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Notes

Consent Forms as Part of the Informed Consent Process: Moving Away from "Medical *Miranda*"[1]

by
VICTOR ALI*

Introduction

The current state of the law of informed consent represents a failure of legal efforts to implement a bioethical doctrine. Despite the fact that the doctrine of informed consent is one of the oldest and most widely accepted efforts to implement an ethical doctrine as part of the law, studies have consistently and recently demonstrated that the results of this effort have been dismal.[2] This Note will examine this failure and trace its roots in part to theoretical misunderstandings about what the goal of informed consent truly is. Specifically, many—both in the medical community and elsewhere—still approach informed consent under a harm-avoidance model, in which the primary goal is to protect physicians from legal liability by providing the patient with massive amounts of complicated medical information. The ethically and legally preferable model is one seeking to enhance the patient's autonomy and understanding of the medical decision through a process of active collaboration between the physician and patient. While the autonomy-enhancing model is widely recognized as being superior to the harm-avoidance approach,

1. Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 ARCHIVE INTERNAL MED. 2521, 2522 (1996).

* J.D., University of California, Hastings College of the Law, 2003; B.A., McGill University, 2000. I would like to thank Professor Lois A. Weithorn for her guidance and insights throughout the writing of this Note, and my family for their encouragement and support.

2. Carl E. Schneider, *The Best-Laid Plans*, HASTINGS CTR. REP., July–Aug. 2000, at 24.

recent studies illustrate that the reality of medical practice remains closer to the latter. Concrete steps can and must be taken to alleviate this problem, and this Note will examine consent forms as both an example of the ills of the harm-avoidance model in action as well as an area in which measures can be implemented to bring informed consent in line with the ethical ideals it is meant to enact.

Part I of this Note will describe and assess the two competing models of informed consent—one representing the past and current ills of the doctrine, the other representing the ethically preferable model of the future. In addition to advancing a theoretical rationale supporting the autonomy-enhancing model, this section will also present a concrete medical outcome-related basis for encouraging the development of informed consent into a collaborative process. Part II will address the current application of the doctrine of informed consent in practice, finding that despite a consensus that the autonomy-enhancing model is superior, actual practice more closely resembles the harm-avoidance approach. In Part III, this Note will examine consent forms and will assert that they are a prime example of the harm-avoidance model in action. This section will also present some steps that can be taken to transform consent forms from waivers of liability, or "medical *Miranda* warnings," into tools to assist in the shared decision-making process. This Note will conclude in Part IV that the improvement of consent forms and closer adherence to the principles underlying the autonomy-enhancing model of informed consent will result not only in a better legal and ethical outcome, but also in improved patient health.

I. Theoretical Background

A. The Harm-Avoidance Model

There have traditionally been two models of informed consent—one based on harm-avoidance and the other on the desire to enhance individual autonomy.[3] Proponents of the harm-avoidance model view the purpose of informed consent law as protecting physicians from legal liability by providing the patient with information[4] and obtaining a literal "consent" to go forward with the procedure. Medical decision-making, according to this model, is a discrete event in which a legal objective is accomplished, rather than a process through which the patient is educated about, and encouraged to participate in, the

3. *See* IRENE S. SWITANKOWSKY, A NEW PARADIGM FOR INFORMED CONSENT 1–2 (1998).

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

decision.[5] Under this approach, physicians disclose the risks of and alternatives to a particular treatment to avoid lawsuits, rather than to allow the patient to make an independent and informed decision.[6] Put simply, the emphasis of the harm-avoidance model is on disclosure in order to dispatch with a legal duty, without regard to the patient's level of understanding or true informed consent.[7] As shall be examined in greater detail below, consent forms are a prime example of this approach to informed decision-making in action.[8] Specifically, rather than being viewed as tools to assist patients in understanding a medical decision, consent forms are seen by both physicians and patients[9] as waivers of liability.[10]

The harm-avoidance model of informed consent has been alternately termed by Paul S. Appelbaum an "event model" of informed consent.[11] Appelbaum's formulation sheds light on an important aspect of the harm-avoidance approach. According to Appelbaum, the event model—at a surface level at least—adheres to the legal informational requirements of informed consent.[12] As alluded to above, the emphasis of this approach is on the full disclosure of information.[13] It should be noted, however, that "[p]atients' understanding, although desirable in the abstract, is less crucial to this model than is the provision of information."[14] In essence, this approach elevates the formalistic provision of information above all other considerations in the informed consent process.

An additional problem with the harm-avoidance/event model is its reliance on the assumption that medical care involves "a single decision, or a small number of decisions, made at discrete points in time, when sufficient information is available."[15] In reality, medical decision-making is much more complex than this. Treatment generally involves a series of interactions and decisions as more information becomes available and the patient's understanding of the

5. *See* PAUL S. APPELBAUM ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 152 (2d ed. 2001).

6. *See id.*

7. *See* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 77 (5th ed. 2001).

8. *See* APPELBAUM ET AL., *supra* note 5, at 175.

9. Barrie R. Cassileth et al., *Informed Consent: Why Are Its Goals Imperfectly Realized?*, 302 NEW ENG. J. MED. 896, 899 (1980).

10. *See* Ellen A. Waldman, *Disputing Over Embryos: Of Contracts and Consents*, 32 ARIZ. ST. L.J. 897, 921 (2000).

11. *See* APPELBAUM ET AL., *supra* note 5, at 152.

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.* at 154.

procedure evolves.[16] Even where there is only a single medical decision to be made, the event model is problematic "because of the model's assumption that the decision will be made at a discrete time."[17] This assumption is flawed because it is difficult to determine when a particular medical decision is made—medical decision-making is much more subtle and complex than the event model assumes.[18]

As a result of these flaws in the harm-avoidance/event model, it is "structured in the worst possible way as far as facilitating patients being informed."[19] The one-shot nature of the medical decision under this model makes it difficult for patients to assimilate the voluminous and complicated information with which they are being presented.[20] Moreover, due to the fact that the patient is presented with this information and forced to make a decision at a single discrete point in time, the patient is likely to be experiencing high levels of anxiety at the moment of the decision—another barrier to the effective integration of relevant information.[21] A preferable alternative would be to present the information in a manner more conducive to reflection and critical analysis.[22]

Consent forms exemplify the problems of the harm-avoidance or event model of informed consent.[23] Indeed, Appelbaum asserts that "the consent form can be said to be the central symbol of the event model."[24] The use of consent forms in this manner has contributed to the view that "[w]hat was intended as a process of dialogue and discussion has developed into an event in which papers are signed and minimal legal requirements are satisfied."[25] As shall be examined in greater detail below, consent forms are often used to inundate the patient with legally required information, without regard to the usefulness of this approach in increasing the patient's level of understanding.

Appelbaum's formulation also accounts for the problem of viewing informed consent as an externally imposed legal requirement.[26] The harm-avoidance/event model "perpetuates a view of informed consent as something detached from the unique rhythm of the clinical setting—something imposed on medicine by an

16. *See id.*
17. *Id.* at 155.
18. *See id.*
19. *Id.*
20. *See id.*
21. *See id.*
22. *See id.*
23. *See id.* at 152.
24. *Id.*
25. Waldman, *supra* note 10, at 920.
26. APPELBAUM ET AL., *supra* note 5, at 156.

uncomprehending legal system."[27] Such a perception of informed consent encourages perfunctory and formalistic compliance with its legal requirements, an approach that renders the doctrine next to useless and betrays its ethical goals. An effective model of informed consent must recognize "both the temporal complexity of medical decisions and patients' pedagogic needs."[28] The goal of the autonomy-enhancing approach is to accomplish these important objectives.

B. The Autonomy-Enhancing Model

The ethical rationale underlying the doctrine of informed consent is firmly rooted in notions of liberty and individual autonomy. As one court stated, "[t]he informed consent doctrine is based on the principle that every human being of adult years and sound mind has a right to determine what shall be done to his or her own body."[29] Stated differently, informed consent protects "the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected."[30] The primary goal of the autonomy-enhancing model is to effectuate these ethical principles underlying the doctrine of informed consent.

In contrast to the harm-avoidance approach's emphasis on providing information to protect the physician against legal liability, the focus of the autonomy-enhancing model is on the patient.[31] Under this view, giving informed consent should be "a result of active, personal interaction with the physician."[32] The physician seeks to involve the patient in the medical decision-making process out of concern for the patient's welfare,[33] allowing the patient to make a decision that is "rational, reflective, [and] well-understood."[34] Viewing medical decision-making as a process is central to this model of informed consent.[35] Ideally, informed consent should be the result of an active process of dialogue between the physician and patient.[36] This approach is better suited to the complex nature of medical decisions. Because medical scenarios and patient understanding

27. *Id.*
28. *Id.*
29. Hondroulis v. Schuhmacher, 553 So. 2d 398, 411 (La. 1989).
30. Cobbs v. Grant, 502 P.3d 1, 10 (Cal. 1972).
31. SWITANKOWSKY, *supra* note 3, at 124.
32. *Id.*
33. *See* Lantos, *supra* note 4, at 2813.
34. SWITANKOWSKY, *supra* note 3, at 2.
35. *See* APPELBAUM ET AL., *supra* note 5, at 156; Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 933 (1994).
36. *See* APPELBAUM ET AL., *supra* note 5, at 156.

evolve over time, the best way to foster a patient's comprehension is through an interactive and dynamic process.

The autonomy-enhancing model of informed consent represents the ethically ideal approach.[37] By focusing on the patient and encouraging his or her active participation in the medical decision, this model more closely adheres to the principles of liberty and autonomy that underpin the doctrine of informed consent. Although there is evidence of a paradigm shift towards greater recognition of the superiority of the autonomy-centered approach,[38] as shall be examined in greater detail in Part II, actual practice in the medical community remains out of step with this ethical goal.[39] Admittedly, perfect patient autonomy, while desirable, is very difficult to achieve.[40] It is only by understanding these ethical ideals, however, that even a moderate level of autonomy can be achieved. Thus the formula remains relatively simple: the goal of informed consent is to pursue patient autonomy through a "process of effective communication between physician and patient."[41] By pursuing this goal, physicians can remain true to the ethical underpinnings of the doctrine of informed consent while accommodating the practical requirements and limitations of actual medical practice.

C. Improved Patient Outcomes

In addition to the ethical rationale for increasing patient involvement in medical decision-making, there is also a persuasive argument that increased patient participation results in improved medical outcomes. Though less emphasis has been placed on this justification for enhancing the informed consent process, it is a compelling reason to encourage patient involvement in medical decision-making. Increased involvement in medical decision-making by patients may lead to better medical outcomes, increased psychological well-being, and a greater likelihood that the patient will adhere to the medical regimen.[42] With regard to improved medical outcomes, Sheldon Greenfield et al. studied the differences in

37. *See id.* at 22.

38. *See* SWITANKOWSKY, *supra* note 3, at 122–25.

39. *See* Clarence H. Braddock et al., *Informed Decision Making in Outpatient Practice: Time to Get Back to Basics*, 282 J. AM. MED. ASS'N 2313, 2319 (1999).

40. *See* SWITANKOWSKY, *supra* note 3, at 122.

41. *Id.* at 10.

42. *See* Sheldon Greenfield et al., *Expanding Patient Involvement in Care: Effects on Patient Outcomes*, 102 ANNALS INTERNAL MED. 520, 526 (1985); Braddock et al., *supra* note 39, at 2319; Lois A. Weithorn & David G. Scherer, *Children's Involvement in Research Participation Decisions: Psychological Considerations*, *in* CHILDREN AS RESEARCH SUBJECTS: SCIENCE, ETHICS, AND LAW 134–36 (Michael A. Grodin & Leonard H. Glantz eds., 1994).

outcomes for groups of patients who were subjected to an intervention designed to increase their involvement in medical care.[43] Greenfield's study produced extremely interesting results. Despite the fact that they were initially in a state of poorer health, "patients in the experimental group reported better role and physical functioning after the intervention than did controls."[44] The researchers concluded that this result was in part due to an increased ability of the members of the experimental group to contain their symptoms of illness.[45] More generally, "the interpersonal aspect of the physician-patient interaction may have an appreciable influence on patients' health outcomes."[46]

Patients who are more involved in medical decision-making also experience a greater sense of control. Studies have established a link between a perception of control and a variety of positive health benefits,[47] including "the ability to tolerate pain . . . , the experience and reporting of physical complaints . . . , recovery from illness . . . , tumor growth . . . , and effective daily functioning."[48] Lois A. Weithorn and David Scherer assert that a sense of control has psychological benefits as well. Specifically, "[p]sychological theory and research clearly tell us that the perception and experience of personal control contribute to healthy psychological functioning and that they even may promote physical health."[49] The psychological benefits of a greater perception of control include decreased anxiety and depression as well as increased self-esteem.[50]

Another benefit of involving patients more extensively in medical decision-making is that, to the greater extent that they are active participants in the process, patients are more likely to adhere to their medical regimens.[51] As a consequence of their diligent adherence to their medical regimens, more actively involved patients will experience improved medical outcomes.[52] Conversely, "inadequate patient involvement may interfere with patient acceptance of treatment and adherence with medical regimens."[53] Thus, it is clear that in addition to the more theoretical ethical rationale for improving on legal efforts in the area of informed

43. Greenfield et al., *supra* note 42, at 521.
44. *Id.* at 526.
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. Weithorn & Scherer, *supra* note 42, at 134–35 (citations omitted).
50. *Id.* at 135.
51. *See id.*; Braddock et al., *supra* note 39 at 2319.
52. *See id.*
53. Braddock et al., *supra* note 39, at 2319.

consent, there is a strong argument based on improved outcomes—both physiological and psychological—for the patient. While the autonomy-enhancing model may be attractive to ethicists, this outcome-based rationale has the benefit of appealing to physicians who, after all, are the ones who are directly participating in the provision of medical care and best situated to implement changes.

II. Problems with Informed Consent

The inadequacy of legal efforts to harmonize the practice of informed consent with its ethical ideals has been well documented.[54] One author has argued that, despite the fact that informed consent is one of the oldest and best-accepted attempts to put bioethical principles into law, it has been a great disappointment.[55] A recent study of informed decision-making by Clarence H. Braddock et al. supports this assertion. Braddock tape-recorded over 1,000 patient encounters with primary care physicians and surgeons and studied over 3,500 clinical decisions of varying degrees of complexity.[56] This study was unique in that it involved direct observation of the decision-making process rather than reliance on indirect measures such as tests of information recall or reports by patients and physicians of what information should be disclosed.[57]

The results were troubling; Braddock found severe deficiencies in the levels of information provided to patients.[58] Only nine percent of the approximately 3,000 observed decisions "met criteria for completeness of informed decision-making."[59] Perhaps even more alarmingly, less than one percent of intermediate and complex medical decisions were complete.[60] These findings led the authors to conclude that "the ethical model of informed decision-making is not routinely applied in office practice" and that "physicians' typical practice is out of step with ethical ideals."[61]

54. *See* SWITANKOWSKY, *supra* note 3, at 123 (noting that "[t]he paradigm shift in medicine from the harm avoidance model to the autonomy-enhancing model has still not been completely accomplished"); Braddock et al., *supra* note 39, at 2319; Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J.L. & MED. 361, 398–99 (2001) (arguing that "informed consent law is still primarily about consent, not the information that is required to increase patient choice and participation").

55. Schneider, *supra* note 2, at 24.

56. Braddock et al., *supra* note 39, at 2317.

57. *Id.* at 2314.

58. *Id.* at 2317.

59. *Id.*

60. *Id.*

61. *Id.* at 2319.

In another article on informed consent, Peter Schuck asserted that, despite the fact that informed consent can only be achieved through the process of meaningful dialogue between the patient and physician advanced by the autonomy-enhancing model, in reality "most physician-patient discussions appear to be rather perfunctory and reinforce physician control."[62] Schuck's survey of empirical studies indicated that physicians tend to avoid the interactive, open-ended dialogue that an autonomy-enhancing approach to informed consent requires.[63] This led Schuck to the dismal conclusion that "informed consent law in action is often ritualistic, formalistic, and hollow."[64]

These findings are strong evidence that the paradigm shift from a harm-avoidance model of informed consent to one based on respect for patient autonomy is far from complete. This is in part a result of the fact that many physicians remain wary of any expansion of the patient's role in medical decision-making.[65] Jay Katz, a leading authority on informed consent, addressed this problem in his book on the ethos of silence that exists between doctors and patients.[66] The history of the doctor-patient relationship, according to Katz, is characterized by silence and authoritarianism.[67] The paternalistic nature of the physician-patient relationship reveals "physicians' inattention to their patients' right and need to make their own decisions."[68]

Resistance to a more expansive approach to informed consent from some members of the medical community is based on the misperception that "there is a fundamental incompatibility between the patient autonomy that informed consent is intended to promote and physician responsibility for a patient's well-being."[69] Essentially, proponents of this view believe that in order to empower the patient, the physician must disempower him or herself.[70] This view illustrates a failure to view informed consent as a collaborative process.[71] In reality the autonomy-centered model of informed consent is not at odds with the physician's role as a medical counselor. Often, in addition to information, the autonomous patient seeks advice on

62. Schuck, *supra* note 35, at 933.
63. *Id.*
64. *Id.* at 934.
65. *See* JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 28 (1984).
66. *Id.*
67. *Id.*
68. *Id.*
69. Meisel & Kuczewski, *supra* note 1, at 2521.
70. *See id.*
71. *Id.* at 2523.

whether to pursue a particular course of treatment.[72] Informed consent does not require that physicians take on a passive role, subject to the micromanagement of the patient, but rather calls for a more egalitarian and interactive partnership in which both sides provide input.[73] Moreover, the fact that increased patient participation in medical decision-making has been shown to result in better health outcomes should also alert physicians to the idea that increased patient participation is a desirable goal. It is only by encouraging such a partnership that the ills described above can be avoided.

III. Consent Forms

A. The Problem of Consent Forms

The common use of consent forms is a particularly salient example of the harm-avoidance model in action.[74] The pervasive view of consent forms as a legal document contributes substantially to this problem. In an illuminating study of this issue, Barrie Cassileth et al. examined patients' views and attitudes towards both consent forms and informed consent in general.[75] Cassileth surveyed 200 cancer patients who had signed consent forms for chemotherapy, radiation therapy, or surgery one day before treatment.[76] The study found that although patients recognized the importance of the information contained in the consent forms, few of them actually read the forms carefully.[77] Moreover, eighty percent of the patients viewed the consent forms as legal protection for the physician.[78] Cassileth argues that the perception of consent forms as legalistic, potentially adversarial instruments is responsible for the passive approach that patients take to the forms and is inconsistent with a doctor-patient relationship based on cooperation.[79] Put simply, because patients view consent forms as legal protection for physicians, they are skeptical of the forms' utility as a tool to enhance their own understanding of the medical procedure.

This perception of the purpose of consent forms exists among physicians as well. Alan Meisel and Mark Kuczewski describe such

72. *Id.*
73. *See id.*
74. *See* Cassileth et al., *supra* note 9, at 896.
75. *Id.*
76. *Id.* at 896–97
77. *Id.* at 899.
78. *Id.*
79. *Id.*

consent forms as "medical *Miranda* warnings."[80] According to this analogy, some physicians believe that a cursory warning of the risks of treatment and a patient signature are all that is legally necessary to obtain informed consent, just as law enforcement agents who take suspects into custody need only briefly advise them of their constitutional rights before beginning interrogation.[81] As illustrated by the Cassileth study, it is clear that patients also subscribe to this view of consent forms.[82] Meisel and Kuczewski argue that while the risks of treatment are a relevant consideration, "the focus needs to be on therapeutic options."[83] Viewing consent forms as a collaborative tool in the informed consent process would help alleviate the medical *Miranda* problem and the concerns raised by the Cassileth study. In order for consent forms to be truly effective, both doctors and patients must attempt to use them as instruments designed to facilitate the patient's understanding of the risks of and options to treatment rather than "as simply a bureaucratic hurdle to be jumped."[84]

B. Potential Improvements

(1) An Adjunctive Approach

There are a number of concrete steps to be taken to improve the efficacy of consent forms. Appelbaum presents a particularly helpful approach to the use of consent forms—what he describes as an "adjunctive approach."[85] An adjunctive approach avoids the problems of the harm-avoidance/event model by using consent forms as a tool to assist in the informed consent process.[86] Specifically, forms should be used as a supplement to the oral disclosure of risks and alternatives that a physician normally gives.[87] To this end, Appelbaum argues that the forms may be provided before or after oral disclosure.[88] Providing consent forms to patients prior to disclosure allows the patient to gain some background knowledge and prepare questions.[89] This would allow the patient, for example, to discuss the information contained in the form with relatives or loved

80. Meisel & Kuczewski, *supra* note 1, at 2522.
81. *Id.* at 2522–23.
82. *See* Cassileth et al., *supra* note 9, at 899.
83. Meisel & Kuczewski, *supra* note 1, at 2523.
84. Waldman, *supra* note 10, at 921.
85. APPELBAUM ET AL., *supra* note 5, at 180.
86. *See id.*
87. *See id.* at 181.
88. *Id.*
89. *See id.*

ones.[90] Alternately, consent forms may be provided after disclosure "to aid reflection, integration, and the formulation of questions."[91]

Appelbaum argues that consent forms may be provided in advance of *or* after disclosure.[92] A preferable alternative would take advantage of the benefits of both of these approaches by allowing the patient to review the consent form *both* before and after oral disclosure. By studying the form in advance, the patient will be better prepared to understand oral disclosure and, after disclosure, the patient will be able to continue to review the consent form on his or her own in order to fully assimilate the information. Admittedly, emergency medical circumstances may preclude such a process; nevertheless, where it is possible, this approach should be implemented to enhance patient understanding of complex medical decisions.

(2) Improving Readability

Much can be done to improve the readability of consent forms as well. As detailed above, there is a tendency for consent forms to be viewed as a means of complying with the legalistic informational requirements of informed consent. This has resulted in very lengthy and dense forms, "[w]ritten in complex language dappled with technical description."[93] T.M. Grundner, in a study of this issue, argued that while much effort has been dedicated to increasing the content of consent forms, little attention has been paid to how easy they are to read and understand.[94] This is problematic because if the information is provided in a manner that is difficult to understand, then the whole informed consent process becomes flawed, irrespective of how much information is provided.[95]

Grundner's study of five diverse major medical facilities in the Los Angeles area found that readability was in fact a significant problem.[96] Specifically, "[f]our of five [consent] forms were written at the level of a scientific journal, and the fifth at the level of a specialized academic magazine."[97] Put differently, on a readability scale of 0 through 10, with 0 being the most difficult to read, four of the five forms scored under 1.5, and the fifth did only slightly better.[98]

90. *See id.*
91. *Id.*
92. *Id.*
93. Waldman, *supra* note 10, at 921.
94. T.M. Grundner, *On the Readability of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900 (1980).
95. *Id.*
96. *Id.* at 901.
97. *Id.*
98. *See id.*

These findings are likely in part a result of the fact that the forms were created by committees of physicians and attorneys.[99] Committee members surely found the forms readable (and well-suited to the purpose of protecting against legal liability), but the same does not hold for the average patient.[100] This led Grundner to conclude that "if every surgical consent form in the country were subjected to similar analysis, few would pass."[101]

These findings are troubling because, as alluded to above, consent forms lose all of their efficacy as autonomy-enhancing instruments if the information they contain is inaccessible to the average patient.[102] While some physicians may rely on oral disclosure to compensate for the shortcomings of a consent form, "individual oral explanations vary widely in adequacy and completeness, as does the listener's comprehension."[103] Readable consent forms serve to counter the variation and subjectivity that is inherent in oral disclosure.[104] An "oral explanation delivered in conjunction with an unintelligible written form is no improvement over the oral explanation alone."[105] Thus, it is clear that reliance on oral disclosure and an indecipherable consent form is not an ethically permissible means of achieving informed consent.

The need to improve the readability of consent forms and thereby enhance patient understanding is apparent. Solace can be taken, however, in the fact that efforts to improve the readability of consent forms are generally successful.[106] A recent study of the effects of a writing improvement program on consent forms in the research context yielded positive results. The researchers concluded that the traditional approach of shortening sentences and using words with fewer syllables to improve readability often ends up causing more problems, by creating more confusion and misunderstanding.[107] As an alternative, the researchers proposed concrete steps to be taken to improve the readability of consent forms.[108] Effective methods of improving readability include: "using less technical vocabulary; . . . defining technical terms; . . . providing explicit information; . . . stating clearly cause and effect; . . . presenting the sequence of events in a

99. *Id.*
100. *See id.*
101. *Id.*
102. *See id.*
103. *Id.*
104. *Id.* at 902.
105. *Id.*
106. *See, e.g.*, Sandra J. Philipson et al., *Effectiveness of a Writing Improvement Intervention Program on the Readability of the Research Informed Consent Document*, 47 J. INVESTIGATIVE MED. 468 (1999).
107. *Id.* at 472.
108. *Id.* at 475.

clear format using numbering or bullet writing; . . . [and] providing concrete examples of difficult concepts. . . ."[109] The implementation of such measures produced "informed consents that are clearly superior in comprehensibility to any produced in the pre-intervention study."[110]

An additional step that should be taken is to involve patients and lay persons in the development of consent forms. As Grundner aptly notes, part of the readability problem stems from the fact that consent forms are developed by committees of physicians and attorneys. Input and feedback from the individuals who these forms are directed at would be an effective and relatively simple way to improve their readability.

A final suggestion in dealing with the readability problem is to change the format of consent forms entirely. Some authors have advocated using video- or audiotapes as an adjunct to oral disclosure.[111] This method would be particularly helpful for those who cannot read,[112] and makes the most of the technological advantages of the multimedia society in which we live. In a similar vein, the Internet may prove to be an extremely useful tool for assisting in the informed consent process as well, by providing for patients with varying educational levels and needs. Moreover, the interactive nature of the Internet has great potential for facilitating a more dynamic process of informed decision-making.

(3) Legislative and Judicial Responses

Legislatures, in addressing whether a consent form is valid, have largely left the issues of patient participation and the manner in which information should be presented untouched.[113] For example, a Florida statute states that a "consent which is evidenced in writing shall . . . if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent."[114] Similarly, an Ohio statute requires only that a written consent describe in general terms the nature and risks of the procedure and alternatives to treatment for the consent to be presumed valid and effective.[115] These examples illustrate a lack of attention to the form in which information is provided and exemplify a legalistic view of the role of

109. *Id.*

110. *Id.*

111. APPELBAUM ET AL., *supra* note 5, at 185; Mary Laska Malone, *Informed Consent and Hospital Consent Forms: Paper Chasing in a Video World*, 61 J. URBAN L. 105, 125 (1983).

112. Malone, *supra* note 111, at 125.

113. *See* Terry, *supra* note 54, at 400.

114. FLA. STAT. ANN. § 766.103(4)(a) (West 2001); *see also* Terry, *supra* note 54, at 400 n.302.

115. *See* OHIO REV. CODE ANN. § 2317.54 (West 2001); Terry, *supra* note 54, at 400.

consent forms. Little is said of patient participation; rather, the emphasis is on signatures and presumptions of consent. This stems from the fact that these statutes concerning consent forms were enacted primarily to protect physicians from lawsuits.[116] The ethical principles and medical findings described above, however, require a legislative approach that views consent forms and informed consent as a means of fostering patient understanding of, and active participation in, medical treatment.

Courts have been equally ineffective in advancing patient understanding of complex medical decisions.[117] For most courts, "the informed consent doctrine supports a relatively unsophisticated, even literal consent model derived from basic autonomy principles."[118] This approach has neglected the patient's involvement in the decision-making process.[119] As a result, "informed consent law is still primarily about consent, not the information that is required to increase patient choice and participation."[120] Courts have had little to say on the use of consent forms as well. At common law, there is no requirement that consent forms even be used, and several courts have stated that the forms are not necessary.[121] In interpreting consent form statutes like the ones described above, courts have viewed the forms as evidence that consent was given, but not necessarily that the consent was informed.[122] Both legislatures and courts focus primarily on whether or not there was formalistic consent to a particular medical procedure, rather than on whether the patient fully understood the information and played an active role in making the decision.

(4) Clarifying the Relationship between Consent Forms and Oral Disclosure

Appelbaum argues that an adjunctive approach would help to remedy the problems of ineffective and confusing consent forms.[123] Viewing forms as an adjunct to the more exhaustive and customized oral disclosure makes it unnecessary to require the inclusion of massive amounts of information in the forms themselves.[124] Under this approach, the forms should still contain important information about the procedure; however they do not need to include the large amounts of technical information that would be required by a view of

116. APPELBAUM ET AL., *supra* note 5, at 177.
117. *See* Terry *supra* note 54, at 397–99.
118. *Id.* at 398.
119. *Id.*
120. *Id.* at 398–99.
121. APPELBAUM ET AL., *supra* note 5, at 176.
122. *Id.* at 178.
123. *Id.* at 183.
124. *Id.*

consent forms as protection against liability.[125] After detailing that the patients have a choice and that information has been presented to the patients to assist their decision, consent forms should "then explain the nature of the procedure and detail the major risks and benefits, along with possible alternatives, while acknowledging that everything of interest to a particular patient may not be covered."[126] The patient is then free to question their physician on any matter they feel is relevant or that they do not adequately understand. To facilitate an interactive process between the physician and patient, the form (and physician) should emphasize that the patient should raise any questions he or she might have with the physician, and encourage the sort of open-ended dialogue that is critical to true informed decision-making.

Steps have already been taken by some state legislatures to expand the role of oral disclosure in conjunction with the use of consent forms.[127] Oregon, for example, requires that after the physician describes the medical procedure and its risks and alternatives, he or she must "ask the patient if the patient wants a more detailed explanation" and if the patient requests further explanation, "the physician . . . shall disclose in substantial detail the procedure, the viable alternatives and the material risks."[128] Using consent forms as a written adjunct to this more dynamic and collaborative process of oral disclosure rather than as a legal record will help eliminate the problem of the inclusion of excessive information and technical language, and will help bring the practical application of informed consent in line with the doctrine's ethical goals.

IV. Conclusion

The paradigm shift from a harm-avoidance model of informed consent to an autonomy-enhancing model is far from complete. While there is little dispute that the goal of increasing patient involvement in medical decision-making is a worthy one, studies illustrate medical responses to informed consent ranging from perfunctory compliance to active resistance. Moreover, many patients adhere to a view of informed consent and consent forms as a means of protecting physicians from legal liability. It is also clear that patients remain largely passive and uninvolved in important decisions concerning their own welfare.

125. *See id.* at 182–83.
126. *Id.* at 183.
127. *Id.*
128. OR. REV. STAT. § 677.097 (1999).

Although these are discouraging findings, comfort can be taken in the fact that attention is being focused on this problem and that there are concrete steps that can be taken to advance towards the goals of an autonomy-enhancing model. At the most fundamental level, both patients and physicians must be encouraged to view the goal of informed consent as being to increase patient understanding of and involvement in the medical decision-making process. A key step in this direction is to emphasize to physicians the fact that a collaborative autonomy-enhancing approach to informed consent has been shown to lead to improved patient outcomes. It would also be encouraging to see legislatures and courts focus more on the content and accessibility of consent forms and the informed consent process *in addition to* the issue of whether or not consent was given. Steps—such as using consent forms as an adjunct to oral disclosure and implementing the specific measures identified in the Philipson study[129]—can be taken to increase the readability of consent forms, thereby enhancing their role as tools to increase patient understanding and involvement. These measures will enable us to move closer to a reality in which informed consent is a process by which patients come truly to understand and to participate in their own medical decisions.

129 *See* Philipson et al., *supra* note 106, at 475.

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