

# Capacity of Forensic Patients to Consent to Research: The Use of the MacCAT-CR

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The ability of psychiatric patients and prisoners to provide informed consent to participate in clinical research has given rise to much debate. Forensic psychiatric patients present a particular concern regarding their competence to consent to research, as they are both patients and prisoners. The primary goal of this research was to evaluate whether, by employing structured assessments of capacity to consent to research, we could determine if this combined vulnerability leads to differences in competence from the published abilities of nonforensic psychiatric patients. Subjects deemed incapable of providing informed consent scored differently and lower than the other consent groups on three aspects of the decision-making process. Diagnosis evidenced only a slight relationship to decision-making abilities, and this difference was only in the ability to understand the basic procedural elements of the research. Psychiatric symptoms were modestly related to decision-making. Positive symptoms were associated with poorer performance on the Understanding subscale of the MacCAT-CR, and negative symptoms were associated with lowered performance on the Reasoning subscale. These results are in accord with several published studies of nonforensic psychiatric patients and suggest that concerns regarding both forensic and nonforensic psychiatric patients' ability to provide informed consent may be unwarranted, especially in patients with few active symptoms.

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Research plays an essential role in advancing medical and behavioral sciences and in improving our ability to understand and treat illness. However, unlike clinical care, which is intended for the direct and sole benefit of the patient, research has the broader goal of advancing knowledge and does not necessarily provide the subject with an ensured clinical benefit. This raises obvious ethics-related concerns and makes voluntary consent to participate essential. For certain

subject populations, consent may be problematic. These subjects include those who may be unable to make informed, voluntary decisions about participation in research, either because of impairments in cognition or reasoning or because they live in an environment that is potentially coercive.<sup>1</sup>

Federal regulations that govern research in human subjects (known as the "Common Rule") formally identify certain "vulnerable" populations,<sup>2</sup> including pregnant women, human fetuses and neonates, prisoners, and children. The Common Rule's definition of "prisoner" includes patients committed to forensic hospitals in lieu of prisons.<sup>3</sup> The concern about prisoners is that the inmates live in an inherently coercive environment where participation may be viewed by them as connected to decisions about release. Research involving these vulnerable populations is subject to special scrutiny, to ensure that the participants are protected; that voluntary, informed consent is

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obtained; and that the research is conducted in an ethical manner. For example, only specific types of research are permissible, the approving institutional review board (IRB) must have a prisoner representative, and protections must be in place to ensure that research participation or results do not affect decisions about release.<sup>4</sup>

In 1998, the National Bioethics Advisory Commission (NBAC) issued a report outlining recommendations for conducting research involving individuals with psychiatric disorders.<sup>5</sup> They expressed concern that certain psychiatric disorders might place individuals at increased risk of being unable to provide informed consent. The commission viewed persons with mental illnesses as an additional vulnerable population and, although not explicitly stated, essentially recommended that the federal guidelines for research involving vulnerable populations include persons with certain psychiatric disorders. This report has raised controversy regarding its assumption that persons with psychiatric conditions are incompetent or have impaired capacity to provide informed consent.<sup>6</sup> Some researchers argue that psychiatric patients have the same capacity to give informed consent as the general population and that being treated as a “vulnerable” population would be unduly stigmatizing for the mentally ill.<sup>7</sup>

Recent research has suggested that psychiatric diagnosis alone does not adversely affect the capacity to consent to research. Moser *et al.*<sup>8</sup> found that 80 percent of subjects with diagnosed schizophrenia demonstrated adequate capacity to consent to a hypothetical research study. Likewise, a recent study found that patients with schizophrenia were generally able to differentiate appropriately among studies that differed in risk-benefit profiles.<sup>9</sup> Appelbaum and his colleagues<sup>10</sup> found that patients with depressive symptoms evidenced few impairments in their capacity to consent to a hypothetical psychotherapy research study. They also found that capacity to consent was unrelated to the severity of symptoms of depression. In contrast, Kovnick and associates<sup>11</sup> compared competence to consent to research in a population of long-term hospitalized patients with schizophrenia with a sample in the community who were without psychiatric diagnosis or history. They found that the psychiatric patients performed significantly worse than the community sample in competence-related abilities. These findings mirror an earlier study of long-term hospitalized patients with

schizophrenia who had not responded to treatment.<sup>12</sup> More recently, Moser *et al.*<sup>13</sup> found that incarcerated psychiatric patients performed more poorly than nonincarcerated control subjects with no mental illness on quantitative tests of competence to participate in a hypothetical study. This capacity was strongly related to neuropsychological functioning and correlated weakly with psychiatric symptoms. These studies suggest that only the most severely mentally ill have significant difficulties with respect to competence to consent to research and that the NBAC’s concern regarding increased vulnerability of psychiatric patients as a group or even patients with specific diagnoses may have been overencompassing. It appears that diagnosis is not the issue; cognitive impairments and symptoms account for more variability in capacity.

Forensic psychiatric patients present a particular concern regarding their competence to consent to research. This group comprises patients with diagnosed psychiatric disorders who have been committed to forensic facilities under provisions of relevant penal codes. These commitments vary from state to state, but in California include defendants found incompetent to stand trial (IST), individuals adjudicated not guilty by reason of insanity (NGRI), and individuals who are transferred from prison at the end of their terms because of ongoing psychiatric needs and risk of violence (mentally disordered offenders (MDOs)). All of these patients are considered “prisoners” under the Common Rule and therefore are viewed as members of a vulnerable population. In addition, the patients, by definition, all have psychiatric illnesses, and so can be viewed as having dual vulnerability. These combined concerns make conducting research in this population difficult. With more stringent federal guidelines for research involving these patients, IRBs are becoming increasingly cautious when approving such studies. However, research in the forensic patient population is crucial, as decisions about release often rest on perceived risk of dangerousness. Assessment of this risk and factors associated with a positive outcome in the community is critical. Research can help inform decisions that will reflect the appropriate balance between patients’ rights and public safety. To conduct this type of research, it is of utmost importance that these research subjects provide a fully informed and knowledgeable consent for participation. Because of the special vulnerability that forensic patients may

have, two agencies in California that grant approvals of research (California Committee for the Protection of Human Subjects and the University of California Davis IRB) now require a formal, documented assessment of competence prior to obtaining informed consent.

To date, no studies have been undertaken to examine the competence of forensic psychiatric patients in a real (i.e., not hypothetical) study. The primary goal of the present study was to evaluate whether, by employing structured assessments of capacity to consent to research, we could determine whether the vulnerabilities of forensic patients differ in any systematic way from the documented vulnerabilities of other long-term care psychiatric patients.

## Methods

This research was approved by the Human Subjects Committee at Napa State Hospital (NSH) on June 1, 2003; the state (of California) Committee for the Protection of Human Subjects on June 6, 2003; and the UC Davis School of Medicine IRB on June 23, 2003.

The study was conducted at NSH, a 1020-bed, long-term care psychiatric hospital in Napa, California. Approximately 80 percent of the patients hospitalized at NSH are under a forensic commitment. These commitments include IST, NGRI, MDO, and a small number of various other commitment types. In the past few years, NSH has contracted with the University of California, Davis (UCD) to institute a collaborative research effort. As part of this collaboration, UCD operates a Clinical Demonstration and Research Unit (CDRU) at NSH. Only patients who are post-trial (i.e., NGRI and MDO, but not IST) presently participate in this research effort.

The present study included all persons expressing an interest in a research project at NSH titled "Assessment of Mental Illness, Violence Risk and Readiness for Release in a Forensic Facility" ( $n = 106$ ; primary study). The primary study was designed to provide feedback to the hospital about the characteristics of forensic patients at NSH and to provide an assessment of factors associated with inpatient aggression and outcome in the community. Subjects were required to transfer to the CDRU for six months to participate in the research. The primary study was purely descriptive in nature. It included a diagnostic assessment in the first month of participation; assessments of psychiatric symptoms in the

first, third, and sixth months, using the Brief Psychiatric Rating Scale (BPRS)<sup>14</sup>; assessments of violence risk in the second month, using a variety of risk assessment instruments; a monthly assessment of aggression and behavioral indicators of aggression; and a readiness-for-release evaluation in the third and sixth months. A thorough record review was also conducted, to document demographic information and psychiatric diagnosis.

Potential subjects for the primary study were chosen from a random list of NGRI and MDO patients committed to NSH. The only exclusion criteria for participation were (1) limited ability to speak and understand English and (2) inability to reside in a co-ed unit (secondary to sexually inappropriate behavior). If the patient expressed interest in participating in the primary study, the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) was administered.<sup>15</sup> The MacCAT-CR is a standardized instrument developed by Appelbaum and Grisso and is based on an earlier assessment instrument the MacArthur group developed to evaluate capacity to consent to treatment. The MacCAT-CR uses a semi-structured interview format, with questions tailored specifically for the research project in question. The instrument contains sections with questions related to four competence-related abilities: Understanding, Appreciation, Reasoning, and Expressing a Choice. The questions in the Understanding subcategory assess the potential subject's understanding of the basic procedural elements of the study, including the risks and benefits of participation (13 items). The Appreciation section requires that the subject express an understanding of the effect of participation on treatment (three items). The Reasoning section requires that the subject articulate the consequences of participation in the study (four items). Finally, the Expressing a Choice section assesses the subject's ability to make a decision about participation (1 item). The subjects' response to each item is rated as 0 (inadequate), 1 (partial), or 2 (adequate).

The MacCAT-CR for the primary study was developed by the senior author (B.E.M.) and reviewed by another author (C.L.S.) for clarity. Research staff were trained in the administration of the MacCAT-CR. An effort was made to complete the administration of the MacCAT-CR with all potential participants. Even patients ultimately judged incompetent were administered the entire MacCAT-CR unless they refused to continue. A small number of inter-

views could not be scored in their entirety because of noncompletion of the instrument. Inability to complete the interview was attributable to several problems, including patient fatigue, nonadministration of the Reasoning section to patients who declined participation in the primary study, and clerical errors. Scoring was not performed by the research assistants administering the interview, but by the investigator (B.E.M.) and a colleague trained in the MacCAT-CR. Ten instruments were scored independently, and discrepancies were discussed, to clarify and resolve differences in scoring. Another nine instruments were rated independently. Interrater reliability was calculated and found to be in the acceptable range for all subscales (correlations between 0.625 and 0.781).

After administration of the MacCAT-CR, the research assistants returned to the Principal Investigator (PI) to discuss patients' responses if they had concerns regarding their capacity to consent. In these cases, the PI made a decision about the potential subject's ability to provide informed consent to participate in the primary study. This decision was based on clinical judgment, not on the MacCAT-CR score. Because the primary study bore minimal to no risk, we required a lower level of competence than for a higher-risk study. Potential subjects had only to demonstrate a basic understanding of the purpose and procedures of the study and to be capable of articulating that he or she was not required to participate. Subjects deemed capable of providing informed consent were then asked to review and sign an approved informed-consent form. Permission was received from all appropriate IRBs to use the results of all MacCAT-CRs for further analyses (including those obtained from clients ultimately judged incapable of providing informed consent), and the requirement for informed consent for the present study was waived.

The recruitment procedure for the primary study resulted in five outcomes that placed the patients in the following categories: (1) those who agreed to participate, signed the informed consent, and were transferred to the CDRU (the "consented" subgroup); (2) those who agreed to participate and signed the informed consent, but withdrew from the study prior to transfer to the CDRU; (3) those who declined to participate (the "declined" subgroup); (4) those who expressed ambivalence regarding participation and ultimately declined; and (5) those judged incapable of

providing informed consent (the "not competent" subgroup). For analysis purposes, patients who consented and withdrew were combined with patients who expressed ambivalence and ultimately declined, as both were considered to be ambivalent about participation ("the ambivalent" subgroup).

Only patients who consented to participate in the primary study were transferred to the CDRU. With this subgroup of patients ( $n = 56$ ), during their first month in the CDRU, diagnostic assessments and symptom ratings were conducted, including the BPRS. The treating psychiatrist performed symptom ratings after receiving training in the administration of the BPRS. Training was conducted by a senior research psychologist and a senior research analyst, both of whom have trained research assistants in the use of these instruments. Routine recalibrations were performed every six months to ensure consistency of scoring. Diagnostic assessments were performed using the Structured Clinical Interview for DSM-IV (SCID)<sup>16</sup> and the Structured Interview for DSM-IV Personality Disorders (SID-P),<sup>17</sup> which were administered by research assistants. The senior psychologists thoroughly reviewed the record to confirm the diagnoses arrived at through the structured interviews. On examining the relationship between the SCID diagnoses and the chart diagnoses, nonagreement was found in only 12 percent of the cases. In the majority (75%) of these cases, the diagnosis was changed from Schizoaffective Disorder to Schizophrenia. This procedure ultimately was replaced with a chart diagnosis confirmation based on the DSM checklist, performed by the senior author. When disagreements between the senior author and the chart were found, a second psychologist was asked to review the record for the final diagnosis.

The present study examined the relationship between the competence-related capacities measured by the four subscales on the MacCAT-CR and whether the subject actually participated in the primary study. If a patient declined to participate or was deemed incapable of signing the informed consent, a record review was conducted to collect information on diagnosis (both Axis I and Axis II), age, gender, and ethnicity. In these instances, chart diagnosis was used without confirmation. These data were then employed to examine relationships between competence-related capacities and diagnostic categories of all subjects who were administered a MacCAT-CR interview. For patients who participated in the pri-

**Table 1** Diagnosis by Consent Category

	Refused	Consented	Withdrew/Ambivalent	Incapable	Total
Total	5 (5)	65 (61)	30 (28)	6 (6)	106
Schizophrenia	2 (4)	34 (74)	8 (17)	2 (4)	46 (44)
Schizoaffective	0 (0)	20 (57)	11 (31)	4 (11)	35 (34)
Other disorders	3 (13)	9 (39)	11 (48)	0 (0)	23 (22)

Data are the number in each category, with the percentage of the total in parentheses.

mary study, relationships were examined between symptom ratings and competence-related capacities. In some instances, the entire MacCAT-CR was not administered, as previously explained. For certain analyses, only completed assessments were used and included in the tables. A variety of statistical methods were used to evaluate differences in capacities and relationships between measures, including chi-square, multivariate analysis of variance (MANOVA), *t* tests, and correlational analyses. All analyses were conducted with SPSS software.

**Results**

The overall sample was 58 percent white and 42 percent minority, and the majority (72%) were male. Ninety-two percent of the group had at least a ninth grade education. Psychotic disorders accounted for 81 percent of the diagnoses, and the patients had committed a range of violent offenses, with 42 percent having been convicted of or found NGRI for assault.

Table 1 presents the relationship between diagnosis and consent to participate in the primary study. Because diagnoses other than Schizophrenia or Schizoaffective Disorder were rarely found, they were combined for a general “other” category. As can be seen in this table, diagnosis was related to choice ( $\chi^2_{(6)} = 16.59, p < .01$ ). Most of the patients with diagnosed schizophrenia consented to participate and were much less likely to express or behave ambivalently. The subjects deemed incapable of providing informed consent primarily had a diagnosis of Schizoaffective Disorder.

Table 2 presents the mean MacCAT-CR scores for each consent group. The overall MANOVA was significant (Wilks  $\lambda = 0.409, p < .000$ ), indicating overall differences between groups. Univariate analyses indicated that the subjects judged incapable of providing consent had significantly lower MacCAT-CR scores than did the other three groups on three subscales: Understanding ( $F_{(3,96)} = 19.93, p < .001$ ), Appreciation ( $F_{(3,102)} = 7.97, p < .001$ ), and Reasoning ( $F_{(3,97)} = 9.42, p < .001$ ). For the Choice subscale, while the overall difference was significant ( $F_{(3,102)} = 6.77, p < .001$ ), *post hoc* testing indicated that the only difference was between the group of patients who expressed ambivalence and the group who consented to the primary study.

Table 3 presents the MacCAT-CR subscale means and interscale correlations. As can be seen in this table, moderate correlations were found between most subscales. However, only the Reasoning subscale was associated with Choice. The strongest associations were between the Understanding subscale and the Appreciation and Reasoning subscales.

Table 4 provides mean scores and ranges for each diagnostic category. The results of the MANOVA indicated no overall differences between diagnostic groups (Wilks  $\lambda = 0.935, p > .65$ ).

To evaluate the relationship between MacCAT-CR scores and symptoms, we divided the BPRS into positive symptoms (Conceptual Disorganization, Hallucinations, and Unusual Thoughts) and negative symptoms (Blunted Affect, Emotional Withdrawal, and Motor Retardation). Only the initial BPRS scores were used, as these evaluations were

**Table 2** Mean MacCAT-CR Scores by Consent

	Refused	Consented	Withdrew/Ambivalent	Incapable	Total
Understanding	19.80 (2.86)	18.40 (4.05)	18.97 (3.78)	6.00 (3.74)	17.89 (4.91)
Appreciation	3.80 (1.48)	3.82 (1.31)	4.30 (0.92)	1.67 (1.03)	3.83 (1.32)
Reasoning	3.00*	4.55 (1.31)	4.28 (1.41)	1.33 (1.51)	4.27 (1.54)
Expressing choice	1.80 (0.45)	1.97 (0.17)	1.67 (0.48)	1.67 (0.52)	1.86 (0.35)

Data are expressed as the mean ( $\pm$ SD).

\* *n* = 1.

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**Table 3** Subscale Means and Correlations for Completed MacCAT-CRs

	Understanding	Appreciation	Reasoning	Choice
Understanding	17.74	0.45*	0.42*	0.18
Appreciation		3.81	0.36*	0.01
Reasoning			4.32	0.34*
Choice				1.86

*n* = 95.

\* *p* < 0.001.

conducted in closest temporal proximity to the MacCAT-CR evaluations. The mean total BPRS score for the sample (*n* = 54) was 41.22 (range, 19–72). Table 5 presents the correlations between both positive and negative symptoms of psychosis and MacCAT-CR subscales. As can be seen in this table, positive symptoms were associated with reduced performance on the Understanding subscale, whereas negative symptoms were associated with lowered performance on the Reasoning subscale. All associations were in the expected direction (i.e., negative correlations).

To determine whether any demographic factors were associated with performance, regression analyses were conducted. The three subscales of the MacCAT-CR (Understanding, Reasoning, and Appreciation) were entered separately as the dependent variable and age, length of stay, gender, and positive and negative symptoms as the independent variables. These analyses supported the conclusion that for these variables, only positive symptoms predicted performance on the Understanding subscale ( $r = 0.323$ ,  $F_{(1,50)} = 5.82$ ,  $p < .02$ ), while only negative symptoms predicted performance on the Reasoning subscale ( $r = 0.283$ ,  $F_{(1,50)} = 4.34$ ,  $p < .05$ ). No measured variables were associated with the appreciation subscale.

### Discussion

Competence-related abilities have received increased attention in recent years, regarding both consenting to treatment and to research. Recently, psychiatric patients have been proposed as a group of individuals who may have reduced capacity to con-

sent secondary to the cognitive disturbances associated with psychiatric illness. Prisoners, by virtue of their status as involuntarily committed individuals, have been viewed since the early 1990s as vulnerable. Forensic patients share common factors with both groups: psychiatric illness and involuntary commitment. We explored the capacity of these patients to consent to an ongoing (not hypothetical) research project. Although findings in previous research have indicated that neither diagnosis nor symptoms are related to ability as measured by the MacCAT-CR,<sup>8,10</sup> results in other studies have shown that psychiatric symptoms, especially psychotic symptoms, interfere with comprehension and decision-making.<sup>11,12</sup> Our data indicate that patient diagnosis was not related to any competence in a particular area. However, both positive and negative symptoms were associated with performance on the MacCAT-CR, albeit only modestly. Patients with more florid (positive) symptoms of psychosis evidenced a decreased ability to comprehend the basic procedural elements of the primary study. In contrast, patients with more negative symptoms evidenced impairments in their ability to generate reasons for participating in the primary study. These results suggest that diagnosis alone is not a particularly potent predictor of performance on the MacCAT-CR. It appears that the presence of both positive and negative psychotic symptoms may be responsible for the impairment in competence-related abilities in patients with a diagnosis of schizophrenia.

Previous research has found that it is primarily the cognitive deficits associated with negative symptoms

**Table 4** Mean MacCAT-CR Subscale Scores by Diagnostic Group

	Understanding (0–26)*	Appreciation (0–6)	Reasoning (0–8)	Choice (0–2)
Schizophrenia	17.1 (2–25)	3.87 (1–6)	4.18 (0–7)	1.83 (0–2)
Schizoaffective	17.47 (3–25)	3.57 (0–6)	4.17 (0–8)	1.77 (0–2)
Other disorders	19.9 (13–26)	4.1 (1–5)	4.5 (2–8)	1.83 (1–2)

Data are the mean scores (range).

\* Full range of scores in each category.

**Table 5** Correlations of MacCAT-CR Subscale Scores with Symptom Ratings

	Understanding	Appreciation	Reasoning	Choice
BPRS positive symptoms	-0.31*	-0.03	-0.08	-0.16
BPRS negative symptoms	-0.10	-0.12	-0.29*	0.03

*n* = 54.

\* *p* < 0.05.

that interfere with the ability to reason.<sup>8,12</sup> Moser and his colleagues<sup>8</sup> found that patients with positive symptoms evidenced no impairments on any subscale of the MacCAT-CR, while negative and disorganization symptoms were associated with impairments in overall decisional capacity. They hypothesized that the cognitive deficits associated with negative symptoms interfered with the decision-making process. Carpenter *et al.*<sup>12</sup> directly examined the relationship between cognitive deficits and performance on the MacCAT-CR. The results indicated that cognitive deficits are a robust predictor of performance. Our results suggest that negative symptoms primarily affect one particular aspect of decision-making capacity: the ability of the patient to integrate the information provided in a useful way and to generate cogent reasons for participation. However, it is unclear from our data whether this deficit in decision-making capacity represents a cognitive processing problem or simply a lack of effort arising from the negative symptoms.

Of note, mean scores on the subscales of the MacCAT-CR obtained by our forensic patients differed from previously reported mean scores of psychiatric patients. In some studies, mean scores on the subscales were lower (12.1, 3.9, and 2.2 for the Understanding, Appreciation, and Reasoning, respectively),<sup>11</sup> whereas in some they were higher (20.4, 5.0, and 4.7).<sup>12</sup> The lower scores were obtained from patients in long-term care facilities. Although our patients are considered long-term, in the criminal justice system defendants are required to be competent before they can stand trial for their crimes. Our subjects were all postadjudication, and presumably they met the competence requirement. It may be that this fact led to higher scores than in other psychiatric long-term care patients. In a study of incarcerated psychiatric patients,<sup>15</sup> mean scores of 20.4, 4.5, and 4.3 were reported on the respective subscales. Our scores more closely resemble the scores of incarcerated psychiatric patients than those of long-term care patients.

In the primary study, very few patients (6%) were judged not competent to consent to the research. These patients demonstrated clear deficits in their ability to consent. A comparison of the MacCAT-CR scores of all consent subgroups (consent, declined, ambivalent, and not competent) revealed that only the very small subgroup of patients deemed not competent to provide informed consent differed from the other consent groups (consent, declined, and ambivalent) and this difference was not evidenced on all four subscales of the MacCAT-CR.

The developers of the MacCAT-CR do not recommend a cutoff score, noting that competence should be viewed as a sliding scale based on risk. Others<sup>18</sup> have suggested that an Understanding score below 15 suggests incompetence. In our data, 16 percent of the patients whom we judged to be competent scored below 15 on the Understanding subscale. However, our judgments of competence were not based on the MacCAT-CR scores; rather, they were based on the patients' ability to show a basic understanding of the procedures (especially regarding the transfer to the CDRU and that participation was for research purposes and was not to benefit them directly) and an understanding that their participation in the research was completely voluntary. We believed that these two factors were crucial for the participants to comprehend—the former secondary to their status as psychiatric patients in a long-term care facility, the latter secondary to their potential for coercion. For a higher-risk study, we would have required a higher level of competence. In examining the ranges for each subscale, we found overlap in all consent categories—that is, patients who were eventually deemed incompetent may have scored at the same level as patients ultimately considered competent. Only the total score uniquely defined the not-competent group. The highest total score in the not-competent group was 15; the lowest score in the group found competent was 17. In addition, we found that in many instances, patients we ultimately deemed not competent to consent often

expressed a strong desire to participate. However, based on their inability to provide cogent reasons for participation (50%; [3/6] received a score of 0 on this subscale) and their minimal understanding of the basic procedures and how research differs from standard treatment, they were determined to be incapable of consenting. This finding suggests that caution should be exercised with all individuals, even those expressing a strong desire to participate, as they may not be basing their decision on rational facts. These two results indicate that the total score may provide useful information, especially for minimal- to no-risk studies for which higher levels of capacity may not be required. Although we do not suggest that competence judgments be based on the total score, our results indicate that a total score may not be entirely meaningless.

In our study, most subscales of the MacCAT-CR were related to each other. The developers of the instrument have suggested that each capacity is independent and as such, a total score does not provide useful information regarding competence.<sup>15</sup> In theory, an individual could perform well on one subscale but poorly on others and be considered incompetent. Our data suggest that patients were able to formulate an adequate appreciation of the effect of participation and to generate reasons for consenting (or refusing) only if they possessed an adequate understanding of the basic procedural elements of the study. Not surprisingly, Reasoning—the ability to generate reasons for participation—was the only subscale related to Choice. In general, individuals who were able to provide a greater number of cogent reasons for participation (or refusal) were more likely to strongly express a choice.

### Limitations

As the primary study progressed, we encountered unanticipated difficulties with data collection that may have weakened the possible relationships found in this study. As described earlier in the article, BPRS ratings were conducted only in the CDRU and only on those patients consenting to research. These ratings were scheduled to be performed by the treating psychiatrist during the first month after transfer to the CDRU. However, clinical demands frequently delayed the formal administration of the BPRS beyond the first month. In addition, NSH is a long-term care facility where patient movement often does not occur rapidly. For these reasons the BPRS ratings

were not always conducted in close temporal proximity to the administration of the MacCAT-CR. In fact, it would never be the case that symptom ratings were made less than 2 to 3 weeks apart from the competence assessment. The average time between the administration of the MacCAT-CR and the BPRS was 94 days, with a range of 22 to 214 days. In examining the change in symptoms over time, as is often the case in long-term care facilities, there was no significant difference in either positive or negative symptoms in the 6 months on the unit (three assessments), indicating that administering the BPRS closer to the MacCAT-CR may not have yielded different results. This time lag between the administration of the MacCAT-CR and the assessment of symptoms may have reduced the relationship between the two measures.

Another limitation of the study was the low consent rate. Of the 106 patients who expressed an interest in the study, only 56 consented, a consent rate of 53 percent. Perhaps more striking is that most of the patients approached did not express an interest and were not administered the MacCAT-CR, which indicates that the sample may not have been representative. In comparing basic demographic and clinical characteristics between those administered the MacCAT-CR and the remainder of the NGRI/MDO patients, there were no differences in diagnosis, age, or length of stay at the facility. Both ethnicity and gender were significant; however, this finding was not unanticipated. We intentionally sampled more women; we necessarily excluded non-English-speaking patients.

Finally, there were no concurrent measures of current cognitive ability, which has been shown to be a robust predictor of performance on the MacCAT-CR. Anecdotally, it was our experience that the individuals we judged to be not competent to consent had intellectual deficits. Unfortunately, routine cognitive assessments are not performed at the hospital and were not part of the primary study. Even if we had included a cognitive assessment in the primary study, only consenting patients would have received the evaluation. As such, our research does not encompass the question of cognitive ability. Rudimentary examinations of education level and previously administered IQ assessments (some being many years old) indicated no relationship to performance on the MacCAT-CR.

## Conclusions

The results of our study suggest that patients with a psychotic disorder (Schizophrenia or Schizoaffective Disorder) have a tendency to exhibit an impaired understanding of the research; however, this lack of understanding appears related to the presence of positive psychotic symptoms. The inability to use this information effectively to generate reasons for deciding to participate (or not) appears related to the cognitive deficits associated with negative symptoms, rather than overall cognitive ability. Our findings indicate that neither diagnosis nor psychiatric symptoms necessarily diminish capacity in potential research subjects, although the more severely psychotic patients evidenced greater impairment. In addition, the results of recent research suggest that even if capacity is diminished, it can be remediated.<sup>12</sup> Our results suggest that a possible solution to enhancing performance of psychiatric patients is to ensure that positive symptoms of psychosis are adequately treated prior to enlisting the participation of the patient. Unfortunately, this method may bias research results on these patients. It is difficult to conduct generalizable research on psychotic patients if the patients have no psychotic symptoms.

Our study indicates that forensic psychiatric patients do not represent a uniquely vulnerable population. The results of our assessments are consistent with other findings in a long-term care psychiatric population. Diagnosis alone is not a predictor of capacity; rather, it is the psychiatric symptoms associated with a psychotic disorder that impair capacity.<sup>8,12</sup> It appears from the extant research that the NBAC's concerns may be overly broad. Although psychiatric patients do evidence slight impairments in capacity in relation to control subjects, this impairment appears to be related to symptomatology. It may be that as symptoms remediate, capacity improves, and that, even with symptoms, capacity can be enhanced by educational efforts.<sup>12</sup>

Finally, the Common Rule identifies prisoners as a vulnerable class based primarily on their purported susceptibility to coercion. For this reason, parole decisions cannot be based on the fact that a prisoner participated in research. Such would be viewed as (and probably would be) coercive. In the second phase of our study, we will attempt to measure the forensic psychiatric patients' perceptions of coercion

after their participation in the research, by using an adapted version of the scale used in the MacArthur study.<sup>19</sup> In this way we may be able to document more carefully the forensic patients' perceptions of coercion.

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