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 au-
tonomy (1).

In the former, actions are seen as cor-
rect if they are conducive to the patient’s
well-being. This is an ethic geared to out-
come, 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 pre-
fer 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 ori-
ented 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 exer-
cise 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 pater-
nalistic 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 diffi-
cult 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 auton-
omy is not all-or-nothing, but rather that
differing situations exist wherein auton-
omy can be exercised to a greater or
lesser degree (1).

INCAPACITY

If respect for autonomy is fundamen-
tal, so is the attempt to restore those ca-
pacities that make it possible. Survival is
necessary but insufficient. Indeed, it is
still a matter of controversy whether sur-
vival 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 es-
sential. It is also true that there are situa-
tions in which both parents and physi-
cians should restrain their paternalism
and leave some decisions to their chil-
dren and patients, depending on how
they are progressing.

Permanent Loss of Autonomy

In this case physicians and close rela-
tives can apply a hypothetical notion of
consent: What decision would the pa-
tient make if he could? If an answer can
be given, then some (if only vestigial) re-
spect can be preserved for what the pa-
tient 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 mean-
less, and medical practice is inevitably
paternalistic to some extent. So the ques-
tion 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 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.

Criticisms of such written information are 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. 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 distracted) have the cognitive capacity to read and understand the information so provided.

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, too extensive, or hard to understand. 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.

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. 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 pa-
tient’s capacity to make a decision about
his treatment needs to be confirmed only
if he and his physician disagree (7). Un-
der these somewhat ill-defined circum-
stances the patient’s competence must be
evaluated, and (except where there are
legal questions) it is ultimately the physi-
cian 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 treat-
ment with antipsychotic drugs. Nev-
ertheless, it has still been possible to treat
these patients legally, despite their re-

dusal (8), by establishing through medical
evaluation that the limitations of their
mental functions make a truly autono-
mous choice impossible.

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

A model has been proposed for deter-
mining 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 ef-
  fective, risk-free treatment, and
  there is no therapeutic alternative,
  tacit consent may be assumed. Con-
  versely, 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 in-
volves 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 in-
ability to understand renders the pa-
tient incompetent; in such cases, it is
correct for the physician to choose
what he considers the best option.

- The extent of the patient’s compe-
tence 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 under-
stands 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 summa-
rizes some broad guidelines that can be
useful in practice. The greatest problems
arise when the patient’s decisions, ap-
parently 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 in-
formed consent controversies, those
posed by patient participation in con-
trolled 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).
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