

CLINICAL PRACTICE

Assessment of Patients' Competence to Consent to Treatment

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This Journal feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the author's clinical recommendations.

A 75-year-old woman with type 2 diabetes mellitus and peripheral vascular disease is admitted with a gangrenous ulcer of the plantar aspect of her left foot. A surgical consultation results in a recommendation for a below-the-knee amputation, but the patient declines the procedure on the grounds that she has lived long enough and wants to die with her body intact. Her internist, who has known her for 15 years, is concerned that she has been increasingly confused over the past year and now appears to be depressed. How should her physician determine whether her decision is a competent one?

THE CLINICAL PROBLEM

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Physicians are required by law and medical ethics to obtain the informed consent of their patients before initiating treatment.¹ Valid informed consent is premised on the disclosure of appropriate information to a competent patient who is permitted to make a voluntary choice. When patients lack the competence to make a decision about treatment, substitute decision makers must be sought. Hence, the determination of whether patients are competent is critical in striking a proper balance between respecting the autonomy of patients who are capable of making informed decisions and protecting those with cognitive impairment.

Although incompetence denotes a legal status that in principle should be determined by a court, resorting to judicial review in every case of suspected impairment of capacity would probably bring both the medical and legal systems to a halt. (The terms "competence" and "capacity" are used interchangeably in this article, since the oft-cited distinctions between them — competence is said to refer to legal judgments, and capacity to clinical ones — are not consistently reflected in either legal or medical usage.) Thus, in most situations there is good reason to continue the traditional practice of having physicians determine patients' capacity and decide when to seek substituted consent.² Indeed, statutes regarding advance directives for medical treatment generally recognize a medical determination of incapacity as the trigger for activating these directives.³ In addition, since consent obtained from an incompetent patient is invalid, physicians who do not obtain a substituted decision may be subject to claims of having treated the person without informed consent.¹ Physicians must therefore be aware that their patients may have impaired decision-making capacities, and they must be skilled at evaluating that possibility.

Patients whose competence is impaired are commonly found in medical and surgical inpatient units, and less frequently in outpatient clinics. Between 3 and 25% of requests for psychiatric consultation in hospital settings involve questions about patients' competence to make treatment-related decisions.^{4,5} In many other cases, impaired decision making in hospitalized patients may go undetected,⁶⁻⁹ even when

patients decline recommended treatment.¹⁰ One study of 302 medical inpatients with acute conditions estimated that as many as 48% were incompetent to consent to medical treatment. This group included patients with a broad array of medical conditions, but most commonly neurologic and infectious diseases. The clinical team responsible for these patients had identified only approximately one quarter of this group as being impaired.¹¹

Any diagnosis or treatment that compromises mentation may be associated with incompetence. However, since a range of severity is associated with most diagnoses, no diagnosis in which consciousness is retained is invariably predictive of incapacity. Data on the diagnostic and other clinical predictors of incapacity are derived from studies of decisions regarding both consent to receive treatment and consent to participate in clinical research. Patients with Alzheimer's disease and other dementias have high rates of incompetence with regard to such decisions; more than half of patients with mild-to-moderate dementia may have impairment, and incompetence is universal among patients with more severe dementia.¹² Stroke can affect the capacity to make decisions, depending on the location and size of the affected area of the brain.¹³ Among psychiatric disorders, schizophrenia has a stronger association with impaired capacity than depression; roughly 50% of patients hospitalized with an acute episode of schizophrenia have impairment with regard to at least one element of competence, as compared with 20 to 25% of patients admitted with depression.^{14,15} Less severe depression, treated on an outpatient basis, may not impair capacity at all.¹⁶ Patients with symptomatic bipolar disorder may have levels of impairment in decision making that are similar to those of patients with schizophrenia.¹⁷ Among psychiatric patients, lack of insight (the lack of awareness of illness and the need for treatment) has been reported to be the strongest predictor of incapacity.¹⁸

In the absence of accompanying cognitive impairment, medical conditions such as unstable angina,¹⁹ diabetes mellitus,²⁰ and human immunodeficiency virus infection²¹ have not been found to be associated with an incapacity for decision making. However, a group of outpatients with cancer had quite variable performance on competence assessments,²² with impairment in decision making correlated with older age, fewer years of education, and cognitive impairment; these data

underscore the need to be attentive to limitations in capacity in every patient group.

Intensive care units⁸ and nursing homes^{23,24} include substantial proportions of incompetent patients. Measures of neuropsychological impairment are among the strongest predictors of limited capacity,²⁵ although the specific cognitive functions that correlate most strongly with impairment in decision making vary across diagnostic groups (e.g., patterns in schizophrenia differ from those in Alzheimer's disease).^{21,26,27}

STRATEGIES AND EVIDENCE

Notwithstanding the importance of the assessment of patients' competence by physicians and the incidence of impaired capacity among patients, data suggest that the performance of capacity assessments is often suboptimal. Physicians are frequently unaware of a patient's incapacity for decision making. When incapacity is suspected, physicians may not know which standard to apply, and, as a result, their evaluations may omit mention of the relevant criteria or may not apply them specifically to decisions about treatment.²⁸ The assignment of diagnostic categories may be confused with the determination of capacity. For example, a diagnosis of dementia or a psychotic disorder may be presumed incorrectly to indicate incompetence.²⁹ Hence, the reliability of unstructured judgments of competence by physicians has been poor. In one study, five physicians reviewing videotapes of capacity assessments and rating the competence of patients achieved a rate of agreement that was no better than chance (kappa statistic, 0.14).³⁰ Although the detection of an incapacity for decision making in patients depends in part on an appropriate level of suspicion by physicians, improvement in the performance of capacity evaluations themselves requires clarification of the applicable criteria and the use of a systematic approach to assessment.

CRITERIA FOR ASSESSMENT OF DECISION-MAKING CAPACITY

Legal standards for decision-making capacity for consent to treatment vary somewhat across jurisdictions, but generally they embody the abilities to communicate a choice, to understand the relevant information, to appreciate the medical consequences of the situation, and to reason about treatment choices.³¹⁻³³ Table 1 describes these four criteria and how they are assessed.

Table 1. Legally Relevant Criteria for Decision-Making Capacity and Approaches to Assessment of the Patient.

Criterion	Patient's Task	Physician's Assessment Approach	Questions for Clinical Assessment*	Comments
Communicate a choice	Clearly indicate preferred treatment option	Ask patient to indicate a treatment choice	Have you decided whether to follow your doctor's [or my] recommendation for treatment? Can you tell me what that decision is? [If no decision] What is making it hard for you to decide?	Frequent reversals of choice because of psychiatric or neurologic conditions may indicate lack of capacity
Understand the relevant information	Grasp the fundamental meaning of information communicated by physician	Encourage patient to paraphrase disclosed information regarding medical condition and treatment	Please tell me in your own words what your doctor [or I] told you about: The problem with your health now The recommended treatment The possible benefits and risks (or discomforts) of the treatment Any alternative treatments and their risks and benefits The risks and benefits of no treatment	Information to be understood includes nature of patient's condition, nature and purpose of proposed treatment, possible benefits and risks of that treatment, and alternative approaches (including no treatment) and their benefits and risks
Appreciate the situation and its consequences	Acknowledge medical condition and likely consequences of treatment options	Ask patient to describe views of medical condition, proposed treatment, and likely outcomes	What do you believe is wrong with your health now? Do you believe that you need some kind of treatment? What is treatment likely to do for you? What makes you believe it will have that effect? What do you believe will happen if you are not treated? Why do you think your doctor has [or I have] recommended this treatment?	Courts have recognized that patients who do not acknowledge their illnesses (often referred to as "lack of insight") cannot make valid decisions about treatment Delusions or pathologic levels of distortion or denial are the most common causes of impairment
Reason about treatment options	Engage in a rational process of manipulating the relevant information	Ask patient to compare treatment options and consequences and to offer reasons for selection of option	How did you decide to accept or reject the recommended treatment? What makes [chosen option] better than [alternative option]?	This criterion focuses on the process by which a decision is reached, not the outcome of the patient's choice, since patients have the right to make "unreasonable" choices

* Questions are adapted from Grisso and Appelbaum.³¹ Patients' responses to these questions need not be verbal.

DETERMINING WHETHER IMPAIRMENT CONSTITUTES INCOMPETENCE

The level of impairment that renders a patient incompetent to make treatment decisions should ideally reflect a societal judgment about the appropriate balance between respecting the patient's autonomy and protecting the patient from the consequences of a bad decision.³⁴ When physicians perform competence assessments, they should attempt to strike the same balance that would result if a court in the jurisdiction decided the case. In that regard, the presumption intrinsic to a mod-

ern democracy is that the vast majority of persons are capable of making their own decisions. Hence, only patients with impairment that places them at the very bottom of the performance curve should be considered to be incompetent. In practice, the stringency of the test applied varies directly with the seriousness of the likely consequences of patients' decisions.^{2,35} Although some commentators object to this "sliding scale" approach,³⁶ it makes sense from a policy perspective, it was endorsed by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Be-

havioral Research,² and in the judgment of many experts, it reflects how courts actually deal with these cases.

APPROACHES TO ASSESSMENT

Given the requirement of competence for valid informed consent, the assessment of the patient's capacity to make decisions is an intrinsic aspect of every physician–patient interaction. Usually, the assessment will be implicit, since in the absence of a reason to question a patient's decision making, the presumption of competence will prevail. When an explicit competence evaluation is required, physicians should be aware of the relevant criteria and should be encouraged to use a structured approach to assessment. In one set of studies, simply providing physicians with specific legal standards to guide their judgments, similar to the criteria in Table 1, significantly increased interrater agreement (the kappa statistic for agreement increased from 0.14 to 0.46).^{30,37} Another research group found that asking physicians and nurses to use a systematic set of questions for competence assessment led to a high rate of agreement with expert judgments.³⁸ Published question sets with good face validity are readily available, and they should be used to guide clinical assessments.^{31,38} Table 1 includes sample questions.

Any physician who is aware of the relevant criteria should be able to assess a patient's competence. Indeed, treating physicians may have the advantage of greater familiarity with the patient and with available treatment options. Psychiatric consultation may be helpful in particularly complex cases or when mental illness is present. Although a simple instrument to screen patients for impaired capacity would facilitate the identification of patients who may require more detailed assessment, to date the quest for a brief neuropsychological screening instrument has not yielded consistent findings. However, the Mini-Mental State Examination (MMSE) has been found to correlate with clinical judgments of incapacity,¹¹ and it may have some use in identifying patients at the high and low ends of the range of capacity, especially among elderly persons with some degree of cognitive impairment.^{39,40} MMSE scores range from 0 to 30, with lower scores indicating decreasing cognitive function. No single cutoff score yields both high sensitivity and high specificity.

MMSE scores of less than 19 are highly likely to be associated with incompetence^{39,40}; studies vary in suggesting that scores of 23 to 26 or higher are strongly indicative of competence.^{11,38-40}

In an effort to further standardize and hence increase the reliability and validity of competence evaluations, several more formal assessment instruments have been developed. Their characteristics and psychometric properties have been described elsewhere.^{41,42} The most widely used of these instruments is the MacArthur Competence Assessment Tool for Treatment, a structured interview that, unlike many other assessment instruments, incorporates information specific to a given patient's decision-making situation.⁴³ Quantitative scores are generated for all four criteria related to decision-making capacity, but evaluators must integrate the results with other data in order to reach a judgment about competence. The high interrater agreement on these scores that has been reported by a number of research groups^{11,41,44} is usually greater than that reported in studies of systematic clinical assessment.

The MacArthur test takes approximately 20 minutes to administer and score, assuming that the person who administers and scores the test has experience with the format and scoring criteria. Given the extra time associated with the use of assessment instruments, they would appear to have particular value when assessment is especially difficult or when a case is likely to be resolved in court, where the availability of systematic data collected in a standard format may be useful to a nonmedical fact finder. However, even if scores are not generated, the use of a structured instrument can help guide the clinical assessment process.

Whatever approach to assessment is used, examiners should first ensure that patients have been given the information that is relevant to making an informed decision about their treatment. Typically, such disclosure includes the nature of the patient's condition, the nature and purpose of the proposed treatment, and the risks and benefits of the proposed treatment and of alternative treatments, including the option of no treatment at all.¹ Since such disclosure cannot be presumed, either the evaluator should ask a physician responsible for the patient's care to disclose the relevant information again in the evaluator's presence or the

evaluator should undertake such disclosure. Given the possibility of fluctuations in the patient's mental state and hence his or her level of capacity, and the seriousness of depriving a patient of decision-making rights, when possible a decision that a patient is not competent should be deferred until at least two evaluations have been performed at different times. Collateral informants such as family members and nursing staff may be helpful in assessing competence. Patients should generally be informed of the purpose of the evaluation, but they need not give explicit consent for the assessment to occur.⁴⁵

CONSEQUENCES OF A FINDING OF INCOMPETENCE

If the evaluator believes that a patient is incompetent to make a treatment decision, unless the urgency of the patient's medical condition requires that a substituted decision be sought immediately, efforts should be made to identify the causes of the impairment and to remedy them. To the extent that cognition may be impaired by fever, hypoxia, uremia, sedation, and other identifiable factors, amelioration may render patients able to make their own treatment decisions. Patients with psychiatric and other disorders that directly affect cognition may benefit not only from a period of treatment but also from more intensive efforts at education, at least with regard to their understanding of relevant information.^{27,46} When fear or anxiety appears to be interfering with a patient's ability to attend to and process information, introducing a known and trusted confidant or adviser to the consent process may permit the patient to make competent judgments.

If, despite such efforts, it is clear that a patient lacks the capacity to make treatment decisions, a substitute decision maker must be sought. In emergencies, physicians can provide appropriate care under the presumption that a reasonable person would have consented to such treatment.¹ For patients with advance directives, either the treatment choice that the patient made in advance or the choice of a surrogate decision maker may be indicated.³ In the absence of an advance directive and when time is available, the recourse is usually to contact family members. Many states have statutes indicating the priority order in which family members may be approached; in general, the order is the spouse, adult children, parents, siblings, and other relatives.⁴⁷ Disagreement among

family members at the same level of priority can often be resolved by assembling the involved parties for clarification and discussion; intractable disagreement may require resolution by a court.

AREAS OF UNCERTAINTY

Notwithstanding general recognition of the criteria for decision-making capacity, there is a divergence of opinion about which criteria should be included and how they should be applied.⁴⁸⁻⁵⁰ Although the development of assessment instruments has increased the reliability of the evaluation process, the various instruments differ in their identification of patients who are impaired, raising questions as to which approach is most valid.⁵¹ There is no clear standard against which clinical determinations can be measured, although sophisticated models of expert judgment are being developed.⁵²

GUIDELINES

There are currently no formal practice guidelines from professional societies for the assessment of a patient's capacity to consent to treatment.

CONCLUSIONS AND RECOMMENDATIONS

To the extent that the patient described in the vignette can clearly communicate her decisions, understands the information about her condition, appreciates the consequences of her choices (especially the likelihood of death if she forgoes amputation), and can weigh the relative risks and benefits of the options, she should be considered competent to make a treatment decision. Given the life-and-death nature of her choice, however, a relatively high level of performance with respect to the relevant criteria should be required, and the use of a structured assessment instrument may be helpful. In light of the presence of depression and mild cognitive impairment or early dementia, psychiatric consultation should be considered, although these conditions do not preclude the patient's ability to make a competent decision.

Dr. Appelbaum reports receiving fees from Professional Resource Press on sales of the MacArthur Competence Assessment Tool for Treatment manual, forms, and training tape. No other potential conflict of interest relevant to this article was reported.

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