The Elderly Patient and Informed Consent

Empirical Findings

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• **Informed consent with the elderly patient and the competency of this patient population have been neglected issues in medicine and law. Particularly, the competency of the elderly patient has received little empirical investigation. The present study examines the capacity of geriatric patients to consent to research participation. Competency is investigated through the use of hypothetical consent information on three dimensions: comprehension of consent material, quality of reasoning about the decision to participate or not participate in research, and reasonable choice regarding participation. The results indicate that elderly patients' choices about those projects in which participation is "reasonable" do not differ, by and large, from younger patients. However, the elderly show significantly poorer comprehension of consent information. Thus, screening for competency and providing special instructions may become an important part of the research process when the elderly are participants.**

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WITH the advancement of medical knowledge and the concomitant increase in life span, the elderly have become a rapidly growing segment of the population. Because the lengthened life expectancy and the greater likelihood of serious illness have increased the elderly's need for medical care and because minimal research has been done on illnesses affecting the elderly (eg, Alzheimer's disease), the aged will be increasingly called on to participate in research projects.

These circumstances have placed the elderly in the position of having to make decisions about their medical care more frequently than other segments of the population. At the same time, physicians, increasingly aware of patients' wishes to be well informed, perceiving a duty to inform patients, as well as desiring to avoid potential legal problems arising from inadequate information giving, want to be assured that such decisions are based on an adequate understanding of relevant treatment information. Consequently, it is very important that patients are supplied with information about the risks and benefits of a particular treatment, the treatment requirements and regimens, and the available alternatives. It is, therefore, vital to physicians, from both ethical and legal viewpoints, to determine whether their elderly patients can make competent decisions (eg, understand treatment information) concerning medical care. If some of these patients are found to be incapable, acceptable procedures for substitute decision making should be considered.

The competency of the aged, as a group, has been the subject of some controversy, and opinions regarding the capabilities of the older population diverge widely. On one hand, they are viewed as highly heterogeneous and, therefore, impossible to classify as a distinct group.[1] A contrasting view pictures them as quite vulnerable, frail, and dependent.[2] Proponents of the latter view often recommend special protective measures such as legal guardianship for the elderly who are faced with medical treatment decisions.[4]

Since opinions regarding the capabilities of the elderly are so diverse, empirical research on the issue is particularly important. Only two studies with the normal elderly[5,6] and none with the medically ill older patient have investigated their competency to give informed consent. In studies of the normal elderly, the aged were found to have some impairment in their ability to remember consent information.[5] Particular impairment was found in those with lower verbal skills.[6] Poor recall ability, however, may have little bearing on ability to give informed consent. Competency to consent has been defined most often as the capacity to comprehend relevant information, the ability to weigh the benefits and risks of the proposed procedure, and the capability to reach a reasonable

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decision. While it is important for subjects to remember that they are participating in research, recall of information is not usually considered to be a valid criterion. Poor recall may be more indicative of the normal forgetting process rather than of incompetency.

While not directly studying informed consent, research on cognitive functioning, memory, and personality changes in the elderly suggests some areas of possible impairment in the consent capacity of geriatric patients. In the realm of cognitive functioning, decrements in cognitive flexibility, recall and recognition, memory, storage and retrieval capabilities, and judgment have been reported.[7-12] However, not all research finds this age-related decrement in memory and other cognitive processes.[13] With respect to personality, changes from an active to a more passive position in relation to the environment and increased introversion and compliance have been noted.[14,15] Changes in both cognitive capacities and personality functioning may have an impact on the consent process of elderly patients.

These studies, although not completely consistent, suggest that the elderly may face some special difficulties giving informed consent. The present study was undertaken to directly examine this issue in elderly individuals who are ill, but, because we have chosen to address capacity to consent for research where the necessity for an informed and voluntary consent is greatest, we cannot directly apply our findings to the treatment setting. However, the capacities required to consent to treatment and research have been found to be similar[16]; thus our findings may have implications with regard to consent to treatment in the elderly. Specifically, the competency of elderly medical patients to consent to research was examined on three dimensions: (1) Do elderly patients agree to riskier procedures more often than nonelderly patients? Conversely, do they refuse highly beneficial procedures more frequently? (2) Do elderly patients demonstrate an impairment in comprehension of consent material compared with younger patients? (3) In the research setting, are geriatric patients capable of the same quality of reasoning with respect to medical decisions as younger patients?

Table 1.—Hypothetical Research Descriptions Risk and Benefit Ratings by Normal Volunteers (N=50)*

Type of Study	Risk Rating $\bar{X}$	Risk Rating SD	Benefit Rating $\bar{X}$	Benefit Rating SD
Low-risk/high-benefit, therapeutic	1.58	0.81	5.08	1.27
High-risk/low-benefit, nontherapeutic	5.14	1.51	2.66	1.33
High-risk/low-benefit, therapeutic	5.84	1.05	2.92	1.20
Low-risk/high-benefit, nontherapeutic	1.30	0.46	5.32	1.73
High-risk/high benefit, therapeutic	4.82	1.19	4.84	1.12
Moderate-risk/high-benefit, nontherapeutic	2.88	1.28	5.26	1.62

*Ratings were performed on seven-point Likert scale.

METHODS

In accord with customary procedures, informed consent was obtained from all patients following a full explanation of the nature of the research project. As a means of assessing competency, a series of hypothetical research studies was presented to elderly and young medical patients. An interviewer read the series of six research descriptions to the patients. The patients had copies of the descriptions available to them, and competency was assessed directly following the presentation of each description. Measures of intelligence and the level of the patient's attention during the evaluation were also obtained immediately following the competency assessments.

Measures

Competency Assessment.—Six hypothetical research projects were developed to assess willingness to participate in studies of various risk-benefit ratios. The studies met several criteria: (1) They were similar to actual studies. (2) They varied in degree of risk and benefit. (3) Half were therapeutic and half were nontherapeutic. (4) Each description was succinct and written at an eighth-grade level.[17] (5) Each description included the purpose, procedure, risks, and benefits of the study. The descriptions were developed according to these criteria by three medical professionals who had experience conducting research studies. Following the initial development, the studies were read to several patients to determine the clarity.

The randomized studies were then administered to a group of 50 normal volunteers to determine whether the risk-benefit ratios were perceived in the intended manner (ie, a high-risk study was rated as high risk). The subjects were asked to rate the studies on a seven-point scale ranging from low to high. They were instructed that the "condition" referred to in the studies was a severe illness. The results indicated that the studies were perceived in the desired way. Each study was rated on a seven-point Likert scale; the means and SDs are presented in Table 1. All studies were rated in the intended direction of risk and benefit, eg, high-risk studies received high-risk ratings.

Competency was assessed by items on a questionnaire evaluating willingness to participate in the hypothetical study (reasonable outcome), quality of reasoning, and comprehension of the purpose, procedure, risks, and benefits of the hypothetical studies.

Six open-ended items were used to assess competency to consent to treatment or research based on three common definitions[18-20]: (1) reasonable outcome of decision (determined by assessing willingness to participate in the higher-risk/low-benefit studies[21]), (2) quality of reasoning of the decision (determined by showing evidence of appropriate weighing of risks and benefits), and (3) comprehension of the consent information.

Reasonable outcome of decision was assessed by determining whether the patient's choice about participation in the hypothetical descriptions was consistent with the degree of risk and benefit in those descriptions. Agreement to participate in a low-risk/high-benefit study was judged to be reasonable, as was refusal to participate in a high-risk/low-benefit study.

To score competency according to the definitions of "quality of reasoning" and "comprehension," a coding scheme was developed. Four raters developed a coding procedure based on a priori criteria derived from legal standards. Quality of reasoning is rated on a seven-point scale and coded in the following manner by one rater who was not present during the interview, and who was not aware of patient diagnosis or background:

1. Shows no evidence of weighing risks and benefits, and gives an entirely irrelevant response to the question, "Why did you decide to be (or not be) in the study?".

2. Shows no evidence of weighing risks or benefits, or mentions irrelevant risks or benefits.

3. Weighs either risks or benefits globally.

4. Specifically identifies and weighs either risk or benefit.

5. Weighs risks and benefits globally.

6. Specifically identifies and weighs either a risk or benefit, and globally weighs the other factor.

7. Explicitly identifies and weighs both the risks and benefits.

Interrater reliability was assessed using a sample of 50 responses to a cross section of the studies. The correlation between raters was found to be fairly high (r=.87) and is judged to demonstrate adequate reliability.

Comprehension responses were also coded using the same procedure as previously described. The coding scheme for these responses is as follows: (1) irrelevant or inaccurate response, (2) response indicating the subject does not comprehend and acknowledges this lack of understanding, (3) partial accurate response (eg, identification of minor risk or benefit without naming major ones), and (4) specific accurate response. Interrater reliability between two raters was computed for all items and across studies. It was found to be quite high (r=.97) and, thus, reliability is adequate. To obtain an indication of overall comprehension, a sum of responses to four comprehension items was computed for each study (highest possible score of 16) and across the four studies of opposite risk-benefit ratios.

Level of Attention.—The attention span of the subject during competency assessment was measured by a five-item questionnaire, which included items such as the patient's distractability, attempts to engage the interviewer in unrelated conversation, and the need to repeat information to the patient. This questionnaire provided a direct means of measuring whether the patient paid attention to the descriptions.

Intelligence.—Intelligence was assessed by the Quick Test, a brief test of verbal ability.[22] On this test, the patient chooses one of four pictures that best describes a stimulus word. This test correlates well with the Full Scale IQ of the Wechsler Adult Intelligence Scale, and in particular with the Verbal IQ portion.[23,24]

Patient Characteristics

Patients were recruited from three facilities in major metropolitan cities. During the data collection phase, every available inpatient in the general medical units was asked to volunteer. For outpatients, every patient at several medical clinics was approached while they awaited their appointment. Thus, data for old and young patients was collected over the same time frame. Approximately 75% of all patients asked to participate agreed to do so. All were diagnosed as having serious medical illnesses. Heart problems (eg, hypertension or myocardial infarction), diabetes, and asthma were the most frequent diagnoses in both the elderly and the young. The sample consisted of 80 medical patients in two age groups: (1) the elderly (N=39) aged 62 and older ($\bar{X}$=69.2, SD=5.3)—12 were medical inpatients and 27 were medical outpatients—and (2) 41 young adults whose ages ranged from 22 to 44 years ($\bar{X}$=33.7, SD=6.6). In this group, 19 were medical inpatients and 22 were medical outpatients. Approximately half of each age group had at least one prior hospitalization for their chronic illness (young=53%, old=44%), which tends to confirm the notion that a significant proportion of both groups were comprised of individuals with long-standing illnesses. Furthermore, both patients had similar perceptions of the seriousness of their illness, with 40% of the elderly and 37% of the young reporting that their condition was very severe. There were more females than males in both the young and elderly groups, 56% and 64%, respectively. All patients spoke English fluently, English being the native language of 84% (young=83%, elderly=85%).

Patients were screened to ensure that their hearing and vision were adequate and were not impaired in a manner that interfered with their full participation in this study. With respect to intelligence and education, no significant differences were found between the elderly and the young. The average IQ was in the normal range (young, $\bar{X}$=97.6, SD=14; elderly, $\bar{X}$=96.4, SD=18; t<1, df=78, not significant). With regard to education, 37% of the young patients had some education beyond high school, while in the elderly group, 27% of the elderly group fell into this category. Again, this is not a statistically significant difference (χ^2=4.0, df=4, not significant).

Patients were screened to ensure that none had serious psychiatric illnesses, as indicated by a lack of psychiatric treatment in the past ten years. In addition, they were screened clinically to rule out the presence of severe organic brain syndrome. However, since extensive neuropsychiatric evaluations were beyond the scope of this study, it is possible that neurological or psychiatric conditions in some patients were undetected.

Table 2.—Comprehension and Reasoning Scores for Young and Elderly Patients

Type of Study	Comprehension Scores,* $\bar{X}$ ± SD: Young (N=36-40)	Comprehension Scores,* $\bar{X}$ ± SD: Elderly (N=29-37)	P Value‡	Reasoning Scores,† $\bar{X}$ ± SD: Young (N=36-40)	Reasoning Scores,† $\bar{X}$ ± SD: Elderly (N=29-37)	P Value‡
High-risk/low-benefit	11.93±3.03	9.61±2.89	< .01	3.05±1.20	3.34±1.36	NS
High-risk/low-benefit	11.61±3.07	9.09±3.14	< .01	3.12±1.14	2.56±1.23	< .05
Low-risk/low-benefit	11.90±3.09	10.24±2.58	< .05	2.85±1.32	2.84±1.65	NS
Low-risk/high-benefit	12.74±3.42	11.31±3.50	< .10	3.71±1.66	2.85±1.63	< .05
High-risk/high-benefit	13.06±2.61	11.55±3.10	< .05	3.26±1.06	3.45±0.99	NS
Moderate-risk/high-benefit	13.53±2.61	11.93±3.23	< .05	3.29±1.27	3.21±1.26	NS

*Possible range of 4 to 16.

†Possible range of 1 to 7.

‡Student's t test for independent means was used to make comparisons. The range of sample size is presented because the data were missing for some comparisons.

Table 3.—Participation Rate in Hypothetical Studies for Young and Elderly Patients

Type of Study	Young, % (N=41)	Elderly, % (N=39)	P Value*
High-risk/low-benefit	25.0	30.6	NS
High-risk/low-benefit	28.9	51.4	< .05
Low-risk/high-benefit	82.5	77.8	NS
Low-risk/high-benefit	80.5	63.2	NS
High-risk/high-benefit	34.2	28.6	NS
Moderate-risk/high-benefit	44.7	34.5	NS

*χ^2 test was used to determine significant differences.

RESULTS

Table 2 gives the results comparing elderly and young medical patients on comprehension of consent information and the quality of reasoning employed in reaching the consent decisions. With respect to comprehension, clear differences emerged between the elderly and young. The aged demonstrated poorer understanding of consent information for five of the six research projects. This finding is further strengthened when

Table 4.—Comprehension Scores of Consent Form Elements for Young and Elderly Patients

Consent Form Elements*	Young (N=37-40), $\bar{X} \pm SD$	Elderly (N=36-37), $\bar{X} \pm SD$	P Value†
Purpose of procedure	11.50±3.31	9.42±2.78	< .01
Procedure	12.54±2.66	10.92±2.24	< .01
Benefits	11.78±3.17	9.51±3.43	< .01
Risks	12.46±3.23	10.45±2.64	< .01

*Possible range for each element is 4 to 6.
†Student's *t* test for independent means was used for comparisons. Sample size varied as a result of missing data.

overall comprehension, derived by summing comprehension scores for the four research descriptions of opposite risk-benefit ratios, is examined. Elderly medical patients showed significantly poorer comprehension than young patients (elderly, $\bar{X}$=40.8, SD=8.6; young, $\bar{X}$=48.3, SD=10.4; t=3.14, df=63, $P<.01$).

With respect to quality of reasoning, the elderly tended to perform somewhat more poorly, demonstrating less rational reasoning than younger patients for two of the research descriptions. However, total quality of reasoning scores for the four descriptions of opposite risk-benefit ratios did not show a significant difference between the two groups (elderly, $\bar{X}$=11.6, SD=4.1; young, $\bar{X}$=12.7, SD=3.6; t=1.26; df=77, not significant). "Reasonable choice" criteria (ie, decisions consistent with risk-benefit ratios), as shown by young and elderly patients' participation rates for each of the studies are reported in Table 3. Five of the six studies had no significant differences in participation rates. However, the elderly did demonstrate less reasonable decision making on one of the higher-risk/low-benefit studies by agreeing to participate at a significantly higher rate.

Table 4 shows comprehension of specific elements contained in consent forms for the four study descriptions, with opposing risk-benefit ratios (ie, risk, benefits, procedures, and purpose of the project. For each of these elements, the elderly demonstrated significantly poorer understanding than young patients despite similar outcome on the choice criterion. This finding indicates that the deficits experienced by the geriatric patients are not specific to a single element of consent information (ie, risks, benefits, or alternatives).

The influence of additional factors such as intelligence and attention level on the relationship between age and capacity to consent were also examined. A partial correlation that controlled for the effect of intelligence in the correlation between age and overall comprehension of the research descriptions showed a significant relationship. When the effect of IQ scores was removed, the performance of the elderly remained poor (r_p=−.37; df=63; $P<.01$). The partial correlation between age and overall comprehension with the effects of level of attention controlled also showed that a significant relationship continued to exist (r_p=−.38; df=63, $P<.01$).

COMMENT

These results present a mixed picture regarding elderly medical patients' capacity to give informed consent. Both the young and the elderly are more likely to agree to participate in low-risk projects than high-risk procedures, and thus tend to make reasonable decisions. The rates of participation for the young and the old do not differ except in one instance when the elderly agreed more often to a risky project. The elderly show some impairment in their quality of reasoning despite the fact that they are able to reach reasonable decisions to the same degree as the young. The greatest differences emerge between the older patients and the younger patients when comprehension scores are examined; the elderly demonstrate poorer comprehension of each of the specific elements of informed consent information. Thus, as a group, geriatric patients may have some impairment in their competency to give informed consent for research; however, this impairment does not appear to have a significant impact regarding the quality of their decisions. Thus, while they show poorer comprehension than their younger counterparts, they generally seem to make equally reasonable decisions. It may be that only a basic awareness of relevant information is necessary to make reasonable decisions, and it is possible that both of the groups studied achieved this level of awareness. Thus, the quality of decision making may not be adversely affected until comprehension ability is severely impaired, as in severe senile dementia.

In attempting to elucidate the reasons for the differences found in comprehension scores, we examined the possible moderating effects of intelligence and attention span, but neither of these variables accounts for the poorer scores obtained by the elderly. Significant differences continue to exist between the age groups after the effects of intelligence and attention span have been removed separately from comprehension scores. Furthermore, level of education did not significantly differ between the two groups. Thus, factors other than education, intelligence, and attention span should be considered in accounting for the poorer comprehension scores of the elderly. In this regard, our findings appear to be somewhat at odds with those of Taub et al,[6] who reported that verbal ability, rather than age, appeared to determine the amount of consent information recalled. These somewhat discrepant findings may be the result of different criterion variables: immediate comprehension in our study and delayed recall in the case of Taub et al.[6] In addition, our samples differed in that we studied medical patients while Taub et al[6] tested normal elderly. Medical illness may affect the capacities required for consent more profoundly in the elderly.

Although the quality of treatment decisions does not appear to be adversely affected by the poorer comprehension scores, a high level of comprehension of consent material may be a desirable goal in itself. Compliance with necessary treatment regimens may be facilitated if patients have a fuller understanding of the procedures they must follow. Furthermore, a full understanding of the risks may help the elderly, who are

frequently more sensitive to medication side effects, to be mindful of possible adverse effects of drugs they are receiving, enabling them to report these effects earlier and more reliably. Consequently, finding aids[25,26] to increase comprehension of consent information and simplifying consent material, as suggested in the preamble of the Department of Health and Human Services regulations,[27] may be worthwhile for elderly research patients.

If these precautions are unsatisfactory, the physician may ultimately decide to seek a proxy consent or may enlist the aid of the patient's family to remind the patient of important aspects of the treatment or research project.

Two cautionary notes should be added with regard to our findings. First, it must be remembered that in our study hypothetical vignettes were used rather than real-life situations. Our elderly patients' competency may have differed had we assessed it when they faced actual decisions, but this seems unlikely. We are in the process of comparing competency as judged by the hypothetical measures with competency in relation to participation in actual research projects for an elderly population (in a different sample of patients than the present study). Our preliminary results show that the two assessments are highly correlated on both the comprehension and quality of reasoning dimensions.[28] Thus, competency as assessed in a hypothetical situation appears to parallel competency for "real" decisions.

A second word of caution should be added with regard to the generalizability of these findings. Although our patients were chosen at random and did not differ on factors such as intelligence and education, we do not know whether they differed on any variables such as personality traits or general sense of well-being. These additional factors may have also influenced capacity to consent. Further studies are needed to examine the influence of these factors as well.

In conclusion, our results suggest that there may be a higher incidence of incompetence in elderly medical patients than in younger patients. These findings are not meant to suggest that aging in and of itself causes incompetence. Concomitant factors of aging may be important influences. Furthermore, it must be remembered that these results do not show that *all* elderly patients have impaired competency. In this regard, it would be useful for physicians to have a screening guide for use in identification of elderly patients who may be considered incompetent.

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