Obtaining Informed Consent: It Is Not Simply Asking "Do You Understand?"

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Although informed consent has many components that have both medical and legal origins, it is generally believed to exist "if the patient with both substantial understanding and substantial absence of control by another intentionally authorizes medical treatment."[1]

The concept of informed consent includes the following components: full disclosure of information, patient competency, patient understanding, voluntariness, and decision-making.[2] The process of obtaining informed consent involves appropriate facts being provided to a competent patient who understands the information and voluntarily makes a choice to accept or refuse the recommended procedure or treatment.[3]

When the concept of informed consent is applied clinically, complexities arise regarding both the content and the process. The concept contains ambiguous requisites such as "appropriate" facts, "full" disclosure, and "substantial" understanding. The process is affected by many variables including the communication skill and range of practice style (ie, paternalistic to laissez-faire) of the physician; the maturity, intelligence, and coping strategies of the patient; and the interaction between the physician and the patient.

The following case, recently discussed by the family practice residents assigned to an adult medicine teaching service of a large community hospital, illustrates the importance of often-overlooked subtleties in the "patient understanding" component of the informed consent process. The facts and follow-up of the case help to illuminate the scope of the health care professional's obligation to respect patient autonomy. Patient autonomy in this case refers to "a recognition of the patient's right to decide important questions concerning his or her case."[4]

Illustrative Case

Mr F., a 74-year-old white man, was admitted because of a cerebrovascular accident. Mr F.'s initial history and physical examination demonstrated a 40-year history of nonspecific "prostate problems," which included infections, an enlarged irregular prostate, and an elevated prostate-specific antigen level. The significance of the chronic "prostate problems" was unknown but believed to be benign and not of immediate concern. The irregularity of the prostate and the elevated prostate-specific antigen level, however, suggested that a needle biopsy of the prostate be considered to rule out prostate cancer.

With rehabilitation for the cerebrovascular accident well underway, a prostate needle biopsy was recommended by the residents involved with the case to confirm the diagnosis of prostate cancer. The patient was told that potentially helpful treatment options could be considered only after the diagnosis was confirmed. Mr F. responded that he wanted no further examinations, workup, or treatment for the possible cancer. He also said, however, that he would want full resuscitative efforts should he become critically ill.

The residents perceived the patient's decisions to be paradoxical: Mr F., making an "informed" decision, refused to have a biopsy performed to determine whether he had a life-threatening cancer, but wanted full lifesaving measures taken should he need to be resuscitated.

When the residents were asked by the authors how they knew Mr F.'s refusal of further cancer testing was an informed one, they replied that when they had asked Mr F. whether he understood the risks and benefits of the proposed needle biopsy, he had responded yes.

Doubting that the patient's informed refusal was valid, the authors visited Mr F. and thoroughly reviewed

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with him the medical findings as well as the potential risks and benefits of the proposed cancer evaluations. The authors carefully explained to the patient that he had two prostate problems: a longstanding benign problem, about which there was no immediate concern, and a new problem that possibly was cancer, for which treatment, although not proven to be effective,[5] could be considered. Mr F. responded by saying that he had "had that problem for over 40 years" and did not want to do anything about it. This follow-up discussion with Mr F. led the authors to conclude that the patient had not given a truly informed refusal of the cancer evaluation, as he was either unwilling or unable to distinguish his 40-year benign prostate problem from the separate, potentially life-threatening problem of possible prostate cancer.

In a subsequent family meeting, the potential risks and benefits of the proposed evaluation for cancer were again explained to Mr F. and were this time reinforced by his nephew. During this meeting, Mr F. finally verbalized an adequate understanding of his two separate prostate problems as well as the potential risks and benefits of the suggested procedure. He then gave a truly "informed" consent to proceed with the biopsy.

Discussion

Informed consent relates to the ethical principle of respect for patient autonomy. Ethically valid consent is a process of shared decision-making based on mutual respect and understanding between the medical provider and the patient. In obtaining informed consent, the physician is expected to "provide sufficient information about the patient's condition and the recommended treatment—its benefits, risks, and alternatives—to enable the patient to make a responsible decision to accept or reject the recommendations."[6]

In this case, despite the residents' perceptions, it became clear to the authors that the patient initially did not understand his medical situation fully enough to make an *informed* decision to accept or reject the recommended evaluation. Had the residents adequately assessed the patient's comprehension of the medical information presented by having him communicate his understanding back to them, they would have discovered the patient's confusion regarding his two prostate problems and the risks and benefits of the proposed biopsy.

Informed consent involves more than informing the patient; the patient must demonstrate comprehension. Obtaining informed consent requires health care providers to do more than ask "Do you understand?"

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For further discussion, see page 385.