

E-CONSENT: CAN INFORMED CONSENT BE JUST A CLICK AWAY?

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I think I felt, . . . maybe cheated, when . . . these physicians would all have their visits computerized. I think this took away from the personal relationship that one could have. We lost it then, when the doctor would come in and shake your hand and have a computer in the other hand. Everything was on the computer. You figure it doesn't go in through their ears or land in their head—it's on the computer.¹

People need to have some understanding of what's wrong with them. What can and can't be done, I mean maybe this is a lot to ask of a doctor, but I don't think it is. I think it's part of their job.²

INTRODUCTION

As hospitals continue to modernize, electronic informed-consent forms or processes—also known as e-formed consent³—are becoming more prevalent. E-formed consent has already been tested and implemented in a variety of hospitals nationwide.⁴ Although it is impossible, and even unwise, to attempt to halt technology, taking time to reflect on its impact can “be seen as an investment of positive caring energy in the patient,” particularly for those patients

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1. LARRY R. CHURCHILL, JOSEPH FANNING & DAVID SCHENCK, WHAT PATIENTS TEACH: THE EVERYDAY ETHICS OF HEALTH CARE 55 (2013).

2. *Id.* at 37.

3. See, e.g., Peter Brensilver, Note, *E-formed Consent: Evaluating the Interplay Between Interactive Technology and Informed Consent*, 70 GEO. WASH. L. REV. 613, 613 (2002).

4. See, e.g., Robert Gatter, *The Mysterious Survival of the Policy Against Informed Consent Liability for Hospitals*, 81 NOTRE DAME L. REV. 1203, 1205 (2006); Michele Krajewski et al., *Automated Informed Consent Helps Health Care Organizations Respond to New JCAHO Survey Tactics*, 9 J. HEALTH CARE COMPLIANCE 5, 5 (2007); Kristin E. Schleiter, *The Dinosaur in the Office: A Consideration of the Technical and Ethical Issues Surrounding the Adoption of Digital Medical Data and the Extinction of the Paper Record*, 16 ANNALS HEALTH L. 353, 360–62 (2007).

considered most vulnerable.⁵ Taking time to reflect is even more important where, as here, scholars speculate that the e-formed consent model may become more common in the primary-care setting.⁶

The increasing use of e-formed consent may negatively impact the physician-patient relationship by: (1) increasing paternalism, (2) replacing face-to-face interaction, and (3) not addressing individual needs.⁷ On the other hand, for all of the criticisms that have been levied against e-formed consent, scholars also point to potential benefits such as: (1) increasing patient knowledge, (2) improving physician-patient interaction, and (3) possibly creating a more effective doctrine of informed consent.⁸

This Essay provides an overview of the ethical and legal basis of informed consent generally. It briefly examines the laws of the fifty states, particularly as those laws concern the use of written consent forms. This Essay then focuses on problems that patients experience with written informed-consent forms. Following this, it examines scientific studies on how the brain processes material differently when that material is read on a screen versus on paper. This Essay also explores some of the e-formed consent systems being used by hospitals and health-care entities today. It concludes by examining in greater depth the promises and pitfalls of e-formed consent and advocating that best practices be identified and that informed-consent laws be harmonized to reflect the interests of health-care providers and patients, specifically patients considered most vulnerable.

5. DAVID SCHENCK & LARRY R. CHURCHILL, HEALERS: EXTRAORDINARY CLINICIANS AT WORK 14 (2012).

6. See, e.g., Arnold J. Rosoff, *Informed Consent in the Electronic Age*, 25 AM. J.L. & MED. 367, 370 (1999); Brensilver, *supra* note 3, at 619–21; Sarah R. Rupp, Comment, *Making Room for Patient Autonomy in Health Information Exchange: The Role of Informed Consent*, 56 ST. LOUIS U. L.J. 885, 888–89 (2012).

7. See, e.g., Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 86 (2010); Rosoff, *supra* note 6, at 373–74; Brensilver, *supra* note 3, at 628.

8. See, e.g., Melissa M. Goldstein, *Health Information Technology and the Idea of Informed Consent*, 38 J.L. MED. & ETHICS 27, 34 (2010); Yael Schenker & Alan Meisel, *Informed Consent in Clinical Care: Practical Considerations in the Effort to Achieve Ethical Goals*, 305 JAMA 1130, 1131 (2011); Gil Siegal et al., *Personalized Disclosure by Information-on-Demand: Attending to Patients' Needs in the Informed Consent Process*, 40 J.L. MED. & ETHICS 359, 363–64 (2012).

I. INFORMED CONSENT

Informed consent is a critical aspect of the doctor-patient relationship in the United States.⁹ However, this was not always the case.¹⁰ The patient-centered movement, and medical, ethical, and legal developments, have led to an increased emphasis on informed consent in the doctor-patient relationship.¹¹

A. *An Overview of the Purpose of Informed Consent*

Self-determination and individual patient autonomy are the principles at the foundation of informed consent.¹² Individual autonomy was advocated by Judge Cardozo in *Schloendorff v. Society of New York Hospital*:¹³ “Every human being of adult years and sound mind has a right to determine what shall be done with his own body”¹⁴ Individual autonomy encompasses an individual’s right to control the choices he or she makes and the right to be free from unwanted interference from others.¹⁵ Individual autonomy can only be achieved, however, if the patient is sufficiently informed of his or her own right to choose a medical treatment, including the right to refuse medical treatment.¹⁶

Scholars define several key elements of informed consent.¹⁷ The first element is disclosure of information.¹⁸ Health-care professionals should disclose the risks, benefits, nature, duration, and likelihood of success of the treatment, as well as alternative

9. Marc D. Ginsberg, *Informed Consent: No Longer Just What the Doctor Ordered? The “Contributions” of Medical Associations and Courts to a More Patient Friendly Doctrine*, 15 MICH. ST. J. MED. & L. 17, 18 (2010).

10. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900 (1994) (“The doctrine requiring physicians to obtain a patient’s informed consent before undertaking treatment is relatively young, having first appeared in a recognizable, relatively robust form only in 1957.”).

11. Barbara L. Atwell, *The Modern Age of Informed Consent*, 40 U. RICH. L. REV. 591, 592 (2006) (noting that scientific advances in medicine have created medical and legal challenges with regard to informed consent); Jon F. Merz, *On a Decision-Making Paradigm of Medical Informed Consent*, 14 J. LEGAL MED. 231, 231 (1993) (“The expansion of the legal recognition of patients’ rights and the evolution of the informed consent doctrine has accompanied an overhaul of the ethics of medical practice.”); Paula Walter, *The Doctrine of Informed Consent: To Inform or Not to Inform?*, 71 ST. JOHN’S L. REV. 543, 545 (1997) (“[J]udicial decisions have spawned the legal principles of consent, which eventually developed into the doctrine of informed consent.”).

12. TERRANCE MCCONNELL, *INALIENABLE RIGHTS: THE LIMITS OF CONSENT IN MEDICINE AND THE LAW* 65 (2000); Ginsberg, *supra* note 9, at 19.

13. 105 N.E. 92 (N.Y. 1914).

14. *Id.* at 93.

15. Walter, *supra* note 11, at 545–46.

16. *Id.* at 546.

17. MCCONNELL, *supra* note 12.

18. *Id.*

treatments and the consequences of refusing treatment.¹⁹ The second element of informed consent is patient understanding.²⁰ The patient must fully appreciate the information that the health-care provider has conveyed.²¹ The third element of informed consent is voluntariness.²² A patient should voluntarily offer his or her consent and not be pressured or coerced into a decision.²³ Last, but certainly not least, is authorization.²⁴ This is where the patient endorses the treatment (or non-treatment) plan.²⁵ A signature on a consent form is often evidence of authorization.²⁶

One primary reason for informed consent is the power differential between the physician and the patient²⁷:

At a time when the patient is in need of treatment, the patient is most reliant on the knowledge and skill of the physician. The patient needs the physician's services and the physician knows it. The physician has all of the medical, scientific, and technical information about the necessary treatment or procedure and the patient knows it. There is no balance of power in this relationship.²⁸

The power differential varies depending upon the vulnerability of the patient. As keynote speakers Larry Churchill, Joseph Fanning, and David Schenck discussed in their book: "Entering into the relationship with the clinician inevitably establishes a power differential—a differential that exists no matter how sensitive to this asymmetry a given clinician is The differential, and the corresponding risk, are generally reduced the less vulnerable the patient is."²⁹

Churchill and his colleagues initially define vulnerability to include "race, ethnicity, class, gender, education, state of health, and age."³⁰ However, they perceptively recognize that in a patient-centered model, vulnerability should be defined broadly to include factors such as:

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. Ginsberg, *supra* note 9, at 18–19.

28. *Id.*

29. CHURCHILL ET AL., *supra* note 1, at 118–19; *see also* CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 303 (2005) ("Every patient is unique and has different cultural values and views of medical treatment, so it is only after the patient is given sufficient information that he or she can truly make an informed decision.").

30. CHURCHILL ET AL., *supra* note 1, at 119.

nutrition, housing, clothing, job status, life stress, time of day, region of the county, neighborhood in the city, violence and trauma, and natural disaster. All of these elements—and an infinite many more—can be found at work in relationships and balances of agency and power between patients and clinicians.³¹

The shifting power differential, as well as shifting patient vulnerabilities, makes it difficult—but even more important—to create a joint decision-making process between the doctor and the patient to reach a decision about the best course of treatment.³² Studies have shown that participating in the decision-making process can enhance a patient's physical and psychological well-being.³³ Moreover, other studies have shown that illness symptoms tend to be reduced where the patient takes a more active role in the treatment decision-making process.³⁴

B. Paternalism to Patient-Centeredness: The Legal Development of Informed Consent

Until the mid-twentieth century, the concept of paternalism dominated the field of medicine.³⁵ Paternalism advocates the idea that the doctor knows best.³⁶ Under a paternalistic model of health-care delivery, doctors only participate in basic disclosure of information to patients.³⁷ Today, paternalism is largely considered unacceptable as a guiding principle in the practice of medicine.³⁸

With medical advances, the idea of consent and disclosure increased in importance.³⁹ Until the twentieth century, medicine was more mysterious because physicians could not easily explain to their patients which treatment would cure them and which treatment would not.⁴⁰ Then, two important developments occurred. First, physicians began using scientific reasoning in medicine and in research to help the medical field learn what treatments would work

31. *Id.*

32. COLEMAN, *supra* note 29, at 547–48.

33. *Id.*

34. *Id.*

35. See Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 72–73 (1994) (noting that in 1847 the American Medical Association created its first Code of Ethics, which explained that patients should be obedient and a patient's opinion should never influence the physician); Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor Is Right" to "Patient Has Rights,"* 50 SYRACUSE L. REV. 1243, 1243 (2000).

36. Diana Nordlund, *Form Reform: Documenting Emergency Department Informed Consent*, 12 T.M. COOLEY J. PRAC. & CLINICAL L. 415, 419 (2010).

37. *Id.* at 421.

38. *Id.* at 419.

39. See Anthony P. Szczygiel, *Beyond Informed Consent*, 21 OHIO N.U. L. REV. 171, 171–72 (1994).

40. Katz, *supra* note 35, at 76.

best for a patient.⁴¹ Second, the use of scientific reasoning led to technological advances, creating a variety of treatment options.⁴² While these developments opened the possibility for patient involvement in treatment decision making, paternalism persisted.⁴³ It was not until the legal development of informed consent that the paternalistic model transformed into a more patient-centered mode of health-care delivery.⁴⁴

The idea of consent for health-care treatment and procedures arose from common law principles, specifically the common law tort of battery.⁴⁵ Under common law battery, one was prohibited from intentional bodily contact with another without his or her consent.⁴⁶ This common law principle was applied to health-care situations in the landmark case of *Mohr v. Williams*.⁴⁷ In that case, the surgeon was found liable for battery when he operated on a patient's left ear and not the right ear to which the patient had given consent.⁴⁸

The phrase "informed consent" did not actually appear in a legal opinion until 1957 in *Salgo v. Leland Stanford Jr. University Board of Trustees*.⁴⁹ In that case, the patient became paralyzed in his lower extremities after an aortography, and the procedure's details and possible risks were not explained to the patient.⁵⁰ Then, in 1960, the court in *Natanson v. Kline*⁵¹ applied informed consent to a

41. *Id.*

42. *Id.*

43. *Id.*

44. *See id.* at 77.

45. Atwell, *supra* note 11, at 593.

46. *Id.*

47. 104 N.W. 12, 15–16 (Minn. 1905) (explaining that consent imposes a contractual obligation on the surgeon); *see also* Atwell, *supra* note 11, at 593–94.

48. *See* Atwell, *supra* note 11, at 593–94 & n.10.

49. 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) ("A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment The instruction given should be modified to inform the jury that the physician has such discretion consistent . . . with the full disclosure of facts necessary to an informed consent."); Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 270–71 (1999).

50. *Salgo*, 317 P.2d at 174–75, 181. This case framed the informed consent discussion with a great deal of focus on the actions and duties of the doctor. *Id.* at 181 ("A physician violates his duty . . . if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment [T]he physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. . . . [T]he physician must place the welfare of his patient above all else").

51. 350 P.2d 1093 (Kan. 1960).

malpractice suit, rather than the traditional common law tort of battery,⁵² transitioning informed consent to a negligence theory.⁵³

Today, when a doctor does not obtain informed consent, it is generally litigated as a negligence claim.⁵⁴ *Canterbury v. Spence*⁵⁵ is considered the landmark case in this area.⁵⁶ In that case, a patient became paralyzed after surgery and claimed the doctor failed to inform him of the risks of the surgery before the surgery occurred.⁵⁷ The court, in emphasizing the role of patient autonomy,⁵⁸ held that the doctor had to disclose information that the reasonable patient would consider material to his or her decision whether to consent or not.⁵⁹

As the doctrine of informed consent evolved under the negligence theory, various courts developed different standards of “reasonability.”⁶⁰ First, there is the reasonable-physician standard, also known as the professional standard.⁶¹ Under this standard, “the question is whether the doctor has provided the same information that another reasonable doctor would provide under the same or similar circumstances.”⁶² Second, there is the reasonable-patient standard.⁶³ This is the standard the *Canterbury* court adopted.⁶⁴ Under the reasonable-patient standard, the question is whether the physician disclosed all the information that a reasonable patient would need in order to make an informed decision.⁶⁵ Specifically, under a reasonable-patient standard:

52. *Id.* at 1106–07 (holding that malpractice liability can be applied to the physician’s obligation to disclose); Krause, *supra* note 49, at 271.

53. *See* Krause, *supra* note 49, at 271.

54. Atwell, *supra* note 11, at 595.

55. 464 F.2d 772 (D.C. Cir. 1972).

56. Krause, *supra* note 49, at 271.

57. *Canterbury*, 464 F.2d at 777–78.

58. *See id.* at 781 (“[I]t is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie.”).

59. *Id.* at 786–87 (“The scope of the physician’s communications to the patient, then, must be measured by the patient’s need, and that need is the information material to the decision.” (footnote omitted)); Kurtz, *supra* note 35, at 1249.

60. Atwell, *supra* note 11, at 595–96.

61. *Id.* at 596.

62. *Id.* In the courtroom, this standard is generally measured by expert testimony. *See id.*

63. *Id.*

64. *Canterbury*, 464 F.2d at 786–88 (rejecting the professional standard in favor of the reasonable-patient standard); *see also* Atwell, *supra* note 11, at 596–97.

65. George P. Smith, II, *The Vagaries of Informed Consent*, 1 IND. HEALTH L. REV. 109, 116 (2004).

[A] physician is liable to his or her patient if (1) the physician fails to disclose any risk in the recommended treatment, or the existence of any alternative method of treatment, that a reasonable person would deem material in deciding whether to undergo the recommended treatment; (2) the patient would have foregone the recommended treatment had he or she known of the undisclosed information; and (3) as a result of the recommended treatment, the patient actually suffers an injury the risk of which was undisclosed, or the patient actually suffers an injury that would not have occurred had the patient opted for one of the undisclosed methods of treatment.⁶⁶

A third model, though less frequently used, is the subjective standard.⁶⁷ Under the subjective standard, a patient should receive information that satisfies the patient exclusively.⁶⁸ The patient needs to receive and understand information substantial enough to be able to make a personal, confident, and knowledgeable treatment decision.⁶⁹

C. *The Law of Informed Consent Today*

Today, informed-consent law is dictated by state statutes as well as by common law.⁷⁰ While the courts have shaped the informed-consent doctrine in the health-care setting, in many states the legislature regulates informed consent through statute.⁷¹ In the 1970s, about half of the states passed informed-consent statutes.⁷² This was partly due to a lobbying effort on the part of physicians to counteract the reasonable-patient standard articulated in *Canterbury*.⁷³ In many cases, states adopted a professional standard if there was no common law standard or replaced an existing, more liberal common law disclosure standard.⁷⁴

As of today, at least twenty-three states have a general informed-consent statute, or another type of statute that addresses

66. *Id.* at 116–17 (quoting *Neal v. Lu*, 530 A.2d 103, 111 (Pa. Super. Ct. 1987)).

67. See MARK A. HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 203 (2d ed. 2008).

68. See *id.*

69. See *id.*; Karen Ivey, *Medical Malpractice: A Subjective Approach to Informed Consent in Oklahoma*, *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979), 15 TULSA L.J. 665, 665–66 (1980).

70. Krause, *supra* note 49, at 272.

71. Nordlund, *supra* note 36, at 425–26; see sources cited *infra* note 75.

72. Krause, *supra* note 49, at 272; Szczygiel, *supra* note 39, at 192 (“In the short span of 1975 to 1977, almost half the states enacted statutes that made the legal doctrine less threatening to the medical profession.”).

73. Szczygiel, *supra* note 39, at 191–92 (explaining that the patient-oriented disclosure standard required physicians to give more information than they usually gave to patients).

74. *Id.* at 192.

informed consent in the health-care setting.⁷⁵ In the states that do not have a statute that specifically addresses informed consent, the common law of the state determines the informed-consent law.⁷⁶

D. *The Use of Informed Consent Forms*

Particularly in hospitals, and with any type of surgical procedure, informed-consent forms are a prominent part of the process of informed consent.⁷⁷ “[C]onsent forms have evolved to achieve two primary goals—to document a conversation and to be exculpatory in the event of any later disputes over whether relevant information was adequately conveyed.”⁷⁸

Out of the twenty-three states that have a general informed-consent statute, approximately thirteen mention written informed consent in the statute.⁷⁹ Specifically, in Utah, a signed consent form functions as a defense to a lack-of-informed-consent claim.⁸⁰ In Nevada, a signed consent form is a requirement in order to obtain informed consent.⁸¹ In Washington, a signed consent form is prima facie evidence of having obtained informed consent.⁸² A signed consent form is presumed valid in Iowa.⁸³ In Georgia, Idaho, Louisiana, and Ohio, a signed consent form is presumed valid,

75. ALASKA STAT. § 09.55.556 (2014); DEL. CODE ANN. tit. 18, § 6852 (2014); FLA. STAT. § 766.103 (2011); GA. CODE ANN. § 31-9-6 (2012); HAW. REV. STAT. § 671-3 (2013); IDAHO CODE ANN. § 39-4507 (2011); IND. CODE § 34-18-12-1 to -3 (2008); IOWA CODE § 147.137 (2014); LA. REV. STAT. ANN. § 40:1299.39.5 (2014); ME. REV. STAT. tit. 24, § 2905 (2014); NEB. REV. STAT. § 44-2816 (2010); NEV. REV. STAT. § 41A.110 (2006); N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2012); N.C. GEN. STAT. § 90-21.13 (2014); OHIO REV. CODE ANN. § 2317.54 (LexisNexis 2014); OR. REV. STAT. § 677.097 (2013); 40 PA. CONS. STAT. § 1303.504 (2014); TENN. CODE ANN. § 29-26-118 (2012); TEX. CIV. PRAC. & REM. CODE ANN. § 74.104 to .106 (West 2011); UTAH CODE ANN. § 78B-3-406 (LexisNexis 2012); VT. STAT. ANN. tit. 12, § 1909 (2014); WASH. REV. CODE § 7.70.060 (2015); WIS. STAT. § 448.30 (2014).

76. See Krause, *supra* note 49, at 272.

77. See Nordlund, *supra* note 36, at 424 (“Legally, informed consent documentation may be as important as the consent process itself.”).

78. Jennifer Matiassek & Matthew K. Wynia, *Reconceptualizing the Informed Consent Process at Eight Innovative Hospitals*, 34 JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 127, 129 (2008), available at <http://www.ingentaconnect.com/content/jcaho/jcjq/2008/00000034/00000003/art00001>.

79. FLA. STAT. ANN. § 766.103; GA. CODE ANN. § 31-9-6; IDAHO CODE ANN. § 39-4507; IND. CODE ANN. § 34-18-12-1 to -3; IOWA CODE ANN. § 147.137; LA. REV. STAT. ANN. § 40:1299.39.5; ME. REV. STAT. tit. 24, § 2905; NEV. REV. STAT. ANN. § 41A.110; N.C. GEN. STAT. ANN. § 90-21.13; OHIO REV. CODE ANN. § 2317.54; TEX. CIV. PRAC. & REM. CODE ANN. § 74.105; UTAH CODE ANN. § 78B-3-406; WASH. REV. CODE ANN. § 7.70.060.

80. UTAH CODE ANN. § 78B-3-406.

81. NEV. REV. STAT. ANN. § 41A.110.

82. WASH. REV. CODE ANN. § 7.70.060.

83. IOWA CODE ANN. § 147.137.

absent certain conditions specified by the statute.⁸⁴ A signed consent form creates a rebuttable presumption of validity in Florida, Indiana, and Texas.⁸⁵ In Maine and North Carolina, a signed consent form is presumed valid, but is rebuttable if specified conditions are met.⁸⁶ In these states, from a physician or health-care perspective, a signed consent form provides legal evidence of authorization.⁸⁷

II. HEALTH LITERACY: PAPER VERSUS SCREEN

While informed-consent forms are given much weight legally, legal and medical scholars have identified a major problem with respect to patient understanding and comprehension of the information contained in the written forms.⁸⁸ About twenty-five percent of adults in the United States have low literacy skills—that is, reading at a sixth-grade level or below.⁸⁹ The average adult in the United States is at an eighth- or ninth-grade reading level.⁹⁰ The 2003 National Assessment of Adult Literacy estimates that thirty-six percent of U.S. adults are at a basic or below basic health-literacy level.⁹¹ The use of forms is a particular problem for the elderly, recent immigrants, and patients with limited educational

84. GA. CODE ANN. § 31-9-6 (presuming consent is valid absent fraudulent misrepresentations of material facts); IDAHO CODE ANN. § 39-4507 (2011) (presuming consent is valid absent evidence that it was secured maliciously or by fraud); LA. REV. STAT. ANN. § 40:1299.39.5 (presuming consent is valid absent a misrepresentation of material facts); OHIO REV. CODE ANN. § 2317.54 (presuming consent is valid absent proof, by a preponderance of evidence, that there was bad faith, a fraudulent misrepresentation of material facts, or the patient is unable to communicate effectively in spoken and written English (or the language in which consent is written)).

85. FLA. STAT. § 766.103 (2011); IND. CODE § 34-18-12-2 (2008); TEX. CIV. PRAC. & REM. CODE ANN. § 74.106 (West 2011).

86. ME. REV. STAT. tit. 24, § 2905 (2014) (creating a rebuttable presumption of valid consent if there is fraud, deception, or misrepresentation of material fact); N.C. GEN. STAT. ANN. § 90-21.13 (2014) (creating a rebuttable presumption of valid consent if there was fraud, deception, or misrepresentation of a material fact).

87. See Nordlund, *supra* note 36, at 424.

88. Jessica J. Flinn, Comment, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 379, 380, 396 (2009) (noting that in most states a signed consent form creates a legal presumption that consent was obtained and arguing that “inadequate patient health literacy as a barrier to obtaining genuine informed consent that is not adequately taken into account by the legal system”).

89. *Id.* at 381.

90. *Id.* at 382.

91. Bonne Lorenzen et al., *Using Principles of Health Literacy to Enhance the Informed Consent Process*, 88 AORN J. 23 (2008).

attainment.⁹² Health literacy generally requires more knowledge than basic literacy skills.⁹³ Since *understanding* is a crucial element of informed consent, the question becomes whether these forms provide actual proof of informed consent.⁹⁴

In addition, according to one survey by the Institute of Medicine's Committee on Health Literacy, over seventy-five percent of adults have admitted to not reading consent forms because the forms were too long, the format was crowded or intimidating, the font size was too small, or the form used unexplained medical and legal terms.⁹⁵

Some attempts at reforming written consent forms have been successful. According to one study, the percentage of adults who actually read the forms increased substantially when the forms were created using principles of reader-friendly materials, including:

- limit to one page, one- or two-sided
- simple words
- short sentences
- minimal medical terms
- 12- to 14-point serif fonts
- generous white space
- numbering and bullets
- clear headings
- key use of bold text
- 1.5 line spacing⁹⁶

With respect to e-formed consent, however, concerns about patients' abilities to read and understand the information may be exacerbated because of reading and comprehension differences online versus in print:

Understanding how reading on paper is different from reading on screens requires some explanation of how the brain interprets written language. We often think of reading as a cerebral activity concerned with the abstract—with thoughts and ideas, tones and themes, metaphors and motifs. As far as our brains are concerned, however, text is a tangible part of the physical world we inhabit. In fact, the brain essentially

92. Matiasek & Wynia, *supra* note 78, at 127.

93. Flinn, *supra* note 88, at 382 ("Health literacy skills include all the traditional literacy skills (reading and writing), plus several additional or enhanced skill sets, such as, knowledge of common health-related vocabulary, abbreviations, and how the healthcare system works.").

94. MCCONNELL, *supra* note 12, Flinn, *supra* note 88, at 396–97.

95. Lorenzen et al., *supra* note 91, at 25.

96. *Id.* (citing H. OSBORNE, HEALTH LITERACY FROM A TO Z: PRACTICAL WAYS TO COMMUNICATE YOUR HEALTH MESSAGE 8 (2005)).

regards letters as physical objects because it does not have another way of understanding them. . . . After all, we did not invent writing until relatively recently in our evolutionary history, around the fourth millennium B.C.⁹⁷

Recent research has shown that when online readers were limited in navigation (for example, where readers were limited to on-screen PDF versions of a document) comprehension decreased.⁹⁸ Readers who read text on computers performed slightly worse, in terms of comprehension, than readers who read on paper.⁹⁹ They also performed statistically worse in their ability to recall the information on a more long-term basis.¹⁰⁰ With respect to information where readers scrolled down on a computer for text, participants performed worse on attention and working-memory tests than their hard-copy counterparts because the reader who must both focus on the text and how he or she is moving the screen drains more mental resources than turning or clicking a page.¹⁰¹ In addition, studies have found that individuals “reading on screens take a lot of shortcuts—they spend more time browsing, scanning and hunting for keywords compared with people reading on paper, and are more likely to read a document once, and only once.”¹⁰²

III. E-FORMED CONSENT SYSTEMS

While several scholars have predicted an increase, if not universal adoption, of e-formed consent, the health-care industry has been slower on the uptake than expected.¹⁰³ Despite this overall lag, many hospital systems have implemented various e-formed consent programs, such as iMedConsent¹⁰⁴ and Emmi.¹⁰⁵ This Part will briefly examine these two programs and the perceived benefits of e-formed consent.

The Department of Veterans Affairs (“VA”) has implemented the iMedConsent system.¹⁰⁶ It “provides online treatment information in written form, which can be viewed electronically or

97. Ferris Jabr, *The Reading Brain in the Digital Age: The Science of Paper Versus Screens*, SCI. AM. (Apr. 11, 2013), <http://www.scientificamerican.com/article/reading-paper-screens/>.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. Gatter, *supra* note 4, at 1205, 1238, 1240; see Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 745–46, 752 (2012).

104. Gatter, *supra* note 4; Krajewski et al., *supra* note 4, at 7.

105. Gatter, *supra* note 4, at 1239–40.

106. *Id.* at 1205.

printed on paper.”¹⁰⁷ This information includes “procedure-specific consent forms for all medical/surgical procedures, patient education documents for thousands of diagnoses and treatments, and an extensive anatomical image gallery.”¹⁰⁸ While the process is electronic, it is not entirely automated, as it requires physicians “to populate specific sections and fields . . .”¹⁰⁹ After presenting the risks of a specific procedure, as well as risks and benefits of alternatives, iMedConsent then records the patient’s signature electronically.¹¹⁰

Emmi, on the other hand, “is a narrated slideshow combining graphics and written text, which can be accessed repeatedly online or printed.”¹¹¹ Like iMedConsent, Emmi presents the risks of the procedure, as well as risks and benefits of alternatives. However, rather than recording only the patient’s signature, Emmi requires patients “to acknowledge the explanation of risks one-by-one with a mouse click,” each of which is separately recorded.¹¹² Generally, these programs have been regarded as successful, and some scholars opine that the programs are an improvement over existing, paper-based consent forms.¹¹³

For example, scholars point to the fact that these and other e-consent programs offer the patient the opportunity to view information at a more deliberate pace, allowing them to quickly go through content they understand, while taking the time to learn about content that is new to them.¹¹⁴ This contrasts with current practices, in which patients are often handed a written consent form right before a procedure, giving them little chance to fully read and comprehend the information.¹¹⁵ Additionally, e-formed consent allows information to be provided to patients in a variety of formats.¹¹⁶ This allows patients to view the information in a format that enables them to comprehend the necessary information more easily.¹¹⁷ Moreover, the electronic medium allows the patient to receive more information than available through the paper format.

107. *Id.* at 1239.

108. Krajewski et al., *supra* note 4, at 7.

109. *Id.*

110. Gatter, *supra* note 4, at 1239.

111. *Id.*

112. *Id.*

113. Tenenbaum, *supra* note 103, at 747–48.

114. *Id.* at 748.

115. Schenker & Meisel, *supra* note 8, at 1130–31.

116. See Sidney T. Bogardus et al., *Perils, Pitfalls, and Possibilities in Talking About Medical Risk*, 281 JAMA 1037, 1041 (1999).

117. See *id.*

While an increase in the amount of information is, by itself, not necessarily a benefit,¹¹⁸ proponents argue that increased information may improve the patient-physician relationship.¹¹⁹ For example, a patient can be given instructions on how to access informational material, such as a website or information delivered by CD, flash drive, etc., and can view that information at his or her own pace and in his or her own home. The program could have built-in features that test the patient's knowledge, providing better levels of comprehension.¹²⁰ This information can then be sent to the physicians, who can then use their limited time¹²¹—often only seven minutes¹²²—to have more meaningful conversations tailored to their patients' specific needs, instead of possibly overwhelming patients with a generic consent form.¹²³ As one scholar noted:

While innovated technologies could impose distance between physician and patient, they have the potential instead to improve physician-patient communication by increasing access to information and decision-making aids. We could and should maximize this potential by taking the institutional focus away from a one-time, signature-based consent form, to a process that engages the patient in decision making regarding both information exchange and treatment decisions in such a way that honors true autonomous choice.¹²⁴

IV. THE PROBLEMS WITH E-FORMED CONSENT

On the other hand, there are several potential shortcomings to e-formed consent.¹²⁵ For example, some of the studies on brain development, summarized above, support the concern that increased reliance on e-formed consent increases the existing potential for physician paternalism.¹²⁶ Patients are unlikely to read written consent forms for a variety of reasons, and they are even more unlikely to read them when the information is on a screen or tablet versus hard copy.¹²⁷ As a result, the treatment decision becomes more physician-based rather than a decision reflecting the joint

118. Jessica W. Berg, *Ethics and E-medicine*, 46 ST. LOUIS U. L.J. 61, 69–70 (2002).

119. See Brensilver, *supra* note 3, at 625.

120. *Id.* at 624.

121. *Id.* at 625.

122. *Id.*

123. Several authors have described the benefits of this model of interaction. See, e.g., *id.* at 624–25.

124. Goldstein, *supra* note 8, at 29.

125. Almost all of these concerns are also applicable to existing paper-based consent forms.

126. Moulton & King, *supra* note 7 (“Beneficence unbounded by concerns for patient autonomy quickly turns into paternalism.”).

127. Schenker & Meisel, *supra* note 8, at 1130.

physician-patient decision-making process.¹²⁸ This paternalistic tendency has been criticized as defeating the true purpose of the informed-consent principle because if the physician unilaterally makes the treatment decision, then the patient has not truly been informed, nor has the patient truly consented.¹²⁹

Additionally, there are concerns that e-formed consent could reduce, or even eliminate, face-to-face interaction.¹³⁰ As noted above, the average doctor spends about seven minutes with a patient.¹³¹ If the informed-consent process becomes even more automated, and the patient receives the legally required medical information remotely, this may reduce the face-to-face interaction time even further and detrimentally affect not only the informed-consent process but the entire treatment relationship as well.¹³² Certainly, the possibility of reducing face-to-face interaction further increases the likelihood that physicians would not recognize shifting patient vulnerabilities and would therefore neglect to tailor their conversations and treatment plan accordingly.

There is also a concern that e-formed consent, much like its paper predecessor, has the potential to increase the use of generic forms, rather than tailor the informed-consent process to a patient's individual needs.¹³³ This raises the issue of whether consent, when not tailored to a patient's specific needs, is ever truly informed.

With the electronic format of e-formed consent, there are also concerns about patient privacy.¹³⁴ These concerns do, of course, apply broadly to all electronic medical records. It appears that this may be an important hurdle to overcome for purposes of patient trust.¹³⁵ "Patients must also trust their physicians to maintain confidentiality, so they can feel comfortable disclosing necessary personal information."¹³⁶

Finally, and perhaps most importantly with respect to vulnerable populations, there are concerns about patient computer accessibility and literacy.¹³⁷ In order for e-formed consent to be

128. Moulton & King, *supra* note 7, at 85 (noting the effect physician recommendation has on procedure choice).

129. *Id.* at 86.

130. Brensilver, *supra* note 3, at 628.

131. *Id.* at 625.

132. Rosoff, *supra* note 6, at 384.

133. *Contra* Krajewski et al., *supra* note 4, at 8 ("[P]aper-based informed consent documents are typically generic and seldom offer patients information specific to the treatment or procedure they may undergo. The [electronic] application developed by the VA supplies a library of treatment-specific informed consent templates, providing detailed information so patients gain a comprehensive understanding of their treatment options.").

134. Brensilver, *supra* note 3, at 626.

135. *See id.* at 628.

136. Berg, *supra* note 118, at 65 (footnote omitted).

137. *See id.* at 81.

effective, a patient must be able to access and navigate a personal computer, an office tablet, or other electronic device.¹³⁸ While computer literacy is probably far greater than anyone could have predicted when e-formed consent first appeared, there is the potential that computer illiteracy may further disadvantage vulnerable and underserved populations, particularly the elderly and the socioeconomically disadvantaged. Even today, many individuals in these populations do not have sufficient computer literacy skills necessary to use and understand e-formed consent.¹³⁹ As one scholar noted, there is “potential for these new technologies actually to widen the schism between the wealthy and the poor with respect to health care.”¹⁴⁰

V. RECOMMENDATIONS

As this Essay suggests at the beginning, it is likely impossible and probably unwise to attempt to halt technology in the informed-consent process. However, because of the legal importance of informed consent, as well as the corresponding benefits of true informed consent and joint decision making in healing, scholars and practitioners should take the time to reflect and engage in meaningful dialogue about its impact and to determine best practices.

In determining best practices, the focus should include technological practices that promote a patient’s willingness to read or listen to the information, that enhance patient understanding and ability to recall the information, and that move away from the generic use of forms. Best practices should, moreover, provide for patient interaction and shifting patient vulnerabilities. These practices should include appropriate training to individuals for whom electronic modes of communication may be overwhelming by providing access to the technology away from the treatment center and, if necessary, by creating the ability to have information translated into different languages. Best practices should also include recommendations that information only supplement, rather than supplant, face-to-face interaction between the physician and patient.

In addition, physicians should avoid relying on outdated laws that are already criticized for their “use of rule-based consent,”¹⁴¹ that is, that the consent is effective primarily because it satisfies the

138. See Julie Reed, Note, *Cybermedicine: Defying and Redefining Patient Standards of Care*, 37 IND. L. REV. 845, 852 (2004) (noting that adverse outcomes are more likely when direct doctor-patient contact is lacking, particularly if the patient does not know how to use the technology).

139. See Berg, *supra* note 118, at 81 n.91.

140. *Id.* at 82.

141. See, e.g., Goldstein, *supra* note 8, at 28.

rule of law (or the institutional policy or practice), typically through use of an informed-consent form.¹⁴² While this type of consent process may provide for true informed consent, that is not necessarily, or even generally, the case.¹⁴³

The legal doctrine of informed consent needs to be updated to encompass changing technologies and shifting patient vulnerabilities. Scholars and practitioners should be at the forefront to suggest ideas that not only protect health-care workers, but will also promote the underlying principles of informed consent: self-determination and autonomy. Some scholars have previously suggested that informed-consent standards be revised in such a way that would provide for patient autonomy,¹⁴⁴ but would also allow for a presumption of informed consent to satisfy legal requirements.¹⁴⁵ While more study, dialogue, and debate would be needed, such a standard would make use of increasing changes in technology and may be in the best interest of all parties involved. Specifically, by meeting the ethical requirements of informed consent through self-determination and autonomy, the patient's best interest would be protected, and by creating a legal presumption of informed consent, the physician's best interest would also be protected.¹⁴⁶

The current trend toward e-formed consent within health-care institutions, and the likelihood that it may occur more frequently in the primary-care setting, should provide an incentive to capitalize on its best uses and potential benefits. This can be done by implementing best practices and by adopting laws that harmonize the ideals and interests of health-care providers and patients, while taking into account patients' individual and shifting vulnerabilities.

142. Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 762 (1986).

143. Goldstein, *supra* note 8, at 28.

144. *Id.*

145. *See id.*

146. *See* Moulton & King, *supra* note 7, at 91–95.