Informed Consent: Psychotic Patients and Research†

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> The fundamental aim of a useful informed consent standard should be the preservation of the individual's right to "determine what shall be done with his own body."[1,2]

> Informed consent. (T)he term is so semantically felicitous, so easy to say, so straightforward and uncomplicated that it must seem churlish indeed to suggest that it is a fraud.[3]

Introduction

The legal, ethical and moral issues surrounding informed consent have recently been receiving wide discussion.[4-18] Greater effort on the part of physicians has been demanded by the courts to

> . . . disclose and explain to the patient as simply as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions.[19]

Most physicians, either out of moral concerns, economic worries, or both, have become more concerned with what constitutes the information needed to "inform," and the mental states legally and ethically compatible with "consent." As the impact of the "medical consumer movement" has broadened,[20] as the distinction between treatment and research has blurred,[21] and as the courts,[22-30] legislatures[31-34] and regulatory agencies[35,36] have intervened, psychiatrists, especially those committed to research involving patients, have necessarily become more mindful of the problems of obtaining informed consent from

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psychotic patients.[37-44]

There is an ongoing conflict in the psychiatric-legal community regarding the applicability and usefulness of informed consent doctrines. Many articulate commentators, typically physicians, decry these doctrines as overly formalistic,[45] frequently ambigious,[46,47] diluting the investigator's integrity,[3] disrupting collaboration,[48] and failing to acknowledge that periodic regression is part of most illnesses.[49] Others, typically attorneys, urge bolstering informed doctrines to prevent subjects from being dehumanized in the name of medical progress. Specifically, they urge grading the risks and benefits,[50] increasing the number of kinds of review committees,[51] limiting the participants,[52] applying the legal principles of duress, illegality, fraud and incapacity,[53] and restricting the physician's right to withhold information.[54,55]

In this paper some aspects of the conflict between the goal of optimal individual treatment and the goal of furthering psychiatric knowledge are explored. How these goals might be served more aptly in the context of informed consent with psychotic patients is then discussed. Finally, some specific proposals for clarifying informed consent doctrines are presented.

History

The legal doctrine of informed consent is theoretically straightforward, though it has a complex history. As generally applied, it presupposes competent adults who, after learning from their physician about their illness, and assimilating that information, voluntarily and rationally decide about their own treatment needs.[56] Practically though, the doctrine is often inexact and difficult to apply, for court-adopted standards vary from case to case. Cases involving minors,[57,58] prisoners,[59,60] and the mentally ill have been most difficult for the courts, especially when the proposed treatment is experimental.[61] This makes sense, for with each of these groups there are genuine questions about the proposed patient's ability to understand and/or voluntarily determine treatment. Almost seven years ago, a Michigan superior court utilized a three-part standard of informed consent (the *Kaimowitz* decision) in the difficult areas of mental illness and experimental treatment.[62] That test of informed consent set forth in that opinion has received wide comment.[63-67] It is composed of three elements: competency of the patient, knowledge of the risks, and voluntariness of the consent. A brief review of the history of informed consent will clarify some of the present standards, illustrate the manner in which some present shortcomings arose, and demonstrate why that court's opinion has been useful, yet difficult.

Two centuries ago, in England, the first case involving consent to experimental treatment was heard.[68] The court, in affirming judgment for the plaintiff-patient, stated that the defendant-surgeon acted improperly in using a new instrument without consent. The court also

indicated that the specific treatment employed was imprudent. Thus the case incorporated both legal theories of modern malpractice — battery (touching without informed consent) and negligence (practice that is not up to standard). However the court did not precisely delineate whether the surgeon's liability rested on one or both of these theories. That case illustrates a fundamental aspect of our common law heritage: liability can only stem from a strictly limited set of legal doctrines, so-called causes of action.[69] A primary reason that informed consent theories are still employed is that they allow the plaintiff's recovery even when negligence cannot be proved, if failure to obtain consent can be shown.

Though the physician's duty to disclose risks to his patients continued to receive periodic attention by the courts during the next two hundred years, relatively little progress was made in defining the precise nature or extent of that duty until recently.[70]

Three recent cases, though, define that duty more completely and establish the background of the *Kaimowitz* decision: *Salgo v. Leland Stanford Jr. University Board of Trustees,*[71] *Natanson v. Kline,*[19] and *Canterbury v. Spence.*[72] In *Salgo,* the court discussed the duty of the physician to disclose, and found a duty of "full" disclosure exists, to be tempered by the physician's perception of the patient's mental state. In *Natanson,* the court drew the duty of disclosure slightly differently, using as a standard the degree of disclosure of a "reasonable medical practitioner." Finally, the *Canterbury* court focused in depth on the physician's duty of disclosure, expanding that duty by employing a "reasonable patient" standard. Using that standard, the court held that all risks must be disclosed which a reasonable patient would need in deciding which treatment alternative to select. Thus, by the time of *Kaimowitz,* the physician's duty to disclose was considerable, especially in the experimental situation.[73-76]

The *Kaimowitz* case involved a male patient who, after allegedly raping and murdering a nurse, had been confined to a state hospital for 17 years. He volunteered to be a subject in a study on the effects of experimental psychosurgery (amygdalectomy) on aggressive behavior. His consent was approved by two separate committees, one of which approved the nature of the experimental design, the other the adequacy of the consent. However, prior to surgery, a local attorney (Kaimowitz) sought to release the patient from both the study and the hospital. The court concluded that valid consent for the experimental procedure had not been given, because of the circumstances of involuntary confinement, the patient's institutionalization and the experimental nature of the surgery. The court thus disallowed the patient's participation in the study (and ultimately released the prisoner/proposed patient).

Legally, the case established the previously mentioned three-part test of informed consent. The court in citing *United States v. Karl Brandt* apparently drew this test from the first principle of the Nuremburg

Code.[77] That principle enumerates the elements of "voluntary" consent: the legal capacity to give consent, the ability to exercise free power of choice, the possession of sufficient knowledge of the subject matter to make an enlightened decision. The *Kaimowitz* court thus stated that "competency requires the ability of the subject to understand rationally the nature of the procedure, the risks, and other relevant information" and that the patient's mental problems, his confinement and his institutionalization might decrease his competency.[62] The court further stated that because the proposed surgery was experimental, the knowledge of the risks involved was uncertain; and hence, the patient could not have given knowledgeable consent. As to voluntariness, the court stated:

> It is impossible for an involuntarily detained mental patient to be free of ulterior forms of restraint or coercion where his very release from the institution may depend upon his cooperating with the institutional authorities and giving consent to experimental surgery.[62]

Problems

This three-part test of informed consent simultaneously solves and creates problems for research. By precisely detailing relatively clear standards it points the way toward more refined and implementable guidelines. However, it also creates obstacles for research: first, given the notoriety of the opinion, it is reasonably likely that portions of its broad language may be incorporated into decisions beyond Michigan; second, the language concerning knowledge would appear to make any clinical investigation where the results are uncertain nearly impossible; third, the language concerning competency would appear to proscribe research with psychotic, retarded, unconscious, demented, delirious, or pediatric subjects; and, fourth, the court periodically confused its own carefully delineated concepts of knowledge, competency, and voluntariness. Thus, each of the *Kaimowitz* criteria merits discussion.

The *Kaimowitz* court dealt first with competency. It held that competency requires the ability to understand the nature of the procedure, the risks and other relevant information. Though the decision appears to hold that mental patients as a class are incompetent, a more critical reading suggests that competency is dependent upon the specifics of the given case. Unconscious, delirious or demented patients by definition cannot understand the risks and thus, by this test, are considered incompetent to give informed consent. For these patients, the law recognizes as valid the vicarious consent of a third party, providing the contemplated procedure is not experimental.[78,79] Under the *Kaimowitz* tests, the investigator appears to have the responsibility of determining whether the particular patient can fully comprehend the proposed procedure and its risks. This task is clearly one to be

approached with great caution, considering the moral and legal risks. The problem is compounded by the wide variations in psychotic patients' mental status over time.

The court's second requirement for informed consent was knowledge of the risks. By holding that informed consent cannot take place where risks (and thus knowledge) are uncertain, the court rendered informed consent nearly unobtainable in the experimental situation. Its opinion appears to be based on the assumption that where competency is in doubt, the risks should be more explicit if informed consent is to be allowed. With well-established procedures, the requirement of knowledge is of little moment. With more untested procedures though, particularly if competency is in doubt, this requirement is very difficult.

The court also ignores the fact that psychotic patients may not react as non-psychotic ones do. With rational patients, complete disclosure of experimental treatments and their risks is generally appropriate. However, for some psychotic patients, certain kinds of procedures sound so irrationally frightening that consent becomes virtually unobtainable. If the risks are low, the benefits great, and the procedure frightening, complete disclosure to psychotic patients becomes quite problematic. By implication, the *Kaimowitz* decision makes experimentation (even with rational patients) or treatment of psychotic patients (even in a non-experimental situation) virtually impossible if the opinion is read literally.

The third requirement of voluntariness has received much authoritative discussion, notable in the context of experimentation with prisoners.[80-83] The *Kaimowitz* decision, in disallowing experimentation with involuntary subjects, reaffirms the principles previously elaborated by the Nuremburg Trials,[77] the Declaration of Helsinki,[84-87] the British Medical Research Council,[88] the American Psychiatric Association,[89] and the American College of Neuropsychopharmacology.[90] For most research, even with psychotic patients, this is not a problem because investigators are increasingly reluctant to use captive subjects.

At several points in the opinion the court appears to mix these three criteria of informed consent. This is unfortunate because the major contribution of *Kaimowitz* is its delineation of specific requirements for informed consent. For example, when it states that institutionalization might decrease competency, it confuses competency with voluntariness. Later, in holding that where the knowledge of the risks is uncertain informed consent cannot take place, the court seems to assume that where competency is questionable, the risks must be more explicit. Thus, the court appears to confuse knowledge with competency.

A final dilemma is posed by recent laws which are overturning earlier legislative presumption that mental patients do not have the capacity to consent.[91] Competency is thus becoming a rebuttable presumption, *i.e.*, it is assumed until established to the contrary.[92] In most jurisdictions, psychiatric patients may now contract, make wills and vote.[93] Excepted

are those patients whom the state has previously (*via* a formal hearing) found incompetent.[94] Presumably, one of the mental patients' new rights is the right to enter into experimental therapy. Because the *Kaimowitz* decision makes the capacity to consent dependent upon the case-by-case determination of competency, knowledge and voluntariness (and thus subjects each consent to scrutiny, rather than assuming adequacy of consent), it conflicts with the clear trend of the law.

One way to make sense of what appears, at least in retrospect, to be rather broad — and at times sloppy — language on the part of the court, is to remind oneself of the legal maxim: hard cases make bad law. Probably, the *Kaimowitz* court was more concerned with the specific results (stopping the proposed surgery) than in carefully defining, from the social policy perspective, the extent to which knowledge requires certainty of the risks. Indeed, it is difficult to imagine that the court meant to stop, in the wholesale fashion which a literal reading would imply, all medical experimentation where risks are uncertain. Future courts in adopting the *Kaimowitz* criteria need to be explicit about this most troubling aspect of the case, *i.e.,* need to allow for research treatments where risks are uncertain.

Clinical Illustration

Many of these issues are raised in the following clinical example.

The patient is a 34-year-old, unemployed, single, Caucasian male with a 17-year history of schizophrenia. He was admitted to the locked ward of a local Veterans Administration Medical Center after being placed on a 72-hour hold (involuntary commitment) as gravely disabled.[95] Two days after admission he was evaluated to determine his suitability to participate in a study assessing an experimental treatment for schizophrenia. He was found suitable because of his severe and chronic schizophrenic symptoms.

It was explained to the patient that he was being considered as a candidate for the Research Ward, where he would have to be a voluntary patient to participate. After hearing about the pleasant physical surroundings, he agreed. He was then told that to participate he would need to plan on a four-month hospitalization, during which, with his consent (though he could withdraw at any time), he would be treated with experimental medications.

After a thorough medical and psychiatric evaluation, the patient was informed of the nature of the proposed research and the need to obtain the signed consent forms. The patient was most willing to sign each of the consent forms, without even hearing the nature and risks of the proposed procedures. These aspects were, however, discussed before he was allowed to sign. His willingness may have been due to his relief at being removed from the locked ward. Given the patient's level of delusions, hallucinations and loosening of associations, it is questionable that much understanding took place, in spite of the numerous

explanations he received.

Believing that, at best, consent in form but not in substance had been obtained, the investigators considered filing for a conservatorship and having the conservator, if willing, sign vicarious consent forms for the patient. The patient, with whom this was discussed, vehemently opposed such a filing, for it would have required that he be formally adjudicated as gravely disabled (*i.e.,* incompetent).[96]

Because the investigators considered the risks slight, and because the potential benefits seemed considerable in light of the patient's 17-year history of chronic symptoms, only partly responsive to neuroleptics, the investigators decided to include the patient in the investigation.

The patient's mental status changed little during the initial two-week drug-free period. During the two-month period of treatment with the experimental medication, there was again little change in symptomatology. The patient was then re-started on neuroleptic therapy and (sadly) remained severely symptomatic.

This case has been described because it is among the most challenging. Had the patient had a legally appointed conservator/guardian who was willing to sign the requisite consent, then, at least from a legal standpoint, the case would have been less difficult. Conversely, had the patient been periodically intact, even if only during the explaining of the procedures and the signing of the consent, then one could feel more comfortable in honoring his protestations against filing for a conservatorship and in accepting the validity of his consents. Ironically, the severity and chronicity of this man's illness make him an ideal subject, both from the standpoint of minimizing the risk of prolonging his illness by withholding known and effective treatment, and from the perspective of having a subject whose symptoms are sufficient to be accurately rated. Thus, the problems posed by this case are relatively common in research with psychotic patients.

Ultimately, the reason that legal and ethical principles seem to break down in cases such as this is that the dilemma they pose is genuine. Though it is comforting to speak of research being a collaborative effort between responsible, knowledgeable investigators and informed, consenting participants,[48] a more realistic view is that this is an ideal seldom reached,[97-99] and essentially unreachable with many psychotic patients.[100] The core of society's conflict about safeguarding psychotic patients' rights is that society's wishes are ambivalent. The wish to guarantee effective, timely and compassionate treatment must always be reconciled with the desire to further basic understanding and to test potentially more effective and less dangerous treatments.[101] Sometimes these ambivalent goals are oppositional; in such cases informed consent doctrine may become convoluted or even contradictory. This is the irony of the *Kaimowitz* criteria: that, at a time when state courts and legislatures are expanding the rights of mental patients by abolishing preexisting presumptions of incompetency, the court has adopted a

very restrictive test of informed consent which severely limits that ability of mental patients to self-determine their treatment needs.

Proposals and Conclusions

The initial step in defining informed consent guidelines is recognizing that significant, but not insurmountable, problems exist. These problems are presently manifested by researchers who elevate the form of consent over its content, and by courts which rationalize a decision without carefully detailing the requirements of informed consent. Certain tentative solutions can be suggested.

First, all concerned need to reject the extreme remedies.[102] Because of the persuasive reasoning articulated during the Nuremburg Trials, few would support experimentation without consent. Similarly, one needs to reject the notion that experimentation without detailed consent is always morally wrong. Such a position unrealistically stifles research into those conditions where subjects by definition are unable to judge the information and make an informed decision.

Second, the component requirements of informed consent need to be more precisely delineated; the courts need to stop confusing voluntariness with competency, and knowledge with understanding. Several recent commentators have proposed models of informed consent which extend the *Kaimowitz* approach.[4,7] One way to do this is to articulate more precisely the components of informed consent, as in Figure 1.

It depicts the three broad requirements of informed consent and categorizes the various components of each. Competency and voluntariness are conceptually straightforward, though practically complex at times. Knowledge, however, embodies several disparate elements. Specifically, the presentation includes not only what is said in fact, but what should be said, as outlined by a variety of legal tests.[103] The courts have employed at least three tests of what should be said: what the reasonable patient would want to know or consider,[72] what the reasonable physician would disclose to the patient,[19] and what the physician in the community does disclose.[104-106] The courts need to standardize on one of these tests — preferably not the last, for such a "community" standard unrealistically leaves disclosure solely in the hands of physicians.

FIGURE 1
COMPONENTS OF INFORMED CONSENT

I. Competency — the ability to understand rationally
   A. Rationality includes
      1. Intelligence
      2. Judgment
      3. Awareness
   B. Legal Standards
      1. Generally presume competency unless:
         a. Previous adjudications of incompetency
         b. Less than a specific age, *e.g.*, children

II. Knowledge of the protocol
  A. The "facts"
    1. The risks
      a. Harmful effects of the procedure(s)
        i. Generally — *e.g.,* the new medication exacerbates existing symptoms
        ii. Idiosyncratically — *e.g.,* the patient develops anaphylaxis from medication previously well-tolerated
      b. Harm of delaying known effective treatment
      c. Unnecessary exposure to other risks
        i. Intrinsic — *e.g.,* poorly designed protocol subjects patient to risks without anticipated benefits occurring
        ii. Extrinsic — *e.g.,* patient on research ward assaulted by another patient
    2. The benefits
      a. To the subject
        i. Cure or treat subject's preexisting condition(s)
        ii. "Moral" benefit of helping others
      b. Helping others with similar condition(s)
      c. Helping society by increasing knowledge
    3. The procedures
      a. Nature, duration and purpose of experiment
      b. Inconveniences reasonably expected
  B. The presentation
    1. Completeness
      a. Legal standards of completeness
        i. Information that "reasonable patient" would need to know in order to decide
        ii. Amount of disclosure of reasonable practitioner
        iii. Amount of disclosure of practitioner in community
        iv. Exceptions
          A. Risks likely to be known by the average patient, *e.g.,* no pregnancy after hysterectomy
          B. For patient's mental state, *e.g.,* where usual disclosure would seriously aggravate patient's condition (experimental procedure not contemplated)
    2. Honesty
    3. Communication
      a. The subject's sophistication
      b. The investigator's ability to translate information into patient's terms
    4. Comprehension — legal tests of knowledge
      a. Objective — patient presumed to know what reasonable patient knows and would know after explanation
      b. Subjective — patient's "actual" comprehension needs to be ascertained by practitioner

III. Voluntariness
  A. No improper inducements
    1. Release from unpleasant circumstances
    2. Favored treatment
    3. Money(?)
  B. No coercion
    1. No threats of force to subject or to others
    2. No force to subject or to others

Third, as Wolfensberger has written — the concept of risk-benefit may be sensibly applied to suggest the desirable degree of informed consent safeguards.[50] He proposes disclosing more where the risks are greater, irrespective of benefit; and disclosing more than ethical considerations alone require in emotionally charged arenas, *e.g.,* with children, prisoners, psychotics or controversial treatments such as electroconvulsive therapy. When there is doubt about the degree of proper disclosure, he sensibly argues that one should err on the side of "overdisclosure."

Fourth, limits need to be placed on experimentation with human subjects beyond those of informed consent alone.[107] Capron espouses limiting the risks, the participants and the damages.[52] Risks could be limited, for example, in evaluating a new neuroleptic, by testing the drug for adverse side effects in non-psychotic patients,and only if it is adequately safe, proceeding to trials with psychotic patients. Participants could be limited by deciding *a priori* never to do research with certain classes of institutionalized subjects, and/or by disallowing economic or other "improper" inducements to participants. Damages could be limited by insuring, *via* peer review, that experiments are well designed, and/or by creating a no-fault system of compensation.[108]

Fifth, assessing the adequacy of informed consent needs to be segregated from supervising the soundness of research designs and from determining the necessity of conducting the proposed research in human subjects. Such a division has recently been proposed by several commentators and subsequently incorporated into the requirements for ADAMHA funding.[8,51] It could have at least two benefits: increasing the likelihood that informed consent judgments are reached impartially, and allowing the committees for each task to be composed of those most expert and sensitive. Specifically, the physician(s) assessing the proposed subject's competency should generally be a disinterested third party, *i.e.,* not part of the investigational team.

Sixth, the problem of vicarious consent needs to be faced. To the extent that informed consent doctrines serve legally to insure that each human being determines what shall be done with his own body, vicarious consent fails, for when it is invoked, another decides. Yet, eliminating vicarious consent altogether is not a practical solution, for though some research might continue, much — that with children for example — would have to cease.[57,58] More sensibly one could limit vicarious consent by developing new standards detailing the contexts in which it could be properly employed.[109]

Seventh, empirical research on the costs (human) of informed consent needs to be encouraged. Several commentators, reasoning from the damage to subjects caused by placebos, have recently underscored the costs of broad disclosure to patients and proposed more limited disclosures.[110] However, the placebo literature is not directly in point. And, just as no single test of competency is adequate,[7] it is unreasonable to argue, even if continued empirical studies support the notion that some informed consent disclosures harm some subjects, that more experimental subjects should not have fairly broad disclosures.

Eighth, medicine needs to acknowledge that ethical issues have frequently received short shrift.[47] Barber's extensive reviews of medical investigators decision-making process suggest that attention to ethical issues is essential, both in medical schools and subsequently in practice.[111,112] Physicians should not abdicate ethical issues to ethicists, attorneys, courts, and regulatory and legislative bodies, for clinical

perspective is essential and needs discussion.[113]

Informed consent guidelines are not yet precise. The balance (between the individual right to optimal immediate treatment and the public goal of more complete understanding and better future treatment) is still uncomfortably fluid. The proposals outlined here are thus tentative. More radical approaches, such as the casting aside of informed consent doctrines do not seem judicious.[53,114] For though recent research suggests that only partial comprehension takes place when physicians attempt to inform, such attempts are essential if research is to involve investigator-subject collaboration.[115]

Lastly, it is important that psychiatry consider informed consent something other than a gratuitous legal obstacle. Decisional (*i.e.*, court-determined) law occurs in a specific context and in the public view; as such it tends to produce guidelines rather than firm rules. At best such guidelines reflect a broader consideration of social policies and ethical issues than researchers (or physicians) can readily command.[116]

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