

Capacities of Hospitalized, Medically Ill Patients to Consent to Treatment

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This study was designed to compare the abilities of hospitalized, medically ill patients with non-ill comparison subjects to engage in an informed consent process. Eighty-two inpatients under the age of 70 were recruited from patients admitted for evaluation or treatment of ischemic heart disease (N = 675). The comparison subjects (n = 82) were matched person-to-person on age, gender, race, educational level, and occupation and did not have histories of ischemic heart disease. The hospitalized subjects did not differ from the non-ill comparison subjects on three instruments developed to assess abilities related to decision-making competence. Demographic and mental state variables did not correlate with performance, except for verbal cognitive functioning. There is no reason to believe that hospitalized patients similar to this sample—even if being treated for potentially life-threatening conditions—are at increased risk of inability to engage in a meaningful informed consent process.

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Physicians must obtain informed consent from patients before initiating medical or surgical treatment. Informed consent—as opposed to mere assent or concurrence—requires disclosure of information by the physician to the patient, a sufficient degree of patient competence to ensure meaningful participation in the decision process, and the absence of unfair coercive pressures exerted by professional caregivers. Treatment in the absence of informed consent leaves the physician open to potential liability for malpractice or battery.¹

In the more than two decades since informed consent has become an integral aspect of medical practice, objections have been raised by physicians about the competence of patients, especially when hospitalized, to participate in the process. Critics have claimed that the stress of acute, life-threatening illness, amidst a bewildering hospital environment, severely limits a patient's capacity to choose among complex

treatment procedures, each with its own array of risks and benefits.^{2,3} Whatever the demands of the law, this argument goes, most hospitalized patients simply are not able to play a meaningful role in decisions about treatment.

Only limited conclusions can be drawn from existing data about these assertions. Decision-making competence can be assessed by examining its component parts—usually conceptualized as including abilities to communicate a choice, understand relevant information, appre-

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ciate the nature of the situation, and manipulate information rationally⁴—or by global judgments of decision-making capacity. A small number of studies have measured medical patients' understanding of disclosed information, with performance ranging from poor^{5,6} to reasonably good,⁷ depending in part on the means used to convey the information and the nature of the patient population. Patients' appreciation of the nature and severity of their conditions has been explored under the rubric of assessing the degree of "denial" they manifest. Although some denial of serious illness appears common, the studies differ on whether few⁸ or many⁹ patients manifest major denial, and on the impact of denial on outcome.^{9,10}

Few studies, using measures of multiple functions or global assessments of capacity, have looked more broadly at patients' decision making. Only two studies have included medically ill samples selected for reasons other than a suspicion of incapacity. Examining 200 patients newly admitted to an intensive care unit, Cohen and colleagues found 60% of their sample had impaired Mini-Mental State Exam scores, a global measure of cognitive functioning; nonetheless, physicians and nurses judged only about one-third of patients incapable of giving informed consent.¹¹ The only controlled study, done by Fitten and Waite, compared 25 hospitalized elderly patients (mean age: 68) with an equal number of age and educational level-matched community residents.¹² By using three vignettes of increasing complexity, the investigators examined the subjects' understanding and reasoning abilities. Fitten and Waite's patients scored significantly worse than the control subjects, with 28% to 36% (depending on scoring criteria) of patients falling below the 99.5% confidence limit of the control group mean. Again, physicians appeared markedly to underestimate the degree of impairment in the patient group.

Although these studies suggest considerable decision-making impairment in hospitalized patients, they focused on high-risk groups (intensive care unit patients and the elderly), varied the sample sizes and range of functions

studied, and used scoring procedures of uncertain reliability. This study, conducted in 1991–1993, part of a larger study of decision-making capacity in medically ill and mentally ill populations,^{13–15} was designed to shed additional light on the degree to which impairment might exist in the capacities of hospitalized medical patients to provide informed consent to treatment.

METHODS

Sampling Procedures

Subjects were selected from patients admitted to two university hospitals (the University of Massachusetts Medical Center, Worcester, MA, and Presbyterian-University Hospital, Pittsburgh, PA) for evaluation or treatment of ischemic heart disease. This diagnostic group was chosen because it includes a substantial number of potential subjects who ordinarily face choices among several treatment options, and for whom neither the disorder nor its treatments typically result in mental impairment. Potential subjects were excluded if they were over 70 years of age, or met screening criteria for major depression or schizophrenia, using the Diagnostic Interview Schedule–Screening Instrument, which uses DSM-III-R criteria.¹⁶ The study was approved by the institutional review boards at the participating institutions.

Six hundred and seventy-five patients with ischemic heart disease who were under the age of 70 were admitted to the units studied. Potential subjects were not approached if their physicians did not permit us to approach their patients ($n = 56$, 8.3%) or if they were unavailable when the research assistants were present ($n = 437$, 64.7%). Of those approached ($n = 182$), 16.5% ($n = 30$) refused to participate, and 152 patients gave written informed consent to participate in the study. At this point, the subjects were screened for major depression or schizophrenia, and 46 subjects (30.3% of those who consented) were excluded. Almost all of those excluded met criteria for major depression; it is possible that the screening instrument overidentified patients

as having major depression. Five interviews were unusable. Of the 101 completed interviews, 19 were dropped from further analysis because matched comparison subjects, using the strict criteria described next, were unavailable.

This left a final study sample of 82 hospitalized subjects. Despite attrition, the final sample of 82 subjects did not differ significantly from all patients admitted with ischemic heart disease in age, gender, or race. The subjects were paid \$10 for their participation. Testing took place a median of 3.0 days after admission (range: 1–9 days).

Comparison subjects were recruited from advertisements in the community. They were matched person-to-person with hospitalized subjects on age (goal was to match within 5 years), gender, race, educational level (goal to match within 2 years), and highest lifetime occupation (goal to match within 1 increment on a standard 8-point scale).¹⁷ Comparison subjects were excluded if they had prior hospitalizations for ischemic heart disease, or met screening criteria for depression or schizophrenia. They were paid \$10 for their participation.

Independent Variables

Demographic data were obtained and, for the hospitalized subjects, information on number of previous admissions for ischemic heart disease and age at first hospitalization (measures of chronicity) was elicited. Each subject also completed the Beck Depression Inventory, a 21-item self-report measure,¹⁸ and was assessed using three subtests of the Wechsler Adult Intelligence Scale–Revised (Vocabulary, Similarities, and Digit Span) to provide an index of current verbal cognitive functioning.

Dependent Variables

Four categories of abilities related to decision-making competence were identified, based on a comprehensive review of case law and the legal, medical, and psychological literatures.^{4,13} These included the abilities to communicate a choice, understand relevant information, appreciate

the nature of the situation and its likely consequences, and manipulate information rationally. The following three instruments were designed to assess these abilities.¹⁴

Understanding Treatment Disclosures (UTD). The UTD assesses understanding of treatment-related information disclosed in a standard format.¹⁹ For the data reported here, disclosure consisted of five paragraphs dealing with ischemic heart disease, including information about the nature of the disorder, a possible approach to treatment, the possible benefits of treatment, the risks of treatment, and an alternative treatment, along with its benefits and risks. The disclosure was read aloud to the subjects, as they read along from their own copies. Understanding was measured in several ways, but the data we present here focused on a task that required the subjects to demonstrate understanding by paraphrasing the information communicated after each paragraph was read and their printed copy was removed. Scoring criteria were standardized, with possible scores ranging from 0 to 10 points. (Lower scores on this and the other instruments indicate poorer performance.) We have presented data elsewhere indicating that the UTD has good internal consistency and high interscorer reliability.¹⁴

Perceptions of Disorder (POD). The POD assesses patients' appreciation by examining the degree to which they acknowledge the existence of disorders and the potential value of treatment.²⁰ It is not designed to be used with non-ill (comparison) populations. Scores are generated on two subscales, Nonacknowledgment of Disorder (NOD) and Nonacknowledgment of Treatment Potential (NOT), as subjects indicate their degree of agreement or disagreement with statements about their condition. Possible scores range from 0 to 6 on each subscale. Subscales correlate with each other only marginally ($r = 0.23$), suggesting that they measure discrete areas.¹⁴

Thinking Rationally About Treatment (TRAT-2). The TRAT-2 assesses the quality of subjects'

reasoning about treatment choices, stimulated by a vignette (for this sample) about a patient with ischemic heart disease.²¹ The subject is asked structured questions about his/her thinking, and he/she also responds to standard problems involving probability and transitivity. Factor analysis indicated high internal consistency for a version of the instrument based on six subtests;¹⁴ data from that version were used in this study. Interscorer reliability is generally good.¹⁴ Possible scores range from 0 to 14. Embedded in the TRAT-2 is a measure of subjects' abilities to identify their preferences with regard to treatment options, Expressing Choices (EC). It is administered as part of the discussion of the TRAT-2 vignette, and this portion is asked in the third person (i.e., subjects are asked to identify the preferred option as though they were advising the person described in the vignette).

TABLE 1. Characteristics of hospitalized and community comparison subjects

Variables	Hospitalized Subjects	Community Comparison Subjects
Age, mean (range)	55 (29-70)	55 (24-75)
Male, %	64	64
Non-white, %	7	7
Socioeconomic status, % ^a		
Levels 1-2	19.5	24.4
Level 3	29.3	32.9
Levels 4-5	51.3	42.7
Beck Depression Inventory, ^b median (range)	7 (0-29)	5 (0-28)
Verbal cognitive functioning ^c (Wechsler Adult Intelligence Scale-Revised subscales), median (range)	95 (74-137)	100 (78-131)

^aSocioeconomic status based on Hollingshead & Redlich,¹⁷ using years of education and highest level of occupation attained since age 18. 1 = highest, 5 = lowest.

^bGroups differ significantly (Wilcoxon matched pairs [two-tailed] $Z = -2.006$, $P = 0.001$)

^cGroups differ significantly (paired t -test [two-tailed] $t_{80} = -3.57$, $P = 0.001$).

RESULTS

Table 1 shows the characteristics of the hospitalized and community comparison subjects, demonstrating the success of the matching procedure. The groups differed significantly on the measures of depression and verbal cognitive functioning (VCF), but the differences are small from a clinical perspective.

The hospitalized subjects' performance on the understanding (UTD) and rational thinking (TRAT-2) measures did not differ significantly from the performance of the comparison subjects (Table 2). This was true individually for every subtest of the TRAT-2, including the embedded measure of ability to evidence a choice (EC). Because of the nature of the appreciation measure (POD), comparisons with the non-ill group are unavailable. Inspection of the scores in Table 2, however, reveals little evidence of impairment on either subscale, though roughly 10% of the hospitalized subjects had scores suggesting substantial difficulty acknowledging the nature and severity of their ischemic heart disease.

Logistic regression analyses were used to

TABLE 2. Scores on dependent measures of decision-making abilities

Measures	Hospitalized Subjects	Community Comparison Subjects
Understanding Treatment Disclosures, mean \pm SD	8.35 \pm 1.9	8.08 \pm 2.0
Perceptions of Disorder		
Nonacknowledgment of Disorder, mean \pm SD	5.37 \pm 1.2	*
Nonacknowledgment of Treatment Disorder, mean \pm SD	5.80 \pm 0.5	*
Thinking Rationally About Treatment, mean \pm SD	10.81 \pm 2.0	10.86 \pm 2.2

Note: There are no significant differences (paired t -tests and Wilcoxon matched pairs) between the groups on any measure.

*Perceptions of Disorder subscales were not administered to community subjects.

examine whether the small but statistically significant differences between the hospitalized and control subjects on measures of depression and VCF, or differences in the subjects' performance across sites, might have accounted for our failure to find significant variations in the scores between the hospitalized and comparison groups. With depression, VCF and site entered as covariates, only VCF had a significant impact on UTD and TRAT-2 scores (Model: $\chi^2 = 18.241$, $df = 5$, $P = 0.0027$, odds ratio [OR] = 0.9463, $P = 0.001$, 95% confidence interval = 0.9158-0.9776). The direction of the effect, however, indicates that, but for the difference in VCF, the hospitalized subjects would have performed even better relative to their comparison subjects.

Although overall performance of the hospitalized sample was good, exploratory analyses were done in an attempt to identify variables that might indicate a propensity for lower scores. Table 3 demonstrates that several independent variables were related significantly to performance on one of the dependent measures: significant correlates of understanding included VCF (+ correlation), age at first admission (- correlation), and race (non-white > white); the only significant correlate of appreciation of disorder was socioeconomic status (+ relationship). The small number of subjects in many cells and the large number of

analyses performed, however, should be a caution against overinterpreting these findings.

DISCUSSION

Physicians may resist engaging in the informed consent process with hospitalized medical patients in part because they believe that patients generally lack the capacity to absorb information and participate in decision making at this stressful time in their lives. This study suggests that such a generalization is unwarranted. Our sample of patients hospitalized for evaluation or treatment of a severe—and potentially life-threatening—medical disorder performed no more poorly on a set of measures related to decision-making capacities than did a matched sample of community residents.

Is it possible that performance was so good because the tasks assigned to the subjects were too easy to distinguish impaired from unimpaired patients? Since the law will only reject the presumption of decision-making competence for a small fraction of the population with the most severe impairments, a legally relevant measure of competence-related abilities should allow almost all members of the general population to do well. Too simple a measure, however, will not be able to discriminate between normal and truly impaired populations. It

TABLE 3. Relation of hospitalized patients' performance on measures of decision-making abilities to independent variables

Variables	Measures			Thinking Rationally About Treatment
	Understanding Treatment Disclosures	Perceptions of Disorder Treatment	Thinking Rationally About Treatment	
Beck Depression Inventory	0.03	-0.13	-0.03	0.08
Verbal cognitive functioning	0.38*	0.03	-0.08	0.21
Previous admissions	0.18	-0.06	0.13	0.03
Age at first admission	-0.23**	-0.08	-0.08	-0.004
Socioeconomic status	4.50	11.54***	1.91	0.99
Age	-0.13	-0.02	-0.01	-0.05
Gender	0.20	-0.46	-1.05	-0.93
Race	-2.86****	-0.22	-0.07	-0.85

Note: Figures for continuous variables represent Spearman's ρ ; figures for gender and race represent Z-values from Wilcoxon's Rank Sum Test; figures for socioeconomic status are χ^2 analyses ($df = 4$, corrected for ties) from the Kruskal-Wallis Test.

* $P < 0.001$; ** $P = 0.04$; *** $P = 0.02$; **** $P = 0.004$ (nonwhite > white).

should be reassuring with regard to the validity of the dependent measures that, when applied in the broader study to samples of schizophrenic and depressed patients, the measures identified substantial numbers of subjects with decision-making impairment, including in one analysis roughly one-half of the sample with schizophrenia.¹⁵ Thus, lack of instrument sensitivity to the presence of real impairment probably does not explain these findings.

On the other hand, our findings cannot necessarily be extrapolated to all hospitalized medical patients. The diagnostic group studied was chosen deliberately because the disorder and its treatment were unlikely to impair mental functioning. Moreover, subjects with diagnosable major depression or schizophrenia, whose decision making about treatment is often affected by their disorders,^{13,15} were excluded from the study sample. The purpose of fashioning the sample in this way was to allow a test of the effects of severe illness and hospitalization per se on decision making. That effect proved to be minimal. Such will not necessarily be the case for patients with disorders (e.g., stroke) or treatments (e.g., high-dose steroids) that directly impair mental functioning, or for persons with concurrent psychiatric disorders. It is also difficult to know what biases, if any, were accounted for by treating physicians' refusal to allow access to nearly 10% of potential subjects; by those subjects who refused to participate; and by assessment of subjects a mean of 3 days after admission, as opposed to immediately on hospital entry.

Even given generally good performance, it would have been useful to identify variables that might correlate with poorer performance. This might allow physicians to pay particular attention to the capacities of a smaller group of high-risk patients. Our efforts, though, were limited by the very small number of patients who fell into the lower half of the scoring range on any of the dependent measures. Thus, further exploration of this finding with larger samples may be warranted. It is of interest, nonetheless, that some of the demographic variables that might be assumed to correlate with perfor-

mance, such as age (although patients over 70 were excluded from the study), did not do so. VCF bore a significant relation to understanding, suggesting that impairment in this area may predict dysfunction in some tasks requiring higher level cognitive performance.

Should these data be interpreted as indicating that most of our sample was legally competent to participate in an informed consent process? Although our instruments were based on legal conceptualizations of competence and tested capacities likely to be relevant to competence determinations, there is not a one-to-one correspondence between scores on our measures and legal competence. For one thing, the standards applied by the courts to determine competence vary across jurisdictions, and may even vary within jurisdictions depending on the context in which a decision needs to be made. The designation of cutoffs below which a person will be found incompetent may vary in a similar fashion. Our measures, therefore, should not be considered as definitive mechanisms for establishing legal competence.

Yet, the fact that this selected group of hospitalized patients differs not at all in its level of performance from a matched community sample—and that the number of poor-performing outliers was relatively small—suggests that we are dealing with a group whose members are very likely to be considered competent by a court of law. Not only can physicians' obligations to engage such patients in informed consent discussions not be avoided, but also our data suggest that the results are likely to be gratifying. Presented with appropriate information, patients such as these are likely to understand it, appreciate its context, and be able to use it in a rational process to reach a treatment decision. That should portend optimism regarding the future of physicians and patients working together to select optimal approaches to care and treatment decisions.

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