On Informed Consent

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The question of whether patients should influence medical decisions, and if so how much, is not simple. Among other things, it is necessary to decide whether the patient's well-being should take precedence over respect for the patient's autonomy, or vice versa; whether or not the patient has the capacity to exercise true autonomy; what information should be furnished in order to provide the patient with the basis for making a decision about treatment; and how such information should be provided. This article examines these matters, reviews the pros and cons of various methods for obtaining patients' informed consent, presents some broad guidelines for dealing with informed consent issues in a therapeutic setting, and discusses ethical principles that should be applied in obtaining patients' informed consent to participate in clinical research.

In recent years there has been considerable debate about whether patients should influence medical decisions. There are at present no guidelines that may be regarded as valid for all physicians or all countries. Those involved are divided into two main camps on the basis of ethical principles regulating not only the physician's behavior but also that of the society to which he belongs.

If it is held that the paramount value in medical practice is the patient's well-being, his participation in the making of decisions may be secondary. If, contrariwise, respect for the patient is the higher ethical value, then it is possible, in some circumstances, for the patient to make decisions that do not further his well-being.

For the patient to make a decision, it is essential that he be autonomous and competent to do so. There are, of course, circumstances that interfere with the patient's competence to act autonomously. However, neither autonomy nor competence should be regarded as absolute concepts, but rather ones that should be related to each particular case.

There is no general model governing how the patient is to be given the information he needs to provide the basis for his decision. Furthermore, the significance of the patient's informed consent regarding what is done by his physician varies from case to case. Subjecting the patient to normal therapeutic procedures, for example, is not the same thing as including him in a clinical research project, especially one where he is assigned at random to a particular treatment group in a controlled clinical trial.

THE CONCEPT OF AUTONOMY

The conduct of the physician as such is governed as much by his personal values as by the basic ethical principles of medical practice. Now, there are two general ethical frameworks in medical practice: In one, interest in the patient's autonomy

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is subordinated to his well-being, and in the other the reference point is respect for the patient and the exercise of his autonomy (*1*).

In the former, actions are seen as correct if they are conducive to the patient's well-being. This is an ethic geared to outcome, in which autonomy is marginal and paternalism is wrong only when the benefits desired for the patient are not attained. It is clear that many people prefer to be treated paternalistically and "put themselves in the doctor's hands." For them, the exercise of autonomy is more a source of frustration and anxiety than of satisfaction.

On the other hand, in the ethic oriented toward what is done rather than its outcome, the point of departure is the conditions under which action is taken. Autonomy becomes fundamental as a condition for action. For a person to exercise his autonomy, he must be treated with respect. This means that his consent must be sought for any procedure carried out, and all coercion—including paternalistic coercion—must be avoided.

Some persons, however, lack the thinking capacity and volition needed for autonomous action, and in a medical context their state of health may be such as to reduce these abilities still more.

As this suggests, a consensus is difficult to reach when the controversy over autonomy is viewed in absolute terms. Ethical rules cannot be framed that apply to all patients under all circumstances. Hence, it must be concluded that autonomy is not all-or-nothing, but rather that differing situations exist wherein autonomy can be exercised to a greater or lesser degree (*1*).

INCAPACITY

If respect for autonomy is fundamental, so is the attempt to restore those capacities that make it possible. Survival is necessary but insufficient. Indeed, it is still a matter of controversy whether survival without autonomy is a valid goal of medical practice. On the other hand, it seems clear that a risky treatment can be performed to reestablish some functions of autonomous life even if survival is more assured without it.

Lack of Capacity for Autonomous Action

This circumstance arises most often in cases involving children, the original subjects of paternalism. In addition, within the context of medical practice, prolonged and debilitating physical and mental diseases tend to impose a variety of limitations on autonomous action.

In such cases, ongoing evaluation is essential. It is also true that there are situations in which both parents and physicians should restrain their paternalism and leave some decisions to their children and patients, depending on how they are progressing.

Permanent Loss of Autonomy

In this case physicians and close relatives can apply a hypothetical notion of consent: What decision would the patient make if he could? If an answer can be given, then some (if only vestigial) respect can be preserved for what the patient had been and his erstwhile autonomy.

Total Lack of Autonomy

Here, even if the question "What would he have done?" can be asked, the idea of respect for autonomy is meaningless, and medical practice is inevitably paternalistic to some extent. So the question becomes, Who is going to exercise the paternalism, the patient's relatives or the physician?

INFORMATION AND CONSENT

Granting or refusing consent to a medical procedure is a particular manifestation of autonomous action. However, medical advice is accepted or rejected by the patient on the basis of information available to him about his disease, its prognosis, and possible treatment options. Therefore, the question arises as to what the patient should know.

The answer to this question will depend on the ethical framework within which the physician functions. If his conduct is governed by the principle of maximum benefit to the patient, he will withhold information if he feels that revealing it may generate anxiety, depression, or self-destructive behavior. Conversely, if the physician's actions are governed by respect for the patient's autonomy, he will provide all necessary information before taking any decision.

There are at least two settings in which the patient can be given information: the therapeutic setting and the research setting. Though in some cases they overlap, it is useful to consider each setting independently.

Within this context, it should be noted that the relevant information can be provided to the patient either through a frank discussion or on a printed sheet or form requesting his consent. Use of the printed form is very common in some countries, but it seems clear that such forms often fail to accomplish the purpose of informing the patient. Patients read them and sign them, but they often cannot remember afterwards what they read, or even whether they read it (2).

Criticism of such written information is mainly of two kinds. For one thing, it has been noted that there is an increasing tendency to provide such written information mainly in order to comply with legal requirements and avoid possible legal problems, rather than to communicate with the patient (3). Thus, once the patient has signed his "informed consent" form, a lawsuit is less likely to prosper, for it can always be argued that the patient "was aware" of what he would undergo. Of course, it often happens in emergencies that neither the patient (who is sometimes unconscious) nor the close relatives (who are usually distressed) have the cognitive capacity to read and understand the information so provided (4).

The second criticism of this written information, specifically that presented on printed consent forms, relates to its structure and content. Such forms often use a language that only a highly educated patient can grasp and sometimes present information that is incomplete (2), too extensive, or hard to understand (5). There has been much discussion of other ways information might be presented (by videotape, brochure, group discussion, etc.), but no studies have yet been done to determine the relative merits of these methods (5).

It has also been proposed that, in addition to preprinted legal consent forms, other forms should be drafted by professional writers with the advice of physicians, evaluated through presentation to healthy subjects and patients to make sure they can be understood, and put to use. Such prepared material could include detailed information on the nature, risks, and benefits of the intended procedure, and the patient could be given a copy for discussion with his family and friends (6). Though not a bad idea, it is felt that this approach would work only in certain cases.

More generally, it should be noted that there is no need to polarize the alternatives: The patient need not know everything, and the physician need not decide everything. The act of informing is part of the doctor-patient relationship, and within this context the doctor can decide

which information may be appropriately given to the patient he is interacting with. Some information can be not just unnecessary but indeed undesirable for the patient to know (*2, 3*).

Some authors maintain that the patient's capacity to make a decision about his treatment needs to be confirmed only if he and his physician disagree (*7*). Under these somewhat ill-defined circumstances the patient's competence must be evaluated, and (except where there are legal questions) it is ultimately the physician who determines whether the patient is or is not competent to refuse a course of treatment.

In psychiatry, for example, patients have increasingly been refusing treatment with antipsychotic drugs. Nevertheless, it has still been possible to treat these patients legally, despite their refusal (*8*), by establishing through medical evaluation that the limitations of their mental functions make a truly autonomous choice impossible.

For consent to be a manifestation of autonomy, the patient must be aware of, understand, and appreciate his disease, the therapeutic alternatives, and the risks involved. In addition to adequate cognitive function, the patient's affective state is critical, for any affective disorder can distort the patient's view.

A model has been proposed for determining the need for the patient's consent and his ability to give it based on the characteristics of the treatment (*9*). This model is summarized as follows:

- If for a given disorder or disease (which may be fatal) there is an effective, risk-free treatment, and there is no therapeutic alternative, tacit consent may be assumed. Conversely, a terminal patient who knows that a treatment will be futile is competent to reject it.
- If there is any alternative treatment, or if the treatment proposed involves some risk, the patient must understand the differences between the existing alternatives and/or the risks involved and must be capable of making a decision on the basis of that understanding. Ignorance or inability to understand renders the patient incompetent; in such cases, it is correct for the physician to choose what he considers the best option.
- The extent of the patient's competence must be especially carefully evaluated when he makes decisions that appear irrational, dangerous, or at odds with medical judgment. To be deemed competent, the patient needs to appreciate the nature and consequences of the decision he is making. The term "appreciate" in this context signifies understanding at the highest level. To be deemed competent in making an apparently irrational decision, the patient must show that he knows and understands all the relevant details of his disease and the therapeutic options, and must be able to state the reasons for his decision.

The foregoing model briefly summarizes some broad guidelines that can be useful in practice. The greatest problems arise when the patient's decisions, apparently irrational and destructive, are not true expressions of autonomy but are a by-product of his disease, which the physician is obliged to treat (*10*).

CONSENT IN CLINICAL RESEARCH

Among the problems relating to informed consent controversies, those posed by patient participation in controlled clinical trials stand out. Indeed, sometimes the ethical and methodologic interests in this area seem diametrically

opposed, though often the contradictions are more apparent than real.

In general, the best experimental design available for determining the efficacy or efficiency of a given treatment is that of the controlled clinical trial. In such a trial, different groups of patients receive different treatments (or one group serving as a control may receive no treatment), and the ensuing results are compared. The treatment each patient receives is determined by random selection, and it is here that the principal ethical questions arise, notably, Is random selection necessary? and Is the patient's consent essential for participation in these trials?

Random selection is a very important methodologic condition, for it permits the investigators to minimize other differences while examining the effects of different treatments. Hence, what is at issue in the debate over clinical trials is not their utility, scientific importance, or methodologic appropriateness, but rather their ethical aspects, to the extent that they may compromise the physician's obligation to his patient as well as the patient's rights and welfare.

To resolve this seeming dilemma between medical progress and the patient's well-being, it is necessary to properly apply the following ethical principles governing research on human beings: First, the prime consideration is protection of the patient's rights and well-being; second, treating the patient takes precedence over research; and finally, in evaluating different treatments the best possible experimental design must be used, useless or harmful procedures must be eliminated, and loss of time and resources must be avoided. In this vein, it should be noted that a new procedure can always be compared with "the best available procedure"; the patient always has the right to refuse to participate in a controlled clinical trial; and the researchers always have an obligation to request the patient's consent.

Where disagreement often arises is over what to tell the patient. Among other things, it has been observed that in some studies consent may influence the studies' outcome (*11*). However, for a person to participate in a clinical trial it is necessary that his consent be voluntary, that he be competent to give it, and that he base his consent on the information needed to arrive at a sound decision. This information must include a description of the study's nature, purpose, duration, procedures, and probable risks and benefits, plus descriptions of the alternative procedures available, how confidentiality will be protected, the institution's policy on compensation, to whom the patient must turn if he has any questions or if other symptoms emerge, the voluntary nature of his participation, and his right to withdraw from the study at any time.

Unfortunately, situations do arise in which apparently voluntary consent has been secured with a degree of manipulation. This happens when the patient is made an offer that is hard to refuse, when he is made to think that care will be withheld afterwards if he decides not to participate, if he is given wrong or alarmist information about his prognosis, or if he is simply not informed about other treatment options.

On the other hand, there are cases in which the request for consent is couched in excessively rigorous terms, which increases the likelihood that patients will refuse to participate. As a result, the recruitment phase is prolonged, the number of withdrawals increases, random assignment is distorted, and sampling errors occur—all of which impairs the clinical trial's reliability. In these cases care should be taken not to make the request for consent too rigorous, or else the clinical trial should be forgone. After all, there are other research designs (*12*). All

in all, therefore, even in the area of clinical trials, there is no solid argument for supposed incompatibility between scientific medicine and medical ethics.

REFERENCES

1. O'Neill, O. Paternalism and partial autonomy. *J Med Ethics* 10:173–178, 1984.
2. Riecken, H. W., and R. Ravich. Informed consent to biomedical research in Veterans' Administration hospitals. *JAMA* 248:344–348, 1982.
3. Lewis, P. The drawbacks of research ethics committees. *J Med Ethics* 8:61–64, 1982.
4. Weatherall, D. J. Commentary. *J Med Ethics* 8:63–64, 1982.
5. Meisel, A., and L. Roth. What we do and do not know about informed consent. *JAMA* 246:2473–2477, 1981.
6. Adequately informed consent (editorial). *J Med Ethics* 11:115–116, 1985.
7. Spencer, E. Competency and consent to treatment. *JAMA* 253:778–779, 1985.
8. Applebaum, P. The right to refuse treatment with antipsychotic medications: Retrospect and prospect. *Am J Psychiatry* 145:413–419, 1988.
9. Drane, J. Competency to give an informed consent. *JAMA* 252:925–927, 1984.
10. Drane, J. In reply to Spencer. *JAMA* 253:779, 1985.
11. Dahan, R., C. Caulin, L. Figea, et al. Does informed consent influence therapeutic outcome? A clinical trial of the hypnotic activity of placebo in patients admitted to hospital. *Br Med J* 293:363–364, 1986.
12. Kopelman, L. Consent and randomized clinical trials: Are there moral or design problems? *J Med Philos* 11:317–345, 1986.