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 categories: 1) patient- or subject-related factors, 2) consent-, treatment-, or protocol-related factors, or 3) physician- or investigator-related factors (See Table). 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