Informed Consent of the Mentally Disabled: A Failing Fiction

By NEIL L. CHAYET

Informed consent constitutes a major dilemma. The concept has always proved difficult for law and medicine to handle, because the legal and medical perspectives on the subject are fundamentally incompatible—particularly in the area of the mentally disabled, where appreciation of the concept of informed consent is well on its way to paralyzing research and treatment.

Briefly stated, the fundamental principle at issue is that if a person is going to receive treatment or participate in a research project, the law requires that he give his consent to do so. Such consent must be based on an understanding of the procedure and its risks and benefits to the person. From the legal perspective the concept is a sound one, but many lawyers and regulators fail to appreciate the difficulties encountered in securing informed consent from patients facing life-threatening operations or who are mentally disabled.

Virtually all of the case law in the area of informed consent has come from medical and dental malpractice cases. It is of interest to note that the earliest malpractice case on record concerned human experimentation, where the defendant doctor used an unconventional method in treating a leg fracture with a poor result:

... The defendant Baker put on to the plaintiff's leg an heavy steel thing that had teeth... and broke the leg again, and three or four months afterward the plaintiff was still very ill and bad of it.... It seems as if Mr. Baker wanted to try an experiment with this new instrument.1

The clearest example of a failure to obtain informed consent comes from the classic case in which the wrong tooth is extracted or in which the wrong limb is operated on. The skill with which the procedure is performed is irrelevant if it can be shown that no consent was obtained. The only exception to this rule has been in the area of emergency care and treatment, where consent has been implied in a line of cases beginning with Luka v. Lowrie.2 There has been some criticism of these cases, but for the most part there is agreement that in cases of serious physical injury at least, the best interests of the patient require prompt treatment, with the legal questions concerning consent relegated to lesser importance.

It is obvious, however, that when one moves from the wrong-tooth or wrong-hip cases and from the emergency situation, the issues become far more complex. The basic questions are what constitutes proper consent, who are the appropriate persons from whom it should be secured, and, assuming that informed consent has been properly secured from the appropriate person, how does one prove that fact in litiga-
tion that may occur many years subsequent to the event.

The law has defined informed consent in a variety of ways, and it is important to differentiate between the common law and statutory and regulatory statements on the subject. Regardless of the particular definition, the premise of informed consent is that “every human being of adult mind and sound body has a right to determine what shall be done with his own body. . . .”3 Valid consent must emanate from the informed exercise of choice, which entails the opportunity to evaluate the options available together with all the attendant risks.

For the most part, however, the basic ingredient appears to be the indication of a willingness to have a procedure performed after an explanation and understanding of the procedure and the risks and benefits associated with it. There has been much controversy as to which risks have to be described — some courts requiring that virtually all risks be revealed, with the result that physicians become extremely concerned that if a risk that they do not mention occurs, they will be liable regardless of how unforeseen or rare the risk might be. Other courts have sought to bring in a community standard usually reserved for the proof of negligence cases — that is, what another average qualified practitioner with similar training and ability would have told the patient or research subject about the procedure.

The major problem with this approach, difficult for the law to grasp, is that a full statement of all or even the major risks of a procedure will very often have a serious adverse psychologic effect on the patient or research subject. This is true with a “normal” preoperative patient; it becomes particularly serious and often impossible if the patient is mentally disabled or otherwise impaired.

The physician or researcher who regularly faces the question of securing informed consent is extremely concerned and defensive about this issue: his concern is not diminished by the rather bizarre Connecticut case (not yet reported) of a patient who visited a physician to discuss his forthcoming coronary bypass operation. The physician, who had become extremely concerned about being sued and who thought that this patient was excessively litigation conscious, decided to take extraordinary precautions and in minute detail informed the already frightened patient of all the potential risks of coronary bypass surgery. The patient left the office, refusing to continue the conversation or undergo the surgery, returned to his home, and died a short time later. Suit is being brought against the physician for wrongfully causing the death of the patient by the means in which he sought to secure his informed consent.

The influence of the psychologic factor and its relationship to consent has received some attention. Perhaps the earliest and most often quoted reference is found in the Helsinki doctrine, which provides: “. . . If at all possible, consistent with patient psychology, the doctor should obtain the patient’s freely given consent after the patient has been given a full explanation” (emphasis added).

The Food, Drug, and Cosmetic Act also makes reference to this subject: “. . . and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interest of such human beings. . . .”

However, the Department of Health, Education, and Welfare regulations ignore the need for considering the well-being of the patient/subject in obtaining informed consent. Thus a serious conflict exists in the event of drug-efficacy studies being financed by HEW, with FDA regulations allowing consideration of the best interest of the patient in securing consent while HEW regulations are silent on the subject.

It should also be noted that the most recent draft of the legislation providing for regulation of medical devices, now in House and Senate conference, does not contain anything that continued
would permit the consideration of psychologic factors in deciding the scope of explanation to be given to persons in whom devices will be placed for clinical or research purposes.

Assuming for the moment that proper consent is obtained, and bypassing briefly the question of whom it is obtained from, there are major problems in the manner in which the gaining of consent is documented so that it may be proved years later in the event litigation results. Traditional methods of documentation require a form signed by the patient that may or may not be witnessed. Another method is a note.

“Noting consent on the chart is hazardous; it is subject to the obvious attacks made on self-serving statements”

Further problems arise when one introduces the question of competence to give informed consent. In my opinion, a relatively small percentage of people are truly competent to assess the full measure of risk and benefit of research procedures. Most situations that call for the giving of informed consent are exceedingly stressful, and concern over an illness, denial, and anxiety contribute to an impairment of the full understanding of procedures and risk-benefit ratios.

The problem becomes acute when one deals with the mentally disabled, particularly in the research setting. Presumably, a person is legally competent to give consent or take any legal action unless declared legally incompetent by a court of appropriate jurisdiction. The fact of a person’s commitment to or residency in an institution in and of itself does not render that person legally incompetent. In fact, it is the legal presumption of incompetency that causes many problems, since one cannot ordinarily act for another unless a determination of incompetency has been made and a guardianship has been created. This is unrealistic for many reasons. First, the cost of securing the guardianship is usually prohibitive and, second, there is frequently no one willing or able to accept the responsibility of becoming the guardian. Thus, there are thousands of patients who are in need of treatment and who are legally competent to give consent but in fact are unable to do so, and no appropriate surrogate mechanism exists to assist them.

The dilemma becomes even clearer when one reviews the recent line of cases purporting to give a right of treatment to the mentally disabled. While many of these decisions in fact speak of basic human dignity rather than a right to appropriate treatment for mental illness, or require a person to be discharged if he in fact is not being treated, their implication is clear—that mere custodianship of the mentally ill is not acceptable. Yet, when the clinician and research scientist seek to treat and discover better methods of alleviating mental illness, they are prevented from so doing by being unable to secure the requisite informed consent.

The dilemma is further highlighted when one looks at the standards of the FDA, which require well-controlled clinical studies — “sub-
stantial evidence," as it is legally known — yet make it virtually impossible to conduct these studies because of other regulations requiring informed consent.

Attempts to resolve this basic dilemma have been almost completely unsuccessful, and most treatment and research is carried out either in ignorance of the dilemma (or an ignoring of it) or by carefully rationalized schemes that may give the appearance of legal propriety but in fact would not stand the light of virtually any scrutiny. I am aware of one situation in which a probate judge appointed a lawyer as guardian to facilitate research with a group of mentally ill patients. The lawyer signed consent forms without even visiting his wards or having a full understanding of the research project. The judge and lawyer were depending on the judgment of the researcher and his superb reputation, but the legal hazards of such a procedure are obvious.

In Louisiana, a researcher was able to secure an opinion of the Attorney General for the State of Louisiana to the effect that next of kin could legally consent to an institutionally committed relative's participation in a research project. The opinion has not been specifically tested, but its full impact is questioned by a Louisiana kidney transplant case in which the Louisiana court prohibited one sibling from donating a kidney to another, terminally ill. Similarly, in the earlier case of Strunk v. Strunk,9 the court refused to permit a retarded person to donate a kidney to a dying sibling.

While there has been little to facilitate research with the mentally disabled, there has been considerable activity that has had a chilling effect on research. One of the most destructive of these cases — in principle if not in fact — is the Kaimowitz case in Michigan. This case holds that a mentally disabled person could not consent for psychosurgery because such a person simply does not possess the knowledge and voluntariness that are essential components of consent.9

The facts of the case are not sympathetic to the cause of research or treatment of the mentally ill, because with psychosurgery the risk-benefit ratio is so heavily weighted towards the side of risk; this case is a fine example of the legal maxim that "hard cases make bad law."

Nevertheless, the case has been widely touted as supporting the position that research cannot be lawfully done with the institutionalized mentally disabled because of the inability to secure informed consent, an ability that is not impaired but simply does not exist.

Other clear statements prohibiting research have begun to emerge. An example is a recent Michigan regulation prohibiting the conduct of research on persons under the age of 18 who are institutionalized.

Also, many states are beginning to utilize the criminal law as a sanction for the conduct of research without the securing of informed consent. Massachusetts and Louisiana are but two of the states that have utilized the criminal law in this area. In these states, failure to gain informed consent in research projects can result in conviction of the researcher. Physicians and other researchers are understandably worried; the indictment of four physicians in Massachusetts for the crime of graverobbing based on their work in fetal research indicates that the researcher's concerns about the criminal law are not at all unrealistic.

Is there a way out of the dilemma? I believe that there is, but it will require a substantial degree of innovative action on the part of both the law and the medical and research community. First, the law must develop a set of criteria for determining competence to give informed con-

"Failure to gain informed consent in research projects can result in conviction of the researcher"

sent, and make these criteria fully available to those physicians and other researchers who are called upon to judge such competence every day. Second, it is imperative to determine the nature of the research and the patient/subject involvement. In many situations, risk is virtually absent and confidentiality is the only concern. Certain types of sociologic research fall into this category, but so does research entailing

continued
analysis of blood or urine and hundreds of other procedures that carry no risk for the patient and are basically noninvasive procedures. In such situations, review of the study by the Institutional Review Board (I.R.B.), which receives dependable assurances of confidentiality, should be sufficient.

In case of invasive procedures or procedures that pose a measurable risk to the patient, the investigator must make a judgment as to the competence of the patient to give informed consent. Again, he should be in possession of an intelligible set of criteria for making this judgment and should have available assistance from the I.R.B. or other sources for making this judgment.

If the patient has not been declared legally incompetent and if he is not deemed factually incompetent in accordance with the established criteria, he or she should execute an informed-consent form sufficiently detailed to make it quite clear that the subject understands the purpose of the project, the possible discomfort or risks, and possible benefits. This is submitted to the I.R.B.

If the patient is not considered competent in accordance with the established criteria, the fiction of securing informed consent from the patient or guardian should be dispensed with. Instead, a system needs to be evolved to permit an appropriate determination of the risk-benefit ratio as applied to the particular patient, and a means for allowing the research to proceed in a manner that will protect the patient’s health and welfare. Such a system would include five parties — the patient, the patient’s physician, the Institutional Review Board, the investigator, and a person to be known as the patient surrogate. The surrogate would have legal authority to allow the research to proceed, provided that it was approved by the I.R.B. and the patient’s physician indicates that there is no reason why the patient should not participate in the research project. The concept of informed consent would thus be relegated to its proper place of nonexistence, and instead the research could proceed with the fullest measure of communication and protection being provided to the patient. The surrogate should report to the I.R.B. and be compensated in a manner that facilitates his maximum independence. His major task would be to communicate the facts to the patient; in appropriate cases, where the patient is unable to sufficiently understand the situation to give informed consent, the surrogate would have legal authority to permit the research to proceed.

This model would also be useful in the clinical practice setting, except that the investigator would be absent and the patient’s physician would be the active party.

The patient surrogate system would eliminate the need for consent committees, guardianships, or other complicated mechanisms, which simply do not work. It would instead provide a workable means by which the decisions of the I.R.B. could be effectively implemented. It would also address the major problem that now exists — the inability of the physician and researcher to have the time or opportunity to properly communicate with the patient.

In summary, the present system has created major barriers to research, without really protecting the patient. In fact, if prohibition of research continues to be the protective device that is utilized, we may well “protect” thousands of institutionalized mentally ill persons to death or to lives of misery. What is needed is responsibly conducted therapeutic research projects, carried out in a manner that will secure vitally needed information about the diseases that have caused the institutionalization to begin with, while in fact protecting the general health and welfare of the patient.

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