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Impact of Medical Hospitalization on Treatment Decision-Making Capacity in the Elderly

1/2 of group per control.

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• A growing population of hospitalized elderly will need to make an increasing number of treatment decisions. No generally accepted criteria currently exist to assess the decision-making capacity of these elders. In this study, three hypothetical clinical vignettes were developed to assess treatment decision-making capacity in 25 presumably competent, medically ill, nondistressed, hospitalized elders and 25 healthy, age- and education-matched controls. The patients' understanding of the vignettes was evaluated and compared with their understanding of a standard consent form; with their performance on a mini-mental state examination; and with physician judgments about their decisional capacity. Vignette results indicate a significant difference between study and control groups in understanding of key treatment issues. Healthy controls demonstrated a better understanding of these issues. Twenty-eight percent of the patients had significant decisional impairments by vignette assessment but were not identified by mental status scores or physician judgments. Results suggest that presumably competent, medically ill elders may be at risk for developing decisional impairments during hospitalization for acute illness. Obtaining informed consent directly from many of these patients may not be feasible.

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Presently, one of every eight Americans is 65 years of age or older. Yet older Americans disproportionately need medical care. Persons 65 years of age or older are hospitalized at 3.5 times the rate of those under 65, and their length of stay increases with age.¹ The elderly are becoming the hospitals' largest group of health care users.² By the year 2000, more than one out of every two hospital beds will be occupied by an elderly person.³

This growing population of elders will need to make an increasing number of decisions regarding medical treatment, but their capacity to make such decisions may be jeopardized by the higher incidence⁴ and prevalence^{5,6} of chronic brain disease and by the sheer burden of the multiple medical illnesses present in this population. These patients may be further at risk for being excluded from the decision-making process because of reduced physician contact, ageism, and

paternalism, and because of their attitudes toward their physicians and toward themselves.¹⁰⁻¹⁴

Whereas patient informed consent for medical decision making has been the standard of practice in medicine for many years, the focus of obtaining informed consent has centered primarily on disclosure of information, while the issue of patient competence to consent to treatment has received considerably less attention.¹⁴

Several approaches to the determination of treatment decision-making capacity have been recently proposed.¹⁰⁻¹⁴ However, as yet, no widely accepted criteria for capacity to consent to, or to refuse, medical treatment have been established, nor have objective, valid, and reliable methods for the assessment of decisional capacity been developed. In clinical practice, indirect measures of decisional capacity are frequently made by using one of several mental status assessment approaches as a guide. This practice, however, may lead to unwarranted assumptions about the relationship between performance on these clinical examinations and treatment decision-making capacity per se, particularly in patients who are moderately rather than grossly impaired.

Only a very few studies have attempted to explore decisional capacity in the elderly.¹⁰⁻¹⁴ To our knowledge, there are no studies in the current literature that report on the treatment decision-making capacities of acutely ill, hospitalized, elderly patients—one of the populations most concerned by the informed consent process. The present study therefore attempts to provide information about the status of the decision-making capacities of this vulnerable population and proposes a more direct method of assessing decisional capacity in situations in which doubt over the presence of this ability has arisen.

PATIENTS AND METHODS

Population

The study population consisted of 25 acutely, but not critically, ill, hospitalized patients aged 60 years or older. None had neurologic or psychiatric histories or symptomatology and were functioning independently in the community prior to hospital admission. Critically ill and severely distressed patients were excluded from the study for ethical reasons. The control group consisted of 25 age- and education-matched healthy, independent, community dwelling volunteers from the same community who had no neurologic or psychiatric histories and whose decisional capacity was presumed to be intact.

Recently admitted medical and surgical patients were screened for the study group by chart review and physician interview. Community-dwelling volunteers were screened for participation in the control

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	Age, y	Years of School	MMSE	No. (%)				
				Informed Consent	V ₁	V ₂	V ₃	V _{Total}
Patients (n=25)	68.4 ± 6.5	12.0	27.6 ± 1.9	191 (44.9)	228 (82.2)	349 (73.5)	219 (67.4)	794 (73.9)
Controls (n=25)	70.9 ± 9.2	11.9	29.2 ± 0.7	244 (57.4)	262 (95.3)	428 (90.1)	268 (82.0)	958 (89.0)
P value	NS	NS	<.001	<.001	<.001	<.001	<.001	<.001

*Age and Mini-Mental State examination (MMSE) scores were compared using Student's *t* test. Informed consent and clinical vignette scores (V₁, V₂, V₃, and V_{Total}) are given as raw and percent unassisted correct answers. † The χ^2 test was used for intergroup comparisons. NS indicates not significant.

group by structured interview. All patients and volunteers signed a standard Veterans Administration (VA) informed consent form.

Materials

Demographic and medical information was obtained for each subject by chart review and by patient and physician interview. The standard VA informed consent form for this study was signed by all subjects. Understanding of the informed consent document was evaluated by asking the subjects previously prepared questions about the material presented. Normalcy of mood was evaluated in each case by an experienced clinician, and cognitive status was tested by the Folstein Mini-Mental State examination (MMSE).²⁵

To assess each subject's treatment decision-making capacity more directly, three structured, hypothetical clinical vignettes of increasing complexity were presented to each subject. Each vignette was written in language understandable to persons with a sixth-grade education. Vignette and informed consent reading levels were confirmed by the Flesch Readability Test.²⁶ Each vignette presented a medical condition commonly found in the elderly (as determined by geriatricians) that required treatment decisions to be made by patients and controls. The conceptually simplest vignette involved the presence of insomnia and its treatment options. The intermediate one posed the problem of a pleural effusion with workup and treatment choices to be made; and the third vignette addressed the issue of resuscitation in the context of chronic but not terminal illness.

Completeness and quality of understanding of the VA informed consent document and of the vignettes were evaluated by posing specific questions. These fell under the following categories: (1) understanding facts about patient's condition and circumstances; (2) understanding the nature of the treatment or procedure in question; (3) understanding the purpose of the treatment or procedure; (4) understanding the risks, benefits, and alternatives involved; (5) quality of patient's or subject's reasoning process. For each question category, a scoring criterion was developed that assigned a score for complete, partial, or no understanding of a question, as well as for cueing if needed.

Finally, the patients' physicians were questioned about their views on the patients' decision-making capacity, their practices regarding the procurement of informed consent, and their own background in bioethics.

Procedure

Each investigator was responsible for carrying out a part of the study protocol with each subject. One of us (L.J.F.) collected the demographic and medical information, administered the VA informed consent document and tested for its understanding, conducted a brief psychiatric interview, and gave the MMSE. The other (M.S.W.) conducted the chart review, gave the physician questionnaire, and presented all three vignettes.

After verifying that no significant hearing or visual deficit was present, patients were handed a copy of the VA informed consent document for review and then for signature. The investigator then read the consent document aloud and gave the subjects the opportunity to ask questions about the material presented and answered any questions posed by the patient. Any portion or all of the consent form

was reread to the subjects if necessary. Testing for understanding was conducted immediately after the complete presentation. The same procedure was followed for each vignette. The answers to each question were scored in each case with reference to previously established scoring criteria. In developing the criteria, the essential ingredients of a question were identified and the patient then was scored on whether he or she included them fully (2), partially or with cueing (1), or not at all (0) in his or her response. The same method was followed for volunteers, except that there was no chart review and no physician contact was made.

Statistical analysis for comparison of data between the groups was carried out using Student's *t* test and analysis of covariance for continuous measures and the χ^2 statistic for categorical values. To determine which patients might be significantly impaired in their understanding of consent and vignette information, and therefore probably also impaired in their treatment decision-making capacity, we chose as our standard of sufficient understanding the performance of the healthy, independent community-dwelling controls on the consent form and on the vignettes. It was decided that patients (or controls) with scores below the lower 99.5% confidence limit of the control group mean would be considered significantly impaired in treatment decision-making capacity.

RESULTS

Patient and control groups were equivalent in age, education, and absence of clinical depression. Within-control group comparisons demonstrated that health, age, and schooling were not associated with significant performance differences. However, highly significant differences were found between patient and control groups when performances on the MMSE, the informed consent document, and the vignettes were compared. The scores of the patients were invariably lower than those of the controls. Control scores remained consistently high on all vignettes and on the MMSE (Table 1). For both groups, the highest scores were obtained on V₁, the easiest conceptually, and the lowest on V₃, the most difficult.

Table 2 demonstrates the number of patients and controls whose informed consent and vignette scores were below the lower 99.5% confidence limit of the control group mean. These patients and controls were defined as decisionally impaired. Because V_{Total} or V_{T3} generally reflects the fact that those who were impaired in this category were also impaired in at least one vignette, V_{T3} scores were used to determine impairment. However, impairment may be "marginal" or "partial" if only one or two vignette scores were below confidence limits, or it may be severe if all three vignette scores were below confidence limits. Table 2 indicates that when only unprompted correct answers were used to calculate scores, seven patients (28%) failed at least one vignette (V_{T3}); two of these (8%), failing all three. Table 3 provides the same information as Table 2 but is based on scores resulting from the combination of unprompted and prompted correct answers, a method that

†
misinterpreted
no patient
decisionally
impaired
in V_{T3}
simplest
de vignette 3

3 minutes de entrevue par psychiatre → Simple: hmniv 1/70
→ révisé = décision planifiée, études/patient
→ complex: RCP en fonction des cas non terminal.

	Informed Consent	V ₁	V ₂	V ₃	V _{Total}	% of Group Impaired
Patients (n=25)	3	8	5	3	7	28
Controls (n=25)	0	1†	1	1†	1†	4

*For abbreviations, see Table 1. Number of subjects (impaired) with scores below the lower 99.5% confidence limit of the control group mean when unprompted correct answers (2) were counted. All subjects impaired by V_{Total} score were impaired in at least one vignette. One patient and one control were impaired in V₁ and V₂, respectively, but not by V_{Total} score. Two of seven V_{Total}-impaired patients were below the lower 99.5% confidence limit on all three vignettes (severely impaired).
†Same patient.

	Decisionally Impaired by Vignettes	Decisionally Not Impaired by Vignettes	Total
Decisionally impaired according to physician	1 (1)	1 (1)	2 (2)
Decisionally not impaired according to physician	6 (8)	17 (15)	23 (23)
Total	7 (9)	18 (16)	25 (25)

*Physician judgments about patient decisional capacity are contrasted with vignette assessments using the lower 99.5% confidence limit cutoff. Physician and vignette assessments disagreed in 28% of cases. Data in parentheses are results for the method using prompted plus unprompted correct answers (1+2). In this instance, there was a disagreement in 36% of cases.

should allow the greatest number of patients to be considered unimpaired.

When physicians' evaluation of their patient's decision-making capacity was compared with the vignette standards, there was significant discordance. The V_T scores indicated substantial decision impairment in seven patients who were not considered to be impaired by physicians. Conversely, in one instance, a physician thought that a patient was decisionally impaired, but this was not borne out by the V_T score. In sum, there was disagreement between physician and vignette scores in 28% of the cases when the unprompted correct answer method was used (Table 4).

A comparison by informed consent and vignettes was made between patients and controls with regard to categories of questions missed. This relationship is expressed in Table 5. In this general comparison between the two groups, the category of questions relating to understanding the procedure was more frequently missed by the patient group. Next, we examined the type of question most frequently missed by those patients who were assessed as being significantly impaired. In this subgroup, the most frequently missed questions belonged to the category of risks, benefits, and alternatives, representing 49% of all questions missed by this subgroup.

Finally, of the 16 physicians questioned, 7 were female, 6 were interns, and 10 were residents. Approximately half of the physicians stated they did not (1) attempt specifically to determine patient decisional capacity, (2) think about the issue of informed consent for their patients, (3) inquire about patient treatment preferences, and/or (4) discuss treatment options with patients. In almost 90% of the cases, the physi-

	Informed Consent	V ₁	V ₂	V ₃	V _{Total}	% of Group Impaired
Patients (n=25)	8	3	5	7	9	36
Controls (n=25)	1	1	1	0	2	8

*For abbreviations, see Table 1. The same relationships are expressed here as in Table 2. However, scores for determining the lower 99.5% confidence limit are based on the sum of unprompted and prompted correct answers (1+2), providing the most liberal standard for determining impairment. All subjects below the lower 99.5% confidence limit for V_{Total} were impaired in at least one other vignette. Two (8%) of 25 subjects were impaired in all three vignettes and were thought to have severely impaired decisional capacity.

	Lower Difficulty → Higher Difficulty				
	V ₁	V ₂	V ₃	Informed Consent	V _{Total}
Factual information	NS	<.01	<.05	NS	<.05
Understanding the procedure	<.05	<.01	<.001	<.001	<.01
Understanding the purpose of treatment	NS	NS	NS	<.001	NS
Understanding risks, benefits, and alternatives	<.05	<.05	NS	<.001	<.05
Quality of reasoning	NS	NS	NS	NS	NS

*For abbreviations, see Table 1. The χ^2 test was used to compare the frequency of errors made in each category of questions by patients and by controls. Where significant differences are indicated, the controls failed fewer questions.

cians thought that the patients were clearly competent to give informed consent. However, 75% of these physicians thought that their own bioethics background was insufficient.

COMMENT

Summary of Principal Findings

The results of this study indicate that the healthy elderly controls consistently performed very well on all vignettes and on the Folstein MMSE. Furthermore, among this group, education did not seem to influence scores on the vignettes or on the MMSE. In contrast, patients scored significantly lower on the vignettes and on the MMSE, even though on the latter, scores remained in the "normal" range.²⁴ Both groups had noticeably lower scores for understanding of the informed consent document, although the patient group's were strikingly lower. This was not unexpected since the official form appears dedicated to the bureaucratic and procedural aspects of disclosure rather than to the actual understanding of the issues by patients.

The V_T scores below the lower 99.5% confidence limit of the control group mean were thought to indicate a clear decisional impairment. Twenty-eight percent of the hospitalized patients were in this category, but only one control was impaired. Using the most liberal scoring criteria, the percentage of impaired patients rose to 36%, suggesting that prompting is more helpful to healthy individuals than it is to ill ones.

As a group, the patients performed most poorly on questions regarding the understanding of the nature of treatment

En este estudio, cuando un método se logra identificar a los pacientes que no son capaces de tomar decisiones, ¿hay que usar herramientas de screening o sea más cuidadosas en la historia clínica de capacidad?

and/or a procedure. The subgroup that was found to be decisionally impaired clearly performed most poorly on questions regarding the risks, benefits, and alternatives of treatment.

Finally, physicians failed to identify decisionally impaired patients and identified as "incompetent" one patient who was not impaired. The residents and interns in this study frequently did not inquire about patient treatment preferences, nor did they see a need for assessments of decisional capacity in medically ill patients. Whereas these physicians expressed confidence in their "competency" assessments, most felt that their bioethics background was inadequate.

The Literature

Several standards have been proposed in the medical literature to assess decision-making capacity ("competency").^{16-18,21,22} Yet there is still no uniform understanding of the problem, nor are there any clinically applicable tests to routinely assess decisional incapacity.^{20,22}

In medicine there has been a tendency to consider patients either completely competent or totally incompetent to make treatment decisions. In law, however, it is now appreciated that a person may be competent to perform some tasks, while being incompetent to perform others. As applied to kinds of treatment decisions, this perspective is only slowly being assimilated in medicine. However, even if the notion of "specific competences" with regard to treatments is valid, we must recognize that competence is also a continuum that ranges unbroken from complete competence through various degrees of partial competence to full incompetence for a given task. As Faden and Beauchamp¹⁸ have pointed out, where one situates the cutoff line on this continuum that separates competence from incompetence is a normative problem with three levels: for any given task, the specific requisite abilities must first be established; then a threshold for each ability must be determined; finally, empirical tests for thresholds of these abilities must be developed.

Choosing a threshold is a normative problem and will likely reflect a particular stance in the balance between the competing moral principles of beneficence and autonomy. But it also reflects varied assumptions about the level of functioning of "normal," unimpaired individuals. No "gold standard" exists for determining thresholds. This is an unavoidable uncertainty on the one hand, but on the other is further complicated by the diverse assumptions of "normality" that are implicitly and necessarily entertained in the minds of assessors because of the little factual knowledge available on the actual treatment decision-making skills of large numbers of unimpaired individuals.

While some attempts have been made to describe the characteristics of the decisionally impaired older patient, no literature describes the particular type of decision-making deficits common to these impaired patients. Few studies exist exploring which groups of elders may be most vulnerable to decisional impairments.²³

Implications

Contrary to some popular perceptions, our results showed that the healthy, independently living elderly substantially understood all key treatment issues and thus appeared to be capable of making a variety of treatment decisions regardless of their educational background, provided the language and form of consent documents were simplified. In contrast,

significant numbers of medically ill patients failed to substantially understand key issues in treatment despite language and form simplification of consent documents. In fact, patients appeared considerably more vulnerable to the complexities of informed consent documents than did their healthy counterparts.

By clarifying that healthy elders were capable of *substantial* understanding of key treatment issues, our results may offer some assistance with the problem of choosing a threshold of understanding when decisional capacity is being evaluated. Those persons with vignette scores below the lower 99.5% confidence limits of the healthy group norm formed a different and decisionally impaired population. This group demonstrated substantially less understanding of *key* treatment issues, casting strong doubts about their capacity to give truly informed consent, particularly if complex or risky treatments are involved.

Frequent approaches to the assessment of decisional capacity in the hospital have involved the use of mental status testing or physicians' clinical impressions and subjective judgments alone.²⁴ However, in this study, neither the Folstein MMSE nor the physicians' own evaluations were able to identify the seriously decisionally impaired patients. Furthermore, the physicians erroneously called "incompetent" one unimpaired patient. Physician bias appears to be in the direction of administering treatment. Results show that more than 28% of the patients received treatment even though their capacity to participate in the decision-making process was impaired. Potential surrogate decision makers for the patients, such as spouses, were not included in the decision-making process nor was Durable Power of Attorney for Health Care²⁵ utilized, thus patient wishes may have been underserved.

It should be noted, however, that in no case was a patient's obvious or expressed wish not to be treated overridden by a physician in this study. Instead, physicians initiated treatment regimens whose complexities and consequences were beyond the understanding of many decisionally impaired patients, making truly informed consent unlikely. This may be a consequence of two factors. The first involves a form of patient passivity, which may be often inevitable during illness. Most patients appeared to be willing or resigned to accept some form of care or treatment as ordered by their doctor, with little discussion about, or interest in, the nature of the treatment or its risks, benefits, and alternatives. In reality, these patients were silently but effectively transferring the choice of treatment options to their physicians. The second factor involves the physicians' pro-treatment bias and a general lack of awareness of the potential impact of major illness on decision making. Physicians also seemed to be unaware of their moral obligation to attempt to safeguard the options and wishes of patients with limited capacity to enter the decision-making process.

Finally, the results of our study indicate that as a group, medically ill but neurologically and psychiatrically intact hospitalized patients performed at a significantly lower level in every test of cognition given, suggesting that either the process of hospitalization or major medical illness per se impacts on mentation. Furthermore, when the performance of the decisionally impaired patients was analyzed, the greatest impairment was found in their inability to adequately understand the risks, benefits, and alternatives of treatment.

This is consistent with the notion that the weighing and balancing of alternatives may be the most difficult part of the deliberative process and thus the most vulnerable to insult. It may also explain why decisional impairment was present when MMSE scores remained in the "normal" range. Most MMSEs do not adequately explore the deliberative process that may be impaired even though other more basic cognitive functions are still adequately performed.

Limitations

Sample sizes and makeup (eg, physicians-in-training) limit the generalizability of our conclusions. With regard to the vignettes, it should be remembered that the process of understanding hypothetical vignettes may be different from that of understanding the issues of one's own real treatment." Furthermore, the vignettes themselves explore only one important aspect of understanding and deciding—cognitive function. Other impairments of mental activity may play a role in the inability to deliberate and decide. These impairments may be volitional, emotional, or ideational. However, cognitive impairment remains a major concern in the elderly because of the increased prevalence of brain disease in this population.

Finally, the vignettes were not intended to diagnose "competence" or "incompetence," rather they were used as a means of identifying those patients, particularly the marginally competent, who may have difficulty in making important decisions about their treatment. Nonetheless, in this process, certain evaluative assumptions were made. One such assumption is that a desirable balance between the need for patient protection and respect for the patient's autonomy may be achieved by a clearer identification of levels of decisional capacity. Other assumptions made are that (1) a substantial

(though not necessarily complete) understanding of a treatment procedure and its risks, benefits, and alternatives must be attained before truly informed consent can be given; (2) a reference for what constitutes "substantial understanding" may be more easily derived with information obtained from the study of a generally healthy, autonomous elderly population; (3) patients whose level of understanding is reflected by vignette scores below the lower 99.5% confidence limits of the healthy norm show a decisional impairment in that situation; and (4) patients showing impairment at one level of decisional complexity are not necessarily impaired at all levels.

Recommendations

A greater commitment to the teaching of bioethics in medical school and during postgraduate training is needed. Particular attention should be given marginally competent patients. Their decision-making abilities and limitations must be clearly defined so that their limited autonomy can be respected and, at the same time, so that appropriate protection can be instituted when needed. Clearly, riskier treatments without clear-cut benefits are of particular concern for the marginally competent patient. We recommend further development of instruments to assist the physician in assessing patients' decisional incapacities. Reliable instruments that help to structure the approach to assessment will be particularly helpful since so much variation currently exists among clinicians who are performing these evaluations.

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