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, clinic, 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,