming explanations of data.

VI. Implementation

One practical barrier in implementing the proposed changes involves defining exactly which interventions are standard of care, which are controversial, and which are neither. Though, in many cases, whether an intervention is the standard of care may be disputed, in many other cases it is not. This paper argues for clear disclosure of the standard of care whenever experts clearly support one medical intervention over others—annual influenza vaccinations, beta blockers and ACE inhibitors for patients who have suffered a heart attack, appropriate glycemic control for patients with diabetes, etc. Currently, no unified national guidelines enumerate all of the accepted standards of care. Nevertheless, these interventions are generally supported by strong medical evidence and recognizable by providers practicing in the field. Therefore, requiring standard of care disclosures may be successfully employed, with little inter-provider variability, without explicitly stating what the accepted standards of care they ought to discuss are. However, with the placement of quality metrics for Accountable Care Organizations under the ACA,[66] which are thought to likely expand in the future, providers will need to think of national standards of care anyway. With increasing attention to evidence-based medicine, unwarranted variability in care, and value-based care, the quality of resources providing reliable synthesized information on standards for practice has been improving (i.e., Cochrane databases and the Choosing Wisely campaign). Of course, requiring disclosure of the standard of care will not eliminate variations in what providers believe is standard of care. Sometimes, providers' intuitions will differ. Nonetheless, even with moderate variation between what providers call standard of care, patients would better understand which interventions experts are confident in and in which they are not. Patients would more aptly distinguish the certainties from the uncertainties, leading to more honest and transparent discussions and, as argued above, increased trust and more autonomous decision-making.

Deciding when an intervention is controversial may also pose a challenge to implementation. As one standard of care becomes supplanted by another, a non-standard intervention may gain support until the clinical situation becomes "controversial," then, if support continues to grow it may become the new standard. Therefore, it may not always be clear how much support for a new intervention is sufficient to challenge an existing standard of care. How much expert

disagreement is sufficient to call morcellation controversial? Naturally, experts' intuitions will vary. However, most providers who stay reasonably updated with medical innovation would notice a certain level of dissent in the literature, which should trigger balanced conversations with patients during informed consent.

The modifications to informed consent standards proposed in this paper entail disclosing the standard of care, whenever one exists, and discussing any controversial aspects of a recommended medical intervention or its alternative, whenever fully informed consent is necessary. Amending informed consent laws would requires large efforts applied one State at a time and overcoming resource and administrative barriers. However, if providers were convinced these additions to informed consent practices benefit patients, the medical community can adopt them despite the fact that they are not legally mandated, just like many providers have done with shared-decision making. Nevertheless, amending informed consent practices is not without challenges. First, for some busy providers, even discussing two extra pieces of information may seem like a burden. As I argue above, incorporating these changes into informed consent helps safeguard autonomy and further beneficence and patient trust. The latter is associated with increased satisfaction with providers, adherence to treatment, and continuity of care. [67] Also, with many studies suggesting that patients do not feel adequately informed during informed consent, changes must be made. [62,68]

VII. Conclusion

While legal and ethical standards of informed consent push providers to convey all the relevant and necessary medical information, providers are left to use their own judgments and expertise to determine what information most patients or physicians find material for informed decision-making. This proposed modification to informed consent standards safeguards patient autonomy and furthers trust and beneficence. It also ensures that most patients receive information on the present state of the medical field rather than individual providers' views.

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References

1. Dworkin G. The theory and practice of autonomy. Cambridge: Cambridge University Press; 1988.
2. Hill T. Autonomy and self-respect. Cambridge: Cambridge University Press; 1991.
3. Beauchamp T, Childress J. Principles of biomedical ethics. New York, N.Y.: Oxford University Press; 2001.
4. Berg J, Appelbaum P. Informed consent. Oxford: Oxford University Press; 2001.
5. Kant I, Gregor M. Groundwork of the metaphysics of morals. Cambridge, U.K.: Cambridge University Press; 1998.
6. Schloendorff v. Society of New York Hospital, 105 N.E. 92, 1914.
7. The Nuremberg Code. In Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Volume 2. Washington, DC: U.S. Government Printing Office; 1949.
8. World Medical Association. Code of Ethics of the World Medical Association: Declaration of Helsinki. Helsinki, Finland: World Medical Association; 1964.
9. Protection of Human Subjects, HHS. 45 C.F.R. Part 46.
10. Beauchamp T. Informed Consent: Its History, Meaning, and Present Challenges. Cambridge Quarterly of Healthcare Ethics. 2011;20(04):515-523.
11. Faden R, Beauchamp T, King N. A history and theory of informed consent. New York: Oxford University Press; 1986.
12. Weinmeyer R. Lack of Standardized Informed Consent Practices and Medical Malpractice. Virtual Mentor. 2014;16(2):120-123.
13. *Natanson v. Kline*, 350 P.2d 1093, 1106 (Kan. 1960)
14. *Bryan v. Burt*, 486 SE2d 536, 539 (Va 1997)
15. *Pierce v. Caday*, 422 SE2d 371, 374 (Va 1992)
16. *Raines v. Lutz*, 341 SE2d 194, 196 (Va 1986)).
17. *Tashman v. Gibbs, 556 SE2d 772, 777 (Va 2002)*
18. *Canterbury v. Spence*, 464 F2d 772, 787 (DC Cir 1972).
19. *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979).

20. King JS, Moulton BW. Rethinking informed consent: the case for shared medical decision-making. Am J Law Med. 2006;32(4):440-445
21. Teno J, Hakim R, Knaus W, et al. Preferences for cardiopulmonary resuscitation: physician-patient agreement and hospital resource use. J Gen Intern Med. 1995;10(4):179-186.
22. Barry M, Edgman-Levitan S. Shared Decision Making — The Pinnacle of Patient-Centered Care. NEJM. 2012;366(9):780-781.
23. Fowler F, Levin C, Sepucha K. Informing And Involving Patients To Improve The Quality Of Medical Decisions. Health Affairs. 2011;30(4):699-706.
24. Sepucha K, Simmons L, Barry M, et al. Ten Years, Forty Decision Aids, And Thousands Of Patient Uses: Shared Decision Making At Massachusetts General Hospital. Health Affairs. 2016;35(4):630-636.
25. Whitney S. A Typology of Shared Decision Making, Informed Consent, and Simple Consent. Annals of Internal Medicine. 2004;140(1):54.
26. Henry M. Uncertainty, responsibility, and the evolution of the physician/patient relationship. Journal of Medical Ethics. 2006;32(6):321-323.
27. Rosenbaum L. Communicating Uncertainty — Ebola, Public Health, and the Scientific Process. NEJM. 2015;372(1):7-9.
28. Sawicki N. Modernizing Informed Consent: Expanding the Boundaries of Materiality. SSRN Electronic Journal. 2015.
29. Moore v. Regents of Univ. of California, 793 P.2d 479, 485 (Cal. 1990)
30. Gunderson M. Eliminating Conflicts of Interest in Managed Care Organizations Through Disclosure and Consent. The Journal of Law, Medicine & Ethics. 1997;25(2-3):192-198.
31. Morreim E. Economic disclosure and economic advocacy. Journal of Legal Medicine. 1991;12(3):275-329.
32. Hall M. A Theory of Economic Informed Consent. GA Law Rev. 1997;31:511.
33. Krause JH. Reconceptualizing Informed Consent in an Era of Health Care Cost Containment, IOWA Law Rev. 1999;85:261.
34. Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996).
35. Twerski AD, Cohen NB. The Second Revolution in Informed Consent: Comparing Physicians to Each Other. Northwestern U Law Rev. 1999;94(1).

36. Gostin L. HIV-Infected Physicians and the Practice of Seriously Invasive Procedures. The Hastings Center Report. 1989;19(1):32.
37. Daniels N. HIV-Infected Professionals, Patient Rights, and the 'Switching Dilemma'. JAMA. 1992;267(10):1368.
38. Estate of Behringer v. Medical Center at Princeton, 592 A.2d. 1251 (N.J. Super. Ct. 1991).
39. Ubel P, Abernethy A, Zafar S. Full Disclosure — Out-of-Pocket Costs as Side Effects. NEJM. 2013;369(16):1484-1486.
40. Hall A. Financial Side Effects: Why Patients Should Be Informed of Costs. Hastings Center Report. 2014;44(3):41-47.
41. Riggs K, Ubel P. Overcoming Barriers to Discussing Out-of-Pocket Costs With Patients. JAMA Internal Medicine. 2014;174(6):849.
42. Hersch J, Barratt A, Jansen J, et al. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. The Lancet. 2015;385(9978):1642-1652.
43. Hoffman J, Schriger D. A Graphic Reanalysis of the NINDS Trial. Annals of Emergency Medicine. 2009;54(3):329-336.e35.
44. Hoffman J, Cooper R. How is more negative evidence being used to support claims of benefit: The curious case of the third international stroke trial (IST-3). Emerg Med Australas. 2012;24(5):473-476.
45. Fatovich D. Believing is seeing: Stroke thrombolysis remains unproven after the third international stroke trial (IST-3). Emerg Med Australas. 2012;24(5):477-479.
46. American Cancer Society. Survival rates for uterine sarcoma, by stage. 2015 (http://www.cancer.org/cancer/uterinesarcoma/detailedguide/uterine-sarcoma-survival-rates).
47. Seidman M, Oduyebo T, Muto M, Crum C, Nucci M, Quade B. Peritoneal Dissemination Complicating Morcellation of Uterine Mesenchymal Neoplasms. PLoS ONE. 2012;7(11):e50058.
48. U.S. Food and Drug Administration. Updated Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication. Nov. 24, 2014. (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm)

49. Rosenbaum L. N-of-1 Policymaking — Tragedy, Trade-offs, and the Demise of Morcellation. NEJM. 2016; 374:986-990.
50. Levitz J, Kamp J. Gynecologists Resist FDA Over Popular Surgical Tool. The Wall Street Journal. Sept. 21, 2014. (http://www.wsj.com/articles/gynecologists-push-back-on-fdas-caution-about-cancer-when-using-morcellation-in-hysterectomies-1411358341)
51. Croskerry P. The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them. Academic Medicine. 2003;78(8):775-780.
52. Bogardus ST Jr, Holmboe E, Jekel JF. Perils pitfalls, and possibilities in talking about medical risk. JAMA. 1999; 281(11):1039
53. Lutz, Amy. Deadly Medical Device? WPMT FOX43. N.p., 29 Jan. 2015. (http://fox43.com/2015/01/29/deadly-device/)
54. El-Wakeel H. What do patients really want to know in an informed consent procedure? A questionnaire-based survey of patients in the Bath area, UK. Journal of Medical Ethics. 2006;32(10):612-616.
55. Lenzer J. Why we can't trust clinical guidelines. BMJ. 2013;346(jun19 1):f3998-f3998.
56. Lenzer J, Hoffman J, Furberg C, Ioannidis J. Ensuring the integrity of clinical practice guidelines: a tool for protecting patients. BMJ. 2013;f5535.
57. Condorcet, N. Essay sur l'Application de l'Analysis a la Probibilite des Decisions Rendue a la Pluralite des Voix. Paris. 1785. French, English.
58. Cohen RA, Patricia FA. Use of the Internet for Health Information: United States, 2009. Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, July 21, 2011. (http://www.cdc.gov/nchs/products/databriefs/db66.htm)
59. Wennberg JE, Peters PG. Unwanted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies? Wake Forest L. Rev. 2002;925(37): 925-941.
60. Wennberg J. Unwarranted variations in healthcare delivery: implications for academic medical centres. BMJ. 2002;325(7370):961-964.
61. Wennberg J. Time to tackle unwarranted variations in practice. BMJ. 2011;342(3):d1513-d1513.

62. Zikmund-Fisher B, Couper M, Singer E, et al. The DECISIONS Study: A Nationwide Survey of United States Adults Regarding 9 Common Medical Decisions. Medical Decision Making. 2010;30(5 Suppl):20S-34S.
63. Sutherland L, Verhoef M. Why Do Patients Seek a Second Opinion or Alternative Medicine?. Journal of Clinical Gastroenterology. 1994;19(3):194-197.
64. Wagner T, Wagner L. Who gets second opinions? Health Affairs. 1999;18(5):137-145.
65. Andrews M. Second Opinions Often Sought But Value Is Not Yet Proven. Kaiser Health News. May 26, 2015. (http://khn.org/news/second-opinions-often-sought-but-value-is-not-yet-proven/?utm_campaign=KFF%3A+The+Latest&utm_source=hs_email&utm_medium=email&utm_content=17929489&_hsenc=p2ANqtz--C2NOIVbqZxH6B0mlsR2FskNn6kjsCOBitAi4lon_OHhdljT6cwTYQYuzTTAGX58ocZP8DWIInqSqXYfXpcNsqxAF7Fw&_hsmi=17929489)
66. CMS. Accountable Care Organization 2015 Program Analysis Quality Performance Standards Narrative Measure Specifications. RTI International; 2015.
67. Rolfe A, Cash-Gibson L, Car J, et al. Interventions for improving patients' trust in doctors and groups of doctors. Cochrane Database of Systematic Reviews. 2014;3: CD004134.
68. Braddock III C, Edwards K, Hasenberg N, Laidley T, Levinson W. Informed Decision Making in Outpatient Practice. JAMA. 1999;282(24):2313.