Correspondence

Flaws in Revising Medical Consent Forms

Dear Editors:

There are serious deficiencies in the suggestions for drafting consent forms appearing in *Revising Medical Consent Forms: An Empirical Model and Test*, which was written by Professors Kaufer and Steinberg and Ms. Toney, and published in the September issue. This article was written, of course, by people who are not lawyers and should not be expected to know about the law of informed consent or the way that consent forms are used. People who really write consent forms, I hope, know better. We all agree that when a consent form is used (whether it should be used is another matter), it should make sense to the person signing it; however, there are serious legal and practical flaws in some of the authors' suggestions.

First, it chills me to consider the effects on family members of using a *form* to note their agreement to an order not to resuscitate a patient. Consider having that form stuck under *your* nose if the patient were someone *you* loved. In any situation in which any such order is pertinent, the least that the family ought to expect and receive is a discussion of the situation at hand. The attending physician's note in the chart must detail exactly what was told to them. Consent forms are for routine procedures; terminating treatment in order to allow someone to die in peace is *never* a routine procedure. This form trivializes to the point of indecency what may well be the worst moment in that family's lives. If for some reason the physician feels the need not only to document the situation but also to provide evidence of the family's assent, the physician should either write a note in the chart and ask a family member to sign it or instruct a member of the family to write and sign the note. A jury would be extremely suspicious of any institution so blasé as to have a form for these decisions.

Second, if there is such a form, it should never be a checklist. In addition to the trivialization of a dreadful decision, people who are coping with the imminent death of someone they love might very well check the wrong line, or the person in charge when a cardiac arrest occurs may read the wrong line. Yale-New Haven Medical Center's policy, for example, forbids the use of any abbreviations (such as DNR) in any such order, lest they be misread in a moment of crisis. Consider the horror to all parties of a death followed by the discovery that someone read the wrong line on a check-sheet; consider the liability.

Similarly, "extraordinary measures" are not subject to definition on a "separate checklist and glossary" for doctors to consult. What is "extraordinary" depends on the patient. For example, penicillin is not "extraordinary" for a 16-year-old with an infection and no other problem; it may, however, be very "extraordinary" for an 86-year-old patient with cancer who develops pneumonia.

Readers interested in a policy establishing the documentation required in a decision not to resuscitate a patient at Yale-New Haven might be interested in reading it in the August 1983 issue of *Connecticut Medicine*.[1]

In addition, no consent form should ever, under any circumstances, include any language indicating an attempt by the hospital or the physician to have a patient release them from liability if something goes wrong. In the first place, as court after court has held with absolute uniformity in every state in which the issue has been raised, such waivers do not work.[2] Releases are unenforceable as contracts of adhesion in the absence of proof of negligence, and no one can consent to negligent treatment. Moreover, such efforts present a posture of defensiveness that seems to tell the patient that the institution is more interested in not getting sued than it is in taking care of the patient. This is usually inflammatory enough to guarantee that if anything does go wrong, the first stop the patient makes after discharge is the lawyer's office. In addition, in any research consent form,

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such attempts to limit liability are specifically prohibited by federal regulation.[3]

In the best of all possible worlds, from the perspective of a hospital lawyer, there would be no consent forms. The physician would talk to the patient and write a note in the chart documenting what was said, and the patient would countersign the note to indicate his or her understanding and agreement. Thus, the patient might have some cause to feel that he or she is not a widget rolling off a medical assembly line and that consent negotiations are taken seriously. Even with a standard procedure, the disclosures may quite reasonably vary between one patient and another, depending on what the physician determines a particular patient's concerns to be. Since a consent form that does not discuss the specific disclosures made to that patient is useless in defense of a malpractice case anyway, such forms should be eliminated.

Readability scales, however, are not responsive to the problem in this context. To cite one example, given in Robert J. Levine's book, *Ethics and Regulation of Clinical Research*, the following statement is very common in consent forms in the context of research: "In the preparation of this consent form it was necessary to use several technical words; please ask for an explanation of any you do not understand."[4] Levine notes that on the Fry Readability Scale, that statement rates very high on a college reading level (which may tell us something about college admissions). Levine continues:

> [A]ccording to the Flesch Readability Yardstick, it is in the upper range of difficulty for academic or scholarly prose. The statement may be reworded as: "Some arcane words are on this page. I'll construe them as you wish." According to the Fry test, this is suitable for a first grader; Flesch rates it as easier than "pulp fiction."[5]

I am concerned about having people who are not familiar with the legal system or medical care write consent forms; one specific example from the article will illustrate this concern. If a patient's condition is not terminal — for example, a Jehovah's Witness who has been in a motor vehicle accident, but who would be expected to recover if blood is given — the adult patient may, of course, refuse treatment, but no next of kin may do so if the patient cannot speak for himself or herself. Thus, the authors' reference to a form on which spouses may refuse blood or other treatment for an incompetent patient on religious grounds exhibits an unnerving lack of understanding of the applicable law as well as a lack of familiarity with the rather basic fact that standing in an emergency room saying "He's a Jehovah's Witness, do not give him blood" is a good deal cheaper than getting a divorce.

Angela R. Holder, J.D., LL.M.
Clinical Professor of Pediatrics (Law)
Counsel for Medicolegal Affairs
Yale University School of Medicine
Yale-New Haven Hospital
New Haven, Connecticut

References

1. Committee on Policy for DNR Decisions, Yale-New Haven Hospital, *Report on Do Not Resuscitate Decisions*, CONNECTICUT MEDICINE 47(8): 477-83 (August 1983).

2. *See, e.g.*, Emory University v. Porubiansky, 282 S.E.2d 903 (Ga. 1981); Olson v. Molzen, 558 S.W.2d 429 (Tenn. 1977).

3. Protection of Human Subjects, 45 C.F.R. §46.116 (1981). "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

4. R. J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH (Urban & Schwarzenberg, Baltimore, Md.) (1981) at 101.

5. *Id.*

The authors respond:

Professor Holder makes several arguments against our article. We would make the following comments. First, she assumes that we advocate consent forms as an alternative to open discussions with the physician. Nowhere do we state such an opinion. Indeed, we hope that our consent forms would encourage questions by patients; as we mentioned in the article, the consent form is "a record of the discussion that has taken place."

Professor Holder refers to us as "people who are not familiar with the legal system or medical care." The work we described was done for a law firm, many of whose clients are hospitals. We worked with lawyers in that firm on our revisions, and the firm approved those revisions. It continues to recommend the revised forms to its clients.

Professor Holder says that checklists "trivialize" decisions to consent and that they are highly prone to error, but she offers no evidence for this assertion. She claims that "extraordinary measures" are not subject to definition on a "separate checklist and glossary" for physicians to consult. She backs her claim by asserting that "extraordinary" depends on the patient. But it seems that this assertion could also be used to support keeping a separate (and updated) glossary for explaining in lay terms the wide variety of treatments that could reasonably fall under the rubric, "extraordinary measures."

Professor Holder also discredits readability scales — which she seems to represent us as endorsing unconditionally. We were very careful to detail the assumptions under which readability scores can be used judiciously by the reviser. As we noted, "readability formulas are highly corrigible instruments. . . ."

Professor Holder claims that "no consent form should ever, under any circumstances, include any language indicating an attempt by the hospital or the physician to have a patient release them from liability if something goes wrong. Perhaps this is true — but for prudent, not legal, reasons. We had, after all, revised a form that had made these inclusions and was nonetheless in use. Our article only took responsibility for suggesting how to revise consent forms already judged legal. We did not claim to cover all the considerations of prudence that go into *making up* such forms — only the considerations of comprehensibility that go into revising them.