

The MacArthur Treatment Competence Study. I

Mental Illness and Competence to Consent to Treatment*

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This is the first of three papers reporting the results of the MacArthur Treatment Competence Study, a project designed to develop reliable and valid information with which to address clinical and policy questions regarding the abilities of persons with mental illness to make decisions about psychiatric treatment. Four commonly applied legal standards for determining decision-making competence are described: abilities to communicate a choice, understand relevant information, appreciate the nature of the situation and its likely consequences, and rationally manipulate information. Previous research related to the capacities of persons with mental illness in relation to these standards is reviewed and critiqued. The principles underlying the design of the MacArthur Treatment Competence Study are described.

The legal doctrine of informed consent to treatment is aimed at promoting a meaningful role for patients in making decisions about their care. Conceived in U.S. courts in the 1950s, under the influence of common law rules proscribing unwanted intrusions on bodily integrity, informed consent law was fully developed over the two subsequent decades. Since then, informed consent has become a

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nearly universal prerequisite to the initiation of medical diagnostic and treatment procedures (Appelbaum, Lidz, & Meisel, 1987). Its principles have been applied to a range of other clinical interventions, from psychotherapy to release of confidential information (Appelbaum & Gutheil, 1991).

Informed consent law has established three requirements for valid consent to treatment. First, care-givers, usually patients' physicians, are responsible for providing patients with information regarding the nature and purpose of the recommended procedure, probable benefits, likely risks, and the alternatives to the proposed treatment—including the option of forgoing treatment altogether—along with their benefits and risks. In most jurisdictions, the amount and precise details of the information to be disclosed are determined by what a reasonable person would find material to a decision about treatment (Merz & Fischhoff, 1990). Second, patients must have the opportunity to make decisions in the absence of coercion by those providing their care. This requirement for a voluntary decision is the least well-analyzed and least frequently litigated component of informed consent law (Faden & Beauchamp, 1986).

Finally, patients must be competent to make treatment decisions. Since informed consent law is aimed at encouraging patients' participation in the decision-making process, its rationale is undermined when patients' incapacities preclude them from playing a meaningful role. In those cases in which mental disabilities result in substantial decision-making impairment, a substitute decision maker will be called upon to protect patients' interests (Meisel, 1979).

This article and the two articles that follow (Grisso, Appelbaum, Mulvey, & Fletcher, 1995; Grisso & Appelbaum, 1995) focus on the requirement that patients be competent to give valid consent to treatment and, in particular, on the role that mental illness may play in impairing decision-making abilities. The first article in this series explores recent changes in how medicine and law have responded to persons with mental illness who may be legally incompetent to make decisions about their medical and psychiatric treatment, reviews what is known about the impact of mental illness on decision-making abilities related to legal competence, and describes the design of the MacArthur Treatment Competence Study, an effort to develop standardized means of assessing decision-making abilities in the context of consent to treatment. In the second article (Grisso et al., 1995), the measures developed for the study are described and their psychometric properties are detailed. The final article (Grisso & Appelbaum, 1995) reports the results of an application of these instruments to samples of patients with mental illness and medical illness and non-ill control groups, with consideration of the implications of these findings for policy regarding consent to treatment.

Mental Illness, Competence, and Consent to Treatment

Consent and Persons with Mental Illness

Before the development of informed consent law, relations between patients and physicians had been governed for centuries by the requirement that patients' simple consent be sought for medical interventions (Appelbaum et al., 1987; Slater

v. Baker & Stapleton, 1767). That is, physicians were obligated, on pain of liability for battery, to inform patients of the nature of the proposed intervention and to obtain their agreement before proceeding. Until recent years, however, persons with mental illness had been dealt with as exceptions to the usual requirements for consent.

Nineteenth-century medicine, for example, expressed the belief that mental illness invariably destroyed decision-making capacities, rendering patients unable to make valid decisions of any kind (Ray, 1864). Thus, although statutes authorizing involuntary hospitalization of persons with mental illness became widespread in the 1830s and 1840s, it was not until 1881 that the first state (Massachusetts) codified a procedure for voluntary hospitalization (Brakel, 1985). Families usually made the decision to hospitalize persons with mental illness in the nineteenth century, and their consent to treatment generally was accepted as valid. Indigent persons without involved families often were hospitalized by authority of the overseers of the poor (Appelbaum & Kemp, 1982). Whether patients were committed involuntarily or admitted themselves voluntarily, the question of consent to treatment once hospitalized seems not to have been raised.

With the growth of informed consent law after the middle of the twentieth century, the assumption that people with mental illness were uniformly deficient in decision-making abilities and should be considered legally incompetent began to be called into question (Shapiro, 1974). Advocates argued that persons with mental illness, like persons with mental retardation, often suffered selective impairment of decision-making abilities or none at all, with retention of competence for many purposes. It was unfair, therefore, to deprive them of decision-making rights, especially about treatment, without an individualized determination of their residual capacities. By the late 1970s, courts began to accept this argument, frequently imposing requirements that a formal hearing occur at which persons with mental illness are found incompetent before treatment can take place over their objections (e.g., *Goedeke v. State*, 1979; *In re the Mental Health of K. K. B.*, 1980; *Jarvis v. Levine*, 1988; *Riese v. St. Mary's Hospital*, 1987; *Rivers v. Katz*, 1986; *Rogers v. Okin*, 1979; *State ex rel. Jones v. Gerhardstein*, 1987). Conversely, if patients were found to lack the requisite abilities, several courts suggested that their agreements to undergo hospitalization or treatment may be considered invalid (*Rogers v. Commissioner*, 1983; *Zinermon v. Burch*, 1990).

Patients' "right to refuse treatment," the rubric under which this issue was usually discussed, became a highly contentious matter, particularly as applied to involuntarily committed mental patients (Appelbaum, 1988, 1994). Many mental health professionals argued against the new rules on the basis that their nineteenth-century predecessors had been correct: Severe mental illness almost always destroyed decision-making abilities, particularly with regard to treatment of the disorder itself. Thus, they contended, most patients with severe mental illness were not able to recognize the existence of their illness and their need for care (American Psychiatric Association, 1980). Others objected to the imposition of formal legal proceedings for determining competence. They maintained that if not universal, serious deficiencies in decisional abilities were sufficiently frequent among patients that the burden of preparing for and attending court hearings

would be overwhelming (Mills, Yesavage, & Gutheil, 1983; Rachlin, 1975).¹ Reliable and valid means of assessing the decision-making abilities of persons with mental illness, and means of comparing them to groups of people without mental illness, became crucial to the resolution of these controversies.

Simultaneously, the introduction of requirements for individualized assessment of decision-making capacities, especially in treatment settings, underscored the critical need for clearly defined standards and procedures for making determinations concerning competence (Cutter & Shelp, 1991; McKinnon, Courmos, & Stanley, 1989). Clinicians required guidance in weighing whether to accept patients' consent or refusal on the basis that their competent wishes should be respected or to challenge them in the belief that patients were incompetent to make decisions. When general medical or surgical treatment was in question, the clinician's judgment, perhaps augmented by a colleague's consultation, was likely to be determinative; commonly accepted practice calls for physicians to abide by the family's wishes in such cases, without legal formalities (President's Commission, 1982). With regard to psychiatric treatment, for which many states require judicial or administrative review of competence determinations, a new set of nonclinical decision makers was now also in need of assistance in reaching conclusions about patients' competence.

Legal Standards for Assessing Decision-Making Competence

Despite the conceptual importance of competence as the touchstone for determining whether a person's decisions will be set aside, until recently relatively little attention has been given to the legal standards to be employed in determining competence. Indeed, the most influential scholar of competence prior to this generation suggested that, in practice, when a party's competence was challenged, courts often focused more on the reasonableness of the contract in question than on the decision-making abilities of the alleged incompetent person (Green, 1944). Even the article that reawakened modern interest in legal standards of competence to consent to treatment despaired of identifying a single operative standard as "a search for the holy grail" (Roth, Meisel, & Lidz, 1977).

The work of Roth and his colleagues (1977), however, has led to an evolving consensus on the standards that are generally applied by the courts when determining competence to consent to treatment (Annas & Densberger, 1984; Bonnie, 1993; Drane, 1984; Grisso, 1986; McKinnon, Courmos, & Stanley, 1989; Tepper & Elwork, 1984). Their critical insight was that courts did not apply a single standard in all cases, but generally chose from a small number of possibilities in selecting the standards to be used in particular instances. Depending on the facts of a case and precedent in that jurisdiction, court decisions might be based on one standard or some combination of standards. As refined in subsequent work (Appelbaum &

¹ Opposition to the right to refuse treatment was not always centered on the question of patients' decision-making capacities. Some commentators argued that competence was irrelevant in the case of involuntarily committed patients: Whatever gave the state right to deprive them of liberty (i.e., the police power or the *parens patriae* function) also provided sufficient basis for nonconsensual treatment aimed at restoring liberty (Appelbaum, 1994).

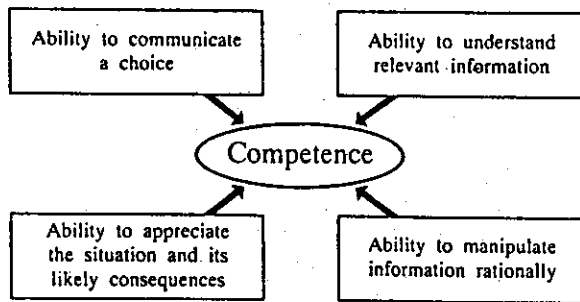


Fig. 1. Structure of competence to consent to treatment.

Roth, 1982; Appelbaum & Grisso, 1988), four legal standards for determining competence have been identified.² Each standard implicates a set of decision-making abilities that must be considered to assess whether the standard has been met (Grisso, 1986).

Ability to communicate a choice is the first, and least stringent, standard that ordinarily is applied. When patients are unable, as a result of illness, to reach a decision or to indicate to their caregivers what course of treatment they desire, they uniformly will be considered incompetent (*Matter of Conroy*, 1985; *Matter of O'Brien*, 1986; President's Commission, 1982). Indeed, so self-evident is this standard that courts often fail to mention it explicitly, taking the incompetence of noncommunicative patients as a matter of course (*Superintendent of Belchertown State School v. Saikewicz*, 1977). Some patients are able to express choices, but their decisions vacillate to such an extent that a course of treatment cannot be implemented before they change their minds again. They also may be considered not to have met this standard. Although maximally protective of individual decision-making rights, a standard that focuses only on the ability to communicate a choice recognizes decisions as valid regardless of the process by which they are reached.

The second and most common component of judicial standards for competence is the *ability to understand relevant information*, a standard that emphasizes the importance of patients' comprehension of information related to the issue at hand. This requirement is often overtly derived from contract law (White & De-

² The original article by Roth et al. (1977) included two standards not discussed here and omitted one that has become accepted since. Roth and colleagues distinguished between ability to understand relevant information and actual understanding; rather than representing separate standards, however, these can be seen as the statement of a standard (i.e., one must have the ability to understand) and specification of how achievement of that standard will be measured (i.e., the patient must actually understand the information). Their paper also pointed to reasonable outcome of the patient's choice as an alternate standard. As they themselves acknowledged, however, this is less a standard of decision-making competence than it is a way of voiding patients' decisions on grounds other than the process by which the decision was made. Although, as suggested by Green (1944), the choice made may have an important influence on judicial decisions, it is not, strictly speaking, a standard of judging patients' competence. Finally, the original paper omitted mention of appreciation of the nature of the situation and potential consequences, a standard described by Appelbaum and Roth (1982).

nise, 1991), where it serves as the basis for determinations of competence to contract. Its application is seen in *Grannum v. Berard* (1967), a case in which a patient challenged the validity of a consent he had given for nasal surgery, alleging that he had been incompetent because of the effects of the medications he was receiving. The court held that "The [test of] mental competency or capacity of an individual to execute an agreement . . . [is] whether the person . . . possessed sufficient mind or reason to enable him to understand the nature, the terms and the effect of the transaction" (p. 814). In treatment situations, the information that must be understood is generally that which must be disclosed to the patient under the law of informed consent.

A third legal standard is the *ability to appreciate the nature of the situation and its likely consequences*. This standard differs from an ability to understand information in requiring that patients be able to apply the information abstractly understood to their own situation. Thus, patients who understand that their physicians believe they are ill, but, in the face of objective evidence to the contrary, deny that this is so, or who understand that an effective treatment exists, but refuse to believe that it is likely to help them, will be said to lack appreciation. Use of the appreciation standard is demonstrated in two contrasting Massachusetts cases. In *Lane v. Candura* (1978), the appellate court overturned a finding of incompetence concerning a woman who was refusing amputation of a gangrenous leg. The court upheld her right to make that choice, finding that she "appreciat[ed] the nature and consequences of her act" (p. 1236), specifically that she was suffering from gangrene and likely would die without surgery. In contrast, the state's Supreme Judicial Court ruled incompetent a man suffering from schizophrenia whose refusal to take medication was based on denial that he was mentally ill, which prevented him from "appreciat[ing] the need to control his illness with antipsychotic medication," or "the risks associated with refusing it" (p. 1286) (*Guardianship of John Roe*, 1992).

Finally, courts also have applied the standard of *ability to manipulate information rationally* in determining decision-making competence. This standard emphasizes patients' abilities to employ logical processes to compare the benefits and risks of treatment options. Even in the presence of good understanding and appreciation, decision making still might be impaired if patients fail to process information logically. Conversely, the rational manipulation standard might be met even by patients who have impaired understanding or defective appreciation if their reasoning processes are intact. Some courts have shied away from embracing this standard because of an apparent confusion regarding interpretation of the term *irrational*. A decision sometimes has been called irrational merely because the patient's choice was unconventional (which is not a sufficient basis by itself to consider the decision maker incompetent) (*In re Milton*, 1987; *In re Yetter*, 1973). In contrast, the "irrationality" to which this standard properly refers pertains to illogic in the processing of information, not the choice that eventually is made. An example of a court adopting this standard is found in *Riese v. St. Mary's Hospital* (1987), a California case dealing with mental patients' right to refuse treatment. After endorsing understanding and appreciation standards, the court indicated that legal competence also required an ability to "knowingly and intelligently

evaluate the information . . . and otherwise participate in the treatment decision by means of rational thought processes" (p. 254).

As suggested by the *Riese* decision, courts often create compound legal standards for their jurisdictions. The New Jersey Supreme Court in *Matter of Conroy* (1985), for example, held that "[a] patient may be incompetent because he lacks the ability to understand the information conveyed, to evaluate the options, or to communicate a decision" (p. 1241), apparently combining understanding, rational manipulation, and communicating standards. Even in cases where courts cite one standard or some combination of standards, it is difficult to know the extent to which their decisions are being narrowly tailored to the facts of a particular case and whether additional standards might be included in other fact situations. Thus, faced with a patient who denied the existence of his or her disorder, New Jersey courts might determine that the ability to "evaluate the options," required by *Conroy*, goes beyond the rational manipulation standard that it appears to endorse and includes an appreciation standard as well.

In addition to helping clinicians and judges clarify the basis for their competence decisions, this conceptualization of operative standards for legal competence laid the groundwork for empirical examination of policy-relevant questions.³ Indeed, almost all of that empirical literature postdates the original Roth et al. (1977) paper, and much of it refers explicitly to their work. For our purposes here, it is important to determine what that literature tells us about the relationship between mental illness and the psychological abilities relevant to competence to make decisions about treatment, and what questions the previous studies have left unanswered.

Research on Mental Illness and Decision-making Capacities

Mental illnesses involve alterations of mental functioning, including attention, perception, cognition, and mood, all of which might be expected to affect decision making. We review here those studies that explicitly have attempted to ascertain the impact of mental illness on abilities related to one or more of the four legal standards for decision-making competence described above. Several considerations should be kept in mind in assessing these data.

First, mental illness is not a homogeneous category. Patterns of deficits in cognitive functioning would be expected to differ across diagnostic groups. Thus, studies of patients with schizophrenia might yield quite different findings than studies of depressed patients. The care with which diagnostic determinations are made will affect the composition of subject groups and, thus, the results of the study. Meaningful conclusions are likely to be made only within well-defined diagnostic categories.

Second, the impact of symptoms of mental illness on mental functioning may

³ Although this model was formulated explicitly to describe competence judgments related to consent for treatment, it may well be more broadly applicable to decision-making competence in general. For an effort to apply the model to defendants' competence to make decisions related to their defense, see Bonnie (1993).

fluctuate with the severity of the disorder. Acutely ill patients who recently have been hospitalized may show greater degrees of impairment than patients who have undergone a course of treatment and are about to be discharged; samples recruited in the community may manifest still higher levels of function. Comparisons among studies must take this issue into account. Independent measures of symptom severity are crucial in characterizing the populations under examination.

Third, considerable variability is introduced into these data by the lack of standardized means of measuring the dependent variables. Investigators frequently devise their own measures of understanding, appreciation, and rational manipulation, with varying (and often unspecified) psychometric properties. Adoption of standardized measures has been impeded by the difficulty of translating legal standards for decision-making competence into psychological constructs that lend themselves to consistent operationalization (Grisso, 1986).

Finally, sampling problems are omnipresent. Researchers investigating the decision-making abilities of people with mental illness must begin by asking them to decide whether or not to participate in the research study. Patients who lack even minimal abilities to consent to participation or who are so disorganized as to be unable to complete the study protocols almost always must be excluded. Thus, the very population of greatest interest—persons whose decision making is manifestly impaired—tends to be selectively eliminated from most studies. This problem is somewhat mitigated by the use of a relatively low threshold of abilities for determining subjects' competence to consent to participation in studies with little or no risk; most investigators require minimal understanding of the consent disclosure. Nonetheless, almost all existing data systematically underestimate the prevalence and degree of impairment in more severely ill populations, because of the necessary exclusion of the most severely impaired patients.

Ability to Communicate a Choice

Relatively few studies have examined the abilities of people with mental illness to reach and communicate choices, perhaps in part because of the methodologic issues referred to above: Unless patients' abilities in this area are intact, they cannot decide whether to participate in the study itself, nor can they indicate their willingness to do so. In reporting their data, unfortunately, most investigators fail to separate potential subjects who did not respond to their requests to join the study from those who refused to participate. Some data, however, offer rough approximations regarding the frequency of severe impairments in reaching and communicating choices.

Appelbaum, Mirkin, and Bateman (1981) evaluated decision-making capacities in a group of 75 diagnostically heterogeneous, but primarily schizophrenic (62%), inpatients, who were admitted consecutively to a community mental health center. They found that 7 patients (9%) were mute or catatonic when approached about participating in the study (although one was deaf and another spoke no English, lowering the probable incidence of truly incapable subjects to 6.7%). Another inpatient study, using a sample mostly suffering from mood disorders,

presented subjects with two vignettes requiring resolution of dilemmas not involving treatment (Radford, Mann, & Kalucy, 1986). Seven of 39 subjects (18%) were noted to be "incapable of deciding."

This dearth of information regarding the distribution of abilities to communicate a choice can be remedied in two ways. Clinical populations can be observed in naturalistic settings to ascertain the incidence of actual failures to communicate choices (e.g., patients in an emergency room for whom admission is being recommended or potential subjects being approached for participation in research). Alternatively, hypothetical choices can be placed before research subjects, as in the study of Radford et al. (1986). The latter strategy affords a greater degree of control over the decision task and offers more opportunities to collect data on predictive variables, whereas the former is less likely to result in the exclusion of the most severely impaired subjects from the sample.

Ability to Understand Relevant Information

Studies of comprehension of relevant information can be divided into two categories. The first group comprises surveys of what people with mental illness know about their treatment (Appelbaum et al., 1981; Hoffman & Srinivasan, 1992; Jaffe, 1986; Linden & Chaskel, 1981; Norko, Billick, McCarrick, & Schwartz, 1990; Olin & Olin, 1975; Soskis, 1978; Soskis & Jaffe, 1979). In general, the findings in these studies are similar to those of Geller (1982), who surveyed all 281 patients in a state hospital on a single day regarding knowledge of their medications. Sixty-nine percent of patients could not name even one medication they took, and 59% did not know how often their medications were administered. Fewer than one half of the patients surveyed knew what the medications were supposed to do.

Although this group of studies reveals an alarming lack of knowledge regarding treatment, the relationship to impaired ability to understand is unclear. The method assumes that patients have been given the information being sought, which other studies suggest often is not the case (Benson, 1983; Lidz et al., 1984). Even if the information was revealed (for example, in consent forms patients were asked to sign), patients may not have attended to the disclosure, or their comprehension may have been limited by poor literacy skills, not mental illness (Berg & Hammitt, 1980; Coles, 1978). In some cases, disclosure may have occurred at such a remote time that, although once understood, the information was long since forgotten. Finally, the relation of mental illness to subjects' poor understanding remains unclear without an evaluation of the performance of subjects without mental illness.

In the second group of studies on abilities to understand, some of these problems were reduced by observation of the disclosure (Benson, Roth, Appelbaum, Lidz, & Winslade, 1988; Lidz et al., 1984) or presentation of a standardized disclosure (Beck, 1988; Beck & Staffin, 1986; Benson et al., 1988; Grossman & Summers, 1980; Irwin et al., 1985; Janofsky, McCarthy, & Folstein, 1992; Kleinman, Schacter, & Koritar, 1989; Munetz & Roth, 1985; Palmer & Wohl, 1972; Roth et al. 1982). Results from Irwin et al. (1985) demonstrate both the usual

findings of this group of studies and the methodologic problems common to many efforts. Forty-seven psychotic inpatients were assessed, of whom two thirds had schizophrenic and the remainder affective disorders. Information about antipsychotic medication was read to each subject, followed by a series of questions. Most patients claimed they understood the information, but 19% to 43% were classified as having poor comprehension (depending on the criteria used), and only 26% to 60% as having substantial comprehension. Most of the other studies in this category report similar degrees of deficits.

Unfortunately, the procedures used in the study compromise the degree of assurance with which its findings can be endorsed. The disclosure was read to subjects, obviating the problem of poor reading skills, but its level of complexity was not measured in any standard way. Scoring appears to have been performed in a nonblind fashion by the interviewer, with no efforts reported to establish reliability. Criteria for scoring of responses are not specified. Thus, subsequent researchers desiring to replicate this study would be unable to do so.

Implicit in many of the studies of understanding is the assumption that detected impairments can be attributed to mental illness. Other factors, however, such as the stress associated with any illness, might compromise understanding even in persons without mental illness. A few studies have compared the performance of samples with and without mental illness. Jaffe (1986), for example, found no differences in understanding (without controlled disclosure) between two groups of 16 outpatients, one treated for mental disorder and the other for a physical condition. The sample, however, was small, and the scoring criteria were vague and of uncertain reliability. Nonetheless, similar results appeared in comparisons of elderly depressed patients with nonpsychiatrically ill older persons after information disclosure (Stanley, Stanley, Guido, & Garvin, 1988) and in two studies of inpatients with mental and medical illnesses (Janofsky et al., 1992; Soskis, 1978).

On the other hand, examinations of the correlates of poor performance within groups with mental illness have revealed significant relationships with various kinds of symptomatology. Thought disorder (Irwin et al., 1985), evidence of organic impairment (Janofsky et al., 1992), psychosis (Roth et al., 1982), and a diagnosis of schizophrenia as opposed to depression (Benson et al., 1988) all predicted poorer performance. Thus, suggestive evidence exists both supporting and refuting the impact of mental illnesses on ability to understand relevant information.

To avoid the problems of most earlier studies, future research on understanding in mentally ill persons should use standardized disclosures of predetermined levels of complexity, structured probes, and scoring procedures of known reliability. Analyses should control for diagnosis, symptomatology, and sociodemographic factors that might affect comprehension (e.g., age, education, social class). If causal relationships are to be established with mental disorders, control groups without mental illness must be included.

Ability to Appreciate the Nature of the Situation and Its Likely Consequences

Competent decision making according to the appreciation standard requires recognition that one is suffering from a disorder and that the generally accepted

risks and benefits of treatment apply to one's own situation. An enormous literature exists in this area, perhaps because failures in appreciation often are considered to be core components of the major psychiatric disorders. (Efforts also have been made to assess appreciation in medical patients—e.g., Levine et al., 1986—a literature that will not be reviewed here.)

Many studies document impairments in the abilities of patients with schizophrenia to appreciate that they are ill (usually termed *denial* or *lack of insight*) (Amador et al., 1993; Appelbaum et al., 1981; Brooks, Deane, & Hugel, 1968; Davidhizar & Wehlage, 1984; Greenfield, Strauss, Bowers, & Mandelkern, 1989; Heinrichs, Cohen, & Carpenter, 1985; Hoffman & Srinivasan, 1992; Lin, Spiga, & Fortsch, 1979; Markova & Berrios, 1992; McEvoy, Aland, Wilson, Guy, & Hawkins, 1981; McEvoy, Appelbaum, Apperson, Geller, & Freter, 1989; McEvoy, Apperson et al., 1989; McEvoy, Freter et al., 1989; McEvoy, Schooler, Friedman, Steingard, & Allen, 1993; Munetz & Roth, 1985; Norko et al., 1990; Takai, Uematsu, Ueki, Sone, & Kaiya, 1992; Van Putten, Crumpton, & Yale, 1961; Walker & Rossiter, 1989; Wing, Monck, Brown, & Carstairs, 1964). Indeed, lack of insight was identified as the most common symptom in the core group of schizophrenics in the World Health Organization's International Pilot Study of Schizophrenia (Carpenter, Bartko, Carpenter, & Strauss, 1976), a finding confirmed in another multinational study by Wilson, Ban, and Guy (1986). Nonetheless, when dichotomous judgments have been made, the percentage of patients with schizophrenia reported as lacking insight has varied widely, from 97% (Carpenter et al., 1976) to as little as 27% (Wing et al., 1964), despite similar measures of the concept.

Recent studies have separated insight into subcomponents, looking at the ability to acknowledge current problems as a separate dimension from acknowledgment of problems in the past or the possibility of problems in the future (Amador et al., 1993; McEvoy, Apperson et al., 1989). Conflicting results have been reported on the degree of correlation among these dimensions. Recognition of the presence of abnormal mental events has been distinguished conceptually from identification of those events as symptoms of a mental disorder, although these characteristics seem to be highly correlated (Amador et al., 1993; Greenfield et al., 1989). Investigators also have examined the ability of patients with schizophrenia to appreciate their need for treatment in the present and the future (Lin et al., 1979; McEvoy et al., 1981; McEvoy, Apperson et al., 1989), both of which generally have been found to be impaired.

Patients with depression are the other major group whose degree of appreciation has been subject to extensive study. The association of depression with feelings of hopelessness and helplessness (American Psychiatric Association, 1987) has led investigators to wonder whether people with depression might have impaired appreciation of likely consequences of a situation, focusing too one-sidedly on negative outcomes (Ackermann & DeRubeis, 1991). Research was stimulated by early findings suggesting that depression, paradoxically, might contribute to more realistic assessments, stripping away the illusions that contribute to false optimism in nondepressed populations (Taylor, 1989). Reviews of this literature have pointed to conflicting findings in this regard, as well as the tendency to use subjects who display symptoms of dysphoria but do not meet criteria for clinical depression (Ackermann & DeRubeis, 1991).

Indeed, results from the small number of studies with clinical populations support Taylor's hypothesis: Mild depression may be associated with depressive realism, but severe depression is characterized by overt cognitive distortions (Taylor, 1989). Morgado, Smith, Lecrubier, and Widlocher (1991), for example, assessed 25 patients with major depression on a scale of social adjustment, comparing the data with patients' self-reports. When depressed, but not when recovered, patients markedly overreported maladjustment. Unfortunately, we are unaware of studies directly examining decision making relative to treatment of patients with depression.

Limited investigations have examined the relationship of impairments of appreciation in groups with mental illness to the presence or severity of the mental illness itself. Comparisons with populations without mental illness are almost entirely lacking. In one study, a mixed group of psychiatric inpatients was shown to be significantly less likely to acknowledge mental problems at admission, but not at discharge, compared with medically ill controls (Small, Messina, & Small, 1964). Several studies have examined correlations between impaired appreciation and severity of symptoms, with results both supporting (Markova & Berrios, 1992; Takai et al., 1992) and refuting (Amador et al., 1993; McEvoy, Apperson et al., 1989) the presence of a relationship between them. Much attention has been given to the relationships among insight into illness, compliance, and outcome of treatment. Most studies, although not all, have suggested that better compliance and more positive outcomes are associated with greater insight (Amador, Strauss, Yale, & Gorman, 1991).

Recent efforts to develop valid and reliable measures of appreciation have improved the quality of work in this area (Amador et al., 1993; McEvoy, Apperson et al., 1989). Most studies, however, have attempted to illuminate the phenomenology of mental illness, rather than to provide information about functioning relative to decision-making competence. Thus, they generally fail to provide comprehensive assessments of the relevant aspects of appreciation. Insight into the presence of illness has been studied extensively, whereas appreciation of the risks and benefits of treatment rarely has been examined. The majority of work has been done with patients with schizophrenia, although there are reasons to suspect impaired appreciation in other diagnostic groups as well. The differences in appreciation between groups with and without mental illness, and the relationship between particular symptoms and failures in appreciation, remain to be determined.

Ability to Manipulate Information Rationally

Rational manipulation of information by persons with mental illness has not been studied extensively. In contrast to understanding, examination of this ability requires more complex methods than merely asking for recall of disclosed information. Compared with appreciation, which has always been thought to affect compliance and therefore outcome, its clinical relevance seems weaker. Nonetheless, some investigators have developed paradigms for assessing rational manipulation of information in various diagnostic and symptomatic groups.

Focusing on persons with schizophrenia, Rosenfeld, Turkheimer, and Gardner (1992) devised a gambling paradigm to assess reasoning. Inpatients and outpatients with schizophrenia were compared with non-schizophrenic siblings or parents. Subjects were asked to indicate their choices between two possible bets displayed graphically on a computer screen; the options differed in probability of winning, amount that could be won, and amount that might be lost. Inpatients were significantly less likely to conform to a rational choice model (one that maximized gain and minimized loss) than were outpatients and controls. Predictors included severity of symptoms and IQ measures.

Reasoning also has been examined in patients with depression, but no consistent results have been obtained across studies. Compared with nondepressed controls, subjects with depression were found to show greater decisional stress, lower decisional self-esteem, and more dysfunctional decisional response styles, all of which correlated with degree of depressive symptoms; subjects with depression in Australia and Japan showed similar results, although nondepressed controls in Australia differed significantly from those in Japan (Radford, Mann & Kalucy, 1986; Radford, Nakane, Ohta, Mann, & Kalucy, 1991). Another study measuring quality of reasoning about treatment choices in subjects with and without depression found no differences between the groups (Stanley, Stanley, Guido, & Garvin, 1988). A vignette study, in which subjects were asked to make hypothetical decisions, showed significant differences in choices between depressed and nondepressed groups (Lee & Ganzini, 1992). In a study that stimulated much of the work on "depressive realism," Costello (1983) asked women with depression to decide at what level of expected utility they would favor risky choices over more certain ones. She concluded that they performed closer to a rational choice model than did nondepressed controls, who favored risk-prone judgments.

Mixed diagnostic groups were examined by Stanley et al. (1982), who asked subjects whether they would consent to participate in hypothetical research projects. Forty percent of acutely hospitalized patients said they would agree to participate in high-risk/low-benefit research, whereas up to 32% refused low-risk/high-benefit participation. A second study that compared performance of psychiatric inpatients with medical inpatients, however, found no differences in choices between the groups (Stanley, Stanley, Lautin, Kane, & Schwartz, 1981).

Finally, the impact of particular symptoms on rational decision making has been explored. Delusional subjects with schizophrenia were asked to guess which of two jars colored beads were being drawn from, knowing the distribution of colors in each jar (Huq, Garety & Hemsley, 1988). They required fewer trials before reaching a decision and expressed higher certainty in their choices than did nondeluded patients and nonpatient controls. This would seem to suggest that deluded subjects were likely to jump to conclusions based on limited data; the way in which the task was constructed, however, allows the inference that the nondeluded subjects may have been overcautious and the deluded group closer to a rational choice model. Nonetheless, at least a subgroup of deluded subjects seemed to decide more impulsively than normals. Similarly, in another study by the same research group, persons with paranoid schizophrenia were more likely than nonparanoid patients and normal controls to report illusory correlations

between word pairs (Brennan & Hemsley, 1984). The investigators suggested that paranoid patients integrated new information rapidly into preexisting explanatory schemata, short-circuiting an inductive reasoning process.

Overall, studies of rational manipulation of information often have used tasks that do not resemble treatment decision making, resulting in uncertainty about the application of these findings to clinical decision-making competence. Indeed, some of the tests used, relying for example on Bayesian models, may be so complex that ordinary people could not be expected to perform adequately (e.g., Costello, 1983). In many cases, the outcome of patients' choices has been used as a proxy for their rational thought processes, an equation that may be fallacious; failures in understanding and appreciation, as well as values different from the norm, might equally well explain deviations from a rational choice model. The need in future work is for clinically relevant tasks of appropriate complexity that focus on thought processes, rather than outcomes.

Relationship Among Standards

Most investigators have limited themselves to examining psychological functions related to one standard of decision-making competence: understanding, appreciation, or rational manipulation. The few exceptions usually involve concurrent measures of understanding and appreciation (e.g., Linden & Chaskell, 1981; Munetz & Roth, 1985), or focused on samples without mental illness (e.g., normal children compared with adults; Weithorn & Campbell, 1982). No investigators, however, have explored the relationships among these standards. Unexamined questions include the extent to which the standards have similar associations with diagnostic and symptomatic entities, the relative stringency of each standard, in particular whether one is subsumed by another, and the effects of applying several standards simultaneously. Because courts frequently employ compound standards, this latter question has important clinical and legal relevance.

Design of the MacArthur Treatment Competence Study

The MacArthur Treatment Competence Study was designed to develop reliable and valid information with which to address clinical and policy questions regarding the abilities of persons with mental illness to make decisions about psychiatric treatment: Do persons with mental illness differ from nonmentally-ill persons in their decision-making abilities, particularly as they relate to legal standards of competence? Are whatever impairments may be detected common to all persons with mental illness, or do they vary in type and magnitude? If the latter, what clinical and demographic characteristics are associated with particular patterns of impairment?

Methods were sought of addressing these questions that would yield more interpretable findings than earlier studies. This required the development of reliable and valid measures of decision-making abilities conceptually related to the four major legal standards for competence to consent to treatment. These measures then were applied to clinical populations to generate data on the comparative functioning of persons with and without mental illness.

Development of Dependent Measures

Based on our understanding of the limitations of previous research, criteria were established to guide the development of our measures to assess abilities related to each of the four standards of competence. Six of these criteria were formulated.

The functions being assessed should have close conceptual relationships with the appropriate standards of competence. Tasks should not be drawn reflexively from standard psychological approaches (e.g., standard IQ measures). These may have little relevance to the ways in which the law has thought about the abilities required to consent to treatment. Moreover, the tasks themselves may tap general cognitive abilities that only imperfectly reflect the specific functions required for decision making. Measurement tasks should be derived from a study of the legal standards, with the goal of identifying functional abilities that the courts are likely to consider relevant.

The content of the instruments should be relevant to the decision being studied (i.e., whether or not to proceed with treatment). As a legal construct, competence is now generally recognized to be task-specific (Faden & Beauchamp, 1986). Performance on measures designed to assess decision making in one domain (e.g., gambling paradigms) may lack relevance to the question of subjects' performance in the treatment context. This is because content in other domains may differ in familiarity, complexity, and the degree to which it motivates subjects to perform. Even if the correspondence in performance across content domains is high, measures that target decisions other than those related to treatment will lack face validity with clinicians and, even more importantly, with the courts.

The content of the instruments should be meaningful to the persons being studied. Research participants may perform differently when faced with content that relates directly to their own situation (i.e., when it concerns treatments for their own disorder) than with content that is personally irrelevant (e.g., hypothetical descriptions of research projects in which they will never actually be asked to participate). Performance may be heightened by greater motivation to reach a good decision about a personally relevant issue or reduced by the overwhelming anxiety that attends their consideration of their own situation. Because the net effect of these factors is unpredictable, content should focus on information relevant to research participants' own situations, insofar as possible. Persons with different disorders may require different versions of the instruments.

Content should be sufficiently standardized that comparisons within and across research groups are possible. At the limit, maximum validity might be obtained by individualizing the content to focus on the precise details of persons' own situations. A compromise is required, however, that allows stimuli to be standardized to the extent that valid comparisons are possible. Content should be selected so as to be generally relevant to all members of a diagnostic group and to allow parallel versions to be generated for other diagnostic groups.

Measures must have objective criteria for scoring that can be applied in a reliable fashion. A consistent problem with previous research has been the absence of objective scoring criteria, often leading to an inability to demonstrate

reliability and making replication problematic. Development of reliable methods for assessing competence-related functions would be a major contribution in its own right.

Instruments should be practical for use in a research setting and potentially adaptable for clinical use. The instruments must be brief enough to allow administration of all experimental measures and several measures of independent variables in a single sitting, with patients with severe mental and physical illnesses. This has been less of an issue in previous research, in which investigators rarely have attempted to measure abilities related to more than one legal standard at a time. Moreover, to ensure adequate sample size at acceptable cost, the instruments should be capable of being employed by interviewers without extensive clinical training. They should be designed to allow them, if they are successful as research instruments, to be adapted for routine use in clinical practice.

The instruments developed according to these criteria were tested and refined during the pilot phase of the study (Grisso & Appelbaum, 1991). A full description of the instruments is provided in the second article in this series (Grisso et al., 1995).

Selection of Diagnostic Groups for Study

In recognition of the heterogeneity of mental disorders, two mental illnesses were chosen for study: *schizophrenia*, because it is among the most severe of mental illnesses and is known to have an adverse effect on cognitive functioning (Gold & Harvey, 1993), and because questions of decision-making competence frequently arise among persons with the disorder; and *major depression*, because it is the most common of the major mental illnesses, and in its severe forms may also raise questions of competence. The majority of previous studies of abilities related to legal competence has involved these two disorders, permitting comparison of results with previous findings.

Persons with mental illness are called upon to make treatment-related decisions at multiple points in the course of their illnesses. The study focused on decision-making capacities soon after admission to an inpatient facility. Although it would be of interest to assess functioning at other points in time (e.g., during outpatient treatment), the postadmission period was selected for initial study because it was thought to maximize the possibility of including a range of impairments, including severely disordered patients. In addition, decision making by inpatients is the focus of recent controversies over the implementation of a right to refuse treatment, and those decisions frequently are made during the first few days of hospitalization.

A third group—medically ill patients—was included to allow inferences to be drawn regarding the effects of mental illness, as opposed to the impact on performance of illness *per se* and of the stress associated with hospitalization. The selection of a hospitalized, medically ill sample was constrained by the need to identify a patient group that resembled the two groups with mental illness in several ways: a high incidence of hospitalization, considerable chronicity, frequent treatment with medication, and availability during hospitalization for inter-

view. To allow inferences to be drawn regarding the effect of mental illness *per se* on decision making, it was important that neither the medical disorder nor the treatment typically result in mental impairment. Patients with ischemic heart disease (angina pectoris) were selected as the group that best met these criteria.

Selection of Comparison Groups

Many of the earlier studies designated levels of performance that were said to constitute competent or incompetent functioning. There are several difficulties with this approach. A priori determination of any particular level of performance as a proxy for legal competence or incompetence is likely to be highly arbitrary. The law specifies no particular level of ability for competence when determined according to any of the four legal standards. Moreover, the requisite level of ability is likely to vary as a function of case-specific circumstances (e.g., the degree of intrusiveness or risk associated with the treatment) (Drane, 1984; Grisso, 1986). Functioning of a person with mental illness might be considered inadequate when it deviates substantially from the level that is usually manifested in the population at large. Controls without mental illness, therefore, were included in our design to assess the degree to which the performance of participants without mental illness corresponds to the functioning of the general population.

Sociodemographic factors, such as education and occupation, may be related to performance on cognitive tasks, and a random sample of the general population is likely to differ substantially from groups with mental and medical illnesses on these variables. In addition, groups with medical illness and mental illness are likely to differ from each other on variables other than mental illness that might affect cognitive functioning. Therefore, for each diagnostic group, we recruited a non-ill control group matched with it on age, gender, race, education, and highest occupation. The schizophrenia and depression modules of the Diagnostic Interview Schedule Screening Interview were administered to exclude from the control groups persons who met criteria for those disorders (Marcus, Robins, Bucholz, & Przybeck, 1987).

The study design is shown in Figure 2, which describes the main comparisons (solid-line arrows) and secondary comparisons (dotted-line arrows) to be made.

Other Design Features

Data were collected at three sites (Worcester, MA, Pittsburgh, PA, and Kansas City, MO) to maximize the generalizability of the results by avoiding bias resulting from peculiarities at a single study site. Each site was responsible for collecting 75% of one of the hospitalized groups and its matched controls, and 25% of a second hospitalized group and its controls (see Figure 2). Patients with schizophrenia were recruited in Kansas City and Worcester, patients with depression in Pittsburgh and Kansas City, and ischemic heart disease (angina pectoris) patients in Worcester and Pittsburgh. The degree to which competence-related functioning changes over time is of relevance theoretically, as well as from a policy perspective. Therefore, our design called for between one quarter and one

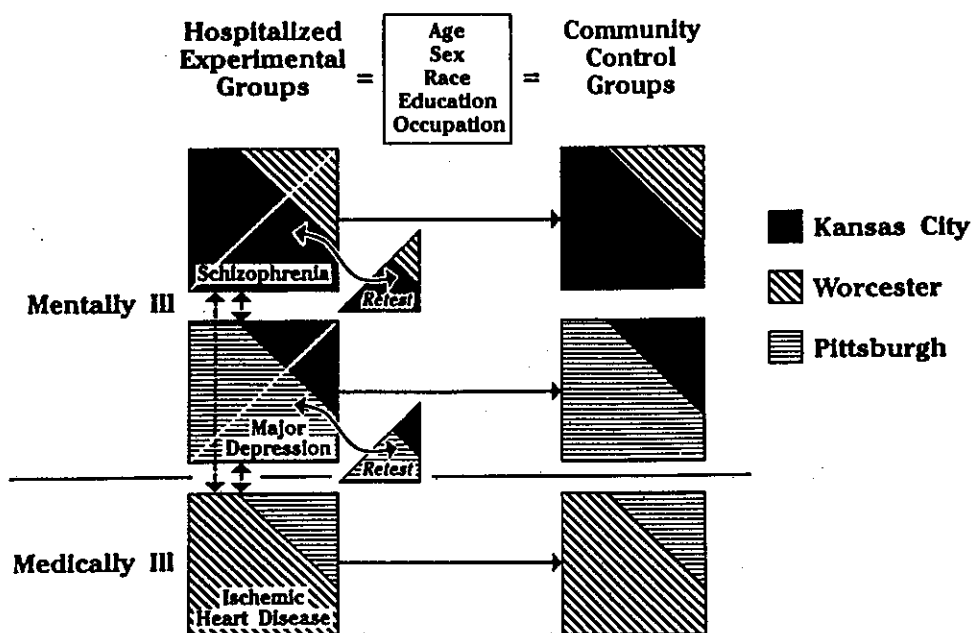


Fig. 2. Design of study.

third of the groups with mental illness to be retested two weeks after the initial evaluation.

CONCLUSION

The MacArthur Treatment Competence Study was designed to minimize many of the problems of previous research in developing and testing measures of patients' abilities related to legal standards of decision-making competence. The following article (Grisso et al., 1995) describes the psychometric characteristics of the instruments developed for this purpose. Initial application of the measures was aimed at shedding light on the degree to which patients with mental illness function differently from medically ill patients and nonpatient controls. These data are contained in the third article in this series (Grisso & Appelbaum, 1995), where we also explore the implications of our results for the question of whether different policies with regard to informed consent can be justified for mentally ill people.

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