REVIEW ARTICLE
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Ethical Issues in Schizophrenia: Considerations for Treatment and Research

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ABSTRACT *~ Clinicians who treat patients with schizophrenia may encounter a variety of ethical issues related to both psychiatric and medical treatment of patients. While informed consent is a crucial aspect of the care of all patients, it may present special challenges for patients with schizophrenia. Schizophrenia is a severe mental illness that is frequently accompanied by neuropsychological deficits. These impairments, as well as psychotic symptoms and lack of insight, can affect patients' abilities to make fully informed decisions about their own care. Ensuring that consent for treatment is informed, voluntary, and competent can thus become a more difficult endeavor. The ethical principles underlying treatment of these patients, however, are the same as those guiding treatment of all patients. Informed consent, as an embodiment of these ethical principles, represents the expression of individual rights in both clinical and research contexts. Attention to the process of informed consent as an ongoing dialogue strengthens the clinician-patient relationship, improves adherence, and helps the patient clarify options, values, and preferences. In the research setting, psychiatric researchers are increasingly concerned with maximizing the abilities of individuals with severe mental illnesses such as schizophrenia to provide meaningful informed consent for protocols. This review addresses decision-making abilities of people with schizophrenia in both treatment and research contexts.* Psychopharmacology Bulletin. *2007;40(4):145-155.*

INTRODUCTION

Schizophrenia is a severe mental illness accompanied by functional, occupational, and social disturbances that can place heavy burdens on the patient, the family, and caregivers. In treating patients with this disorder, clinicians may encounter a variety of ethical issues. Additionally, the development of new treatments for schizophrenia depends on patients with this disorder volunteering for research studies. Ethical conduct of research on schizophrenia depends upon careful enactment of the ethical principles which guide clinical care, but in a different context.

Concepts of respect for autonomy, beneficence, veracity, and justice are fundamental to caring for mentally ill populations. Informed consent, as a pillar of

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ethical clinical practice and human research, embodies these ethical principles, representing the expression of individual rights in both clinical and research contexts. In patients with schizophrenia, in particular, attention to the spirit, and not simply the letter, of informed consent serves not only as a legal safeguard, but also strengthens the dinician-patient relationship. Informed consent is thus an ongoing opportunity to provide information as well as engage in a discussion about options, values, and preferences. This review addresses the elements of informed consent broadly as well as what is known about decision-making abilities of people with schizophrenia for treatment and research-related decisions. The paper then focuses on potential barriers to informed consent and describes recent work exploring ways to improve consent procedures to optimize the capacity of people with schizophrenia to provide meaningful informed consent.

OVERVIEW OF INFORMED CONSENT

Three key elements are widely considered to be essential for meaningful informed consent.[1] Information disclosure refers to the sharing of full and relevant information a patient needs to know about the proposed treatment or procedure. How much should be disclosed remains a matter of some debate, since different standards such as the "reasonable person standard" versus the "professional practice standard" have been viewed as acceptable at different times and in different jurisdictions.[2] In general, physicians should engage the patient in a dialogue regarding the purpose of the treatment (or in the case of research, the protocol), the procedures involved, the foreseeable risks and potential benefits, and alternatives.[1] In addition, the manner in which information is presented—orally or in writing, with the use of decision aids or multimedia tools—can affect how much patients understand. Recent work is focusing on discovering which methods of information provision work best, for which patients, and in what contexts.

The second necessary element of informed consent is *decisional capacity*, the clinical equivalent of the legal concept of competency. Decision-making capacity actually encompasses four abilities, generally agreed upon by experts in the field as 1) adequate *understanding* of information relevant to the decision, 2) *appreciation* of the information, ie, applying it to one's own situation, 3) *reasoning* with the information, weighing options logically, and 4) expressing a stable *choice* regarding the treatment or research decision.[3]

Finally, probably the least well-studied aspect of consent relates to the requirement of the patient or subject to make a *voluntary* decision. The decision should be autonomous, free from coercion, and authentically reflective of the wishes of the individual. But what constitutes

voluntariness or coercion is not always clear and has not been well explicated.

As a step in the right direction, Roberts[4] asks us to consider a conceptual model of voluntarism in which four domains of possible influence may affect an individual's capacity for voluntarism in the treatment or research context. Developmental, illness-related, psychological, cultural, religious, and external factors or pressures can all conceivably influence patients' decision-making and may in some cases amount to diminished capacity for voluntarism. In patients with schizophrenia, all of these factors may play roles in patients' decision-making, and clinicians should be aware of these potential spheres of influence. For example, developmental factors include patients' abilities to form their own sets of preferences, apart from family wishes or peer pressure. Illness-related factors may include altered cognitive processes or psychopathology that may affect the abilities to understand or reason with information, or to appreciate the significance of the information. For instance, a paranoid belief that others are out to do harm to oneself may result in a great deal of mistrust of the physician, dinic, or hospital. A patient's authentic wishes about treatment could be overridden by fears which may cause him or her to misjudge risks or discount a provider's information or opinion.

Under the more general category of psychological, cultural, or religious influences fall many possible factors that influence the capacity to make voluntary choices. A patient with schizophrenia, for example, may be reluctant to disagree with their physician or even to speak up regarding their own difficulties adhering to a treatment plan. The physician may have no idea about these issues unless he or she is attuned to their possibility. Asking not just about whether a patient understands the proposed treatment, but also about beliefs, values, and concerns that a patient may have regarding the treatment is thus crucial in promoting this aspect of informed consent.

Putting the above into the context of the medical encounter, a helpful model described by Ness[5] delineates three content areas of the medical interview—medical decision-making, informed consent, and the physician-patient relationship. Informed consent is clearly just one component of medical discussions. In addition, Ness describes two useful techniques to assist physicians in adapting their interviewing for the complex task of optimizing collaboration while advocating as necessary. These techniques explore the patient's views (eg, by asking open-ended questions and empathizing), and assert the physician's views while negotiating with the patient's issues and concerns in mind.

An additional consideration, particularly for primary care physicians and OB/GYNs, stems from research indicating that women may rely more heavily on relational considerations in their decision-making.[6]

Although gender differences have not been as well-studied in the health care context and minimally in patients with schizophrenia, clinicians and investigators must consider the possibility that women's decision-making may be qualitatively different from men's. For example, some women may be more likely than men to perceive the physician as an authority whose judgment or decisions should not be questioned. While subtle, these are all possible influences on the capacity to make fully informed, voluntary choices. The more clinicians are aware of these factors, the more they assure that decisions arise out of an ongoing dialogue.

SCHIZOPHRENIA AND DECISION-MAKING ABILITIES

In patients with schizophrenia, decision-making abilities may be affected by cognitive factors as well as psychopathologic factors. Schizophrenia is a serious mental illness afflicting approximately 1% of the population.[7] Its clinical manifestations include "positive symptoms" including hallucinations, delusions, and disorganized speech or behavior, as well as "negative symptoms," which generally manifest as apathy, anhedonia, avolition, emotional blunting, and affective flattening. Major areas of functioning (work, education, and relationships) are affected in most individuals with this disorder, although it is important to remember that remission is not uncommon, especially in later years.

Schizophrenia is usually, although not always,[8] associated with mild to moderately severe neuropsychological impairments. Research indicates that although psychotic symptoms fluctuate, these cognitive deficits are usually stable over time.[9] Most frequently, patients manifest impairments in attention, working memory, learning, and executive functions/abstract reasoning. These abilities are clearly relevant to medical decision-making capacity, specifically to the understanding and appreciation components. Appreciation of information—application of material to one's own situation—may be hampered in patients who have diminished insight into their illness and situation, another common accompaniment to schizophrenia. Research also indicates comorbid psychiatric conditions, including mood disturbances and substance use, to be common.[10–12] These may impact decision-making abilities at several levels as well.[13–16]

Given the above considerations about how decision-making by patients with schizophrenia may be affected by various aspects of the illness, it is important to address what is actually known about the abilities of patients to make truly informed decisions. Research in this area has been conducted over the last several decades by a number of groups; patients with serious mental illnesses including schizophrenia have been reported in a number of studies to have suboptimal understanding of disclosed information.[17–21] In one of the largest and most well-conducted studies, the MacArthur Treatment Competence Study,[18,22,23] Appelbaum, Grisso and

colleagues examined the abilities of psychiatric inpatients (hospitalized for schizophrenia or depression) and medically ill inpatients (hospitalized for angina), as well as those of healthy, non-hospitalized community controls, to make treatment-related decisions. Overall, the patients with schizophrenia performed more poorly on measures of understanding, appreciation, and reasoning compared to each of the other groups.

Although schizophrenia patients often exhibit deficits on measures of decision-making capacity compared to demographically similar controls, patients nevertheless show substantial heterogeneity. For example, in the MacArthur study, although the patients with schizophrenia performed worse than the comparison groups on each of the four areas of decision-making capacity, the majority of schizophrenia patients did not show poorer performance on any particular measure compared to patients with depression or community controls.[18]

A number of studies have focused on the correlates of decision-making capacity in patients with schizophrenia; the data suggest that psychopathological characteristics and neuropsychological deficits are associated with impairments in patients' decision-making capacity.[18,24] Appelbaum, Grisso and colleagues reported in the original MacArthur instrument studies that overall severity of psychopathology was correlated with impaired understanding.[18,22,23] Carpenter and colleagues reported performance on the understanding subscale of the MacArthur Competence Assessment Scale for Clinical Research (MacCAT-CR; this scale is designed to help assess understanding, appreciation, reasoning, and expression of a choice in the clinical research context) to be significantly correlated with reading ability and overall performance on a brief cognitive battery, whereas reasoning subscale scores correlated with overall cognitive ability and immediate memory, and scores on the appreciation component were associated with visual-spatial performance and working memory.[24] In this same study, higher levels of psychopathology were associated with worse performance on the understanding, appreciation, and reasoning subscales of the MacCAT-CR. Wirshing and colleagues[25] found conceptual disorganization to be associated with poor comprehension at a one-week retest of understanding of a study protocol, but other psychotic symptoms were not associated with comprehension scores.

It is important to note that patients with a variety of medical conditions—as opposed to solely patients with serious mental illnesses—may demonstrate impaired decision-making abilities when asked to consider treatment or research.[26] Frequent deficits include inadequate comprehension or recall of disclosed information, lack of awareness of being in a research study and the ability to withdraw at any time, lack of understanding of research-related concepts (eg, randomization procedures, placebo treatments), poor recall of important risks, confusion

about the dual roles of physician/researchers, and the "therapeutic misconception" (ie, the belief that treatment decisions in a research are being made solely with the individual subject's benefit in mind).[27–41]

It is also well-established that normal adults (including physicians) exhibit psychological biases with regard to judgments about probability;[42] these may affect reasoning, one of the component abilities of decision-making capacity. A large literature in medical decision-making also documents that manipulations of the way information is framed (ie, potential loss vs. potential gain, quantitative vs. qualitative descriptions of risks) also influence people's judgments and decisions.[43] Not surprisingly, people are not purely rational in their reasoning; their medical decision-making reflects emotional factors as well as cognitive abilities.

OVERCOMING BARRIERS TO INFORMED CONSENT IN PATIENTS WITH SCHIZOPHRENIA

Why is informed consent important in schizophrenia treatment and research? We live in an era of great progress in the treatment of schizophrenia. Recent years have witnessed a mini-revolution in psychopharmacologic advances, and promising new treatments—both biological and behavioral—are continuously being developed and tested. Many patients have been able to resume productive and fulfilling lives as a result of new treatments. Thus, patient volunteers will continue to be needed for clinical trials to establish the utility of these treatments. Additionally, although the advent of the atypical antipsychotic era has led to improved outcomes and generally fewer serious side effects, no treatment is completely without risks. As both clinical and research experience with newer drugs accrues, sometimes-unforeseen side effects emerge. Finally, patients with schizophrenia also need medical care. In fact, poor physical health is extremely common among the chronic mentally ill.[44,45]

As screening and diagnostic tests, medical procedures, and treatment options become more varied and sophisticated, patients need to be fully informed about preventive health screening and maintenance, treatment options, and side effects (not only those from psychotropic medications), as well as about the risks of no treatment for their medical problems. Informed consent thus needs to be viewed not as a discrete event (ie, occurring at the start of a new medication or at entry into a research protocol), nor simply as a legal requirement, but as an ongoing process underlying the patient-physician relationship and the ethical conduct of research. Informed consent optimizes patients' abilities to make autonomous decisions that are most consonant with their own values, beliefs, and preferences.

Potential barriers to informed consent in patients with schizophrenia may be categorized as belonging to one of the following three

TABLE 1

POTENTIAL BARRIERS TO INFORMED CONSENT FOR TREATMENT AND RESEARCH

A. Patient- and subject-related factors:
- Age (effects amplified by other factors listed)
- Education
- Vocabulary, literacy, numeracy
- Cognitive impairment (eg, neuropsychological deficits; delirium)
- Previous experiences
- Psychopathologic factors (eg, paranoia, suspiciousness)
- Emotional variables (eg, depression, denial)
- Factors influencing capacity for voluntarism

B. Consent and protocol-related factors:
- Readability
- Presentation/format
- Length
- Complexity/level of detail
- Risk:benefit ratio
- Expression of risk information (quantitative, qualitative)

C. Clinician- and investigator-related factors:
- Attitudes/beliefs/biases (eg, toward informed consent and toward patients with certain diagnoses)
- Knowledge (of informed consent requirements and strategies)
- Skill in presenting information
- Previous experiences
- Conflict of interest

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categories: 1) patient- or subject-related factors, 2) consent-, treatment-, or protocol-related factors, or 3) physician- or investigator-related factors (See Table 1). It should be apparent that these factors play a role in many types of illness, not just psychiatric ones. Considering the possible influences on the informed consent process from these multiple perspectives can help clinicians and investigators to optimize individuals' abilities to provide meaningful consent. Consent-related factors, for example, involve the way information (whether oral or written) is organized or presented.[29,46] In the research context, many studies have documented the high estimated reading level needed to understand the consent forms.[47,48] In the clinical treatment context, communicating with a patient clearly—whether a psychiatric illness is present or not—should involve attention to using simple terms, avoiding jargon, and asking questions to engage the patient.

In a previous review, we examined the literature on methods to improve understanding of informed consent for research or for treatment.[26] Of the 34 studies included in that review, five included patients with psychiatric disorders. Despite assorted methods and types of

interventions, most (25 of 34) of the articles found a positive effect on patients' understanding or recall. Beneficial strategies included better organized or more structured consent procedures, testing with iterative feedback/multiple learning trials, "advance organizers" (previewing information that will be presented), and summarizing information.

A number of groups including our own have been studying methods to enhance informed consent in patients with schizophrenia. We examined 102 middle-aged and older (40 to 80 years of age) outpatients with schizophrenia or related psychotic disorders and 20 normal comparison subjects using a structured, 20-item questionnaire to assess understanding of consent for participation in a low-risk research protocol. Participants were randomized to receive either a routine (paper-based, read aloud by a staff member) or an enhanced (computerized, structured slideshow incorporating greater review, also read aloud slide by slide by a staff member) consent procedure. We found that patients with schizophrenia, compared to normal controls, experienced more difficulty answering the open-ended questions, including those focusing on study procedures, time involved, and potential risks and benefits. However, patients who received the enhanced consent procedure performed better on questions about potential risks and time required compared to those who received the routine procedure.

In the Carpenter et al. study[24] mentioned earlier, the authors evaluated the capacity of 30 schizophrenia patients and 24 normal comparison subjects to provide informed consent for research participation.[49] Consistent with the original MacArthur findings, patients performed significantly worse than normal controls upon initial testing of decisional capacity to consent for a hypothetical study protocol. However, when those patients who scored below the median of the normal controls on the understanding component of the MacCAT-CR were given an educational remediation program, the majority later retested above the cut-off score. No significant differences between patients and controls in understanding scores remained; in addition, patients' scores on the appreciation and reasoning components of the MacCAT-CR also improved.

Wirshing and colleagues[25] reported the beneficial effects of repeated learning trials and corrected feedback on schizophrenia patients' comprehension and retention of key research-related information. Similarly, Stiles and colleagues[50] reported that providing feedback during the consent process improved performance by schizophrenia patients on a test of understanding. Similar to the original MacArthur studies, patients with schizophrenia performed more poorly on a test of understanding compared to depressed patients and normal controls, but—consistent with Carpenter and colleagues' work—the schizophrenia patients showed

improvements after being given corrective feedback, not differing significantly from the other two groups after feedback. Thus, the results of a number of studies provide substantial evidence that patients with schizophrenia, although at risk for impaired decision-making capacity, do demonstrate improved performance on measures of consent-related abilities when educational or remedial interventions are provided during the informed consent process.

CONCLUSIONS

Physicians and investigators need to be aware of ethical issues relevant to decision-making in patients with schizophrenia—a severe mental illness that can potentially diminish autonomy by interfering with the necessary prerequisites of decision-making capacity. Medical advances in the treatment of schizophrenia owe much to the willingness of patients with this disorder to participate in research. Patients with schizophrenia also must collaborate with their primary care physicians in treatment-related medical decision-making. Patients with schizophrenia or other mental illnesses should not be presumed a priori to lack decision-making capacity. Much still remains unknown about decision-making capacity in patients with schizophrenia in both research and treatment contexts. For example, further work should be done to explore the uses of enhanced consent procedures and decision aids in decision-making. Fortunately, research is underway to find ways to optimize decision-making abilities of patients with chronic mental illnesses. When a question about capacity arises, clinicians should strive to assess the component abilities of capacity. It should be emphasized, however, that there is no "magic formula" for determining capacity. When in doubt, consultation with a psychiatric colleague can be extremely helpful. ✤

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