Editorial

Missing the Boat: Competence and Consent in Psychiatric Research

This is a time of great concern about the ethics of psychiatric research. The doubts that have been expressed fall into two broad categories: 1) that some research methods—e.g., medication wash-out periods, placebo-controlled designs, symptom provocation studies—may sometimes or always present unacceptable risk-benefit ratios and 2) that many psychiatric patients who are recruited as research subjects may lack the capacity to make acceptable decisions about their participation (1). I focus here on the second of these issues.

The origins of concerns about subjects' decision-making capacities are not difficult to apprehend. Psychiatric disorders, especially the more severe syndromes like schizophrenia, typically affect cognition, emotion, and motivation. Combined with the positive symptoms of psychotic disorders, such as delusions and hallucinations, these impairments might well limit subjects' abilities to understand, appreciate, and reason about the choices with which they are faced (2). Indeed, one large-scale study in treatment settings demonstrated that a substantial percentage of patients with schizophrenia and, to a lesser extent, depression had marked limitations in these competence-related capacities (3). It is only a short, and not unreasonable, leap to the conclusion that such deficits are in evidence in the research context as well.

What might the consequences be of restricted decision-making capacities among psychiatric research subjects? Participation in research usually involves some degree of risk, discomfort, or sacrifice of the personal care that patients enjoy when they receive ordinary treatment (4). (Of course, some research, including studies involving the description of psychopathology, epidemiologic and other interviews, and cognitive testing, involves few risks or discomforts beyond diminution of privacy and loss of time.) When new therapies are being tested, in place of approaches chosen with their particular needs in mind, research subjects may receive medications selected for them at random, the doses fixed by protocol design, with adjunctive treatments excluded and placebos substituted for active compounds. They may face risks that simply cannot be specified at the inception of the study, and they may be asked to undergo research-related procedures that are sometimes uncomfortable (e.g., blood drawing, MRI scanning) and may carry some possibility of harm (e.g., radiation, medication side effects).

Ordinarily, we allow research subjects to incur these discomforts or sacrifice personal care because we believe that people have the right to run certain risks for rewards that seem to them worthwhile. These rewards may include the pride that comes from altruistic behavior, the hope that they themselves might benefit from the results of the study at some point in the future, and the more immediate possibility that they may have access through the study to assessment techniques or therapeutic approaches that would not otherwise be available to them. The free and competent choice of research subjects is a critical element in the ethical justification of psychiatric research.

When subjects' capacities to make decisions are impaired, however, they may materially misconstrue the situation into which they are entering. Subjects who fail to understand the risks inherent in research studies, to appreciate the impact of participation on their own care, or to reach reasoned decisions about whether to enter a

study cannot fairly be allowed, on the basis of their own decisions, to surrender the benefits of personal care for the uncertainties of a research setting. The tendency of even relatively unimpaired subjects to mistake procedures designed to enhance the validity of the research as being intended to benefit them—the so-called therapeutic misconception—makes these concerns even more acute (5).

With these issues now widely recognized, there is no shortage of suggestions for how to respond. Proposals range from banning certain types of research with psychiatric patients, to requiring independent evaluation of the capacities of potential subjects, to appointing representatives to remove subjects from studies when the risk-benefit ratio appears to be swinging against them (1). Surprisingly little attention, however, has been given to means of restoring a situation that all involved recognize as ideal: competent patients making their own decisions about whether to enter a research study.

Neglect of this possibility appears to be based on the mistaken assumption that impaired capacities necessarily imply that potential research subjects cannot give competent consent for research participation. Impairments, of course, exist on a spectrum, and some degree of dysfunction is not incompatible with competent decision making. On any given measure of decisional capacity, the majority of patients with schizophrenia—even when acutely ill—perform as well as matched comparison subjects without mental disorders (3). Thus, although the presence of cognitive and related impairments in schizophrenia, for example, warrants concern about subjects' abilities to decide whether to enter a research project, by no means does it call for the exclusion of all persons with schizophrenia from investigational studies.

Even more unfortunate is the failure to recognize that even substantially impaired understanding does not mean that a person with schizophrenia cannot comprehend information about a research project; rather, it means that he or she has a harder time grasping the content of a disclosure than a person who is not ill. Instead of writing off the possibility of such people making their own decisions about research and either excluding them from studies that may advance knowledge of their disorder or turning to surrogate decision makers to consent on their behalf, we ought to be focusing on improving their understanding, appreciation, and even reasoning abilities so that they can make decisions for themselves.

The study by Wirshing and colleagues in this issue of the *Journal* underscores this point. With repeated disclosure of information, all 49 of the subjects with schizophrenia they tested were able to respond correctly to a lengthy series of questions about the research projects to which they were being asked to consent. Reports from other investigators offer confirmatory data (W. Carpenter, personal communication, June 1998), as do studies in the treatment setting (6, 7). Repetitive teaching will not work with all patients, of course; some will be too impaired to comprehend enough of the information to offer an acceptable consent. But we have just begun to explore the possibilities here. It is simply unclear at this point what percentage of subjects with schizophrenia or other mental disorders will not respond to creative interventions designed to improve their capacities to consent.

Repeated disclosure of information is not the only technique available. Some investigators use group sessions at which potential subjects can have their questions answered, sometimes by subjects who have already completed the protocol. Videotapes and computer programs have been developed to explain the nature of research projects to subjects. Family members have been involved in the teaching process, sometimes with materials created especially for them. Possible approaches are limited only by the creativity of the investigators (8–10).

All of this has implications for how we deal with decisional impairment in potential subjects. Poor performance on screening with any of the instruments now being developed to measure decision-making abilities or incomprehension after initial disclosure of consent-related information should not be grounds for excluding patients from research participation. Rather, it should be the trigger for intensive efforts to

educate potential research subjects regarding the nature of the projects to which they are being asked to consent. If such efforts can be demonstrated to be successful, subjects can be permitted to make their own decisions about the research project. Which educational approaches work best with which group of subjects, and whether we can identify in advance those subjects unlikely to respond positively to such efforts, remain questions for further research.

No one denies the importance of continuing to advance knowledge of the pathogenesis of and treatment for severe mental disorders. Inevitably, at some point, this means seeking the assistance of individuals with these disorders who are willing to volunteer for research studies. It is critical that the rights and well-being of these human subjects be protected. Unarguably, there will be times when this imperative requires rejecting research proposals that carry unreasonable risks of harm or restricting the range of potential subjects who will be allowed to participate, but one way of protecting people's rights and interests is to help them make decisions for themselves. As we search for mechanisms to maintain high ethical standards in psychiatric research, this is an option we ought not to forget.

REFERENCES

1. Research Involving Subjects With Mental Disorders That May Affect Decisionmaking Capacity: A Draft Report of the National Bioethics Advisory Commission. Rockville, Md, National Bioethics Advisory Commission, July 1, 1998
2. Jones GH: Informed consent in chronic schizophrenia? Br J Psychiatry 1995; 167:565–568
3. Grisso T, Appelbaum PS: The MacArthur Treatment Competence Study, III: abilities of patients to consent to psychiatric and medical treatment. Law and Human Behavior 1995; 19:149–174
4. Fried C: Medical Experimentation: Personal Integrity and Social Policy. Amsterdam, North Holland, 1974
5. Appelbaum PS, Roth LH, Lidz CW, Benson P, Winslade W: False hopes and best data: consent to research and the therapeutic misconception. Hastings Cent Rep 1987; 17(2):20–24
6. Kleinman I, Schachter D, Jeffries J, Goldhamer P: Informed consent and tardive dyskinesia: long-term follow-up. J Nerv Ment Dis 1996; 184:517–522
7. Chaplin R, Kent A: Informing patients about tardive dyskinesia: controlled trial of patient education. Br J Psychiatry 1998; 172:78–81
8. Silva MC, Sorrell JM: Enhancing comprehension of information for informed consent: a review of empirical research. IRB: A Review of Human Subjects Res 1988; 10:1–5
9. Tymchuk AJ: Informing for consent: concepts and methods. Can Psychol 1997; 38(2):56–75
10. Pincus HA, Lieberman JA, Ferris S (eds): Ethics in Psychiatric Research: A Resource Manual for Human Subjects Protection. Washington, DC, American Psychiatric Association, 1998

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