Cognitive Functions in the Informed Consent Evaluation Process: A Pilot Study

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Assessment of capacity to give informed consent in the general hospital setting usually rests on a clinical judgment made of a patient's understanding and appreciation of his or her illness, a process limited by its subjective nature, interexaminer variability, and relative deficiency of quantitative instruments available to provide collateral information. Inasmuch as identification of associated variables could strengthen this process, this study examines the association of cognitive functions to the capacity to give informed consent. Over a one-year period, 65 patients were evaluated independent of medical or psychiatric diagnoses. The study population consisted of medical and neurology inpatients seen for neuropsychiatric evaluation. All evaluations included assessment of capacity to give informed consent as it related to the reason for the admission to the hospital, followed by administration of the Hopkins Competency Assessment Test, the Mini-Mental Status Examination, the Trail-Making Test, Parts A and B, and the Executive Interview. Of 65 patients, 34 were excluded based on preset criteria. The remaining patients were assigned to either a "competent" or "noncompetent" group based on clinical evaluation. Number of patients, gender, and handedness distributions between groups were similar. The groups did not differ significantly in terms of age or education. Significant between-group differences were found on an empirical measure of competency, a general mental state measure, and on measures of attentional and executive cognitive functions. An analysis of classification rates indicated that a measure of executive cognitive functioning (Executive Interview) had the best sensitivity and specificity in correctly classifying competent and noncompetent patients. The results of this study support the association between the capacity to give informed consent in the hospital setting and measures of cognitive functioning, suggesting that utilization of cognitive function measures may strengthen the competency assessment process.

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The assessment of a patient's capacity to give informed consent in the general hospital setting, a common psychiatric consultation procedure, involves examining a patient's understanding of his or her medical condition, associated tests and treatment options, possible outcomes, and consequences of the decision the patient is making. As endorsed by the President's Commission on Ethical Problems in Medicine and Biomedical and Behavioral Research, this process usually, with some exceptions, rests on a clinical evaluation and judgment outside of a judicial proceeding.[1] One clinical approach to the assessment of a patient's capacity to give informed consent, as described by Appelbaum and Gutheil,[1] involves exploration of four areas or standards: the ability to communicate a stable choice; the ability to understand the facts relevant to the case; an appreciation of the situation and it's consequences to that individual beyond merely understanding the facts; and the ability to rationally manipulate information (comparing the benefits and risks of various courses of action). The recent development of the Hopkins Competency Assessment Test (HCAT), a rating scale that correlates with independent blinded competency assessment, has potential to assist in this clinical process.[2] However, the assessment of a patient's capacity to give informed consent remains limited by several factors, including the subjective nature of the examination, interexaminer variability, and a relative lack of other quantitative instruments and outcome measures available to provide collateral data in addition to the clinical examination results.

Decision-making capacity can be influenced by a variety of factors (situational, psychological, medical, neurological, and psychiatric) and may either be fluid and subject to change over time or remain static and consistent. A wide variety of neurological conditions can disturb a patient's ability to make complex decisions,[3] requiring a broad evaluation of a patient's cognitive functions[4] before assessing a patient as noncompetent. The importance of assessing cognitive functioning as part of the competency assessment process is highlighted by the results of two studies questioning patients' retention of important clinical information. These two studies suggest that, in addition to the importance of patient teaching and clinical evaluation, cognitive functioning (namely memory) is relevant to the informed consent process. In one study examining the teaching of issues related to specific procedures prior to obtaining informed consent in neurosurgical patients, patients were noted to have a retention rate of only 43 percent immediately after a formal patient teaching session, with the retention rate for the information dropping to 38 percent after six weeks; these results pose a serious question about the informed consent process.[5] This study is consistent with findings from another study examining information recall in orthopedic patients six months after surgery, in which only 25 to 38 percent of patients recalled some aspect of the risks or benefits of the procedure.[6]

A complete examination of a patient's cognitive functioning involves testing of attention, executive functioning, memory,

language, and visuospatial functions.[7] Decision-making capacity and its functional neuroanatomy are not unitary in nature. Nevertheless, attempts can be made to relate the various aspects of "competency" to certain functional systems. For example, the ability to communicate a stable choice can be linked to regions of the left frontal lobe critical to expressive aspects of communication. Similarly, the capacity to understand relevant facts can be linked to substrates for oral comprehension and written comprehension in the left temporal and left parietal lobe, respectively. These more "modular" aspects of competency are more easily conceptualized and localized within the cerebral cortex. Aspects of competency involving more complex mental operations, such as appreciation of a situation and its consequences and comparing the risks and benefits of courses of action, likely rely on more broadly distributed functional networks within the brain. Executive control functioning is a term that is meant to describe selective aspects of cognitive functioning. A textbook definition of executive control functioning is the capacities that enable a person to engage successfully in independent, purposeful, self-serving behavior.[7] Some of the best explanations of executive control functioning are derived from explanations of the functions of the frontal lobe of the brain. We do not intend to use the term frontal lobe function and executive control function interchangeably, as this would lead to confusion between structure and function. Rather, we rely on the description of frontal lobe function for its explanatory value and will

use the term executive control functions exclusively to reflect a specific aspect of mental function measured by selected neuropsychological procedures. At any rate, the classical behavioral neurologist Luria[8] refers to frontal lobe function (and by inference, executive control function) as the preliminary integration of all stimuli and the attachment of regulatory significance to this, the formation of the provisional basis of action and the creation of complex programs of behavior, and the constant monitoring of the performance of these programs. Fuster[9] distills frontal lobe function (and again, by inference, executive control function) as the temporal organization of behavior. He then goes on to explain a more complicated model of temporal organization that involves preparatory set, provisional memory, and suppression of interference. Similarly, cognitive neuroscientists use lay or clinical terms such as decision making, intention, concentration, and planning to describe executive control functions.[10] In summary, the term executive control function is used in this article to mean a selective aspect of mental function measured by a neuropsychological test, which focuses on an individual's capacity to engage in complex sequenced and planned actions. Because these complex mental operations depend on working memory, sequencing, and planning, they may particularly rely on prefrontal-subcortical networks. Damage to these network systems may result in deficits in attention, memory, and higher-order executive functioning, and present clinically with difficulty in insight, foresight, planning, social judgment, and complex rea-

soning. A variety of neuropsychological measures are available to quantitatively assess specific functions influenced by these network systems.[7]

Decision-making capacity is based on general cognitive abilities as well as the specific ability of executive control functions. For that reason, we included (1) a measure of general cognitive function (the Mini-Mental Status Examination or MMSE, which measures orientation, language processing, attention, memory, and visuospatial ability); (2) a measure of attention, rate of information processing and complex sequencing (the Trail-Making Tests A and B); and (3) a measure of executive control function (the Executive Interview or EXIT); in addition to (4) a bedside measure of competency (the Hopkins Competency Assessment Test or HCAT). These measures were administered to patients in a Department of Public Health hospital inpatient medical setting. All patients included in this study had undergone evaluation for capacity to make informed decisions for clinical reasons. The purpose of this study was to explore which of these measures most strongly supported the distinction between "competent" and "noncompetent" patient groups based on clinical examination.

Methods

Over a one-year period, patients were assessed for capacity to give informed consent and administered a battery of bedside neuropsychological measures. All patients evaluated were medical inpatients located at the Lemuel Shattuck Hospital, a Department of Public Health hospital in Boston, MA, and were admitted with primary medical or neurological conditions. All patients evaluated were assessed for capacity to give informed consent as part of a clinical neuropsychiatric consultation or admission process. Competency assessment was framed around the nature of the clinical problems for which the patient was hospitalized and the reason for the consultation or admission, following the format described earlier.[1] The sequence of examinations adhered to during this study involved psychiatric and medical/elementary neurological evaluations, followed by competency evaluation, followed by administration of the cognitive measures. All patients were assessed in the same manner and sequence independent of medical, neurological, or psychiatric diagnosis or reason for consultation or admission.

The following bedside neuropsychological measures were administered to each patient:

(1) The HCAT[2] is a brief instrument consisting of a short essay involving the informed consent process and substitute decision making (sixth-grade reading level) followed by a 10-item questionnaire for determining the patients understanding of the essay.

(2) The MMSE[11] is an 11-item scale assessing orientation, immediate recall, attention and calculation, delayed verbal memory, language, and visuospatial skills.

(3) The Trail-Making Test, parts A and B,[12] is a standard neuropsychological measure of attention, visual-conceptual shifting, and visuomotor tracking, consisting of a two-part paper and pencil test,

which is very sensitive to cognitive decline. In part A, the patient must consecutively connect numbered circles on a single test page. The score is equal to the number of seconds required to connect all 25 numbers. Errors were corrected during the task and incorporated indirectly into the score by adding extra time. In part B, the test page contains circles with both numbers (1 through 13) and letters (A through L), and the patient must connect the circles consecutively, alternating between the sequence of numbers and letters. As in part A, the score consists of the amount of time required to complete the task. The maximum amount of time allotted was 10 minutes for each task. The entire test generally requires between 5 and 10 minutes to administer.

(4) The EXIT,[13] is a 25-item instrument designed to assess executive cognitive and subcortical functions at the bedside. The EXIT takes between 5 and 10 minutes to administer and requires the patient to perform a series of brief and varied tasks believed to be associated with executive systems functioning. Items include such tasks as the Luria three-step task, word list generation, and a variation of the go/no-go task and provide opportunities for errors of intrusion, motor impersistence, and disinhibition. Administration of all cognitive measures used in this study followed standard test procedure for those measures[11-13] and required little advanced training or preparation.

During the one-year study period, 65 patients were referred for clinical neuropsychiatric evaluation. Reasons for evaluation included assessment of affective or psychotic symptoms, suicidal ideation, capacity to leave against medical advice or consent to treatment, agitation or aggression, alcohol or substance withdrawal, and assessment of dementia, delirium, or other altered mental state. Of the patients referred and evaluated, 34 were excluded from this study due to the following preset criteria: meeting DSM-IV criteria for delirium (from any etiology), motor or functional impairment (such as quadriplegia, blindness, catatonia, etc.), aphasia, being in the Department of Corrections medical unit, or inability to speak fluent English. Patients were also excluded if their competency "fluctuated" on repeated examinations during the hospital course or if the patient tended to change his or her mind repeatedly as related to diagnostic procedures or treatment interventions during the hospital course. All patients included were awake, alert, and responsive at the time of the evaluation, and were felt to have a relatively stable level of decision-making capacity throughout their hospital course. The remaining 31 patients were divided into a competent ($n = 15$) and noncompetent ($n = 16$) group, based on the clinical competency evaluation (blinded to the neuropsychological test results).

Results

Data analysis involved independent samples of two-tailed t tests for age, education, HCAT scores, MMSE scores, EXIT scores, and Trail-Making A and B times. In addition, classification rates were computed on the test scores and times between groups. The t test comparisons between the competent and non-

Table 1
Age, Education, Sex, and Handedness Data Between Groups

Variable	Competent	Noncompetent	p Value
Age (years) (mean ± SD)	40.60 ± 13.07	46.31 ± 14.35	.257
Education (years) (mean ± SD)	10.54 ± 1.56	10.87 ± 2.47	.684
Sex	73% male	69% male	
Handedness	80% right-handed	81% right-handed	

competent groups indicated that they did not differ significantly with regard to age (40.60 years ± 13.07 versus 46.31 ± 14.35, $p = .257$) or years of education (10.54 years ± 1.56 versus 10.87 ± 2.47, $p = .684$). The groups were evenly distributed with respect to gender, with 11 males and 4 females in the competent group, and 11 males and 5 females in the noncompetent group, and with respect to handedness, with 12 right-handers and 3 left-handers in the competent group, and 13 right-handers and 3 left-handers in the noncompetent group. Table 1 describes age, education, sex, and handedness data between groups.

Significant between-group differences were noted on all of the cognitive measures and on the competency screening instrument (HCAT), indicating greater cognitive impairment in the noncompetent patients. That the competent patients were generally more intact in their cognition than the noncompetent patients was indicated by better scores on the MMSE (mean $= 27.47 \pm 3.42$ versus 22.94 ± 5.37, $t = 2.78$, $df = 29$, $p < .01$). Greater executive cognitive dysfunction in the noncompetent patients was indicated by higher scores on the EXIT (mean $= 18.73 \pm 4.59$ versus 7.00 ± 3.80, $t = -7.47$, $df = 27$, $p < .001$). Visuomotor
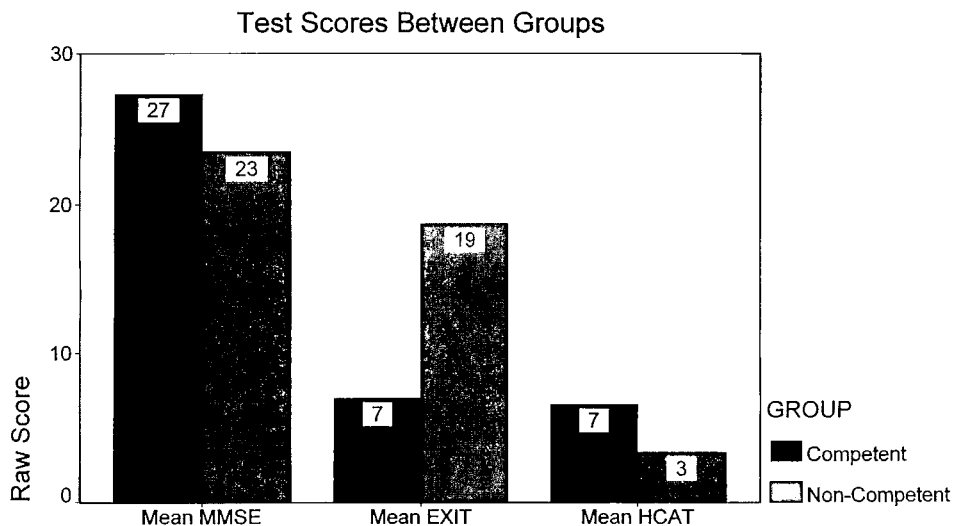

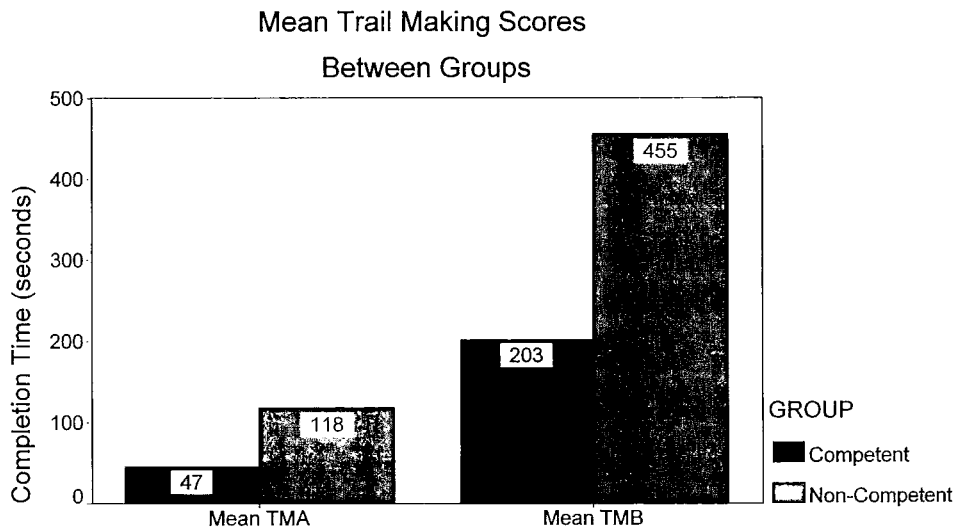Test Scores Between Groups

Figure 1.

Figure 2.

tracking was better for the competent patients than the noncompetent patients as indicated by faster time scores on Trails A (mean time to complete task (seconds) = 47.20 ± 23.55 versus 117. 75 ± 73.44, $t = -3.55$, $df = 29$, $p < .01$). Similarly, competent patients were able to track and shift their attention more efficiently than the noncompetent patients, as reflected in faster time scores on Trails B (mean time to complete task (seconds) = 202.8 ± 183.83 versus 455.25 ± 171.42, $t = -3.96$, $df = 29$, $p < .001$). HCAT scores for the competent group were significantly higher than for the noncompetent group, indicating better verbal decision-making ability in the competent group (mean = 6.73 ± 2.34 versus 3.31 ± 1.45, $t = 4.92$, $df = 29$, $p < .001$). Table 2 summarizes analysis results for the test scores and times. Figures 1 and 2 display test results between groups in bar graph format.

Of all the cognitive measures, the EXIT had the best sensitivity and specificity in comparison with the other variables, correctly classifying 95 percent of the competent group and 88.23 percent of the noncompetent group when a cutoff of two SD above the mean for the competent

Table 2
t Test Analysis Results for MMSE, EXIT, Trails A and B, and HCAT Scores Between Groups

Variable (mean ± SD)	Competent	Noncompetent	t Value	df	Two-Tail p Value
MMSE	27.47 ± 3.42	22.94 ± 5.37	2.78	29	<.01
EXIT	7.00 ± 3.80	18.73 ± 4.59	−7.47	27	<.001
Trails A (seconds)	47.20 ± 23.55	117.75 ± 73.44	−3.55	29	<.01
Trails B (seconds)	202.80 ± 183.83	455.25 ± 171.42	−3.96	29	<.001
HCAT	6.73 ± 2.34	3.31 ± 1.45	4.92	29	<.001

Table 3
Analysis of Classification Rates: Percentage of Subjects Correctly Classified by Each Measure

Variable	Competent %	Noncompetent %
EXIT	95.00	88.23
MMSE	95.24	61.11
Trails A	81.05	77.78
Trails B	81.00	61.11
HCAT	73.30	81.23

group was used. Please see Table 3 for results of the analysis of classification rates for the test scores and times.

Discussion

The standard approach to the assessment of a patient's ability to make an informed decision in the hospital setting usually involves exploration of a patient's understanding and appreciation of the illness and potential outcome, which at present remains a largely subjective and variable process. By definition, intact executive functioning is critical to the neurologic aspects of a patient's ability to make a complex decision. Aspects of competency that involve appreciation of consequences and weighing risks and benefits of options appear particularly related to the construct of executive cognitive functioning. In addition, other spheres of cognitive functioning (attention, memory, language) may play equally important roles in the decision-making operation. The role cognitive functioning plays in the informed consent process is supported by the results of this study, namely, competent patients perform better on neuropsychological test performance (as measured by the tests included in this study)

than noncompetent patients. The results support the usefulness of assessing general cognitive functioning in addition to executive functioning.

Results of the analysis of classification rates in this study imply that poor executive cognitive functioning, as measured by the EXIT, was most specific to the state of noncompetency, in comparison with functions represented by the other tests. This result indicates that, in the population studied, the process of poor executive cognitive functioning may be critical to having impaired decision-making performance (and therefore being potentially assessed as noncompetent).

In the current study, the MMSE was used as a measure of general cognitive functions. The use of the MMSE in the competency assessment process has had limited results. The MMSE was not able to differentiate competent from noncompetent medical and psychiatric patients with reasonable sensitivity or specificity when used in the development of the HCAT.[2] In a study of geriatric patients assessed for faulty decision making, it was found that poor performance on the EXIT was a more sensitive indicator when compared with results of the MMSE.[14] Recently, in a study looking at specific neuropsychological predictors of competency in Alzheimer's disease,[15] word fluency measures predicted performance and competency status of patients with Alzheimer's disease and normal older controls, and cognitive capacities related to frontal lobe function appeared to underlie the capacity to formulate rational reasons for a treatment choice. Results of our study are consistent with the

results of Mills and colleagues[14] and Marson and colleagues[15] implicating cognitive measures assessing executive functions and capacities related in part to frontal lobe functioning, respectively, as important to the adequate assessment of a person's ability to make informed decisions.

Based on this study and the literature cited, an assumption can be made that dysfunction in selective aspects of cognition can result in being assessed as noncompetent. Impaired language functioning will result in a decreased ability to communicate a stable choice. Poor memory functioning may result in an inability to retain even a basic fund of knowledge critical to adequately weighing out various options available. Difficulty with visuospatial processes may limit further a person's ability to communicate, if verbal abilities are already limited. The ability to sustain one's concentration over time, shift back and forth between options, "filter out" trivial matters to focus on matters of more value, have insight, foresight, plan effectively, be flexible, and reason appropriately are all consistent with intact decision-making capacity.

The efficacy of utilizing cognitive measures in evaluating competency in the clinical setting may have implications for assessing competency and decision-making capacity in other settings or situations, such as ability to make sound financial decisions, ability for a defendant to stand trial, or capacity of a person to enroll in a clinical research trial. One retrospective study of patients assessed for ability to make financial decisions noted a lack of evaluation around issues

thought to be critical in this process, including calculating ability, judgment, appreciation of the situation, and knowledge of the factual information.[16] No formal studies were found in a recent literature search addressing the use of specific neuropsychological measures in the process of determining a defendant's competency to stand trial. Nevertheless, in a recent study in which forensic psychiatrists analyzed case histories to make a competency or noncompetency decision retrospectively, information that had the most influence on the forensic psychiatrists assessment of cases included the cognitive status of the defendant, in addition to psychosis, courtroom behavior, and understanding of the adversarial process.[17] Adequate assessment of competency in individuals enrolling in clinical research trials is particularly critical following a review conducted by the Department of Human and Health Services Office for Protection from Research Risks of the University of California, Los Angeles (UCLA) study on schizophrenic patients[18] in which deficiencies in the study investigator's procedures for obtaining informed consent were found. The lead articles in the February 1997 issue of *Archives of General Psychiatry*[19–22] underscore how important adequate competency assessment is in individuals with potential cognitive impairment in the clinical research setting.

Based on the results of this preliminary study, cognitive evaluation has potential value in the competency assessment process. Whether the utility of cognitive assessment in this process will be limited to the hospital setting or can be extended to

other settings and situations, as implied above, will need to be addressed.

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