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Measuring Decision-Making Capacity in Cognitively Impaired Individuals

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Abstract

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Keywords

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Comments

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Measuring Decision-Making Capacity in Cognitively Impaired Individuals

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Abstract

Cognitive and functional losses are only part of the spectrum of disability experienced by persons with Alzheimer's disease and related dementias. They also experience losses in the ability to make decisions, known as decision-making capacity. Researchers have made substantial progress in developing a model of capacity assessment that rests upon the concept of the 4 decision-making abilities: understanding, appreciation, choice and reasoning. Empirical research has increased our understanding of the effects of late-life cognitive impairment on a person's ability to make decisions. This review examines studies of the capacity to consent to treatment, research and the management of everyday functional abilities. The results illustrate the clinical phenotype of the patient who retains the capacity to consent. They also suggest that measures of capacity can improve how researchers measure the benefits of cognitive enhancements and stage dementia.

Keywords

Cognitive impairment; Decision-making capacity; Alzheimer's disease; Medical ethics

Introduction: Why Should We Care about Decision-Making Capacity in Cognitively Impaired Individuals?

The prevalence of cognitive impairment steadily increases with age [1]. In the United States and other Western nations, the chief cause of this impairment is Alzheimer's disease and related late-life neurodegenerative dementias. Persons with dementia are, by definition, disabled. That is, the diagnosis requires evidence of a decline in a person's ability to perform his or her usual and everyday tasks [2].

Researchers have made considerable progress in measuring the pattern and progression of these disabilities. Specifically, substantial data describe the kinds of functional losses persons with dementia experience [3]. The earliest changes are in complex instrumental activities of daily living, especially managing money, medications, telephone messages and transportation. By the moderate to severe stages, knowledgeable informants report that the patient has difficulties in performing basic activities of daily living (ADL).¹

Progress in this research has allowed the development of staging instruments such as the Clinical Dementia Rating [4] and the ADCS-ADL inventory [5]. These instruments are also valuable in assessing the effectiveness of potential treatments. For example, European regulatory officials require that approval of an antimentia compound must show efficacy on a functional measure in addition to measures of cognition and global change.

However, cognitive and functional losses are only part of the spectrum of disability experienced by persons with Alzheimer's disease and related dementias. They also experience losses in their ability to make decisions, also known as decision-making capacity. Unlike the field of functional assessment that began in the 1960s when Powell Lawton and Elaine Brody published their landmark article 'Assessment of older people: self-maintaining and instrumental activities of daily living' [6], the science of capacity assessment is comparatively recent. The conceptual and empirical framework was established in the 1980s with the work of the MacArthur network [7,8] and Marson and colleagues' studies of the capacity of persons with Alzheimer's disease to consent to treatment [9].

The last 20 years have seen considerable progress in the science of capacity assessment. The material reported in this paper is the result of several years of both conceptual and empirical scholarship with collaborators at as well as outside the University of Pennsylvania. This work has at least 3 benefits.

First, it expands our understanding of the nature and severity of the kinds of disabilities persons with cognitive impairment experience. Second, it introduces an additional method to assess the clinical benefits of treatments for persons with cognitive impairment. For example, measures of capacity can serve as endpoints to measure the effectiveness of a therapy to enhance cognition. Finally, it provides conceptual and methodological coherence to resolving ethically challenging decisions, such as whether a person with cognitive impairment retains the ability to choose a risky treatment or enroll in a potentially burdensome clinical trial. Capacity assessments negotiate the boundary between either respecting a person's autonomous choices or acting out of the principle of beneficence to promote that person's welfare. Specifically, persons who lack capacity need someone else to decide for them.

The Conceptual Framework of Capacity Assessment

A capacity assessment is a clinical assessment. The term clinical assessment captures 2 features. A health care practitioner talks to a patient to gather data, and then the professional uses that data together with other relevant information to make a judgment whether the patient does or does not have a diagnosis or has responded to an intervention.

An example of a clinical assessment is the use of a mood measurement scale to inform a diagnosis of depression. Scores on the geriatric depression scale do not determine that a person has depression. Instead, they are part of a clinical interview that informs the clinician's judgment whether the patient has depression. For example, a person who scores 6 on the 15-item geriatric depression scale [10], a score above the cutoff of 5, may in fact not be depressed because, for example, his or her symptoms are the result of an acute grief reaction.

What does this have to do with capacity assessment? The data derived from a capacity interview, like any clinical interview, inform the clinical judgment that the person lacks sufficient capacity to make a decision on his or her own [11]. In such a case, someone else, such as a close friend or family member, has to decide for the person. This judgment incorporates the results of capacity assessment with the risks, benefits and immediacy of the decision. For example, a clinician would be inclined to set a low threshold for judging a patient capable of making a decision if the decision involves little risk and great benefit and must be made relatively quickly.

The term capacity is distinct from the term competency [12]. Competency describes a legal judgment. That is, only a judge can declare a person noncompetent. In contrast, a physician judges whether someone has sufficient capacity to make a decision. The distinction made here is based solely on who is making the judgment and the role society assigns that person. Specifically, while judges do have the unique authority to declare a person not competent in a legal context, meaning the person needs some form of a guardian to make decisions for him or her, physicians make the same kind of decision all the time. On a day-to-day basis, clinicians decide that a patient is not competent to decide whether to take a treatment and, therefore, based on this assessment, the clinicians turn to a surrogate to choose on behalf of the patient. In sum, the terms competency and capacity distinguish between legal and medical judgments, but their outcomes are the same: a person can no longer choose for himself. In this paper, I will use the term capacity in order to retain the dimension quality of the construct.

How to Measure Capacity

Capacity is a dimensional quality of a person. By dimensional, I mean it is akin to weight, body mass index or blood pressure. A person's capacity is a point along a continuum. This continuum is described by the 4 decision-making abilities.

Considerable legal and ethical research has been undertaken in defining these abilities and standards to measure them [13]. They are: understanding, appreciation, choice and reasoning. Understanding is the ability to comprehend the meaning of information, such as the details of a research protocol, its alternatives, and the benefits and harms of the options. Appreciation is the ability to recognize how information applies to a person, information such as a diagnosis and the risks and benefits of the range of possible solutions for that diagnosis. Reasoning is the ability to compare options and infer the consequences of choices in a logically consistent manner. Expressing a choice is the ability to state a decision.

The general strategy to measure decision-making ability is to ask a patient a series of questions that assess that ability and to score those answers using criteria (for example: adequate answer = 2, marginal answer = 1, inadequate answer = 0). The sum of scores for the questions then represents a score on the measure of ability.

For example, suppose a clinician wants to assess a mild-stage Alzheimer's disease patient's capacity to consent to a treatment for Alzheimer's disease that carries a risk of encephalitis. In measuring the patient's ability to understand this risk, the clinician would ask the person to paraphrase the meaning of the information disclosed. Specifically, after the clinician discloses this risk to the patient, he or she would ask the patient "Tell me in your own words what I said about the risk of the drug?" An answer such as "It might damage my brain by causing it to get inflamed" is an example of adequately understanding of the risk of encephalitis. If the clinician was scoring performance, because for example, he or she was studying the capacity of patients to make a decision, such an answer would receive a score of 2.

The clinician uses this same strategy to assess the abilities to appreciate, choose and reason. In the case of assessing appreciation, the clinician needs to measure how well the person accepts that facts, such as the benefits and risks of a treatment, apply to his or her particular situation. For example, to demonstrate appreciation of the benefits of a treatment the patient needs to express some plausible explanation why the treatment will or will not benefit him or her. In particular, a patient with Alzheimer's disease who appreciates the benefits of a treatment might state that she has some memory problems that she does not want to get worse and a drug that can prevent that would be of value to her.

To assess the ability to reason, a clinician has 3 categories of questions: measuring a patient's ability to compare 2 options, such as taking versus not taking a medication; measuring a

patient's ability to infer how a choice will affect his or her daily life; assessing the logical consistency of the patient's answer to these 2 questions.

At the close of a decision-making ability assessment, the clinician has a set of data that describes the patient's performance on the 4 abilities, that is, how well the person can make the decision. These data are the foundation for a judgment of whether the person has adequate capacity to make a decision.

Studies of Capacity in Persons with Cognitive Impairment

In this section, I review our laboratory's work on studies of capacity in persons with cognitive impairment. Much of this work has focused on the most common cause of cognitive impairment, Alzheimer's disease. Before reviewing these results, I will overview the general design of our research.

A capacity study, like any study to test a measure, relies on the principles of reliability and validity developed in psychology [14]. Reliability is assessed by examining internal consistency, and inter- and intrascorer variability. Validity is assessed using the techniques of convergent, divergent and criterion validity.

Convergent and divergent validity refers to the association between 2 measures that either measure similar (convergent) or different (divergent) things. For example, we would expect that a valid measure of depression would show a positive association with a measure of anxiety, because anxious people tend to be depressed, and, in contrast, the measure of depression should show a negative association with a measure of happiness, because depressed people tend not to be happy. Criterion validity refers to the degree that summary scores of a measure differ between 2 groups who are expected to differ with respect to the measure under study. Thus, persons with diagnosed major depression should have higher scores on the depression scale than persons who are not diagnosed as having major depression.

In studies of capacity assessment, typical measures for convergent and divergent validity include measures of cognition, both overall cognition and specific domains of cognition such as executive function, and other measures of capacity. Two common criterion measures are comparing patient performance to a group who is expected to perform well on the measures of ability, such as cognitively normal elderly or knowledgeable informants, and expert judgments of whether the person has sufficient capacity to make the decision on his or her own.

The studies summarized below cover a spectrum of decisions: treatment for Alzheimer's disease, consent to research, and solving everyday functional problems. It should be evident that there are as many ways to measure capacity as there are unique decisions. For example, researchers have developed instruments to assess the capacity to stand trial [15] and to vote [16].

The Capacity to Consent to Treatment

Previous research on Alzheimer's disease patients' capacity to consent to treatment has focused on decisions about hypothetical health states (cardiac disease or a brain tumor) [9]. We were interested in examining the more clinically relevant issue, namely patients' capacity to decide about treatment for their Alzheimer's disease. Our study addressed 3 questions [17]:

1. What is the clinical significance of patients' impairments in decision-making abilities?
2. How is the loss of insight related to the other decision-making abilities and determinations of competency?

3. What is the relationship between overall cognition and judgments of competency?

The value of these questions rests upon 3 interrelated issues. Treatments for Alzheimer's disease may carry substantial risks [18]. Therefore, clinicians and family members could benefit from knowing the characteristics of patients who are capable of deciding whether to take a risky treatment. Two characteristics warrant study: insight and the severity of a patient's cognitive impairments.

Persons with Alzheimer's disease often have diminished insight into their cognitive and functional deficits [19], but it is not known how these impairments relate to their performance on measures of capacity. We were especially interested in learning how patients' failure to endorse the presence of cognitive impairments, their prognosis and the diagnosis of Alzheimer's disease impacts on their ability to decide whether to receive a risky treatment. These data can assist clinicians' and families' understanding of why a patient cannot make a decision. Moreover, if deficits in insight are in fact associated with the lack of capacity, clinicians and families have reason to take steps to foster a patient's insight, such as diagnostic disclosure and participation in a support group for persons with cognitive impairment.

It is also important to examine the association between capacity and the severity of cognitive impairments because diagnostic criteria are moving to diagnosing Alzheimer's disease in persons with mild degrees of cognitive impairment [20,21]. In particular, it is important to understand differences across the stages defined by traditional cut points on the mini-mental state examination (MMSE) [22].

Why use the MMSE? The answer to this question rests upon the clinical value of this measure of overall cognition. The MMSE is one of the few measures of overall cognition that is widely used in dementia clinical practice and to set eligibility criteria for clinical trials to test new treatments. Showing associations between both capacity and traditional MMSE cut points gives clinicians additional tools to better understand how the stages of dementia affect their patient's ability to make a decision.

Measuring the Capacity to Consent to Treatment-We used the MacArthur Capacity Assessment Tool for Treatment (MacCAT-T) [23] to assess the 4 decision-making abilities in 2 groups: persons with very mild to moderate Alzheimer's disease ($n = 48$) and their family caregivers ($n = 102$). We then asked 3 expert psychiatrists to independently listen to the patient interviews and judge whether the patient was competent to consent to the treatment. The Alzheimer's disease treatment was modeled after a disease-slowing therapy with a risk of gastrointestinal bleeding using a scenario we have developed and tested in previous research investigating caregivers' tolerance for risk to treat Alzheimer's disease [24].

The Capacity to Consent to Treatment in Persons with Alzheimer's Disease- Among the 48 patients with mild to moderate Alzheimer's disease, we found considerable variation in patients' performance on the measures of 4 decision-making abilities. In contrast, the comparison group of 102 family caregivers generally performed quite well on the 4 measures. Results on the measure of appreciation were especially interesting. We found marked differences in the abilities of the patients to appreciate the risk versus the benefit of the medicine. Specifically, only 7/48 (15%) could fully appreciate the benefit, while 19/48 (40%) could fully appreciate the risk. Three expert raters found 19/48 (40%) of the subjects had the capacity to provide their own informed consent.

Relationships between Capacity to Consent and Insight-Patients judged capable of consent were more likely to show awareness of their symptoms, prognosis and diagnosis. Of particular importance, this association between insight and being judged competent to

consent to treatment was independent of the patients' overall cognitive function. In other words, the impact of impairments in insight was independent of the impact of the severity of overall cognition. After adjusting for MMSE performance, patients who had insight into their memory problems (OR = 4.5, $p = 0.04$, 95% CI 1.1-17.9) and diagnosis of Alzheimer's disease (OR = 4.1, $p = 0.04$, 95% CI 1.0-16.4) were more likely than patients who did not have these insights to be judged to have the capacity to provide consent. Among patients with insight into their prognosis, there was a trend suggesting that independent of overall cognitive function, awareness of prognosis is associated with being judged to have the capacity to provide consent (OR = 3.4, $p = 0.08$, 95% CI 0.85- 13.7).

Relationships between Competency to Consent and Overall Cognition-We

examined the sensitivity and specificity of being judged not competent to consent as a function of performance on the MMSE. MMSE scores below 19 showed increasing specificity, meaning competent patients are not likely to be mistakenly labeled as noncompetent. In contrast, MMSE scores of 23 or higher showed increasing sensitivity, meaning that noncompetent persons with MMSE scores above this value will likely not be mistakenly labeled as competent. Finally, scores between 20 and 22 showed a gray zone of performance where the likelihood of being competent or not was intermediate. Of particular value to these findings is that the MMSE scores were close to the scores used as standard cut points for staging the severity of Alzheimer's disease.

In summary, these results show that persons with very mild to moderate Alzheimer's disease may well retain sufficient capacity to make a decision whether to take a risky treatment for their disease, and this capacity is strongly associated with the preservation of insight into their symptoms, diagnosis and, perhaps as well, prognosis.

The Capacity to Consent to Research

Decisions about research enrollment are ethically challenging. Unlike treatment, an activity that aims to maximize a patient's good, research is an activity designed to create generalizable knowledge. Consequently, research exposes participants to some procedures whose risks and burdens are not justified by the potential to benefit each participant's health and well-being, but instead by the value, or importance, of the knowledge that the study is designed to produce.

Previous studies of Alzheimer's disease patients' capacity to consent to research have examined the capacity to consent to a late-phase clinical trial [25]. Our group was especially interested in studying a more ethically challenging situation: Alzheimer's disease patients' capacity to consent to research that involved more than minimal risks. In particular, we were interested in studying the capacity to consent to participate in an early-phase study designed to test the safety of an intervention [26]. Such early-phase research is of particular scientific value to inaugurate clinical testing of an intervention, but it also presents considerable ethical challenges as the point of the study is to assess risks.

Measuring the Capacity to Consent to Research-We used the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR) to assess the 4 decision-making abilities [27] among 3 groups: patients with probable Alzheimer's disease ($n = 15$), their caregivers who had the role of making decisions for or with the patients ($n = 15$), and elderly persons without cognitive impairment and not involved in a caregiving role ($n = 15$).

A trained interviewer read the subject a one-page description of an early-phase clinical trial written at a 7th-grade reading level. To assure face and content validity, the description contained the general requirements of an informed consent as described in the Common Rule [28, § 46.116] for research informed consent, was based on published early-phase Alzheimer's disease protocols [29] and a panel of Alzheimer's disease clinical investigators reviewed the

description. The trial involved random assignment to daily intravenous injections of drug or placebo in an inpatient facility for 1 week followed by weekly outpatient follow-up visits. Standard language from other phase I Alzheimer's disease studies was used to describe the risks and benefits.

The Capacity to Consent to Research in Persons with Alzheimer's Disease-On

all ability measures except the ability to make a choice, patients performed worse than controls (understanding: $z = 3.2$, $p = 0.001$; appreciation: $z = 2.8$, $p = 0.005$; reasoning: $z = 3.5$, $p = 0.0005$) and caregivers (understanding: $z = 3.8$, $p = 0.0002$; appreciation: $z = 3.0$, $p = 0.003$; reasoning: $z = 3.6$, $p = 0.0003$).

The value of comparison groups such as family caregivers and cognitively normal controls is that they provide a criterion to compare patient performance. That is, the distribution of their scores provides a 'psychometric criterion' that permits us to make conclusions about the clinical significance of the distribution of patient scores. Using the controls' performance to set a psychometric criterion, the proportions of patients with adequate understanding, appreciation and reasoning were 6/15 (40%), 3/15 (20%) and 5/15 (33%), respectively. These results show that nearly half of the patients scored within the range of cognitively normal counterparts on the measure of understanding, but smaller proportions achieved this level of performance on the measures of appreciation and reasoning.

Proportions Judged Competent by Experienced Study Coordinator-A study coordinator with 2 years of experience in Alzheimer's disease clinical trials reviewed each audiotaped capacity interview. The coordinator judged all caregivers and 9 of 15 (60%) patients competent.

Relationships between Judgments of Competency and Cognitive Function-

MMSE scores of patients judged noncompetent by the study coordinator ranged between 12 and 27 (mean MMSE = 17.2 ± 5.7). In contrast, all competent patients had an MMSE score ≥ 19 (mean MMSE = 24.1 ± 3.1).

These results are of considerable ethical importance. They show that some patients with Alzheimer's disease retain sufficient capacity to consent to make their own decision whether to enroll in an early-phase study to test the safety of a drug for persons with Alzheimer's disease. Of particular value, they show that these kinds of patients are most likely persons with very mild- to early moderate-stage Alzheimer's disease as measured by MMSE scores greater than 18. When set against the results of our study of the capacity to consent to treatment, they suggest that while some degree of capacity impairment is a feature of even very mild-stage Alzheimer's disease, these impairments achieve clinical significance in persons with moderate Alzheimer's disease.

The Capacity to Make Everyday Decisions

Decisions about treatment and research are classic examples of decisions that invoke the need to assess a patient's capacity. But there are other kinds of decisions for which capacity is just as important. Our group has developed a conceptual model and instrument to measure the ability of persons with Alzheimer's disease to make a very real-world decision: how to manage their own functional problems [30,31].

We examined how a person who has a functional deficit, such as problems managing money, understands and appreciates this problem, understands and appreciates the risks and benefits of solutions to that problem and can reason through choices about how to solve this problem. The instrument we have developed to measure this capacity is called the assessment of the capacity for everyday decision making (ACED).

ACED is valuable in at least 2 contexts: (1) at the time of planning discharge from a health care setting such as a hospital or skilled nursing facility, and (2) in caring for persons with self-neglect, a syndrome characterized by an elderly person's inattention to health and hygiene, typically as a result of their inability or unwillingness to accept assistance with their ADL.

In both contexts, persons who refuse assistance in performing their ADL are of particular clinical and ethical concern. Clinicians need to assess if the person has sufficient capacity to make this decision. This assessment not only has substantial implications on the course of clinical interventions, but it may also initiate legal actions that may ultimately lead to partial or complete guardianship. At the same time, however, persons who demonstrate sufficient capacity to refuse assistance have the right to do so, even when such choices conflict with their clinicians' recommendations.

Measuring Everyday Decision-Making Capacity-We focused on 2 of the 3 documented functional problems (managing medications, managing finances and preparing meals). The order and heading for each ACED question are: understanding the problem (2 questions), appreciating the problem, understanding the options to solve the problem, understanding the benefits of the options, understanding the harms of the options, appreciating the benefits of the options (2 questions), appreciating the harms of the options, comparative reasoning (2 questions), consequential reasoning (2 questions), expressing a choice, and the logical consistency of that choice.

We studied 2 groups: 39 community-dwelling persons aged 65 or older who were being treated for cognitive difficulties and were evenly divided into 3 stages of cognitive severity [very mild (n = 13), mild (n = 13) and moderate (n = 13)] and a comparison group of 13 family members.

The Capacity to Solve Everyday Functional Problems in Persons with Cognitive Impairment-Although both groups were equally capable of articulating a choice, they differed significantly in their abilities to understand, appreciate and reason. Caregiver performance on all ACED items was skewed towards the higher ranges with all but one person scoring within 1 point of the highest score.

In contrast, patient performance was distributed across the score ranges. Only 15 patients (38%) achieved an understanding score above the lowest score observed in the caregiver group. Only 6 patients (15%) scored in the highest category (7-8) of appreciation, whereas all caregivers scored within the highest category. The majority of patients (29/39) scored between 1 and 4. Contributing to the lower scores was notably poor performance on the appreciation item asking patients whether they believed that they had functional problems. Specifically, 22/39 (56%) demonstrated inadequate recognition (score = 0) of proxy-reported functional problems.

Performance on the ability to reason was similar to appreciation. Only 6 patients (15%) were able to achieve scores of 9 or 10, the range of scores found in the caregiver group for this ability. We did, however, observe total scores above 5 points in this ability for 30 patients (77%), reflecting the relatively strong performance on the 2 comparative reasoning questions and the logical consistency question where 3% of patients scored less than 1 on each item.

To validate the ACED, we compared the cognitively impaired patients' ACED scores to their scores on the instrument we used to assess the capacity to make a treatment decision (MacCAT-T). We observed a moderate to strong correlation between performance on the ACED and the MacCAT-T in each of the 4 decision-making abilities. Spearman correlation coefficients for the abilities to appreciate and reason were 0.38 (p = 0.02) and 0.50 (p = 0.001), respectively. There was a stronger association for the ability to understand and expressing a choice: 0.63 (p < 0.001) and 0.71 (p < 0.001), respectively.

These data show that we can measure a patient's ability to solve his or her everyday functional problems using an instrument that took less than 15 min to administer and can be tailored to fit each patient's specific functional deficits (for example, my husband has left the stove on and bounced 2 checks). Further research is needed to assess the clinical significance of ACED scores, especially those scores just below the range of performance seen in the cognitively intact family members.

Summing Up and Looking Forward

Researchers have made substantial progress in applying the model of capacity assessment in order to develop measures of the decision-making abilities. As a result, this research has increased our understanding of the effects of late-life cognitive impairment on a person's ability to make decisions.

Among persons with very mild- to moderate-stage Alzheimer's disease, there is relative preservation of the abilities to choose and reason, compared to the abilities to understand and appreciate. This finding is of substantial importance because it suggests that the standard clinical approach of asking a person for his or her choice and then asking why the person made that choice, that is, asking the person to reason, will likely miss that the person may have substantial difficulties in understanding and appreciating information. Our studies of everyday decision-making capacity using the ACED suggest that this is especially true in decisions about managing everyday functional problems.

Progress has also been made in describing the clinical phenotype of the cognitively impaired person who retains the capacity to consent. Our research shows that persons with preserved awareness of their diagnosis, symptoms and prognosis are highly likely to retain capacity to make decisions about their care. In addition, persons with very mild to mild dementia as defined using standard MMSE cut points are more likely than those with moderate-stage disease to retain the capacity to consent. However, there are other types of dementia that are distinct from Alzheimer's disease (for example frontotemporal dementia such as Pick's disease) in which judgment, comportment and social behavior are affected more than memory early in the disease course, and future studies should address the question of decision-making capacity in patients affected by these other types of dementia.

Nonetheless, this progress in the Alzheimer's disease arena now opens the field to improve patient care. We need to disseminate methods of capacity assessment to practitioners and families. Preliminary work by Marson et al. [32] shows that instructing clinicians in the standards for capacity assessment can improve agreement in their judgments of whether a patient with Alzheimer's disease has adequate capacity.

We also need to test methods to improve patient performance on measures of capacity, ideally to improve performance to the degree that a person is judged capable of making a decision. Our group will soon complete an investigator-initiated project grant (R-OI) funded by the National Institute of Aging that tests the benefit of a memory and organizational aid for research consent capacity in persons with Alzheimer's disease. This randomized and controlled trial tests whether a single-page summary sheet given to persons after reviewing a lengthy informed consent form for an early-phase clinical trial can improve their decisional abilities and the odds of being judged capable of giving one's own informed consent.

Of particular value is that this study examines the capacity to consent to an early-phase bridging study. Such studies involve considerable uncertainties and thus risks to participants. It is the kind of study for which investigators and institutional review boards would want to minimize the chance that an investigator mistakenly judges a patient capable of consent when in fact the patient cannot consent.

Finally, these data are not only useful to guide ethical conduct of research and clinical care. They are also useful to assess the effectiveness of interventions designed to improve or enhance cognitive function. Specifically, measures of capacity could serve as endpoints in clinical trials to test cognitive enhancement drugs.

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