

Decision-Making Capacity for Informed Consent in the Older Population

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We discuss key concepts and review 12 published research studies relevant to informed consent and decision-making capacity in the older population. The literature suggests that aging is associated with impaired decision-making capacity; the following additional factors amplify the detrimental effect of aging: lower vocabulary level, lower educational level, chronic medical illness (as in nursing home residents), and acute medical illness. Aging may be associated particularly with impaired comprehension of consent forms. We discuss guidelines for clinicians and researchers for improving the process of obtaining a truly informed consent.

Ensuring that the process of informed consent occurs adequately for all the individuals is an important but difficult matter for clinicians and researchers alike. How informed someone becomes through “informed” consent depends on

several issues, such as how well the information is presented, whether the recipient is hampered by mental or sensory impairments, the emotional tone of the situation, and the rapport with the examiner. Although the process can be modified to suit individual needs, there may still be some individuals for whom the information is unclear or unintelligible, and who lack the competence to give an appropriate informed consent in certain situations.

In geriatric psychiatry, there is particular concern about the process of informed consent and about decision-making capacity—which is the clinical equivalent of competence. The older population as a whole is a heterogeneous group, but includes a high proportion of

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subjects at risk for impairments in decision-making capacity (e.g., those with cognitive impairments¹⁻⁵ and/or psychiatric illnesses,⁶⁻¹¹ the groups most commonly seen by geriatric psychiatrists). The older population is also at a greater risk for physical illness, and consequently more often faces important decisions about medical treatment, long-term care, and life-sustaining measures.³ The challenge is to identify subjects at risk for impaired decision making and to ensure an adequate process of informed consent for them—while not infringing upon their rights to autonomous decision making.

First, we will briefly review relevant key concepts. Precise definitions in this area are particularly important, in part due to the presence of both legal and medical definitions. We will next review current research literature related to decision-making capacity and the process of informed consent in older patients. We will then offer guidelines for the clinician and researcher to improve the process of achieving informed consent. Finally, we will make suggestions for future research.

Definitions

Hidden within the process of obtaining informed consent for research or for medical treatment are the related but different concepts of informed consent, competence, and decision-making capacity.

Informed Consent Informed consent includes three aspects: full information, voluntary participation, and competence to make the decision at hand.^{6, 7, 12, 13} The last of these is the most represented in the research in this area, but the first two

deserve a brief comment. Informed consent cannot occur without an adequate presentation of the information. This brings into play such concerns as the readability levels of consent forms and standardization of verbal information-giving processes that may occur without consent forms (e.g., for routine medical treatment decisions).¹⁴ That subjects should participate voluntarily may seem self-evident, but coercion can be subtle.^{5, 10} Peer group pressure, the desire to please authority figures or caregivers, and fear that care or treatment might be withheld can be powerful and not necessarily obvious influences.¹⁰

Competence and Decision-Making Capacity Legally, any adult is competent to make decisions for himself or herself unless the person is declared incompetent by a court of law. Because the term “competence” is a legal term, the use of the term *decision-making capacity* has come to represent what the clinician assesses. An adequate assessment of decision-making capacity is an estimate of what a court would term *competence*.^{13, 15, 16}

Numerous articles have been written as guides for the clinician to assess decision-making capacity, based on the courts' definition of competence.^{8, 9, 11, 13, 15, 17} One of the representative explications of the legal standards on which a determination of competency is based (and therefore also a guideline for the assessment of decision-making capacity) is the following: choice, comprehension, consequences, rationality, and reasonable outcome of choice.^{2, 7, 9, 15, 16, 18, 19}

To satisfy the criterion of *choice*, a

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person must indicate a choice, and the choice indicated must remain consistent, at least long enough for the choice to be enacted.^{11, 15} To meet the criterion of *comprehension*, a person must be deemed able to comprehend the matter at hand in sufficient detail so that the main items are understood.^{2, 20} A person who can demonstrate an understanding of “consequences” is able to identify his or her own role in the situation and to appreciate the personal implications.^{11, 15} *Rationality* is present when a person can give evidence of having considered the benefits and risks of the choices.^{11, 15} In its purest sense, this criterion should not include the examiner’s assessment of whether the decision is wise.^{9, 16, 17} An additional criterion, considered by some examiners, but debated by others, is *reasonable outcome of choice*.^{2, 7, 9} This criterion expressly considers the examiner’s sense (as reflecting what any reasonable person might believe) of the wisdom of choice based upon its potential outcome.

There is often no single correct way to look at these criteria. If they are all met, then decision-making capacity is intact. If only some of them are met, however, the issue becomes more cloudy. One point of view is that the criteria for competence listed above can be regarded in a hierarchical fashion, and can be differentiated by the level of “protection” provided to the individual. Some authors advocate that a different level of decision-making capacity should be present for different levels of decision. Decisions with more risk, or those that do not necessarily benefit the individual, such as some research protocols, may need to be accompanied by a greater indi-

cation of understanding of the situation and its potential risks.^{8, 15, 16, 19} Others argue for a more autonomous stance, wishing to err on the side of protecting the individual’s right to make decisions, even ones that might be viewed by others as “bad” decisions.^{9, 10, 16} Potential influences in all these discussions are matters of ethics, public sentiment, and public policy, as well as protection of legal rights.

Not all the decisions are of the same level of complexity or difficulty. Therefore, a person may have the capacity to make one decision and not another.^{13, 16, 17} The criteria noted above should be closely tied to an individual decision. Furthermore, the basis for determining whether someone has intact decision-making capacity is not the same as the basis for determining whether someone is cognitively impaired, or whether someone has impaired judgement, or even impaired memory. Yet at some point on a continuum of cognitive impairment, individuals are likely to cross a threshold beyond which they have difficulty with decision-making capacity. Just where this threshold may fall is, however, often difficult to determine.

Materials and Methods

For this article we searched the English-language medical and psychiatric literature for studies that would be relevant to decision-making capacity and informed consent in older populations. Our search identified 12 studies addressing the concept of decision-making capacity for informed consent that would be rele-

Table 1
Literature Review: Methodology

Investigators	Patient Characteristics (N = sample size)	Comparison Group	Mean Age (range or standard deviation)	Specific Decision Considered	Aspect(s) of Decision- Making Capacity	Other Scales or Tests	Statistical Tests
Taub, 1979 ²¹	1. Community-dwelling older women (N = 27)	2. Community- dwelling younger women (N = 27)	1. 70 (55-83) 2. 27.3 (19-36)	None	Comprehension of prose materials	WAIS vocabulary and two memory tests	ANOVA and χ^2
Soskis and Jaffe, 1979 ²⁴	Hospitalized men with schizophrenia (N = 25)	None	Not given	Knowledge of their own antipsychotic medication	Factual information about medications	None	
Stanley <i>et al.</i> , 1981 ⁶	1. Psychiatric inpatients with various psychiatric illnesses (N = 27)	2. Medical inpatients (N = 38)	Not given	Consent for hypothetical research of differing risks/benefits	Reasonableness of decision (willingness to enroll in low risk/high benefit studies)	Brief Psychiatric Rating Scale	t tests and correla- tions
Cassileth <i>et al.</i> , 1980 ¹⁴	Cancer patients receiv- ing chemotherapy, radiation therapy, or surgery (N = 200)	None	Median 59 (20-82) [85% > 45]	Consent for actual treatment of differing types	Recall of essential information of treatment consent one day after consent	None	ANOVA and χ^2
Taub, 1980 ²⁵	1. Community-dwelling older women (N = 56)	2. Community- dwelling younger women (N = 34)	1. 71.3 (57-83) 2. 28.5 (22-35)	Actual study consent	Memory of main points of study, assessed two to three weeks after initial consent	WAIS vocabulary	ANOVA and χ^2
Taub <i>et al.</i> , 1981 ²⁰	Community volunteers (N = 42) tested for comprehension and given immediate feedback on consent form	Community volunteers (N = 45) not tested for comprehension or given feedback	(57-87)	Actual study consent	1. Comprehension of main points of study 2. Memory of same points 2-3 weeks later	1. WAIS-R vocabulary	ANOVA and χ^2
Taub, 1979 ²¹	1. Community-dwelling older women (N = 27)	2. Community- dwelling younger women (N = 27)	1. 70 (55-83) 2. 27.3 (19-36)	None	Comprehension of prose materials	WAIS vocabulary and two memory tests	ANOVA and χ^2
Taub and Baker, 1983 ²²	Community volunteers (N = 50) given one comprehension trial and feedback initially	Community volunteers (N = 50) given up to 3 comprehension trials initially	71.3 (59-88)	Actual study consent	1. Comprehension of main points of study 2. Memory of same points 2-3 weeks later	1. WAIS-R vocabulary	ANOVA

Investigators	Patient Characteristics (N = sample size)	Comparison Group	Mean Age (range or standard deviation)	Specific Decision Considered	Aspect(s) of Decision- Making Capacity	Other Scales or Tests	Statistical Tests
Stanley <i>et al.</i> , 1984 ²	1. Older medical inpatients and outpatients (N = 39)	2. Younger medical inpatients and outpatients (N = 41)	1. 69.2 (5.3) 2. 33.7 (6.6)	Consent for hypothetical research of differing risks/benefits	1. Comprehension of consent information (nature of procedure, risks, benefits) 2. Quality of reasoning (weighing risks, benefits) 3. Reasonableness of decision (choice of low risk, high benefit studies)	1. Quick Test for verbal IQ 2. Attention: five-item questionnaire	<i>t</i> tests, χ^2 , and partial correla- tions
Taub <i>et al.</i> , 1986 ²³	Medical patients scheduled for cardiac catheterization (N = 108)	None	1. (< 30) 2. (50–59) 3. (60–69)	Consent for treatment (cardiac catheterization)	Comprehension of range of facts about treatment	None	ANOVA
Taub, 1979 ²¹	1. Community-dwelling older women (N = 27)	2. Community- dwelling younger women (N = 27)	1. 70 (55–83) 2. 27.3 (19–36)	None	Comprehension of prose materials	WAIS vocabulary and two memory tests	ANOVA and χ^2
Stanley <i>et al.</i> , 1988 ⁷	1. Dementia patients (N = 38)	2. Major depression (N = 45) 3. Non-psychiatric controls (N = 20)	1. 70.0 (6.2) 2. 67.8 (6.2) 3. 68.7 (6.4)	Consent for treatment (various medication trials)	1. Comprehensive of consent information (purpose, method, risks, benefits) 2. Quality of reasoning (weighing risks, benefits)	1. Guild memory test 2. WAIS-R vocabulary 3. Attention-questionnaire 4. Global Deterioration Scale 5. Brief Psychiatric Rating Scale 6. Hamilton Depression Scale	ANOVA
Fitten <i>et al.</i> , 1990 ¹	1. Veterans Affairs nursing-home residents (N = 51)	2. Community volunteers (N = 15)	1. (>60) 2. similarly aged	Consent for hypothetical treatments	1. Comprehension of key points 2. Understanding risks, benefits 3. Quality of reasoning	1. Mini-Mental State Exam 2. Short Portable mental status Questionnaire 3. Activities of Daily Living Scale 4. Instrumental Activities of Daily Living Scale	<i>t</i> tests and χ^2
Fitten and Waite, 1990 ³	1. Acutely (but not critically) ill hospitalized medical and surgical patients (N = 25)	2. Community volunteers (N = 25)	1. 68.4 (6.5) 2. 70.9 (9.2)	Consent for hypothetical treatments	1. Comprehension of consent information (medical condition, treatment, purpose, risks, benefits) 2. Quality of reasoning	Mini-Mental State Exam	<i>t</i> tests and χ^2

WAIS, Wechsler Adult Intelligence Scale; WAIS-R, WAIS-Revised.

vant to the older population, either for research or for clinical purposes.

Results

The above-mentioned 12 studies are summarized in Table 1 (methodology) and Table 2 (results). More specific results are discussed below.

Measures of Decision-Making Capacity Used Eight of the 12 studies gave results regarding an assessment of *comprehension*, either as their sole assessment or as a part of their overall assessment.^{1-3, 7, 20-23} Not all of the studies evaluated comprehension in the same manner. Perhaps the greatest difference was in terms of whether or not the study considered differences in memory (i.e., in the ability to recall essential information about the consent days or weeks later). Nonetheless, all eight investigations found comprehension to be impaired to some degree, at least in the experimental group.

Two reports evaluated recall of key items about informed consent for treatment. Soskis and Jaffe²⁴ found that knowledge of antipsychotic medication among hospitalized chronic schizophrenic men varied, ranging from knowing potential side effects (84% with correct information), to knowing how the medication worked (40%), to knowing their correct dosage (36%). Similarly, Cassileth *et al.*¹⁴ reported that knowledge of treatment among 200 patients with cancer varied, ranging from 60 percent who could describe what the treatment would involve, to only 27 percent who could name even one available alternative. These studies did not directly assess

impairment in decision-making capacity. They may therefore reflect the success of the informed consent process by the usual standard procedures, independent of impairments in decision-making capacity.

Other measures of decision-making capacity used in different investigations were rationality or quality of reasoning^{1-3, 7} and apparent reasonableness of choice, as discussed earlier under "Definitions".^{2, 7, 9}

Reported Predictors of Decision-Making Capacity. *Age* Five out of the 12 studies included populations that were both "older" and "younger," although the age cut-offs used varied across the studies.^{2, 14, 21, 23, 25} Age by itself and/or age plus another factor were found to be associated with some aspect of poorer decision-making capacity in four of these five studies.^{2, 21, 23, 25} In three studies, older age by itself was associated with poorer decision-making capacity.^{2, 21, 23} The report by Cassileth *et al.*¹⁴ was the only one that found no difference due to age alone that was independent of educational level. This study included a wide range of ages, from 20 to 82 years old, and a preponderance of older patients, but used age 45 as a cut-off, with 85 percent of the patients being over age 45. Five other studies were performed entirely in populations of older subjects,^{1, 3, 7, 20, 22} and two additional studies did not report age, but their sample populations appeared to include at least some older subjects.^{6, 24} In two of these studies some aspect of decision-making capacity was found to be impaired in both the experimental group and the control older groups, suggesting that aging was some-

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how involved in the process.^{20, 22}

Vocabulary Levels Vocabulary levels correlated with comprehension of consent forms and/or prose materials in the investigations by Taub *et al.*^{20-22, 25} All of these studies found a significant positive correlation between performance on comprehension of consent forms and vocabulary levels. Two of the studies compared different age groups stratified by vocabulary level.^{21, 25} In both studies, older subjects with poorer vocabulary levels had significantly poorer comprehension than younger subjects with comparable vocabulary levels, suggesting an independent contribution of aging to impaired comprehension.

Educational Level When both items were assessed, vocabulary level correlated with educational level.^{21, 25} In the Stanley *et al.* (2) study, older and younger groups were not significantly different in verbal IQ or in education, yet older patients performed worse on measures of comprehension. In contrast, Cassileth *et al.*¹⁴ found that low education, but not older age *per se*, was associated with poor recall of consent information. Taub *et al.*²³ concluded that both older age and lower education contributed to poor comprehension of consent forms.

Chronic and Acute Medical Illness Using their devised construct of decision-making capacity (see Table 1 for details), the two studies by Fitten *et al.*^{1, 3} found significantly higher impairment in decision-making capacity in their two test groups: nursing-home residents (chronically medically ill) and acutely medically ill hospitalized patients.

Psychiatric Illness As one of their

items assessing decision-making capacity, Stanley *et al.*^{2, 6} evaluated reasonableness of decision. The authors organized hypothetical studies on the basis of risk versus benefit (high risk/low benefit to low risk/high benefit) and compared an experimental group to a control group. No significant differences were observed in the assessment of riskiness of decision in psychiatric inpatients versus medical inpatients (ages were not given).⁶ In a similar study, which looked at depressed versus demented versus normal control older subjects, Stanley *et al.*² found that only the dementia group was impaired in its reasonableness of decisions, but that there was no significant difference between elderly depressed patients and elderly control subjects in this respect.

Readability Levels Two studies compared results when using consent forms of substantially different readability levels: Taub²⁵ compared forms written to a 12th grade versus a 6th to 7th grade comprehension level; Taub²³ also compared forms written to a college versus a 7th grade level. Contrary to their hypotheses, neither study found consistent differences attributable to the readability level of the forms.

Other Factors Cassileth *et al.*¹⁴ reported that the care with which the patients thought that they had read the consent forms before signing was significantly associated with subsequent recall of information provided. Taub and colleagues^{20, 22, 23} found that immediate testing for comprehension of the consent form with corrective feedback improved comprehension significantly.

Table 2
Literature Review: Results

Investigator	Results
Taub, 1979 ²¹	Older subjects made significantly more errors than middle-, but not high-vocabulary groups. Comprehension scores were significantly better than memory tasks for both age groups and at all vocabulary levels. Vocabulary scores varied directly with educational level.
Soskis and Jaffe, 1979 ²⁴	Patients' knowledge about different aspects of their psychiatric medication ranged from knowing potential side effects (84%) to knowing how the drugs worked (40%) and the actual dosage (36%).
Stanley <i>et al.</i> , 1981 ⁶	Psychiatric patients and controls were not significantly different in choices to enroll in hypothetical research studies that differed in risks and benefits.
Cassileth <i>et al.</i> , 1980 ¹⁴	Only 60% could describe what treatment would involve, 59% could list a single major risk or complication, and 27% could name an alternative treatment. Poor recall was associated with low education, being bedridden (nonambulatory), and inadequate care with which the patients thought that they had read the consent form. Age, race, gender, or treatment modality had no significant effect.
Taub, 1980 ²⁵	Most patients answered one or more questions incorrectly when tested two to three weeks later. Number of incorrect responses was higher in those with lower levels of vocabulary and education.
Taub <i>et al.</i> , 1981 ²⁰	Recall was poorer in patients with low vocabulary level, and in those with worse initial comprehension. Corrected feedback improved recall significantly at all vocabulary levels.
Taub and Baker, 1983 ²²	Comprehension and memory performance increased directly with vocabulary level. Comprehension performance (but not memory) was enhanced by multiple trials at all vocabulary levels.
Stanley <i>et al.</i> , 1984 ²	Compared with younger patients, the older patients did (1) significantly worse on comprehension of consent form items, and (2) nonsignificantly worse on quality of reasoning, but (3) did not differ on reasonableness of decision in most cases.
Taub <i>et al.</i> , 1986 ²³	Older age and lower education were significantly associated with impaired performance on measures of comprehension on consent forms. The effects of readability of consent form were inconsistent. Corrective feedback improved performance on repeat trials.
Stanley <i>et al.</i> , 1988 ⁷	1. Dementia patients, but not those with major depression, had significantly poorer comprehension of consent forms than controls. 2. The 3 groups did not differ on quality of reasoning, although the quality was only moderate in all groups.
Fitten <i>et al.</i> , 1990 ¹	Compared with controls, only one-third of nursing home residents had intact decision-making capacity, with one-third being severely and another third moderately impaired. Impairment in decision-making capacity correlated with cognitive, but not functional (activities of daily living), impairment.
Fitten and Waite, 1990 ³	Hospitalized patients scored significantly lower than controls on assessment of comprehension and quality of reasoning about hypothetical research studies. Per study's definition, 7 of 25 subjects were impaired compared with 1 of 25 control subjects.

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Table 2 (Continued)
Literature Review: Results

Comments
<p>The authors concluded that inadequate acquisition (assessed here by comprehension) may represent one factor underlying age-related differences in immediate retention of information. No true decision-making capacity was assessed, but cognitive concepts involved have clear bearing on decision-making capacity.</p> <p>Information on age was not given. It was not clear how subjects' knowledge reflected decision-making capacity. Not all subjects had true choices about taking medications.</p> <p>Information on age was not given. Outcome of decision was the only area examined relevant to decision-making capacity.</p> <p>24.9% said they did not read the consent form at all. Hence their performance might not reflect decision-making capacity.</p>
<p>Immediate correction of incorrect answers led to improved recall of items at a later date. Quality of reasoning was not assessed. Correct responses may not truly reflect comprehension or ability to appreciate implications of information.</p> <p>Correct responses may not truly reflect comprehension or ability to appreciate implications of information. Quality of reasoning was not assessed.</p>
<p>Correct responses may not truly reflect comprehension or ability to appreciate implications of information. Quality of reasoning was not assessed.</p>
<p>Groups were not different in IQ or education level. Despite significantly poorer comprehension in older subjects, most decisions reached were reasonable.</p>
<p>Correct responses may not reflect ability to appreciate implications of information.</p>
<p>Consent forms used to assess subjects were not standardized, because subjects were undergoing different medical treatments.</p>
<p>Control scores were adjusted until the reference group achieved nearly a perfect score as the control subjects were assumed <i>a priori</i> to have largely intact decision-making capacity. Nearly one-third of nursing home residents had impaired decision-making capacity for some tasks, but intact capacity for others.</p> <p>Mini-Mental State Examination (MMSE) scores were significantly lower in patients than in controls.</p>

Discussion

Methodological Limitations The studies cited above evaluated different sample populations with different methods. They used varying definitions of decision-making capacity and/or assessed different components of decision-making capacity. The investigators either employed only a few tests of cognitive ability, or did not define or assess cognitive deficits at all. Some of the reports had small sample sizes. Also, some investigators studied actual treatment or research protocols, while others studied hypothetical treatment or research protocols. This distinction between treatment and research, and between actual and hypothetical situations, may have some importance. Thus, conditions from which one may actually derive benefit or harm may have more personal meaning and might lead to better attention and recall for such information as opposed to hypothetical situations. On the other hand, there is a potential for denial and repression as psychological confounders in cases of actual treatment situations, particularly for the seriously ill person. Finally, a majority of the studies listed in Tables 1 and 2 were performed by a small number of researchers. Taub *et al.*^{20-23, 25} accounted for five of the studies, Stanley *et al.*^{2, 6, 7} for three, and Fitten *et al.*^{1, 3} for two. Hence, there were no multiple diverse samples in which these results were replicated using similar methods.

Summary of Results The above-mentioned methodological limitations restrict our interpretation of the data. Nonetheless, some conclusions may be

suggested. Aging appears to be associated with impaired capacity for decision making.^{2, 14, 21, 23, 25} The following factors amplify the detrimental effects of aging on decision making: (1) lower vocabulary level,^{20-22, 25} (2) lower educational level,^{14, 23} (3) chronic medical illness (as in nursing home residents),¹ (4) acute medical illness,³ and (5) cognitive impairment.⁷ Aging may be particularly detrimental for the comprehension of consent forms.^{1-3, 7, 20-23} On the other hand, the following factors were not shown to have great effects on decision-making capacity: (1) depression,⁷ (2) other psychiatric illness,⁶ and (3) readability level of informed consent forms.^{23, 25} Such "negative" results must, however, be interpreted cautiously in view of the study limitations. It is thus likely that major differences in severity of depression or in readability of consent forms would influence the process of informed consent. Finally, informed consent may not be all that informed, even in subjects with presumed intact decision-making capacity. Other factors in addition to decision-making capacity (such as careful reading of the consent form) may also affect the process of informed consent.¹⁴

Overall, the studies that were reviewed examined a very limited number of dimensions of cognitive function. When factors in addition to age were considered, they seemed to have an impact in further separating the older from younger groups, or the experimental groups of older patients from older controls. This may suggest that as one ages there is less "decision-making reserve." Most probably, multiple cognitive skills are utilized

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in decision making. Hence, combined deficits may be more likely to have an impact on decision making than any individual deficit. Increasing cognitive deficits from age may make other items such as vocabulary level or educational status, which are less important at younger ages, more important additive factors in the elderly.

Clinical Implications Our review suggests that aging, in combination with other factors, puts one at risk for decision-making impairments. Vulnerable populations include older patients with lower vocabulary levels, lower educational levels, chronic or acute medical illness, and cognitive impairment. The results suggest that clinicians and researchers should be especially diligent in obtaining and assessing informed consent from these categories of older individuals.

One suggested method for assessing adequacy of informed consent is to administer a multiple choice test immediately after the consent process. Individuals should be allowed to ask questions and to consult the consent form for answers, so that the assessment does not rely purely on memory. The results of studies by Taub and colleagues^{20, 22, 23} suggest that correcting the answers to these tests immediately after consent may positively influence the recall of these same items when asked again at a later date. Although this improved recall does not necessarily reflect improved decision-making capacity, it may reflect better learning that has occurred despite decision-making deficits.^{20, 23} Overall, it becomes the goal of the clinician and the researcher to identify and overcome as

many obstacles as possible to ensure that informed decisions are made and that decision-making capacity is assessed under the best possible circumstances. If deficits are mild, compensation may be possible, which may prevent subjects from being wrongly assessed as incapable, and perhaps from having care denied or delayed, or being excluded from research protocols.

Future Research Directions Future studies should use clearly defined sample populations and standardized procedures. All the likely effectors should be taken into account, especially cognitive deficits. It is important that controls be clearly free of such deficits. Educational level, estimated pre-study or premorbid verbal abilities, and comprehensive neuropsychological assessments should be performed. Attention should be paid to the notion of an additive effect in the data analysis. The definition of decision-making capacity should be clearly delineated as should the method of deciding when decisional impairment is present.

Table 3 presents a flowchart for guidelines on research on decision-making capacity in elderly psychiatric patients.

Among several lines of future directions suggested by this review, one area that remains to be assessed is an analysis of the relationship between neuropsychological variables (e.g., prefrontal "executive functions" such as conceptualization/abstraction) and clinical assessment of decision-making capacity. Additionally, the suggestion that psychiatric illnesses may predispose to decision-making impairments was not borne out by two studies,^{6, 7} yet the third study that assessed

Table 3
Flowchart for Guidelines on Research on
Decision-Making Capacity in Elderly
Psychiatric Patients

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1. Hypotheses: defining specific hypotheses
 2. Subjects:
 - A. Experimental group: elderly psychiatric patients with specific diagnoses based on DSM-IV.²⁶
 - B. Comparison group: nonpsychiatric subjects matched with the experimental group on age, gender, ethnicity, education, physical comorbidity, and sensory impairment. (The choice of comparison group would depend on the specific hypotheses to be tested.)
 - C. Sample sizes: based on power analysis.
 3. Assessments:
 - A. Psychiatric: standardized rating scales such as the Brief Psychiatric Rating Scale²⁷
 - B. Cognitive: well selected neuropsychological test battery
 - C. standardized neurological and other physical examination
 - D. Specific measures of decision-making capacity: comprehension,²² memory,²² quality of reasoning,⁷ reasonableness of decision.²
 4. Data analysis: multivariate statistical analysis that considers dependent, independent, and confounding variables
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informed consent of ongoing treatment showed some impairment.²⁴ It would be helpful to study decision-making capacity in patients with psychiatric illness more thoroughly to determine which aspects, if any (e.g., thought disorder, preoccupation with death), and at what level of severity, may predispose to decision-making impairments. As with impairments in decision-making capacity for other reasons (e.g., cognitive impairments), it may also be possible to identify techniques to compensate for deficits due to psychiatric ill-

ness, after they have been adequately assessed.

Developing a better understanding of the complex cognitive, psychological, and social processes that occur when individuals make decisions would be of great theoretical and clinical value. Overall, future research efforts should allow us more accurate understanding and identification of risk factors for impairment in decision-making capacity. If we can more accurately recognize vulnerable elderly individuals, we will ultimately be better at protecting them from improper consent. At the same time, we would not need to impose limitations on the larger number of elderly persons who are not at risk for impaired decision-making capacity, and therefore we could better maintain their rights to make free and voluntary decisions.

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