

Commentary: Willingness and Competence of Depressed and Schizophrenic Inpatients to Consent to Research

Paul S. Appelbaum, MD

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Interest in the characterization and assessment of decisional capacity in medicine began to develop in the mid-1970s, in the wake of the near-universal endorsement of the legal doctrine of informed consent earlier in the decade.^{1,2} Early commentaries recognized the importance of identifying generally accepted criteria for decisional capacity as a prerequisite to valid assessment, and for a number of years this was the focus of most scholarly attention.^{2–4} By the end of the 1980s, however, a rough consensus had evolved regarding those functions essential for decisional capacity: the abilities to understand the relevant information, appreciate its implications for one's own situation, rationally manipulate the information (often referred to as reasoning), and express a choice.⁵ This conceptualization was applied to capacity for treatment- and research-related decisions, and it is likely to be applicable to other kinds of decisional capacity as well.⁶

Assessment of capacity, a task often assigned to psychiatrists, had meanwhile evolved in an unsystematized fashion, with attending physicians often passing on their idiosyncratic approaches to a new generation of residents. To no one's surprise, studies suggested poor interrater agreement among physicians for these determinations.⁷ Efforts to carry out

capacity assessments for research purposes were similarly handicapped by the absence of a standardized approach. Each research team developed its own instruments, often based on idiosyncratic criteria, making comparisons across studies all but impossible and often leaving readers uncertain how much validity to accord to the methods used and the results reported.

The largest study to date of decisional capacity, which focused on consent to treatment by patients with psychiatric and medical disorders, is the MacArthur Competence Assessment Study, which Thomas Grisso and I conducted in the early 1990s. Even more important than any of the substantive findings of the study, reported in a series of papers in the mid-1990s,^{8–12} were its major spin-offs: the MacArthur Competence Assessment Tools for Treatment and Clinical Research (MacCAT-T and MacCAT-CR).^{13,14} Designed to permit efficient structured assessment of decisional capacity that is nonetheless individualized to the particular situation of each patient or research subject, the MacCATs have become a favorite tool of researchers looking to characterize the decisional capacities of populations of patients^{15–21} or research subjects.^{22–28} At this early stage in the evolution of research and practice related to capacity assessment, it seems unlikely that any existing instrument will constitute the final word on the matter. But the popularity to date of the MacCAT instruments means that for the first time we have a body of roughly comparable data from multi-

Dr. Appelbaum is A.F. Zeleznik Distinguished Professor and Chair of Psychiatry and Director, Law and Psychiatry Program, University of Massachusetts Medical School, Worcester, MA. Address correspondence to: Paul S. Appelbaum, MD, Department of Psychiatry, University of Massachusetts Medical School, 55 Lake Avenue North, Worcester, MA 01655. E-mail: appelbap@umhc.org

ple research groups allowing some generalizable conclusions to be drawn.

This is not the place for a comprehensive review of the MacCAT studies, and in any event such a summary would have to be modified, as additional studies now under way were published. But it may be possible to indicate several areas of consensus that seem to be evolving from existing work.

1. Many persons with serious mental disorders appear to retain substantial degrees of decisional capacity. In general, persons with schizophrenia demonstrate lower levels of capacity than do persons with depression, who in turn do more poorly than persons without a major mental disorder. But even many schizophrenic patients, perhaps a majority in some situations, do no worse than most members of the general population, and hence are presumptively competent.

2. In contrast, persons with dementing illnesses, usually Alzheimer's disease, show significant levels of impairment even early in their course, when symptoms are generally mild to moderate.

3. Persons with severe medical illnesses that do not directly affect mentation, such as ischemic heart disease, and even with illnesses that may have some direct impact on the brain, such as HIV infection, perform no differently than non-ill subjects on decisional tasks.

4. Impairments in decisional capacity can often be overcome by special educational efforts, even in conditions such as schizophrenia that are accompanied by serious impairments in cognition. Hence, it may be helpful to think of persons with impaired capacity as experiencing a condition akin to a learning disability, rendering them in need of special interventions before they can understand, appreciate, reason, and choose adequately, but not absolutely precluding their doing so.

5. The association of psychiatric symptoms with impairment of capacity has been variable. Negative symptoms of psychosis may have more impact than positive symptoms, but cognitive impairment, as measured by neuropsychological tests, displays substantially greater predictive power.

To this list of substantive findings should be appended a methodological one:

6. It is possible to conduct studies that reliably assess decisional capacity and that show substantial indications of construct validity. But defining a gold

standard to measure the validity of any approach to capacity assessment remains an elusive goal.

The study reported in this issue of the *Journal* by Cohen and colleagues²⁹ reflects many of the findings just summarized. They asked a relatively small number of inpatients with schizophrenia and with major depression and a group of non-ill comparison subjects, to consider participation in two hypothetical research studies. One of these studies was lower risk with some possibility of personal benefit, while the second was higher risk with no prospect of direct advantage to participants. Capacities were assessed with the MacCAT-CR. Most members of all three groups did quite well on each of the abilities assessed by the MacCAT-CR; indeed, their performance was at a level that probably would result in their being deemed competent for the decisional tasks they faced. Nonetheless, as in most studies, the overall performance was worst by subjects with schizophrenia, intermediate by those with depression, and best by subjects in the non-ill comparison group. Of particular interest is that the comparison subjects proved most willing to enter one or both of the studies, the depressed subjects considerably less so, and the schizophrenic subjects least willing of all. Willingness to participate was not related to decisional capacity.

Cohen *et al.* offer appropriate cautions against overinterpreting their data, but it may be helpful to underscore several points. The sample sizes for all three groups are quite modest. In particular, regardless of the results of tests of significance, one ought to be reluctant to accord much weight to the findings regarding the performance of the six schizophrenic subjects. The group is simply too small to permit any meaningful extrapolation. Even the findings for the other groups need to be confirmed with larger samples.

Second, perhaps the most interesting finding of the study was the universally expressed willingness of non-ill subjects to participate in one or both of the two research projects (including one that held the prospect of rendering them temporarily psychotic), in contrast to the greater hesitance of the mentally ill group as a whole. Before placing too much confidence in this finding, one must recall the hypothetical nature of the question being posed. No subject was actually asked to enter these research projects, only to indicate if they would do so if the opportu-

nity were actually available. Why were the non-ill subjects so much more acquiescent? Perhaps because the possibility of ever being asked to enroll in such a study in real life seemed extremely remote, and hence the pressure of social convention took precedence. That is, asked by a presumably pleasant research assistant with whom they had already agreed to be in a research study (the one reported here) whether they might consent again in a hypothetical and highly unlikely future circumstance, the costs of continuing to appear to be cooperative were essentially nil. For the mentally ill subjects, however, the decision is likely to have seemed more real and immediate, and thus their greater caution is understandable. This problem is interpreting the data points to a limit in the use of hypothetical decisions in research of this sort.

Finally, a caution must be offered on a terminological issue. The authors claim that their study assessed “capacity for volunteerism,” using Roberts’ term for “an individual’s ability to make ‘authentic’ decisions that truly reflect his or her core values, prior history, and present situation.”²⁹ In fact, all we know about the choices of the subjects in this study is which alternatives they selected. Whether these were reflective of their authentic values is unexamined and hence indeterminable. Indeed, even using a more common definition of what is usually referred to as “voluntariness”—that is, the absence of coercion—we are ignorant of whether these subjects were coerced in any meaningful way or, more likely, perceived themselves to be. In sum, however interesting and difficult are questions of “voluntarism” or “voluntariness,” they are entirely unaddressed here.

Our knowledge of the decisional capacity of persons with mental illness is being built link by link. Cohen and colleagues well describe the importance of identifying the vulnerability of persons with mental illness in the research setting and of seeking effective ways to protect them. The data they offer will add to the cumulative body of knowledge that can be applied to that task. In particular, their findings confirm that many people with severe mental illnesses, even in an acute state, retain substantial decisional capacity and make choices that do not appear objectively unreasonable. Although these and similar findings do not eliminate the need for individualized capacity assessment in higher risk studies with subjects likely to manifest substantial levels of impair-

ment, they are encouraging regarding the moral basis of the research enterprise as a whole.

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