Informed Consent — Why Are Its Goals Imperfectly Realized?

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INFORMED consent has remained a focus of intense interest since the Nuremberg Code was adopted in 1947.[1] Attention has centered on two general aspects of informed consent: its legal and ethical ramifications, and its practical effectiveness in the clinical setting. This study is concerned with the latter.

The goal of the consent process is to provide a mechanism for patients to participate in treatment decisions with full understanding of the factors relevant to their proposed care.[2,3] However, previous studies have shown that patients remain inadequately informed, even when extraordinary efforts are made to provide complete information and to ensure their understanding. This appears to be true regardless of the amount of information delivered, the manner in which it is presented, or the type of medical procedure involved.[4,5,6,7] We explored patients' perceptions of consent and their attitudes toward it, in an effort to understand why the consent process often fails to accomplish its intended objective.

METHODS

Procedure and Subjects

With the physician's approval, consenting patients completed two paper-and-pencil tests: a test of their recall of information regarding consent, and a questionnaire designed to determine patients' perceptions of the purpose, content, and implications of the material in the form and of oral explanations. Arrangements were made with staff in the departments of Radiation Therapy, Hematology/Oncology, and Surgery to notify us when literate, mentally competent, English-speaking patients were about to sign consent forms. As patients became available in this manner, they were approached consecutively within one day of signing these forms by one of the authors (K. S. S. or V. M.). Patients were invited to participate in a study involving their understanding of and feelings about the consent form that they had recently signed. Verbal consent was obtained; the University's Human Studies Committee thought that written consent was not indicated. Research questionnaires were completed wherever patients happened to be located — in private rooms adjacent to clinics or in their hospital rooms. The research assistant remained with the patient to provide any assistance required.

A total of 207 patients were approached consecutively over a five-month period before the desired total of 200 participants was obtained. Seven persons declined to participate either because they felt too ill or because, as outpatients, they could not spare additional time away from their jobs. These seven patients did not differ demographically in any systematic way from the others.

Two hundred cancer patients at the Hospital of the University of Pennsylvania and at an affiliated Veterans Administration Hospital comprised the study population. Participants ranged in age from 20 to 82 years, with a median age of 59. Each patient's medical status was assessed by the research assistant who administered the questionnaire — with assistance from physicians when necessary — according to Eastern Cooperative Oncology Group criteria. The status of the patients was generally good: 60 per cent of the patients were fully

ambulatory, 18 per cent were bedridden less than half the time, and 22 per cent were bedridden most of the time. The demographic and medical characteristics of the patients studied are shown in Table 1**TABLE 1**

Demographic and Medical Characteristics of the 200 Patients Studied..

Tests and Scoring Procedures

A test of recall of written and oral information was given to each patient. The initial question on this test was designed to reflect the care with which patients had read their consent forms before signing them. They answered this question by selecting one of four options: "I read the whole thing very carefully"; "I just gave it a quick reading"; "I only read parts of it"; or "I did not read it." The questionnaire went on to test all areas supposedly covered in patients' consent forms or in discussions with physicians before signing consent forms, following Department of Health, Education, and Welfare guidelines for informed consent.[8] Test topics included knowledge of diagnosis or illness, proposed procedure, purpose of the proposed procedure, possible risks or complications, appropriate alternatives to proposed procedure, and opportunity to ask additional questions. These items were noted explicitly on forms giving consent for chemotherapy and surgery. The form for radiation therapy contained the statement, "The effect and nature of this treatment, possible alternative methods of treatment, and the risks of injury despite precautions have been explained to me." Presumably, therefore, these areas were covered by oral explanation.

On the basis of the patient's grasp of the essential information in the consent form's explanation, items on the recall test were scored 0 (incorrect) or 1 (correct).[9] Six test items were scored as correct if responses indicated the patient's awareness of having signed a consent form and of the points covered in the consent process. The remaining test items were open-ended questions to which patients responded in their own words. The criteria for evaluating these responses as correct included the patients' knowledge of the actual procedure or treatment for which the consent form was signed (radiation therapy, chemotherapy, or surgery); general understanding of what the treatment entailed (e.g., "cut out the lump in my breast" or "inserted radioactive seeds through a hollow tube"); general comprehension of the purpose of the treatment (e.g., "to shrink the tumor"); knowledge of at least one therapy-related risk or discomfort covered by consent-form guidelines (e.g., "swelling" or "hair loss"); mention of at least one alternative treatment covered by consent-form guidelines; and knowledge of diagnosis in lay language (e.g., "a cancer growth in my uterus"). The maximum total score on this test was 12.

A second questionnaire designed and pretested for this study was used to determine patients' perceptions of the material in the consent explanation and of the process and purpose of consent. The complexity of the language in the form was evaluated only from the patient's perspective. Respondents were asked if they understood all, most, or a little of the information given, or if it "was too complicated and I could not understand it." (The test's seven items and their response options are described in the Results section.)

Both questionnaires* were developed and pretested with patients similar to those in the sample population. Test items were phrased in simple and direct language, which patients had found easily understandable (e.g.,

"In your opinion, what are consent forms? Did your consent explanation tell you about the *purpose* of this treatment?").

Statistics

Patients were classified according to demographic and medical factors. Continuous response variables (e.g., scores on the recall test) in each classification were analyzed with the analysis of variance. Differences between numbers of patients in each classification were analyzed with chi-square tests. Proportions of patients' responses in each classification were analyzed with the Bartholomew test,[10] a procedure for detecting trends in proportions with qualitatively ordered samples.

RESULTS

Consent Information-Recall Test

As a group, the patients studied had a mean recall-test score of 8.26±2.56 (mean±S.D.) out of a possible maximum score of 12. Only 60 per cent of all patients correctly described what their treatment would involve, 59 per cent could describe the essential purpose of the treatment, only 55 per cent were able to list even a single major risk or complication, and only 27 per cent could name one alternative treatment. However, 81.5 per cent correctly identified their diagnoses.

Factors that contributed to these scores were identified with the analysis of variance. No differences were found when test scores of men and women were compared. Differences in age, race, hospital used (University Hospital versus Veterans Administration Hospital), and treatment (radiotherapy, chemotherapy, or surgery) had no effect independent of education.That is, when education was held constant, the effects of age, race, hospital used, and treatment disappeared. There were no differences between patients who signed the shorter radiation-therapy consent forms that relied on oral information and those who signed the more comprehensive documents. Two factors proved to have independent effects on test scores: education and medical status. A two-way analysis of variance of recall scores by education and medical status was calculated. The standard deviation was 2.18. Persons with less than a high-school education had significantly poorer understanding or recall of information pertaining to consent. Their mean recall-test score was 6.72, whereas those with at least a high-school education had a mean score of 9.1 (P<0.001). Bedridden patients gave significantly fewer correct responses to each item on the recall test than did ambulatory patients. Mean scores were 7.03 and 9.00, respectively (P<0.01).

A nondemographic variable that proved to be related to test score, even after adjustment for education, was the care with which patients judged themselves to have read the consent form before signing it. The mean recall-test score of the 117 patients who reported reading the entire form either carefully or cursorily was 8.81, whereas the mean score of the 64 patients who read only parts of the form or did not read it at all was 7.19 (P<0.001). As shown in Table 2  **TABLE 2**Care with Which 181 Patients Said They Read Consent Forms, According to Demographic Variables.*, only 40.3 per cent of all patients said that they had "read the whole thing very carefully." What distinguishes persons who read their consent forms from those who do

not? Chi-square analyses revealed that age (P<0.05), race (P<0.01), and education (P<0.001), but not medical status, were associated with the care with which the forms were read. Persons who read their consent forms carefully tended to be younger, white, and better educated.

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Purpose of Consent Forms

After the recall test, patients answered a series of questions designed to elicit their understanding and opinion of consent documents (Table 3  **TABLE 3**Opinions of Explanatory Material among 200 Patients.). Given the opportunity to select one or more responses to the question: "In your opinion, what are consent forms?" more than three quarters of the patients circled "legal documents to protect the physician's rights." Close to half answered that consent forms were "legal documents to protect the patient's rights," and 43 per cent selected "explanations of treatment." Because patients could select more than one response to this item on the questionnaire, it was not possible to evaluate these responses in terms of scores on the recall test.

Need for Consent Forms

Asked their opinion of consent forms, most patients (80.5 per cent) deemed them "necessary." Whether patients believed consent forms to be necessary or unnecessary had no effect on their ability to recall the material. However, the results of an analysis of variance applied to scores on the recall test and the five optional responses to this question were significant (P<0.01): patients with no strong opinion (those who answered that consent forms "don't matter one way or another" or "don't know") had lower scores on the recall test. The variation in opinions of consent forms was not related to any demographic or medical characteristic.

Adequacy of Explanations on Consent

When asked to evaluate the amount of information that they had been given about consent, most patients (76 per cent) reported that they had received "just the right amount"; 20 per cent thought that the information was inadequate; and 2 per cent thought that too much information had been offered. There was a significant relation between response to this question and scores on the test of recall: persons who answered that the explanation offered "just the right amount of information" had higher scores on the recall test than did patients who selected either of the remaining two responses (P<0.001).

Comprehension of Information on Consent

Patients were asked how much they could understand of the explanatory material about consent. Eighty-five per cent said that they could understand "all" or "most" of the information in the explanation; 9.5 per cent could understand "only a little," and 3.5 per cent "could not understand it." There was a positive relation between the amount of information understood and scores on the recall test (P<0.001). As might be anticipated, educational

level was also related to responses to this item: the higher the educational level, the greater the percentage of patients who indicated that they could understand all the information on the form ($P<0.05$ by the Bartholomew test).[10]

Patients' Rights to Refuse Signing

Asked to select one of two statements, 70 per cent of respondents answered that "patients have the right not to sign consent forms," and 28 per cent believed that "if patients are given consent forms, they must sign them." Responses to this item were not related to any demographic or medical variable, nor did they correlate with scores on the recall test.

Efforts to Recall Information about Consent

The great majority of patients (90.5 per cent) said that they would "try to remember most of the information in my consent form explanation." The 6 per cent of patients who would "try to forget most of the information" differed from the others only in items of race: 12.5 per cent of blacks, but 2.5 per cent of whites, said that they wanted to forget ($P<0.01$).

Importance of Explanations about Consent

No differences in recall-test score, demography, or medical status were found with regard to the final item on the questionnaire, which requested a choice between two statements. Seventy-five per cent of the patients thought that "consent form explanations are important, so that I can help decide about my treatment." Most of the remaining 25 per cent preferred the alternative statement, "consent form explanations are silly, because I would do what my doctor says anyway."

DISCUSSION

The results of this study corroborate previous work indicating that many patients fail to recall major portions of information on consent.[4] [5] [6] [7] The relation between educational background and patients' ability to describe the information, together with the similar correlation between education and the care with which patients read consent forms, suggests that such communications are too complex and difficult for many patients to grasp, despite the fact that most patients reported understanding all or most of the information.

Bedridden patients were less able to recall this information than were patients in better physical condition. As patients become increasingly ill, their sense of personal control over their own destinies may give way to intensified dependence on their physicians, and this dependence may result in poorer attention to, interest in, and recall of information about consent. Intellectual as well as physical deterioration may have had a role in poorer recall, although the patients studied were competent enough to sign consent documents and participate in this research.

Although most of these patients thought that the information on the consent form was important, comprehensible, worth remembering, and offered appropriate amounts of data, only a few patients actually read their consent forms carefully. It is possible that some patients merely scan the forms because the material has been explained orally by the physician. Reliance on one's doctor as the preferred primary source of information may reduce the personal relevance of the forms and contribute to the idea that they are legal documents. After completion of the questionnaires, 31 patients spontaneously expressed the feeling that official documents seemed out of place and counterproductive in the clinical setting. In addition, 80 per cent of the

patients studied viewed consent forms as a protection for the physician. The consent form's legalistic, perhaps even adversarial, overtones may appear inconsistent to the patient who has a fundamental orientation to and preference for a doctor–patient relation based on "trust."

The purpose of the consent procedure, to facilitate and ensure informed decisions on the part of the patient, is poorly accomplished and may actually be thwarted by the present procedure. Barriers are imposed by the difficulty of the material and by the legalistic and other negative connotations of the consent document. These barriers need to be removed if consent forms are to achieve their intended objectives and if patients are to function as the informed consumers that many of them wish to become.

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SOURCE INFORMATION

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