TOWARD AN INFORMED DISCUSSION OF INFORMED CONSENT: A REVIEW AND CRITIQUE OF THE EMPIRICAL STUDIES*

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ABSTRACT

Empirical studies of informed consent, or of some aspect of informed consent, have proliferated in recent years. The studies provide some useful information about the manner in which informed consent is obtained and some of the barriers to the operation of the legal requirement. For a variety of methodological, conceptual, and pragmatic reasons, however, empirical findings currently offer no conclusive evidence that informed consent either is or is not feasible.

Because of the willingness of lawmakers to rely on empirical studies and the extensive and often unquestioning faith in anything labelled "scientific," there is a need for great caution in making informed consent policy on the basis of the findings of these or similar studies. On balance, with some notable exceptions, the empirical studies of informed consent are worse than anecdote and speculation because their scientific veneer may mislead lawmakers into according them undue importance.

Although a factual basis for the debate about informed consent is

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much needed, the issue of whether the legal requirement is desirable is ultimately a matter of values to be determined by considerations other than those of practicability. Informed consent policy should be made largely on the basis of values, informed but not dictated by sound social science inquiry and other forms of knowledge.

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I. INTRODUCTION

Informed consent: a myth; a fiction; there's no such thing; impossible to obtain; patients don't want to know; it frightens them; it confuses them; doctors know what's best for patients.[1]

Informed consent: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body;"[2] "allows patients to chart their own course understandably."[3]

1. *See generally* Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 413-16.
2. Schloendorff v. Soc'y of N.Y. Hosp., 211 N.Y. 125, 129, 105 N.E.92, 93 (1914).
3. Canterbury v. Spence, 464 F.2d 772, 781 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

The debate about the advisability and practicability of informed consent to medical care began shortly after the birth of the doctrine itself,[4] and the controversy has not stopped raging since. Fueled substantially by speculation, anecdote, and ideology,[5] occasionally there has been another ingredient in the debate: "fact." Slowly at first, more rapidly in recent years, informed consent has itself become the subject of empirical inquiry. Conducted primarily by physicians, interdisciplinary teams including a physician, or social scientists, there are now dozens of empirical studies of various aspects of informed consent.

A factual basis for the debate about informed consent is much needed. Although ultimately the desirability *vel non* of the informed consent doctrine, indeed of most legal requirements, is a matter of policy, politics, and values, the practicability of the doctrine is a relevant consideration in evaluating its desirability.

The empirical studies of informed consent may also illuminate a larger debate of which informed consent is only a small part. Informed consent is a kind of legal regulation based upon disclosure. Like all disclosure regulation, informed consent seeks to regulate the *manner* of decisionmaking—in this case, medical decisionmaking—but not the outcome. It is an ingredient of the efficient operation of a laissez-faire decisionmaking system, not a replacement for such a system. In short, it epitomizes much of legal regulation today by taking a mixed market approach of attempting to make the free market system work in a political economy characterized by massive inequalities of information.

Whether or not disclosure regulation works is of immense public importance. The operation of such regulatory systems involves a substantial commitment of resources, which if they do not achieve their ends, might better be devoted to other forms of regulation or to no regulation at all. Furthermore, the imposition of legal requirements that are inefficacious and wasteful of scarce resources may foster contempt for law in general. Thus, before lawmakers either wholeheartedly embrace or reject disclosure regulation, effort should be made to evaluate the success of existing disclosure regulation.

As important as these validation efforts are, there is one note of caution that must be sounded. Ordinary citizens and lawmakers alike, as creatures of the twentieth century, place an extensive and often unquestioning faith in "science." Though this faith may be somewhat diluted when "science" is modified by "social," labelling the studies of informed

4. *See, e.g.*, Kelly, *The Physician, the Patient, and the Consent*, 8 KAN. L. REV. 405 (1960); McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549, 586-97 (1959); Powell, *Consent to Operative Procedures*, 21 MD. L. REV. 189 (1961).

5. In recent years the concept of informed consent increasingly has come under the scrutiny of both the medical profession and the public. . . . The approaches [of journal articles on informed consent] have ranged from the pedantic to the inflammatory, the quality from the inpenetrable to the flatly erroneous. Many of the conclusions reached have been little more than opinions, seldom buttressed with facts or objective observations.

Woodward, *Informed Consent of Volunteers: A Direct Measurement of Comprehension and Retention of Information*, 27 CLINICAL RESEARCH 248, 248 (1979).

consent "scientific" imparts a presumption of validity which is often insurmountable, even when unwarranted.

In this Article, we will present the findings of the empirical inquiries into the operation of the informed consent doctrine in clinical practice. We are unwilling, however, to accept these findings at face value—that is, to accept them as truth—without subjecting them to critical examination.

We continue to be surprised at the breadth of the interest in informed consent as a topic of empirical investigation.[6] To the casual observer, it would appear as though there is a vast amount of knowledge about the operation of informed consent. In a sense, there is. But if we are to do more than take these findings at face value, we find that much of what purports to be fact is of dubious validity. The empirical investigations of informed consent are so riddled with conceptual, methodological, and ideological flaws that the sum and substance of the corpus of their findings are of questionable worth.[7] Because of the manner in which many studies are either designed, conducted, or reported, we believe that it is impossible for the discerning reader of these studies to make independent determinations of their validity.[8]

What began as an effort on our part to report on what we do and do not know about informed consent[9] has been partially transformed into a plea to current and potential investigators of informed consent not to repeat the conceptual, methodological, and ideological errors of many of the existing studies. This requires not only a thorough knowledge of empirical methods, but also a far better understanding of the problem under investigation—informed consent—than many investigators seem to have.

Because of the questionable validity of many of the findings of the informed consent studies, lawmakers who seek to rely upon an empirically generated body of knowledge in making informed consent law must proceed cautiously and critically. It is becoming increasingly less unusual for courts in general to acknowledge their reliance upon empirical studies.[10] Although this tendency has not been particularly apparent with respect to judicial lawmaking about informed consent,[11] courts in a closely related

6. In fact, the preparation of this Article has been substantially delayed by the continuing stream of new empirical studies, as well as by the discovery of older studies that have some bearing on the issue but which are often indexed or titled in such a way that our awareness of their existence has been delayed. Indeed, we surmise that there must be a large number of studies having some bearing on the subject of informed consent which have eluded our attention, but we are satisfied that we have reviewed most of the major ones and a large number of the less significant ones too.

7. *See infra* notes 22, 109-14 and accompanying text.

8. They may be accurate portrayals of how informed consent operates, but they may not be. We do not believe that we can conclude definitively that most, or many, or even some of the findings are worthless. Rather, we are convinced that in most cases it is impossible to determine whether the findings of the studies are correct or not.

9. Meisel & Roth, *What We Do and Do Not Know About Informed Consent*, 246 J.A.M.A. 2473 (1981).

10. *See, e.g.*, Loftus & Monahan, *Trial by Data: Psychological Research as Legal Evidence*, 35 AM. PSYCHOLOGIST 270 (1980); Tanke & Tanke, *Getting Off a Slippery Slope: Social Science in the Judicial Process*, 34 AM. PSYCHOLOGIST 1130 (1979).

11. Meisel & Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407 (1980). Although 24 states have enacted informed consent statutes,

area, the right of involuntarily committed psychiatric patients to refuse treatment, have exhibited a willingness to give credence to empirical studies.[12]

Our foremost purpose here is to delineate what is known about how informed consent operates in the clinic and how, if at all, that diverges from the legal vision of informed consent. We will also point out aspects of the doctrine which have been subjected to little or no empirical scrutiny and which could profit from some study. Finally, we will examine those findings about informed consent which are of questionable validity because of deficiencies in conceptualization or execution

II. METHOD OF ANALYSIS

A. *The Relevant Literature*

The threshold problem in reviewing and reporting on the findings of empirical studies of informed consent is the identification of the studies. This is more difficult than it might seem. There is a literature of informed consent so large that it can only be characterized as vast. There are a number of scholarly treatments of the subject, primarily in law reviews but also in medical journals and to a lesser extent in the social science literature. There are a large number of practitioner-oriented articles and anecdotal and case reports in the medical literature. There are also empirical studies, almost exclusively in medical and social science journals.[13]

Besides the articles that deal expressly with informed consent, there are also several bodies of literature which deal with closely related topics and illuminate some aspects of informed consent.[14] We have for the most

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the documented legislative history of these statutes is so sparse, indeed, almost nonexistent, that it is impossible to know the extent, if any, to which legislators have relied upon empirical studies.

12. *See, e.g.*, Rogers v. Okin, 478 F. Supp. 1342, 1360 (D. Mass. 1979), *aff'd and modified*, 634 F.2d 650 (1st Cir. 1980), *vacated and remanded*, 102 S. Ct. 2442 (1982); Rennie v. Klein, 462 F. Supp. 1131, 1137-38 (D.N.J. 1978), *injunction granted*, 476 F. Supp. 1294, 1298, 1306 (D.N.J. 1979) (citations to empirical studies on the efficacy and/or side effects of psychiatric medications), *modified and remanded*, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 102 S. Ct. 3506 (1982).

13. In addition to the journal articles, there are also some monographs reporting empirical studies of informed consent. We will systematically review only one of them here, that of Bradford Gray. B. GRAY, HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION (1975). Three other monographs represent the reports of the research group of which we are members. We will not include the findings of those studies here in any comprehensive way. *See* C. LIDZ, A. MEISEL, E. ZERUBAVEL, M. ASHLEY, R. SESTAK & L. ROTH, INFORMED CONSENT: A STUDY OF DECISION-MAKING IN PSYCHIATRIC TREATMENT (1983) [hereinafter cited as C. LIDZ]; Lidz & Meisel, *Informed Consent and the Structure of Medical Care*, in 2 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 317-410 (1982); Appelbaum & Roth, *Treatment Refusal in Medical Hospitals*, in 2 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 411-77 (1982). One other survey that we have not reviewed is Boyle & Brounstein, *Views of Informed consent and Decisionmaking: Parallel Surveys of Physicians and the Public*, in 2 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 17-316 (1982) (survey by Louis Harris and Associates).

14. There is a literature of "health education," dealing with the movement to make "consum-

part, however, confined ourselves to the literature which deals with informed consent per se. This choice has been dictated more by pragmatic than theoretical concerns. There is much that is relevant to informed consent in the other bodies of related literature, but the enormity of the task of reviewing all of this literature has dictated that we follow a narrower approach.

We have also, for a variety of reasons, confined ourselves to a review of the *empirical* literature of informed consent, that is, articles reporting studies of the operation of an aspect of informed consent or of the entire medical decisionmaking process, in which data is collected in a systematic way. This is not to say that we have reviewed only studies of informed consent which conform to generally accepted rules of sound scientific inquiry. Indeed, many of the empirical studies do not so conform, which is one of the chief findings of this undertaking. There is, no doubt, a great deal to be learned about the practicability of informed consent from the anecdotal and theoretical literature of informed consent. Again, not least among our considerations in the decision to exclude review of such literature is the magnitude of the task of reviewing all of the literature[15] and the fact that our primary goal is to attempt to describe the reality of the medical decisionmaking process.

B. *Organization and Analysis of Data: The Conceptual Model and Components of Informed Consent*

For purposes of analysis, the doctrine of informed consent can be broken down into several components. Although there are some minor differences in how these components are characterized, there is relative agreement as to what they are. We have elsewhere described a conceptual model of informed consent having the following components:[16]

(1) *Information or Disclosure*. Certain information must be provided by the doctor to the patient. Patients in general are presumed to know certain information; a particular patient, on the basis of personal experience, may be presumed to know additional information.

(2) *Competency*. There is a legal presumption that patients have the

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ers" of "health care services" more knowledgeable about their illness or injuries, the prescribed treatments, and prevent measures. There is a closely related literature of "compliance," dealing with the ways in which to get patients to carry out the prescriptions for therapy given them by doctors and the reasons why patients often do not comply. There is a literature about the importance of good "communication" in the doctor-patient relationship and about patients' attitudes toward "communication." There is also a variety of other articles dealing with subjects related to one or another area of medical practice that illuminate small aspects of informed consent.

15. Of course, few, if any, of the studies are explicitly labelled "scientific" or "empirical." For present purposes, we have treated a study as "empirical" if it reports on the operation of the informed consent doctrine in medical practice or in medical or social science research. Empirical studies thus stand in contrast to theoretical articles on informed consent from either a medical, legal, or ethical perspective. At the threshold, we have established no methodological requirements for a study to be considered. Rather, if a study reports on the *operation* of the informed consent doctrine, it meets our criterion for inclusion in this review. If its methodology renders its findings suspect, that is a matter for subsequent criticism but not for initial exclusion.

16. *See* Meisel, Roth & Lidz, *Toward a Model of the Legal Doctrine of Informed Consent*, 134 AM. J. PSYCHIATRY 285 (1977) [hereinafter cited as Meisel].

capacity to comprehend the information that the doctor discloses.[17] Exactly how competency is to be determined is not clear but if a patient is not competent any decision that he makes will not be considered legally valid.[18]

(3) *Understanding*. The judicial decisions implicitly assume that a person who is competent, when provided with information, will understand it. Since competency involves the capacity to understand, competency and understanding are closely related components of informed consent.[19]

(4) *Voluntariness*. The decision that a patient makes must be freely arrived at without undue pressure or coercion.[20]

(5) *Decision*. The patient must actually decide whether to accept or refuse treatment.[21]

Taken together, these five components comprise the doctrine of informed consent, which is the legal model of the medical decisionmaking process. We will organize the empirical findings about informed consent around these five components. We freely acknowledge that these components are useful largely for analytic purposes. In the actual medical decisionmaking process, it is often difficult to separate the components. Indeed, even in theory, there is a great deal of overlap among the various components of informed consent.[22]

III. DISCLOSURE: WHAT PATIENTS ARE TOLD

The disclosure of information material to the medical decisionmaking process is the heart of the informed consent doctrine. Indeed, disclosure is what distinguishes "informed consent" from the earlier and simpler requirement of "consent" to medical care. Standard litany in almost all jurisdictions is that doctors must, to obtain *informed* consent, disclose the risks and benefits of treatment, the alternative forms of treatment, and the nature of the procedure—or at least that degree of information about these topics material to the patient's decisionmaking process.[23]

That the law requires disclosure does not, of course, mean that disclosure actually occurs, nor, if it does occur, can there be any assurance that it occur in the nontechnical manner required by law.[24] To understand how informed consent operates in the clinic rather than in the court, we need to know what doctors tell patients and how it is done.

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17. Grannum v. Berard, 70 Wash. 2d 304, 307, 422 P.2d 812, 814 (1967).

18. RESTATEMENT (SECOND) OF TORTS § 892A(2)(a) (1977).

19. Indeed competency and understanding may be the same thing, depending on how each is defined. *See* Roth, Meisel & Lidz, *Tests of Competency to Consent to Treatment*, 134 AM. J. PSYCHIATRY 279 (1977) [hereinafter cited as Roth]; Meisel, *supra* note 1, at 439-53.

20. RESTATEMENT (SECOND) OF TORTS § 892B(3) (1977).

21. A decision may be manifested by conduct as well as verbally. *Id.* § 892(2).

22. *See infra* section IV, at p. 284.

23. The most significant development in the law regarding consent to medical treatment involves the physician's duty to disclose information to the patient prior to obtaining authorization for such treatment. *See* Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51, 80 (1977); *see also* Plant, *An Analysis of "Informed Consent,"* 36 FORD L. REV. 639 (1968).

24. Cobbs v. Grant, 8 Cal. 3d 229, 239-41, 104 Cal. Rptr. 505, 511-12, 502 P.2d 1, 7-8 (1972).

It is therefore regrettable that so few investigators have undertaken a study of these matters. Worse, however, is that knowledge of what patients are told is an antecedent condition to the knowledgeable study of what patients understand, how they make decisions, and the degree of voluntariness with which those decisions are made. It is difficult, if not impossible, to evaluate other aspects of informed consent without knowing first what patients are told.[25]

A. *What Doctors Tell Patients*

An early study, seeking to determine the nature and extent of disclosure practices among surgeons, revealed that there was considerable variation in the amount and nature of information that was disclosed.[26] Some surgeons reported using common English while others used cryptic, technical language to describe the patients' conditions.[27] Some surgeons appeared to develop a personal disclosure pattern which they followed consistently, while others did not seem to follow any pattern.[28] In addition, there was a reported disparity in disclosure of the risks of a given procedure. One surgeon gave no indication that he had provided information regarding risks to any of his patients, while another indicated that the risk information he disclosed for the same procedure differed greatly from one patient to the next.[29]

Since there are no other studies of what doctors tell patients for purposes of obtaining informed consent,[30] we might drop the discussion and

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25. Because there are so few studies of what doctors tell patients, there is no need to embark on a detailed methodological critique at this point. There are a variety of ways in which investigators might go about studying what doctors tell patients. Potential methods include asking doctors what they disclose, asking patients what they have been told, and a number of ways of third-party observation of the disclosure process such as tape recording, sitting in on doctor-patient discussions, and observing via two-way mirrors. Each method has its pitfalls and each tends to compromise validity in certain ways, unless there is observation unknown to either doctor or patient, which presents ethical (and possibly legal) problems of its own. *See, e.g.*, Hawkins, *Patients' Reactions to Their Investigations: A Study of Five Hundred and Four Patients*, 2 BRIT. MED. J. 638 (1979). In this study, patients were asked what they had been told. The problem with this method is that the investigator does not find out what patients were actually told, but what they remember. Hawkins admits, as he must, that patients forget. *Id.* at 640; *see also infra* section IV(A)(2), at p. 286. He discounts this consideration, however, with the *obiter dictum*, unsupported by evidence, that forgetting "is less likely with diagnosis and tests than with explanations about the illness." Hawkins, *supra*, at 640.

Research which entailed undisclosed observation of contacts between doctors and patients, if funded by a federal grant or contract, would violate federal regulations governing research. *See* U.S. DEP'T HEALTH & HUMAN SERVS., Protection of Human Subjects, 46 Fed. Reg. 8366, 8386-87, §§ 46.101(b)(4) (1981). Such conduct might also be tortious. *See* RESTATEMENT (SECOND) OF TORTS §§ 652B, 652D (1977).

26. N. HERSHEY & S. BUSHKOFF, INFORMED CONSENT STUDY: THE SURGEON'S RESPONSIBILITY FOR DISCLOSURE TO PATIENTS (1969). While this is the only study reviewed that deals with what doctors tell patients for purposes of obtaining informed consent, the authors make it clear that they had no way of knowing whether the doctors actually told their patients the information reported for the study's purposes. Therefore, this is actually a study of what doctors said they told patients.

27. *Id.* at 32-33.

28. *Id.* at 31.

29. *Id.* at 31-34.

30. In making this claim, we exclude our own studies which have attempted to study disclosure. *See* C. LIDZ, *supra* note 13; Lidz & Meisel, *supra* note 13.

proceed to the next topic. There is, however, some empirical evidence of what doctors tell patients for other purposes, which, in the absence of more focused studies about informed consent, is worth considering. Although the findings of these studies will be presented in detail subsequently in this Article, one of these studies is summarized briefly here to provide an overview of the disclosure process.

Boreham and Gibson studied, largely by means of direct observation, patient consultations with four different doctors in their private offices in New Zealand.[31] They were not studying informed consent per se, but rather, whether doctors provide patients with information spontaneously or in response to patients' questions.[32] Doctors revealed diagnoses to more than eighty percent of the patients on first visits, but to less than twenty-five percent of patients on "follow-up" visits.[33] "Very few" patients questioned the doctor about the diagnosis, and "very few" patients were provided with any detailed explanation of their diagnosis.[34] When patients did ask questions, however, in all but one case the questions were answered, though we are not told how thoroughly or accurately. Patients at follow-up consultations were less likely to receive information about treatment than patients at initial consultations.[35] Although patients made more requests for information about treatment than about their diagnoses, these requests were still "rare."[36]

The overall conclusion of the investigators is that patients are not active in seeking information and doctors are not active in giving it.[37] Our

31. Boreham & Gibson, *The Informative Process in Private Medical Consultations: A Preliminary Investigation*, 12 SOC. SCI. & MED. 409 (1978).

32. Assuming for the sake of argument that the existence of a legal duty to provide patients with certain information does make a difference in what doctors tell patients, it is important to note that the status of the informed consent doctrine or its equivalent at the time that this study was conducted in New Zealand is uncertain at best. *See* Smith v. Auckland Hosp. Bd., [1964] N.Z.L.R. 241, *rev'd*, [1965] N.Z.L.R. 191. Although this case has been widely cited in other Commonwealth countries as establishing a duty to disclose, it has been accorded little importance in its country of origin, largely because of the reversal on appeal.

33. Boreham & Gibson, *supra* note 31, at 412.

34. *Id.*

35. "Apparently, the assumption was made by the doctors that follow-up patients are fully aware of the nature of their treatment, or at least as aware as they wish to be." *Id.* at 414.

> Patients having follow-up consultations were more likely to be given information concerning their condition but tended to get only very limited information [about things like whether their condition was improving or worsening, the causes, and symptoms]. While this might normally have been expected, given that the diagnosis had been made at an earlier date, the interviews conducted prior to the consultation indicated that the follow-up patients frequently had only a very incomplete understanding of [specific] items concerning the diagnosis.

Id. at 412.

36. *Id.*

37. "The . . . doctor is clearly the principal determiner of what information the patients receive. This does not occur because the doctor refuses to answer requests for information, but rather, because such requests are rarely made. When they are made, they are almost always answered." *Id.* at 414. Buchwald complains that a factor strongly militating against informed consent is the tendency of doctors to rule out procedures without even discussing with patients the risks involved and their benefits and alternative procedures. In fact, Buchwald believes that the risks and benefits to the individual may not be weighed at all. The physician may simply rule out the procedure "prematurely" due to a prejudice against using certain procedures, for example, bypass surgery. Buchwald, *True Informed Consent in Surgical Treatment of Morbid Obesity: The Current Case for Both Jejunoileal and Gastric Bypass*, 33 AM. J. CLINICAL NUTRITION 482 (1980).

own empirical investigations are in agreement with these findings,[38] as is the bulk of the literature on patient "compliance."[39]

B. *What Patients Ask Doctors*

The informed consent cases clearly establish that patients are not obligated to ask for information about medical procedures; it is the doctor's legal duty to take the initiative in making disclosure.[40] The spirit of the

38. C. LIDZ, *supra* note 13; Lidz & Meisel, *supra* note 13.

39. *See, e.g.*, Svarstad, *Physician-Patient Communication and Patient Conformity with Medical Advice*, in THE GROWTH OF BUREAUCRATIC MEDICINE 220, 225 (D. Mechanic ed. 1976). There has been a rather lively debate in the medical literature about whether to tell cancer patients their diagnoses, focusing on two subissues: (1) whether cancer patients want to be told their diagnoses, and (2) whether doctors should tell cancer patients their diagnoses. Though the debate is by no means over, the peak of this debate seems to have occurred prior to the early 1960's, at a time when informed consent was still in its gestational stage. A parallel debate has involved whether to tell terminally ill patients their diagnoses; certainly for a long time most cancer patients could have been (and might still be) considered "terminally" ill. Novack, Plumer, Smith, Ochitill, Morrow & Bennett, *Changes in Physician's Attitudes Toward Telling the Cancer Patient*, 241 J.A.M.A. 897 (1979).

In a 1961 article, Oken reviewed the literature and found in one study that 89% (n=100) of cancer patients wanted to know their own diagnoses. Oken, *What to Tell Cancer Patients: A Study of Medical Attitudes*, 175 J.A.M.A. 1120, 1120 (1961) (citing Kelly & Friesen, *Do Cancer Patients Want to be Told?*, 27 SURGERY 822, 825 (1950)). Samp & Curreri found that 87% of 560 cancer patients and families felt that a patient should be told his diagnosis. Samp & Curreri, *Questionnaire Survey on Public Cancer Education Obtained from Cancer Patients and Their Families*, 10 CANCER 382, 383 (1957), *cited in* Oken, *supra*, at 1120. In the Kelly study, only 73% felt that other cancer patients should be told their diagnoses. Kelly & Friesen, *Do Cancer Patients Want to be Told?* 27 SURGERY 822, 822-26 (1950), *cited in* Oken, *supra*, at 1120. This study revealed that a similarly large majority (82%) of patients who were "free of cancer" (without known cancer) would want to be told their diagnoses. Kelly & Friesen, *supra* at 823. See also Branch, *Psychiatric Aspects of Malignant Disease, CA.*, 6 BULL. OF CANCER PROGRESS 102 (1956), *cited in* Oken, *supra*, at 1120, for a finding that 48 of 54 noncancer patients would want to be told if they had cancer.

Although patients wanted to know their diagnosis, evidently doctors were not as eager to tell. The studies of what doctors told patients are almost mirror-images of what patients wanted to know. Whereas roughly 80% of patients wanted to be told their diagnosis, only 3% of doctors "always" told patients and 28% "usually" did so. More than half (57%) of the doctors "usually" did not and 12% "never" did. Fitts & Ravdin, *What Philadelphia Physicians Tell Patients with Cancer*, 153 J.A.M.A. 901, 902 (1953), *cited in* Oken, *supra*, at 1121.

Oken's own study of 219 doctors in 1961 found that almost 90% had a "strong and general tendency to withhold this information," Oken, *supra* at 1122, at that "[t]he modal policy is to tell as little as possible in the most general terms . . ." *Id.* at 1123. When questioning by the patient occurred, it almost "invariably [was] disregarded and considered a plea for reassurance. . . ." *Id.* Even when the questioning was "persistent," it was sometimes ignored. *Id.*

In a recent review article, Taub reports a seeming shift in physician's attitudes.

> Several studies have attempted to determine the utility of the therapeutic privilege. Some of them concern physicians' attitudes toward revealing the diagnosis of cancer to the patient . . . . When physicians were asked [whether they would reveal their diagnoses] in 1977, 97 percent said they would tell a cancer patient his diagnosis. The marked change in attitude was not based on any scientific findings about the effects on patients of informing them that they had cancer, but on the physicians' own unproven assumptions about those effects. The authors of the study attributed the change in attitude to numerous actors, including: the recent improvements in cancer therapy which rendered the prognosis more hopeful, the increased public awareness of cancer and the lesser amount of stigma attached to it, the recent upsurge of interest in death and dying, articles in the literature which favored telling the patient his diagnosis, the rise in the consumer movement, and the increasing public scrutiny of the medical profession. The practical requirement of obtaining the patient's consent to therapy was undoubtedly an additional factor.

Taub, *Cancer and the Law of Informed Consent*, 10 LAW, MED. & HEALTH CARE 61, 62 (1982).

40. Nonetheless it has been suggested that under some circumstances, the patient's failure to

doctrine nonetheless envisions a conversation between doctor and patient in which each gives and receives information in the full variety of ways that two human beings usually do when engaged in conversation, including asking and answering questions.[41]

The limited findings that exist show that patients do not extensively question their doctors. For example, in a research protocol for the treatment of depression, fourteen percent of subjects who had not been informed that treatment was randomly assigned and nineteen percent of those who had been so informed "explicitly sought more information about the treatment, its evaluation and the experimental nature of the program."[42] Korsch and Negrate report that the more than 800 mothers they studied in a pediatric emergency clinic also were "reticent about asking questions," indeed "disappointingly" so "in view of the anxiety and desire for more information that they expressed to interviewers afterwards."[43] Similar findings are reported by Lankton *et al.* in their study of patients scheduled for gynecologic surgery, in which none of twelve patients asked any questions about complications.[44]

Whatever the reasons for patients' reticence about asking doctors questions—status differentials, patients' beliefs that doctors are too important or too busy to talk to them, or the physical and emotional pain of illness—reliance upon patients to elicit information from doctors may not be a workable substitute for an affirmative obligation imposed on doctors to make disclosure.[45]

C. *What Patients Already Know*

The informed consent cases, and more recently the statutes, have recognized that some patients may possess some information about treatment before the doctor makes disclosure. Such information may be acquired in the ordinary course of one's life (these are referred to as "common" risks),[46] from one's specialized training[47] (some patients are medically

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ask questions may constitute contributory negligence. *See, e.g.*, Watson v. Clutts, 262 N.C. 2d 153, 136 S.E.2d 617 (1964), where the plaintiff admitted in her pleadings that she had been advised that the proposed surgery was serious and not without risk, but contended that her consent to the operation was obtained because of the physician's negligent failure to inform her of the " 'nature of the operation and its probable consequences.' " *Id.* at 158-59, 136 S.E.2d at 620-21. The court indicated that in this instance, if the patient desired to be further advised, "a simple request would have disclosed the surgeon's view as to adverse possibilities." Her claim was therefore not sustained. *Id.* at 160, 136 S.E.2d 621. *See also infra* note 49.

41. The spirit of informed consent is best captured in 1 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE & BIOMEDICAL & BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 36-39, *passim* (1982).

42. McLean, *The Effect of Informed Consent on the Acceptance of Random Treatment Assignment in a Clinical Population*, 11 BEHAV. THERAPY 129, 132 (1980).

43. Korsch & Negrete, *Doctor-Patient Communication*, 227 SCI. AM. 66, 73 (1972).

44. Lankton, Batchelder & Ominsky, *Emotional Responses to Detailed Risk Disclosure for Anesthesia: A Prospective, Randomized Study*, 46 ANESTHESIOLOGY 294, 295 (1977) [hereinafter cited as Lankton]; *see also supra* section III(C)(1), at p. 276.

45. *But see* OR. REV. STAT. § 677.097 (1977) (requiring doctors to make only limited and general disclosure and doctors to ask patients if additional information is desired).

46. The extent of the disclosure requirement has been defined by indicating that certain categories of information regarding risks need not be disclosed. The category most frequently men-

trained[48] or trained in related disciplines), or from one's prior experience as a patient.[49] We refer to the collectivity of this information, which the patient brings to the medical decisionmaking process from sources other than the doctor who is to render treatment, as "pre-knowledge." Few studies report findings about patients' pre-knowledge of treatment when patients first seek medical care, at least before the doctor begins to make disclosure.[50]

D. *Patients' and Doctors' Attitudes Toward Disclosure*

There is another group of studies which reports not on what patients have been told, but on patients' and doctors' attitudes toward receiving information and making disclosure respectively.

1. *Patients' Attitudes and Waiver*

The doctor's duty to disclose, imposed by the informed consent doctrine, is suspended under several circumstances.[51] One such circumstance occurs when a patient requests or otherwise indicates to the doctor that he does not wish to be informed—in other words, when the patient "waives" the right to be informed.[52] Although there have been no empirical investigations of waiver as such, the studies of patients' attitudes toward disclosure shed some light on the waiver exception to the disclosure requirement. Patients' attitudes have been investigated rather extensively relative to the

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tioned in this respect by the courts is that of "commonly known risks." Meisel & Kabnick, *supra* note 11, at 431. Thus "there is no need to disclose risks that are likely to be known by the average patient . . . ." Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 (1972).

47. *See, e.g.*, Nishi v. Hartwell, 52 Hawaii 188, 194-95, 473 P.2d 116, 120 (1970).

48. *See, e.g.*, Scaria v. St. Paul Fire & Marine Ins. Co., 68 Wis. 2d 1, 4, 227 N.W.2d 647, 649 (1975).

49. The physician's duty to disclose the risks of treatment does not extend to those risks "that are in fact known to the patient usually because of a past experience with the procedure in question." Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 (1972). In thus limiting the physician's duty to disclose information, the courts hold the patient responsible for exercising common sense on behalf of his own well-being. *See* Meisel & Kabnick, *supra* note 11, at 431. This is similar to a defense of contributory negligence. *See supra* note 40. A few courts have tempered the patient's duty by using a subjective test and asking whether the risk in question was in fact known to the patient. But the majority of jurisdictions utilize an objective test based on the knowledge of a reasonable patient, and some states permit this to be used as a defense by the physician. Meisel & Kabnick, *supra* note 11, at 431.

50. Boreham and Gibson report that patients did not have a "high level of knowledge concerning either their diagnosis or their treatment prior to the consultation" with their physician. Boreham & Gibsson, *supra* note 31, at 414. Epstein & Lasagna report that "[a]lmost without exception, the contraindications, precautions, and possible fatal reactions which could occur following aspirin ingestion were unknown" to participants in their study. Epstein & Lasagna, *Obtaining Informed Consent: Form or Substance*, 123 ARCHIVES INTERNAL MED. 682, 684 (1969). *See also* Chandler & Dugdale, *What Do Patients Know About Antibiotics?*, THE LANCET, Aug. 21, 1976, at 422.

51. *See generally* Meisel, *supra* note 1.

52. There are actually three different kinds of waiver. First, a patient may relinquish his right to receive information ("waiver of information") but still insist upon making the decision, though uninformed or less than fully informed. Second, a patient may wish to have relevant information, but after receiving it may decide that he would prefer for the doctor or some other person such as a family member to make the decision ("waiver of decision"). Finally, the patient may wish neither to be informed nor to decide ("waiver of informed consent"). *See generally* Meisel, *supra* note 1, at 453-60.

degree of attention paid to other aspects of informed consent, especially in light of the fact that so little study has been undertaken of *what* patients are told. Although several studies report that, on balance, patients want information and that it does not frighten them, there are a few which report contrary findings. As with most other aspects of informed consent, this rather nicely points out the inability to generalize widely from any particular study.

Alfidi's studies are interesting because they come to contradictory conclusions, which he forthrightly acknowledges. On the one hand, he found that eighty-nine percent of patients who were informed of the serious risks of angiography, without being asked whether they wanted to be informed, "appreciated" receiving the information.[53] However, in a later study in which he made disclosure contingent upon an affirmative response to an inquiry as to whether or not the patient wished to be informed of the risks of various diagnostic radiologic procedures, less than one-third of patients wanted to be told about risks.[54] Not surprisingly, even when patients indicate that they appreciate disclosure, they still report in significant numbers (slightly more than one-fourth) that they are made "less comfortable" by this information.[55]

Alfidi's first study,[56] where patients reported that they were pleased to have been informed, is supported by the findings of others.[57] Also, Alfidi's

53. Alfidi, *Informed Consent: A Study of Patient Reaction*, 216 J.A.M.A. 1325, 1328 (1971).

54. Alfidi, *Controversy, Alternatives, and Decisions in Complying with the Legal Doctrine of Informed Consent*, 114 RADIOLOGY 231, 233 (1975).

55. Alfidi, *supra* note 53, at 1328. Perhaps these two studies by Alfidi can be reconciled. In the 1971 study, the patients had already been given the information when they were asked to indicate their attitude toward disclosure; in the 1975 study, they had not yet been informed. Perhaps patients are inclined to view a *fait accompli* as a good thing, because there is nothing that can subsequently be done to erase the experience. An alternative explanation is that the first study is more likely to be valid because it measures patients' attitudes toward a *real* past event, whereas the second study is hypothetical in that patients are asked no whether they were grateful for information received, but whether they wanted information at all, and information that was characterized as relating to "significant hazards," a phrase with negative connotations.

56. *See supra* note 55.

57. Rosenberg reports that when 100 subjects were given a hypothetical case of a man with a suspected brain tumor and had to determine whether he should undergo a cerebral arteriogram (a procedure with risks and benefits similar to those used by Alfidi, *Informed Consent and Special Procedures*, 40 CLEV. CLINIC Q. 21, 22 (1973)), about three-fourths of 800 patients indicated that a detailed discussion of risks would be helpful to making a decision, that it would not hinder them by worrying them, and that they preferred disclosure of complications and not merely of the nature of the procedure. Rosenberg, *Informed Consent: A Reappraisal of Patient Reactions*, 119 CALIF. MED. 64, 67-68 (1973). Similarly, in a group of 20 women undergoing elective plastic surgery (face-lift operations), only two mentioned that the possibility of complications frightened them. Goin, Burgoyne & Goin, *Face-Lift Operation: The Patient's Secret Motivations and Reactions to "Informed Consent,"* 58 PLASTIC & RECONSTRUCTIVE SURGERY 273, 278 (1976) [hereinafter cited as Goin].

Roling *et al.* report that 34% of patients (n=100) undergoing peroral endoscopy felt that full disclosure increased their apprehension. Roling, Pressgrove, Keeffe & Raffin, *An Appraisal of Patients' Reactions to "Informed Consent" for Peroral Endoscopy*, 24 GASTROINTESTINAL ENDOSCOPY 69, 70 (1977) [hereinafter cited as Roling]. Lankton *et al.* report that 25% (n=16) were frightened by disclosure of the risks of anesthesia. Lankton, *supra* note 44, at 295. It is interesting, however, that although 34% of Roling's subjects stated they were frightened, all agreed to the procedure. Roling, *supra*, at 70.

Among 53 adult patients who consented to treatment for themselves, and 107 parents who consented to treatment on behalf of their children, "most . . . stat[ed] they preferred detailed disclosures." Faden, Lewis, Becker, Faden & Freeman, *Disclosure Standards and Informed Con-*

finding in his third study,[58] that when disclosure is made contingent upon a request from a patient, such requests are not forthcoming even though the patients may wish to have the information,[59] is understandable in light of the findings about patient passivity in asking questions.[60] The studies have not explored the reason why patients do not ask questions, but it is likely that patients' trust, awe, and feeling of inferior status with respect to doctors explain their reticence.[61]

There are other studies that come to the general conclusion that patients do not want information. Lankton *et al.* found that patients who were given a detailed disclosure of risks of anesthesia stated that they would not like to have complete disclosure if they were to have surgery again.[62] One-fourth indicated that they had been frightened by the disclosure, and three of the sixteen frightened patients indicated that they had asked to have disclosure stopped while it was in progress.[63] These findings are in clear conflict with Alfidi's earlier studies.[64]

2. *Patient Satisfaction with Disclosure*

It is also surprising, in light of the large number of investigations of patients' attitudes toward disclosure, that there has been so little examination of patient satisfaction with disclosure that has already occurred. On the basis of interviews with 800 mothers of children who obtained care in a pediatric clinic, Korsch and Negrete report that "[n]early a fifth . . . of the . . . mothers felt that they had not received a clear statement of what was

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sent, 6 J. HEALTH, POLITICS, POLICY & LAW 255, 271 (1981) [hereinafter cited as Faden]. More than 95% of patients expressed a desire for detailed information in patient package inserts for an IUD, but high educational level and experience in a contraceptive trial may have affected subjects' high receptivity to detailed information. Benson, Gordon, Mitchell & Place, *Patient Education and Intrauterine Contraception: A Study of Two Package Inserts*, 67 AM.J. PUB. HEALTH 446, 447-48 (1977) [hereinafter cited as Benson].

In a West German study of the effect of detailed disclosure on cataract patients' attitudes, approximately 90% said that their confidence in the hospital was much increased after receiving the information. Leydhecker, Gramer & Frieglstein, *Patient Information Before Cataract Surgery*, 180 OPTHALMOLOGICA BAESL 241, 241 (1980) [hereinafter cited as Leydhecker]. In addition, "[m]ost patients (59%) felt they had *not* received sufficient information by the referring opthalmologist and most patients (67%) wanted *detailed* information." *Id.* at 244 (emphasis in original). No patient refused surgery after learning about the risks. *Id.*

58. Alfidi, *supra* note 54, at 233.

59. There are other studies in which, when asked, patients indicated a favorable attitude toward disclosure of information about treatment (especially risks). *See* Denney, Williamson & Penn, *Informed Consent: Emotional Responses of Patients*, 60 POSTGRADUATE MED. 205 (1976) (patients who were to undergo hysterectomies); Joubert & Lasagna, *Patient Package Inserts: I. Nature, Notions, and Needs*, 18 CLINICAL PHARMACOLOGY & THERAPEUTICS 507, 513 (1975) (81% of patients wanted to be informed about the possibility of even rare lethal side effects of drugs); Skillern, *A Planned System of Patient Education*, 238 J.A.M.A. 878, 879 (1977) ("patient education" in general). Finally, although not expressly related to informed consent, but highly significant, is a recent Gallup Poll that found that 82-92% of various groups of persons surveyed indicated that they would want to be told if they had a fatal illness. Blumenfield, Levy & Kaufman, *Do Patients Want to be Told?*, 299 NEW ENG. J. MED. 1138, 1138 (1978).

60. *See supra* notes 37-45 and accompanying text.

61. *See* Meisel, *supra* note 1, at 456-57.

62. Lankton, *supra* note 44, at 295.

63. *Id.*

64. Alfidi, *supra* note 53, at 1325 (majority of patients desired straightforward statements about complications); Alfidi, *supra* note 54, at 233 (two-thirds of patients did not wish to be informed of risks).

wrong with their baby, and almost half of the entire group were still wondering when they left the physician what had caused their child's illness."[65] They also found that there was a "substantial correlation" between mothers' satisfaction with what they had been told and compliance with the doctor's instructions for caring for the child.[66] Similarly, Hawkins reports that of 504 medical patients who had undergone standard medical or surgical diagnostic procedures such as biopsy, catheterization, endoscopy, and venepuncture, "[m]any . . . thought that they ought to have been better informed,"[67] and "[s]everal . . . complained that they were not told the results" of the tests.[68]

The level of patient satisfaction with receipt of information should not be mistaken for the level of patient understanding. As Gray cautions, "the expressed understanding of subjects . . . is not the same thing as real understanding. Subjects who had little or no understanding . . . sometimes believed that they understood things completely."[69]

3. *Doctors' Attitudes and the Therapeutic Privilege*

In the legal literature, the medical journal articles dealing with informed consent, and the informed consent case and statutory law, there are numerous discussions of the doctor's "therapeutic privilege" to withhold from patients information that the doctor believes would be injurious to the patient's well-being.[70] Yet despite the great deal of attention paid to this privilege—certainly far more attention than has been paid to any of the other exceptions to informed consent[71]—empirical investigations of the privilege are few in number.

At the threshold, it is important to determine whether doctors actually invoke the privilege. That is, can failures to make full disclosure be attributed in fact to the interests served by the privilege—the patient's well-being—or do doctors fail to make full disclosure for other reasons such as inadequate time, lack of interest in making disclosure, or possibly because patients manifest a wish not to be told? Neither of these questions has received much attention in the empirical studies of informed consent. However, a study by Faden and Lewis[72] found that doctors' own normative standards, rather than legal standards, determined the information routinely provided to patients. In other words, doctors were most influenced in determining what they would tell patients by what they believed would be in the patients' best interests. "[P]hysicians who believed that

65. Korsch & Negrete, *supra* note 43, at 69.
66. *Id.*
67. Hawkins, *supra* note 25, at 639.
68. *Id.* at 640.
69. B. GRAY, *supra* note 13, at 102.
70. *See* Meisel, *supra* note 1, at 460-70 (collecting legal and medical literature and cases); Meisel & Kabnick, *supra* note 11, at 452-53 nn.196-99 (tables 7 & 10) (collecting cases and statutes).
71. Meisel, *supra* note 1, at 460.
72. Faden, *supra* note 57. This study looked at what doctors thought the legal standards required of them in terms of providing information to patients, and compared what doctors themselves thought patients should be told with the information which patients said that they wanted.

detailed disclosure had negative consequences selected less information for disclosure than [those] who believed that disclosure had positive consequences."[73] There was also "a substantial difference" between what patients said they wanted to know and what physicians thought they would want to know.[74] About ninety percent of the patients reported that they wanted to know about alternative treatments; however, only fifty percent of all physicians thought they wanted this information.[75] This study suggests that the therapeutic privilege does affect what is disclosed, but physicians may have a different understanding of what is in patients' best interests than have the patients themselves.

Empirical data relevant to the therapeutic privilege is limited. In his 1960 study of what doctors tell cancer patients, Oken found that "about one-third of the group had 'heard of' suicides" by patients after being told that they had cancer.[76] Interestingly, only six doctors could report "definite known cases" of suicide.[77]

In their study of patient decisionmaking about non-surgical contraceptives, Faden and Beauchamp report that there was "no evidence that disclosed information actually produced . . . negative consequences."[78] They recognize, however, that "[d]isclosed information could have different consequences where the patient is in a more serious condition" than those in their study.[79] However, McLean reports that eighty-one percent of 126 depressed patients in a clinical research protocol who were told that their treatment would be randomly assigned rather than determined by clinical considerations "appeared to be unconcerned about this information or considered the explanation to be 'sensible.' "[80]

It would also be interesting to know the reasons that doctors invoke to justify withholding information from patients and the conditions under which information is withheld. With what sorts of patients having what kinds of illnesses is the privilege employed? The study which comes closest to shedding light on doctors' attitudes toward withholding information from patients is that of Soskis and Jaffe, who investigated how psychiatrists rate the therapeutic value to patients of communication of specific information about various aspects of antipsychotic medications.[81] They report that:

> The psychiatrists felt that it was most important to communicate with the patient about why he is being given medication, and then ranked

73. *Id.* at 268. The physician's age may affect the standard of disclosure that the physician adopts. Physicians who completed residency prior to 1960 interpreted the "reasonable man standard" as requiring disclosure of fewer facts than did younger physicians. *Id.* at 263. It is likely that the standard is affected more by physican training programs than by age of physician per se.

74. *Id.* at 266.

75. *Id.* at 275.

76. Oken, *supra* note 39, at 1126.

77. *Id.*

78. Faden & Beauchamp, *Decision-Making and Informed Consent: A Study of the Impact of Disclosed Information*, 7 SOC. INDICATORS RESEARCH 313, 332 (1980).

79. *Id.*

80. McLean, *supra* note 42.

81. Soskis & Jaffe, *Communicating with Patients about Antipsychotic Drugs*, 20 COMPREHENSIVE PSYCHIATRY 126, 127 (1979). *See also* N. HERSHEY & S. BUSHKOFF, *supra* note 26.

> slightly below this the information that is usually considered crucial for informed consent on side effects and risks. Information on how the medication works and on its name and dosage are seen as of less importance.[82]

Despite the fact that psychiatrists say that they place a high value on such disclosure, "there is a considerable lack of congruence"[83] between what they say and "what their own patients ended up knowing in each of these areas."[84]

It is sometimes claimed by medical researchers that patients should not be told that a particular procedure is experimental, that is, that they are research subjects as well as patients, because patients will then not agree to participate.[85] The findings of Park *et al.* do not support this belief. The investigators found that patients who were not at first informed that they were research subjects, when so informed at the completion of the research, were not distressed about learning that they had been involved in research.[86] The investigators concluded that "patient[s] will be surprisingly accepting of bothersome research procedures if [they] can count on a continuing relationship with an expert [they] trust . . . ."[87]

E. *Disclosure and "Special" Groups: Studies Involving Psychiatric Patients and Research Subjects*

Although a number of studies have investigated informed consent with psychiatric patients and with research subjects,[88] none have systematically studied what information is ordinarily disclosed to such individuals. The only systematic study of disclosure is that of Gilboy and Schmidt,[89] but unfortunately this study looked only at the process of admission to a psychiatric hospital and not treatment within the hospital. The investigators report that patients were inadequately apprised of the difference be-

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82. *Id.* at 127-28.

83. *Id.* at 128.

84. *Id. See also* Brewin, *Consent to Randomised Treatment*, THE LANCET, Oct. 23, 1982, at 919, 921; Brownell & Stunkard, *The Double-Blind in Danger: Untoward Consequences of Informed Consent*, 139 AM. J. PSYCHIATRY 1487, 1488-89 (1982).

Hershey and Bushkoff's earlier study also suggests a lack of congruence in what physicians tell patients about risks; they found a negative reaction among physicians to detailed disclosure of procedures and risks. Doctors indicated that they felt this type of disclosure would make patients apprehensive, so that patients would become sick or refuse the procedure. The authors' findings do not confirm these fears. N. HERSHEY & S. BUSHKOFF, *supra* note 26, at 15-20, 43-45.

85. *Cf.* Chayet, *Informed Consent of the Mentally Disabled: A Failing Fiction*, 6 PSYCHIATRIC ANNALS 295, 296 (1976); Fost, *A Surrogate System for Informed Consent*, 233 J.A.M.A. 800, 801 (1975); Kaplan, Greenwald & Rogers, *Neglected Aspects of Informed Consent*, 296 NEW ENG. J. MED. 1127 (1977).

86. Park, Slaughter, Covi & Griffin, *The Subjective Experience of the Research Patient: An Investigation of Psychiatric Outpatients' Reactions to the Research Treatment Situation*, 143 J. NERVOUS & MENTAL DISEASE 199, 204 (1966) [hereinafter cited as Park].

87. *Id.* at 205. *See also* Park & Covi, *Nonblind Placebo Trial*, 12 ARCHIVES GEN. PSYCHIATRY 336, 344 (1965) (patients can be willing to take a placebo and can improve despite disclosure of the inert content of the medication).

88. These studies are discussed in this section, and in other sections throughout this article. *See infra* §§ IV(D), V(C) & VII(J), at 302, 312 & 328.

89. Gilboy & Schmidt, *"Voluntary" Hospitalization of the Mentally Ill*, 66 NW. U.L. REV. 429 (1971).

tween voluntary and involuntary hospitalization.[90] As a consequence of inadequate disclosure, patients often felt that they had no choice but to sign-in voluntarily.[91]

Furthermore, it is sometimes assumed that what psychiatric patients are told is that which is mandated by state mental health statutes.[92] Unfortunately, none of the studies has attempted to ascertain the extent to which compliance with the law is achieved. Palmer and Wohl, in an attempt to explain why patient comprehension is poor, make an off-hand remark suggesting that the poor comprehension is due to a combination of patient characteristics and the inadequacy of the procedures used, but do not appear to have systematically studied the problem.[93]

As to the value of making disclosure to psychiatric research subjects, Park *et al.* report that patients in a nonblind placebo trial showed more symptomatic improvement than did patients who participated in a double-blind study. They conclude that "[p]erhaps attempts to keep secrets from patients, such as the research nature of a treatment, in conjunction with obvious clues that the treatment is research, can leave patients uneasy and unclear about what is really going on."[94]

F. *Summary*

"Disclosure" is one of the two most critical components of informed consent—the other being "understanding." Yet there has been no really satisfactory empirical investigation of the central question: "What do doctors routinely tell patients?" There is some peripheral data about patients' and doctors' attitudes toward receiving and making disclosure, about what patients already know about their condition and its treatment before disclosure is made, and about the questions that patients ask, but the data is relatively meaningless without first knowing what patients are told. The field is fertile for exploration, especially through the use of observational techniques which make a minimal intrusion into the natural disclosure process.

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90. "Neither at the mental hospital admissions office when persons were brought to that office by the police, nor in court when persons came before the judge at involuntary commitment hearings, was a serious effort made to adequately inform the individuals about the choice they were making." *Id.* at 452.

91. *Id.* at 430.

92. *See, e.g.*, Olin & Olin, *Informed Consent in Voluntary Mental Hospital Admissions*, 132 AM. J. PSYCHIATRY 938 (1975).

93. Palmer & Wohl, *Voluntary-Admission Forms: Does the Patient Know What He's Signing?* 23 HOSP. & COMMUNITY PSYCHIATRY 250, 252 (1972).

94. Park, Covi & Uhlenhuth, *Effects of Informed Consent on Research Patients and Study Results*, 145 J. NERVOUS & MENTAL DISEASE 349, 353 (1967) [hereinafter cited as Park]. *See also* Park & Covi, *supra* note 87 (supports Park *et al.*'s earlier study regarding the value of disclosure). It should be noted that this study was performed in 1959-1960, before the law clearly mandated that research subjects be informed of the experimental nature of their treatment program. *See* 45 C.F.R. § 46.116(a)(1) (1981). In the "double-blind" study, neither the patients nor their doctors knew whether the patients were receiving an active medication or an inert placebo; in the "nonblind placebo trial," patients (and their doctors) knew that they were receiving an inert placebo, yet still experienced relief of symptoms.

IV. UNDERSTANDING: WHAT PATIENTS KNOW

From the perspective of the law, the "understanding" component of informed consent is the most tenuous. It is not certain whether there is any legal requirement concerning understanding, and if there is, what that requirement involves. There is some support for the position that the patient can be said to have rendered an informed consent only if he understands the information that the doctor is obligated to provide.[95] By contrast, an "understanding" requirement might focus not so much on the patient but on whether or not the doctor used reasonable effort to assure that the patient understands the requisite information. Under this view, if the doctor has made such effort, the patient's subsequent authorization of treatment is viewed as legally effective even if the patient does not in fact understand what he has been told.[96]

Another view is that the informed consent doctrine neither requires that the patient understand the information that has been disclosed nor obligates the doctor to make any effort to ascertain the patient's level of understanding or to refuse to act upon the patient's decision if that level of understanding is deemed inadequate.[97] There is even some feeling that the existence of a requirement that the patient actually understand the information to deem his authorization of treatment legally valid demeans the dignity of the individual and is inconsistent with one of the goals of informed consent, namely autonomy or "thorough-going self-determination."[98]

To the best of our knowledge, no court has expressly held that the doctor's duty extends beyond merely providing the patient with relevant information, even if the patient does not understand that information. Indeed, no less an authority than the United States Supreme Court, after proclaiming that "[o]ne might well wonder, off-hand, just what 'informed consent' of a patient is,"[99] went on to state in dicta that it was "content to accept, as the meaning [of informed consent], the giving of information to the patient as to just what would be done and as to its consequences."[100]

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95. *See generally* Meisel, *supra* note 23, at 113-18.

96. *Id.* at 119-23.

97. *See* Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683 (1975).

98. Natanson v. Kline, 186 Kan. 393, 406, 350 P.2d 1093, 1104, *opinion on denial of motion for reh'g*, 187 Kan. 186, 354 P.2d 670 (1960).

> There are arguments that neither next of kin, other legally authorized guardians, nor courts should be able to override the objection of a mentally disabled subject except in extreme cases. The [National] Commission [for the Protection of Human Subjects of Biomedical and Behavioral Research] notes in its report the view of one of its consultants that "The burden in law for incompetence should be very high. No evidence other than a showing that the patient is comatose should ordinarily be accepted as proof of incompetence. To accept proxy consent is to authorize invasions of persons and personality without regard to the wishes of the research subject. . . ." To date, no court has adopted such a view.

U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *Protection of Human Subjects—Proposed Regulations on Research Involving Those Institutionalized As Mentally Disabled*, 43 FED. REG. 53,950, 53,952 (1978) (to be codified at 45 C.F.R. Part 46) (proposed Nov. 17, 1978) (comment to recommendation 2).

99. Planned Parenthood v. Danforth, 428 U.S. 52, 67 n.8 (1976).

100. *Id.*

The term probably also denotes that patient's authorization for treatment, but beyond that the Court felt that "[t]o ascribe more meaning that this might well confine the attending physician in an undesired and uncomfortable straitjacket in the practice of his profession."[101] Thus, the argument that informed consent does not require either actual patient understanding or effort by the physician to ascertain the level of patient understanding is, at the very least, a respectable one.[102]

Nonetheless, strong support for the existence of a requirement that patients understand what the doctor is required to disclose before the authorization to treat can be considered legally effective resides in the fact that the common law establishes that legally effective consent can be given only by one who is "competent."[103] It is quite clear that one who lacks the capacity to consent cannot give effective consent.[104] It is not at all clear, however, what incompetency or lack of capacity entails. Although one who is *de jure* incompetent—children and adjudicated incompetents—by definition cannot give effective consent,[105] the vast majority of persons in-

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101. *Id.*

102. Furthermore, there is a wide discrepancy between the hortatory dicta of many of the informed consent cases proclaiming in resounding tones a patient's right of self-determination and the holdings of the same cases which adopt rules for recovery—such as the "professional" standard of care or the objective "reasonable patient" standard of care, and an objective causation requirement—that substantially undercut these dicta. *See* Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137 (1977).

103. Although not all states have affirmatively recognized the incompetency exception, a state which has not yet done so would be hardpressed not to when actually faced with the question. *See* Meisel & Kabnick, *supra* note 11, at 454-55; *see generally* Meisel, *supra* note 1, at 439-53.

104. RESTATEMENT (SECOND) OF TORTS § 892A(2)(a) (1977). *See, e.g.*, Grannum v. Berard, 70 Wash. 2d 304, 422 P.2d 812 (1967).

105. The distinction between *de jure* and *de facto* incompetency is an important one. A person who is *de jure* incompetent is so either because he is an infant or because, if an adult, he has been subjected to judicial proceedings which have adjudged him incompetent. One who is *de jure* incompetent may *in fact* be incompetent, that is, if subjected to incompetency proceedings, he would be adjudged incompetent.

Assent to treatment by one who is *in fact* incompetent is not a valid authorization, *see, e.g.*, Demers v. Gerety, 85 N.M. 641, 645, 515 P.2d 645, 649 (Ct. App. 1973), nor is his dissent a valid refusal, *see, e.g.*, *In re* President & Directors of Georgetown College, Inc., 331 F.2d 1000, 1008 (D.C. Cir.), *cert. denied*, 377 U.S. 978 (1964). A physician who relies upon such an assent may be liable for rendition of unauthorized treatment, *Demers*, 85 N.M. at 646, 515 P.2d at 50, and a doctor who withholds treatment in reliance upon the refusal of a *de facto* incompetent patient may be liable as well, presumably for some type of negligence. John F. Kennedy Memorial Hosp. v. Heston, 58 N.J. 576, 279 A.2d 670 (1971) (dictum).

In addition, a minor is a member of a class of individuals who are considered *de jure* incompetent even though they have not been adjudicated incompetent and may be *de facto* competent. While it is well established at common law that minors are legally incapacitated from consenting to medical treatment, W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 18, at 102-03 (4th ed. 1971), numerous states have enacted statutes which remove this disability under certain circumstances. *See, e.g.*, PA. STAT. ANN. tit. 35, §§ 10101-10105 (Purdon Supp. 1977). *See generally* Pilpel, *Minors' Rights to Medical Care*, 36 ALB. L. REV. 462, 464-87 (1972); Skegg, *Consent to Medical Procedures on Minors*, 36 MOD. L. REV. 370, 370-71 (1973); Stern, *Medical Treatment and the Teenager: The Need for Parental Consent*, 7 CLEARINGHOUSE REV. 1 (1973); Wadlington, *Minors and Health Care: The Age of Consent*, 11 OSGOODE HALL L.J. 115, 120-23 (1973); Comment, *Minor's Rights to Medical Care*, 14 J. FAM. L. 581, 590-95 (1975). Even before the enactment of these statutes and others dealing specifically with the treatment of certain conditions such as venereal diseases, abortion, contraception, and sterilization, there existed some common law to the effect that mature minors might give effective consent to their own medical care. *See, e.g.*, Sullivan v. Montgomery, 155 Misc. 448, 450, 279 N.Y.S. 575, 577 (1935). *See generally* Capron, *The Competence of Children as Self-Deciders in Biomedical Interventions*, in WHO SPEAKS FOR THE

volved in the medical decisionmaking process are not *de jure* incompetent. Rather, when a question arises, it is invariably about a patient's competency *in fact* to make medical decisions. By what criteria incompetency to make medical decisions is to be determined is terribly unclear,[106] but the most plausible set of criteria focuses on the patient's ability to understand the information disclosed pursuant to the informed consent doctrine.[107] If these criteria are employed, then informed consent does entail patient understanding, and the "competency" and "understanding" components of informed consent effectively merge into a single component. However, since there are other plausible criteria for determining incompetency,[108] the relationship between these two components remains unclear, and thus we will treat them separately in the remainder of the present discussion, keeping in mind, however, that the findings of studies about understanding may be relevant also to competency.

A. *Some Common Problems of the Understanding Studies*

Although judges have failed to address head-on the necessity for patients' understanding of what they are supposed to be told by doctors, the empirical investigators have concentrated on this element of informed consent, generating a mountain of data. Unfortunately, most of the data is not particularly useful because of some serious conceptual and methodologic deficiencies in the studies, to which attention should first be directed.

1. *Defining "Understanding"*

Before setting out to study a concept, it is helpful, if not essential, to define or describe the concept under investigation. Few if any of the investigators who have studied understanding have done so. Perhaps this is because the concept is thought to be so simple that knowledge of its meaning is taken for granted. Or by contrast—and it is here that we believe the truth lies—the meaning of "understanding" may be so complex as to defy definition or description. If the latter is the case, however, it is still incumbent upon investigators to make an effort to describe, define, or operationalize the concept of "understanding" or at least to explain to the reader why it is not possible to do so.

2. *Measurement of Understanding*

Further complicating analysis of the findings of the understanding

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CHILD: THE PROBLEMS OF PROXY CONSENT 57 (W. Gaylin & R. Macklin eds. 1982); Meisel & Kabnick, *supra* note 11, at 460 n.228; Roth, *supra* note 19.

106. Meisel, *supra* note 1, at 439-53; Roth, *supra* note 19.

107. *See* Appelbaum & Roth, *Competency to Consent to Research: A Psychiatric Overview*, 39 ARCHIVES GEN. PSYCHIATRY 951 (1982); Gert & Culver, *Philosophical Overview*, in U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. HEALTH SERV., ALCOHOL, DRUG ABUSE, & MENTAL HEALTH ADMINISTRATION, NAT'L INST. OF MENTAL HEALTH, COMPETENCY AND INFORMED CONSENT: PAPERS AND OTHER MATERIALS DEVELOPED FOR THE WORKSHOP "EMPIRICAL RESEARCH ON INFORMED CONSENT WITH SUBJECTS OF UNCERTAIN COMPETENCE" (N. Reatig ed. 1981) (proceedings of conference at National Institute of Mental Health, Jan. 12-13, 1981) [hereinafter cited as Reatig]; Meisel, *supra* note 1, at 439-53; Roth, *supra* note 19.

108. *See supra* note 106.

studies is the fact that the investigators have employed a variety of techniques for measuring understanding. Though investigators should hardly be faulted for innovation, the nonstandardized methods do make comparison of findings more problematic.

Both theoreticians and investigators of informed consent have been concerned with how to determine whether patients understand what they have been told. This problem is difficult enough in itself, but is complicated further by the fact that it is not always clear that investigators are sure what it is that they are measuring when investigating understanding.

Short of techniques for the direct chemical or electrical measurement of the brain activity that signifies understanding, we are dependent upon traditional means of measurement, involving either written or oral communication with subjects. Many investigators have employed the traditional kinds of tests used in classroom testing, in which patients or subjects are provided with either an oral or a written explanation, or sometimes with both. The subjects are then given a multiple choice[109] or true/false[110] test. Sometimes these "objective" measures are supplemented by open-ended, essay type questions, given either orally by an interviewer[111] or in writing. Some of the studies employ a "two-part consent form,"[112] in which patient understanding is tested immediately after disclosure, by the use of a brief, written test.

Two investigators purport to have expanded upon and improved the two-part consent form. Stuart has used what he refers to as a "three-part consent form." In addition to a traditional two-part consent form, he added another part asking "prospective participants to describe the experiment in their own words . . . ."[113] Silberstein reports that he permits the patient to take "the unsigned form with him to read over and show to friends, family, lawyers, etc."[114] Only after the patient has had an opportunity to discuss participation in a research project with uninvolved persons is his consent sought. This effort, however, appears designed more to improve comprehension that to test it, as well as to reduce coercive pressures on the potential subject. In addition to the foregoing problems which plague the empirical studies of understanding, there are a few others which

109. *See, e.g.*, Flanery, Gravdal, Hendrix, Hoffman, King, May, O'Keefe, Timmerman, Waltman & Roberts, *Just Sign Here . . .*, 31 S.D.J. MED. 33 (1978) [hereinafter cited as Flanery].

110. *See, e.g.*, Williams, Rieckmann, Trenholme, Frischer & Carson, *The Use of a Test to Determine That Consent Is Informed*, 142 MILITARY MED. 542 (1977) [hereinafter cited as Williams]; Hassar & Weintraub, *"Uninformed" Consent and the Wealthy Volunteer: An Analysis of Patient Volunteers in a Clinical Trial of a New Anti-Inflammatory Drug*, 20 CLINICAL PHARMACOLOGY & THERAPEUTICS 379 (1976).

111. *See, e.g.*, McCollum & Schwartz, *Pediatric Research Hospitalization: Its Meaning to Parents*, 3 PEDIATRIC RESEARCH 199 (1969); Howard, DeMets & The BHAT Research Group, *How Informed Is Informed Consent?* 2 CONTROLLED CLINICAL TRIALS 287 (1981) [hereinafter cited as Howard].

112. *See* Miller & Wilner, *The Two-Part Consent Form: A Suggestion for Promoting Free and Informed Consent*, 290 NEW ENG. J. MED. 964 (1974).

113. Stuart, *Protection of the Right to Informed Consent to Participate in Research*, 9 BEHAV. THERAPY 73, 74 (1978).

114. Silberstein, *Extension of Two-Part Consent Form*, 291 NEW ENG. J. MED. 155, 156 (1974). *See also* Howard, *supra* note 111, at 288 (where safeguards were developed to assure careful understanding of the trial and to minimize resistance to participation). Howard *et al.* indicate that a number of spouses seemed better informed than the subjects themselves. *Id.* at 290.

put in question not only the findings about understanding, but the findings about some of the other elements of informed consent as well.

3. *Relevance of Recall to Understanding*

As previously mentioned, most investigators of understanding have chosen to look at one particular facet of understanding, that which we refer to as "recall." There are difficulties inherent, however, in any attempt to extrapolate "understanding" from "recall." That patients do not recall information several days, weeks, or months after treatment is simply not relevant—or at best, only marginally relevant[115]—to whether or not they can be said to have rendered an informed consent at or near the time of the procedure.[116] Thus, to conclude that patients have not given informed consent because they have had difficulty remembering even for a short period of time exhibits a fundamental misunderstanding of informed consent.

Though their usefulness is quite limited, the recall studies are not entirely without merit. To the extent that they establish rather unquestionably that a large proportion of patients do forget a large proportion of what they have been told, doctors are well advised to document what they tell patients, as Robinson and Merav point out.[117] Thus, in the event of future litigation, the doctor will have firm evidence, rather than a hazy recollection or none at all, or reliance on his "customary" practice of what he told the patient in question. Beyond this, however, the recall studies are of little value.

Not all investigators have viewed understanding as a simple stimulus-response process wherein certain information is provided to the patient, and if he is able to regurgitate it (usually in response to fixed questions) after the passage of some appropriately determined (though often not fixed) period of time, it is said that he "understands" it. Unfortunately, those investigators who apparently have employed more sophisticated notions of what understanding is have not supplied any discussion of its meaning. Rather, we are able to infer from reports of what they have investigated and the methods they have used that they were interested in something other than mere recall when they spoke of understanding.

For example, several investigators used structured but open-ended in-

115. *But see* Taub, *Informed Consent, Memory and Age*, 20 GERONTOLOGIST 686, 688-89 (1980) [hereinafter cited as *Taub I*]; Taub, Kline & Baker, *The Elderly and Informed Consent: Effects of Vocabulary Level and Corrected Feedback*, 7 EXPERIMENTAL AGING RESEARCH 137 (1981) [hereinafter cited as *Taub II*]. Taub, *et al.* have reported that relative memory losses associated with very low vocabulary levels in older persons appear to be comprehension-related for this subgroup of the population. *Id.* at 137.

116. It is arguable, though questionable, that if a patient is able to repeat what he was told, he "understands" what he was told, or conversely that because he cannot recall, he did not understand. Assuming for argument's sake that this is so, the greater the lapse of time between disclosure and the measurement of recall, the less valid the conclusion that because the patient cannot recall, he did not initially understand. Certainly, it would be difficult to conclude that a patient understands what he has been told if he is unable to retain it for some short period of time—at least long enough to repeat it back or somewhat longer.

117. Robinson & Merav, *Informed Consent: Recall by Patients Tested Postoperatively*, 22 ANNALS OF THORACIC SURGERY 209, 209 (1976).

terviews to determine what patients understood about what they had been told. Rather than determining patients' understanding by the proportion of "correct" answers given to a written or oral set of questions, these investigators attempted to explore the depth and breadth of patients' comprehension. Thus, the investigators implicitly acknowledge that they realize that understanding is far more complex than recall, though recall may be an aspect of understanding. Perhaps the clearest example of this is a statement of Leonard, Chase and Childs, who studied what persons who had received genetic counseling understood about it: "It was evident that many parents who gave correct answers did not understand them . . . . Others confessed to a lack of comprehension of the correct answers that they had given . . . ."[118]

In a study of patients whose commitment status in a psychiatric hospital was changed from involuntary to voluntary, Klatte *et al.* also employed a concept of understanding different from that of recall although they may not have been aware that they did so.[119] Garnham also realizes that recall and understanding cannot be equated. He comments that "[i]n some instances . . . the terminology was known but there was little understanding of the meaning of the words."[120]

These concepts of understanding are far more subjective and hence far more susceptible to problems of unreliability than are more mechanical approaches, but it is likely that they possess a higher degree of validity.

4. *Control Groups*

Another fundamental flaw in all of the recall studies is the fact that patients' poor recall may merely be part of the normal forgetting process.[121] Indeed, it is possible that patients remember more than normal subjects would have remembered, but there is no way of knowing whether this is the case because of the failure to perform controlled studies. A few studies in other contexts do attempt to use control or comparison groups, but no studies of recall do so.[122]

That forgetting does occur among patients is demonstrated by one recall study in which subjects were administered a questionnaire immediately after disclosure and at two later times.[123] The investigators report

118. Leonard, Chase & Childs, *Genetic Counseling: A Consumers' View*, 287 NEW ENG. J. MED. 433, 436 (1972) [hereinafter cited as Leonard].

119. This is implicit in their statement that many patients whose status was changed "were unable to *appreciate the significance of the situation* . . . ." Klatte, Lipscomb, Rozynko & Pugh, *Changing the Legal Status of Mental Hospital Patients*, 20 HOSP. & COMMUNITY PSYCHIATRY 199, 201 (1969) (emphasis added) [hereinafter cited as Klatte]. *See also* Stuart, supra note 113, at 79.

120. Garnham, *Some Observations on Informed Consent in Non-Therapeutic Research*, 1 J. MED. ETHICS 138, 141 (1975).

121. "Anyone who has taught," Bradford Gray has observed, "is aware from reading students' exams that much of what is 'taught' is not 'learned,' that is, some students will miss the point, get the information garbled, or have no recollection at all." B. GRAY, *supra* note 13, at 106-07. *See also* Meyer & Latz, *What Open Heart Surgery Patients Want To Know*, 79 AM. J. NURSING 1558, 1559 (1979).

122. *See, e.g.*, Stanley, Stanley, Lautin, Kane & Schwartz, *Preliminary Findings on Psychiatric Patients As Research Participants: A Population at Risk?*, 138 AM. J. PSYCHIATRY 669 (1981) (rationality of choices of psychiatric patients compared with those of medical patients).

123. Bergler, Pennington, Metcalfe & Freis, *Informed Consent: How Much Does the Patient*

that a "notable difference in the level of awareness . . . was apparent" at the two later times.[124] This study also reports that among thirty-nine patients being treated for hypertension, a "high percentage [of subjects] responded correctly to most of the questions . . ." when queried immediately after disclosure.[125]

5. *Documentation of Disclosure*

One would have thought that to investigate patient understanding properly investigators would have also investigated the logically antecedent question of disclosure. It is surprising, therefore, that investigators have looked so extensively at the extent to which patients have understood what they have been told, all the while merely assuming that they have been told something. Yet investigators have looked hardly at all at what patients have been told and indeed at whether they have been told anything.[126]

One study, which found that patients receiving chemotherapy for breast cancer have poor understanding of the information they were given about treatment, purports to establish that patients did not merely forget what they had been told but had never understood it.[127] While this conclusion may be correct, it is impossible to be sure without knowing what, if anything, these patients were told in the first place.[128] There is no reason to doubt the good faith of the investigators, but since adequacy of disclosure is a matter of judgment, not good faith, these authors and others who do not disclose to their audience what was told to patients do not earn the credibility that they seek. Where disclosure is supposed to be made to

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Understand?, 27 CLINICAL PHARMACOLOGY & THERAPEUTICS 435 (1980) [hereinafter cited as Bergler].

124. *Id.* at 436.

125. *Id.* Another study shedding some light on this issue compares the level of understanding of prospective subjects in the trial of a new vaccine with the level of understanding of a control group composed of medically trained personnel. About three-fourths (74 of 95) of the controls received no specific information about the vaccine before being tested, whereas the experimental subjects attended a 1-2 day "education session" before being tested. The medical group made an average of 2.8 errors, the experimental group 1.3 errors. In the medical group, 9% had a perfect score; in the experimental group, 42%. Woodward, *supra* note 5, at 249-50. While this may or may not illustrate that normal subjects are capable of understanding as well as medically-trained persons since it is not necessarily reasonable to expect a professional to have instant recall of detailed factual information about a specialized area of his profession, the results suggest that laypersons are capable of being educated about relevant information.

126. In the studies in which an investigator has studied his own patients, the investigator should know what the patients have been told. *See, e.g.*, Priluck, Robertson & Buettner, *What Patients Recall of the Preoperative Discussion After Retinal Detachment Surgery*, 87 AM. J. OPHTHALMOLOGY 620 (1979) [hereinafter cited as Priluck]. However, self-study raises still other methodological problems. *See infra* section IV(A)(7), at p. 292.

127. Muss, White, Michielutte, Richards, Cooper, Williams, Stuart & Spurr, *Written Informed Consent in Patients with Breast Cancer*, 43 CANCER 1549 (1979).

128. Instead of reporting what patients were told, the authors state only that

> [i]n most instances a trained oncology nurse talks with the patient and places particular emphasis on details of possible drug toxicity. It is generally during this interview that the informed consent document is signed . . .

and that

> [d]iagnoses, rationale for treatment, and treatment plans are discussed with the patient by the attending physician.

Id. at 1550.

patients by someone other than the investigator conducting the informed consent study, which for other methodologic reasons ought to be the case, it is incumbent upon the investigator to determine whether in fact disclosure has been made.

6. *Experimental Design*

Most of the studies of informed consent use subjects who are real patients faced with real medical decisions. This is not always the case, however. In some instances, the subjects of the informed consent studies are persons who have been asked to participate in an experiment to study some aspect or another of medical decisionmaking. Sometimes these subjects are totally uninvolved with the medical care system at the time that they participate in the experiment. Often the subjects are patients, but are called upon to make hypothetical decisions about hypothetical procedures which they neither need nor will actually receive. In some instances, the experiments involve procedures that are not even real medical procedures.[129]

Experimental studies[130] create additional possibilities for invalidity of results because of the absence of many of the psychological or affective components of decisionmaking present when people are called upon to make decisions which will have real consequences for them. Since responses to hypothetical questions have no real consequences, the decisionmaker may unconsciously be expressing his hopes, dreams, and aspirations, rather than an accurate prediction of how he actually acts or would act in such situations.[131] With respect to understanding, persons who are making hypothetical decisions may not pay as much attention to disclosure as they would if making a real decision, since there are no consequences to them personally. On the other hand, they might pay greater attention since they are less likely to be distracted by illness and anxiety, and they have been specifically sensitized to the purpose of the hypothetical exercise in which they are participating.

In any event, there are a host of factors in hypothetical decisionmaking distinguishing it from actual decisionmaking so that the findings gleaned from the former may not be valid as to the latter. We do not mean to condemn out of hand studies with experimental designs. Indeed, they may possess certain advantages, especially the ability to control other variables, which clinical studies do not. Nonetheless, they are susceptible to the problem of lack of verisimilitude, which must be kept in mind when interpreting their findings.

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129. *See, e.g.*, Epstein & Lasagna, *supra* note 50, at 683.

130. Strictly speaking, studies utilizing subjects who are patients faced with real medical procedures are "experimental" in the sense that issues may be posed to them that are not a part of their ordinary clinical care. When we use the term "experimental" here, however, we are referring to a narrower set of studies employing a design involving either "normal" subjects or patients faced with hypothetical medical decisions; such studies are sometimes also referred to as "analog" studies.

131. For example, the decisionmaker may be willing to state that he would take greater (or lesser) risks than he actually would, that the absence (or presence) of benefits is not relevant to his decision, or that he would agree to (or refuse) a particular procedure if he actually had to do so.

7. *Dual Roles and Objective Investigation*

A very substantial proportion of the studies of informed consent has been conducted by investigators who are involved in the very process that they are studying. The studies are conducted by physicians upon persons who are not only subjects in the informed-consent study, but who are also their own patients currently under treatment. This may cause at least two difficulties.

First, because the legal requirement of informed consent imposes duties upon the physician (and indeed refrains from imposing any upon the patient), the investigator is studying not only the behavior of patients but also of physicians. If the investigator *is* the physician, then he is involved in a study of his own behavior, which lacks the kind of detachment necessary to impart full credibility to the findings. He may not perceive his behavior in the same way that a neutral observer would, and he may alter his behavior because it is under study.[132]

The second difficulty is that the investigator-physician who studies his own patients may affect their behavior merely by virtue of his status as their physician. For instance, the patients may pay more (or less) attention to what their physician says than to what an independent investigator says. Regardless of the direction of the bias, a potential for bias does exist. In fact, the inability to identify the direction of the bias makes discounting for its existence even more problematic.

B. *What Do Patients Understand?*

Putting aside problems of definition and methodology, we turn to examine the findings of those studies that have sought to determine what and how much people understand of what they presumably have been told.[133]

1. *What Do Patients Recall?*

One of the most widely publicized studies is that conducted by Robinson and Merav,[134] and its methods and findings are typical of many of the other studies. Both investigators are also clinicians, and the subjects of their study of informed consent were also patients upon whom they performed medical procedures—in this case, heart surgery for atherosclerotic heart disease or for acquired valvular heart disease. What the investigators did, essentially, was to tack on to surgical procedures which they were

132. From a methodologic perspective, studying a phenomenon in which one is a participant may compromise the objectivity necessary to assuring the scientific validity and reliability of results, regardless of the degree of good faith exercised by the investigator to maintain objectivity. In other words, there is some reason to suspect that investigators who study informed consent with persons who are their patients are more likely to find what they already thought was the case than are disinterested observers.

133. In some of the studies, it is not entirely clear whether the investigators are measuring the simplest form of recall or something more complex because the questions that they asked the subjects, as well as the information that the subjects were given, are not reported. To the extent, however, that a study employs a close-ended written questionnaire to measure subjects' "understanding," we have treated them as measuring recall since such methods do not easily lend themselves to the study of more complex notions of understanding.

134. Robinson & Merav, *supra* note 117.

routinely performing a study of informed consent. This involved making audio tape recordings of discussions they had with twenty patients, one to two days pre-operatively. Four to six months after the operation, they reinterviewed these patients and again recorded the conversations.

What the investigators found, in summary, was that the patients had "generally poor retention in all categories of informed consent information."[135] More specifically, "even with the influence of suggestion and a point-by-point review of every item covered in the original interview, patients could remember only 42 percent of the items that had been covered in the informed consent interview,"[136] and "[e]ach of the 20 patients failed to recall major parts of the interview."[137] The investigators implicitly acknowledge that recall and understanding are not equivalent. They believe that the patients in their study "understood" the explanations the first time and "gave a truly informed consent to their operations."[138] The investigators conclude, however, that because memory is unreliable doctors should document the disclosure that they make.[139] Aside from whatever else it illustrates about understanding, the Robinson and Merav study demonstrates some of the common problems with studies of understanding.

The basic recall study exemplified by Robinson and Merav has been repeated on numerous occasions with a number of variations.[140] A recent study of this type, which has also been widely touted, is that conducted by Cassileth *et al.* who administered written tests, one day prior to treatment, to 200 cancer patients who had signed consent forms for chemotherapy, radiation therapy, or surgery.[141] They found that "[o]nly 60 per cent of all patients correctly described what their treatment would involve, 59 percent could describe the essential purpose of the treatment, only 59 per cent were able to list even a single major risk or complication, and only 27 per cent could name one alternative treatment. However, 81.5 per cent correctly

135. *Id.* at 210.
136. *Id.* at 211.
137. *Id.* at 212.
138. *Id.*
139. *Id.*
140. In a study of 20 patients who underwent face-lift operations, "[a]lthough all women recalled being told about the possibility of complications, only three remembered as many as three complications; eight mentioned only one; nine were unwilling or unable to recall any." Goin, *supra* note 57, at 277. In another study, 100 consecutive surgical patients were interviewed both before and within seven days after surgery. At the first interview, conducted according to a standard format, patients were informed that they would be participating in a study, that the information was important and specific for them, and that they would be questioned later about the interview. Leeb, Bowers & Lynch, *Observations on the Myth of "Informed Consent,"* 35 PLASTIC & RECONSTRUCTIVE SURGERY 280, 280 (1976). Despite these efforts, the investigators report that "[g]roup retention averaged 35 percent overall." *Id.* at 281.

In a study of the comprehension of 17 patients in a clinical drug trial, the level of understanding was higher than in other studies. Hassar & Weintraub, *supra* note 110. In a study of 100 patients who underwent retinal surgery (scleral buckling procedure), the investigators found that the overall mean accuracy for patient retention was 57%. Priluck, *supra* note 126, at 621.

In addition to the clinical studies of recall, we have also found one experimental study in which 124 undergraduates and freshman medical students were given a consent form and a questionnaire about the consent form. The authors (who were medical students) claim that "comprehension was often poor." Flanery, *supra* note 109, at 36.

141. Cassileth, Zupkis, Sutton-Smith & March, *Informed Consent: Why Are Its Goals Imperfectly Realized?*, 302 NEW ENG. J. MED. 896 (1980) [hereinafter cited as Cassileth].

identified their diagnoses."[142] Like the Robinson and Merav study, it is likely that this study will be widely hailed as establishing that informed consent is difficult or impossible to obtain in a large proportion of patients. But as is also the case with the Robinson and Merav study, this conclusion is open to question because it is a study of recall and the investigators do not tell the readers what the patients were told except in a conclusory fashion.

The investigators state that the consent forms that the subjects signed included the statement, "The effect and nature of this treatment, possible alternative methods of treatment, and the risks of injury despite precautions have been explained to me."[143] From this statement, they conclude, "Presumably, therefore, these areas were covered by oral explanation."[144] Unfortunately, this is a matter for investigation, not presumption, and the authors undercut their own findings by not having investigated, or at least not having reported, what the patients actually were told.[145]

One other recall study is of some interest because, although thirty-eight of forty patients recalled having signed a consent form some five to seven days earlier, a substantial porportion could not accurately recall its contents.[146] The consent form asked for approval to use information gathered from their medical records for "teaching and research purposes," but a week later fifty percent erroneously recalled that they had given consent for the use of research drugs and sixty percent erroneously thought that they had given consent to participate in research tests.[147]

One study reports substantially better levels of recall. Marini *et al.*, in their study involving prisoners taking lithium carbonate as a part of a clinical trial to determine its "antiaggressive effect," found that "approxi-

142. *Id.* at 897.

143. *Id.*

144. *Id.*

145. "In any precise sense statements regarding consent are meaningless unless one knows how fully the patient was informed of all risks, and if these are not known, the fact should also be made clear." Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354, 1355 (1966) (said in regard to the fact that in 50 studies reviewed, only two mentioned consent). The only investigator who seems to have realized the problematic nature of this omission is Gray, who repeatedly cautions that he did not observe what the subjects of his studies were told. *See, e.g.*, B. GRAY, *supra* note 13, at 69, 83, 116. By contrast, most of the studies of understanding are content to state in a conclusory fashion that "informed consent was obtained," rather than reporting what patients were actually told. *See, e.g.*, Dabrowski, Gerard, Walczak, Woronowicz & Zakowska-Dabrowska, *Inability of Patients to Give Valid Consent to Psychiatric Hospitalization*, 1 INT'L J.L. & PSYCHIATRY 437 (1978): "The consent given by a decisive majority (93%) is legally valid." *Id.* at 441.

When we pointed out this problem to Cassileth *et al.*, *see* Meisel & Roth, 303 NEW ENG. J. MED. 459 (1980), their response was the following:

> Meisel and Roth emphasize the need for further understanding [sic; we had criticized the study for lack of "investigation"] of what patients are told by their doctors. As our article indicates, however, this was not the purpose of our study. Instead, we attempted to shed some light on the well-documented problem of patients' not remembering many aspects of what they read or are told . . . .

303 NEW ENG. J. MED. 460 (1980). This reply underscores the fact that the investigators do not understand that one cannot present meaningful findings on what patients recall without knowing what patients were initially told.

146. Kennedy & Lillehaugen, *Patient Recall of Informed Consent*, 7 MED. & PEDIATRIC ONCOLOGY 173, 176 (1979).

147. *Id.*

mately two-thirds of the subjects had the information necessary for an informed consent to [the] experiment at the time of testing."[148] Perhaps the higher level of understanding that they found occurred because the subjects were long-term participants in the study and their continual participation reinforced their understanding of it.[149] It may also be that prisoners are more interested than other subjects, finding such studies to be pleasurable diversions from the monotony of prison life, and this makes them more attentive to the details of the study.

Overall, the recall studies show that patients' recall is not very good. It seems not to matter whether recall is tested shortly after disclosure is made or after a substantial period of time has elapsed. In both cases, patients and subjects either forget or they never really got the information to begin with. Whether this is a failure of comprehension on the part of the recipients or a failure in the manner and means of communication is not clear. We will look shortly at the studies which propose reasons for inadequate understanding,[150] but assuming for the sake of argument that the disclosure was adequate, it is still problematic to conclude that because patients and subjects had poor recall, they did not understand the information well enough to utilize it. The difficulty, of course, lies in equating recall with the kind of understanding necessary to use information in decisionmaking.[151] It is therefore important to turn to other studies which have conceptualized and measured understanding differently to see if they shed any additional light on these issues.

2. *Other Perspectives on Understanding*

One of the studies which rather clearly recognizes that understanding and recall are not equivalent comes, however, to a similar conclusion: the level of understanding in patients to whom disclosure has been made is not very high.[152] In their study of families who had received genetic counsel-

148. Marini, Sheard & Bridges, *An Evaluation of "Informed Consent" with Volunteer Prisoner Subjects*, 49 YALE J. BIOLOGY & MED. 427, 434 (1976) [hereinafter cited as Marini].

149. Perhaps this is because learning occurs over time. *See infra* text accompanying note 424.

150. *See infra* section IV(C), at p. 298.

151. [M]ere parroting of information does not constitute understanding . . . . [S]ome minimal amount of retention of information is a prerequisite to genuine understanding . . . . Thus, while lack of short-term recall is evidence of a lack of genuine understanding, the converse is not so: the ability to recall and repeat what one has been told should not be mistaken for genuine understanding.

. . . .

Courts have used the term "appreciate" in their discussions of consent and competency . . . the [patient] should not merely be able to repeat information that he has been given, but should appreciate its significance in the context. The context that is relevant may include the facts that the individual is a research subject; that he is a patient; that he is in a hospital; that the person speaking with him is a physician; that the procedures are or are not being performed in whole or in part for the acquisition of knowledge. In short, the [patient] must be able to *integrate* the relevant information into a meaningful whole.

Meisel, *What Would It Mean To Be Competent Enough To Consent to or Refuse Participation in Research: A Legal Overview*, in Reatig, *supra* note 107, at 32, 61-62. *See also* Appelbaum & Roth, *Competency to Consent to Research: A Psychiatric Overview*, 39 ARCHIVES GEN. PSYCHIATRY 951, 954-55 (1982); Klatte, *supra* note 119; *supra* section IV(B), at p. 292.

152. Leonard, *supra* note 118.

ing, Leonard *et al.* report that with respect to

> the minimum knowledge that a genetic counselor might hope would be retained as a basis for informed family-planning decisions . . . about ½ of the parents had the kind of comprehension that could make the information helpful to them, whereas in about ¼ that understanding was flawed in some way and for about ¼ the genetic counseling had served little purpose.[153]

Although these investigators do not specify what they mean by "understanding," they appear to employ an operational definition based upon the patient's ability to use information, and to use it in a specific way, namely, to make the very decision for which it was initially provided.

In a study of the meaning to parents of hospitalization of their children on a research ward, McCollum and Schwartz also view understanding as something more complex than recall, but do not indicate what it is. Still, only 6 of 140 mothers "understood" that the hospitalization was purely for research purposes, that is, that there was no anticipated therapeutic value to their children.[154] Klatte *et al.* also appear to use something other than recall in their conceptualization of understanding.[155] For them, understanding appears to involve appreciation of the significance of information.[156] They found that an adequate level of understanding was achieved in only about one-third of the patients studied.[157]

3. *Understanding of Specific Elements of Information*

Many studies have examined not only understanding in general, but understanding of particular kinds of information. For the most part, investigators have looked at the traditional elements of disclosure mandated by the informed consent doctrine.[158] Though there are some important exceptions, the largest group of studies investigates research subjects' understanding of issues peculiar to clinical research.[159]

Flanery *et al.*, using college undergraduates and medical school freshmen in an experimental design, gave their subjects a written explanation of a hypothetical clinical research protocol.[160] The investigators found that substantial proportions of the subjects did not realize that the study involved the use of a blood test and interview, were unaware that they could withdraw from the experiment at any time, and did not understand that the experiment involved random assignment.[161] These poor findings occurred even though "the consent form clearly . . . include[d] the necessary

153. *Id.* at 436.
154. McCollum & Schwartz, *supra* note 111, at 201.
155. Klatte, *supra* note 119.
156. *Id.* at 201. *See also* Appelbaum & Roth, *supra* note 151; Meisel, *supra* note 151; Roth, *supra* note 19.
157. Klatte, *supra* note 119, at 201.
158. The typical common-law elements of disclosure are (1) the nature of the procedure, (2) the "risks" and "hazards" of the procedure, (3) the "alternatives" to the procedure, and (4) the anticipated "benefits" of the procedure. Meisel & Kabnick, *supra* note 11, at 427.
159. *See infra* section IV(D)(1) at p. 302.
160. Flanery, *supra* note 109, at 34.
161. *Id.* at 35-36.

information,"[162] according to the authors. By contrast, Morrow *et al.*'s study of patients in a radiation oncology clinic demonstrated that the patients had good understanding (more than eighty percent correct answers) of procedures, purposes, discomforts and risks, their right to have questions answered, and the area of their body being treated. However, they scored low on knowledge of alternatives and diagnosis (both about thirty-five percent).[163]

a. *Understanding of Risks*

In a clinical trial of a drug, the majority of respondents were found to be well informed about the study, design, and the possible risks of participation but did not do as well in identifying specific as opposed to general risks of participation.[164] Eight-six percent of the study population were aware of a potential for the prescribed medicine to cause side effects, but only sixty-one percent could identify a specific effect such as fatigue or nausea and only thirty-six percent were able to identify more serious side effects such as congestive failure and shortness of breath.[165] The authors suggest that the details may no longer have seemed relevant (two to fifteen weeks after subjects had joined a clinical trial) or that the subjects' awareness of disabling side effects may have been suppressed.[166]

Gray reports findings which, if patients were in fact properly informed,[167] are quite troubling. Forty-one per cent of the research subjects interviewed knew "nothing" about risks of the procedures to which they had consented.[168] In addition "many more believed no risks were present."[169] What is even more troubling, however, is the fact that "relatively few recognized the possibility of unknown risk, and only two indicated that they had been informed on this possibility."[170] This is the only study, as far as we know, that made inquiry about understanding of unknown risks. We would speculate that many physicians and investigators fail to disclose that there are unknown risks, as there always are. This would seem to be a fruitful area for investigation. Another important finding is that patients may have particular difficulty understanding the concept of the probability of risk-manifestation.[171]

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162. *Id.* at 36. *See also Taub I*, *supra* note 115; *Taub II*, *supra* note 115, at 144.

163. Morrow, Gootnick & Schmale, *A Simple Technique for Increasing Cancer Patients' Knowledge of Informed Consent to Treatment*, 42 CANCER 793, 795 (1978) [hereinafter cited as Morrow]. It is difficult to determine proportions because the data are reported on bar graphs.

164. Howard, *supra* note 111, at 290, 292. Concern that research-eligible subjects might have special difficulties in being able to sufficiently understand the information presented because of their recent infarctions led administrators to incorporate special safeguards into the consent process, including a standardized guide of information for presentation to the patient. *Id.* at 287-88.

165. *Id.* at 292.

166. *Id.* at 301.

167. Gray acknowledges that he was unable to obtain data on what patients were told. B. GRAY, *supra* note 13, at 83. *See also supra* note 145.

168. B. GRAY, *supra* note 13, at 117.

169. *Id.*

170. *Id.*

171. Leonard, *supra* note 118.

b. *Understanding of Alternatives*

There has also been hardly an investigation of the understanding of alternatives, another extremely important aspect of information which ought to be disclosed and understood before one's consent should be denominated "informed."[172] Although therapeutic alternatives do not always exist, one alternative to the proposed procedure is no intervention at all. In the case of nontherapeutic research interventions, there is always the alternative of not being a research subject. In Gray's labor-induction study, "almost half" the subjects did not know what their alternatives to participation were and only offered "guesses" about the alternatives.[173]

C. *Barriers to Understanding*

In general, patients do not understand things that they need to as well as they might. This is because they are not provided with adequate information, the information is not provided in a comprehensible manner, or because despite adequate disclosure, there is some obstacle, such as their emotional state, to their understanding the information. As one thoughtful study concludes, "[n]o single act or omission, characteristic, or attribute explains why some patients' understanding is deficient."[174] Surprisingly, however, only a few of the potentially numerous barriers to understanding have been subjected to empirical scrutiny.

1. *Matters of Form*

Several studies shed some light on why patients seem to understand as little as they do. One conducted for the National Commission for the Protection of Human Subjects[175] found that consent forms that subjects in research protocols are asked to sign contained language that was too complex for most people. "[O]verall, no more than 15 percent of the consent forms were in language as simple as is found, for example, in *Time* magazine. In more than three-fourths of the consent forms, fewer than 10 percent of the technical or medical terms were explained in lay language . . . ."[176] This finding is corroborated by two other studies, one which concluded that the language of five consent forms studied was at the advanced undergraduate or graduate level,[177] and the other study of sixty

172. *See, e.g.*, Sard v. Hardy, 281 Md. 432, 379 A.2d 1014 (1977). *Cf.* Scaria v. St. Paul Fire & Marine Ins. Co., 68 Wis. 2d 1, 227 N.W.2d 647 (1975).

173. B. GRAY, *supra* note 13, at 124. This finding is corroborated by the previously mentioned finding of Morrow *et al.* that only about 35% of the patients they studied were familiar with alternative treatment. Morrow, *supra* note 163. *See also* Riecken & Ravich, *Informed Consent to Biomedical Research in Veterans Administration Hospitals*, 248 J.A.M.A. 344, 348 (1982).

174. Riecken & Ravich, *Informed Consent to Biomedical Research in Veterans Administration Hospitals*, 248 J.A.M.A. 344, 344 (1982).

175. U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *Protection of Human Subjects—Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 43 Fed. Reg. 56,174 (1978); *see also* Gray, Cooke & Tannenbaum, *Research Involving Human Subjects*, 201 SCIENCE 1094 (1978) (reporting data from same study).

176. *Id.* at 56,189.

177. Grundner, *On the Readibility of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900 (1980).

forms reports that the average readability score on the Flesch Readability formula was 41, which is in the "difficult" range.[178]

The primary reason for lack of understanding is the technical manner in which information is transmitted by doctors.[179] Compounding the import of the finding that physicians use language that is too technical for their patients[180] is the fact that patients are reluctant to ask questions.[181]

The opposite side of this coin is that the clear and simple presentation of information does assist patients in understanding, though it probably does not guarantee understanding. Bergler *et al.* believe that the high level of recall exhibited by patients who were given information about a clinical trial of hypertension medications is attributable to the fact that the consent form was written in a "clear and popular" style so that "the physician appeared to be addressing the patient directly."[182] Avoiding the use of medical jargon will also increase comprehension, but in many instances this may be difficult.[183]

Comprehension of information in consent forms is inversely related to the length of the form.[184] Lack of time in which to assimilate information may also be responsible for poor comprehension. Patients in a radiation oncology clinic, who had an opportunity to take consent forms home with them to study, understood the information far better than did patients who were asked to sign the consent form without this opportunity.[185] Not surprisingly, patients who were also provided with an opportunity to discuss written forms with a physician understood the information better than did other patients.[186] However, the *medium* of disclosure does not appear to affect comprehension. Patients assigned to four different methods of information presentation about family planning methods—videotape, structured discussion, pamphlet, and informal "rap" groups—did not exhibit

178. This compares with JAMA's score of 34 in the "difficult/very difficult range," Newsweek's score of 63, and The Amazing Spider Man's score of 99, both in the "fairly easy" range. On the Fry Readability Scale, 72.8% of these consent forms required a college level or greater reading ability for comprehension of the description of treatment methods, procedures, discomforts, and risks. U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *supra* note 175, at 56,189. *See also* B. GRAY, *supra* note 13, at 40. Gray found that the most common change required by the institutional review board was in consent forms because of complexity of language. This occurred in 18 cases, almost one-fourth of the total. The standard for "complexity" was the then-extant Public Health Service requirement that disclosure be made in a manner that is "intelligible to 'average' persons." *Id.* at 41. This of course is applied by a committee of highly educated persons, so that it may be that the forms were even more complex for laymen than they thought.

179. Korsch & Negrete, *supra* note 43.

180. *Id.* at 71.

181. *Id.* at 73. *See also supra* section III(B), at p. 271.

182. Bergler, *supra* note 123, at 438.

183. Some claim that it is the manner of disclosure, that is, the doctor's use of technical language, that is responsible for inadequate understanding and thus the remedy is for doctors to attempt to use simpler, lay terminology in talking with patients. Garnham, however, suggests that medical practice is inherently technical and that efforts to obtain informed consent ought to be abandoned in "medically naive" subjects. Instead, persons who are "medically incompetent" ought to have "someone appointed to look after their interests" and presumably make medical decisions for them. Garnham, *supra* note 120, at 143.

184. Epstein & Lasagna, *supra* note 50, at 684.

185. Morrow, *supra* note 163, at 793.

186. Williams, *supra* note 110, at 544.

significantly different levels of comprehension.[187]

Not surprisingly, patients who report that they "carefully" or even "cursorily" read the consent form tend to have significantly better recall of its contents than those who read only parts or none of it.[188] One study found that "[p]ersons who read their consent forms carefully tended to be younger, white, and better educated."[189] Perhaps more care should be taken to impart information orally to persons who may have greater difficulty understanding forms without further assistance. Indeed, perhaps less reliance should be placed on written communication overall and more on oral.

Hawkins suggests, without providing any empirical support, that there are some other barriers to understanding.[190] First, he comments that some patients would rather hear information from nurses than from doctors because "their language is easier to understand."[191] The most obvious implication is that doctors do not speak in lay terms to patients. Another possible explanation is that even if the doctors do speak in lay terms, the status differential perceived by patients makes it more difficult for them to understand. Hawkins also remarks, again without empirical support, that "[p]atients are often misinformed by other patients who give distorted accounts . . . ."[192]

Some studies postulate that the form of disclosure may have a heightened impact on patient understanding, depending on certain patient characteristics. These studies have theorized that certain subgroups, such as elderly or minority group patients, are less likely to understand information than are patients in general. Researchers have therefore attempted to isolate the characteristics of these subgroups to help doctors select more effective methods of disclosure. However, attempts to isolate predictive client characteristics and to link them with a particular method of disclosure have not as yet provided much useful information.[193] Freeman *et al.* report that noncollege-educated patients grasped less of the information presented to them than did college-educated patients.[194] Benson *et al.* sug-

187. Faden, *Disclosure and Informed-Consent: Does It Matter How We Tell It?*, 5 HEALTH EDUC. MONOGRAPHS 198 (1977). *But see Taub II*, *supra* note 115, at 137, 138. Low recall of a subgroup of older persons with low vocabulary levels may be comprehension-related, and this subgroup "might require special methods for information presentation before signing consent forms." *Id.* at 138.

188. Cassileth, *supra* note 141, at 898.

189. *Id.*

190. This was a study of what 504 clinical research patients "knew about their investigations, how much anxiety they had before and during them, and to what extent they suffered physical discomfort." Hawkins, *supra* note 25, at 638. This study drew on patients from 21 different medical and surgical wards who had undergone a large number of different kinds of medical procedures of a diagnostic nature, many of them invasive. *Id.*

191. *Id.* at 640.

192. *Id.*

193. *See* Benson, *supra* note 57; Freeman, Pichard & Smith, *Effect of Informed Consent and Educational Background on Patient Knowledge, Anxiety, and Subjective Responses to Cardiac Catheterization*, 7 CATHETERIZATION & CARDIOVASCULAR DIAGNOSIS 119 (1981) [hereinafter cited as Freeman].

194. Freeman, *supra* note 193, at 127. The study suggests the use of more concrete information-sharing sessions involving audiovisual models and samples when dealing with patients who do not have a college background. *Id.*

gest that high educational level and experience in clinical trials of contraceptives may have positively affected their subjects' high level of understanding and receptivity to detailed printed information.[195] Other studies which suggest that age or race may have highly significant effects on understanding also include data showing that race and age have no significant impact on understanding among those with higher educational levels.[196]

Riecken and Ravich, in a study of research subjects, concluded that a group of patients who had signed consent forms but were nonetheless "unaware" that they were taking part in research were not distinguishable by personal characteristics.[197] Rather, their "unawareness" seemed to be attributable to certain features of the consent process such as who did the information-sharing, the brevity of the consent form, whether or not the consent form was read aloud, and the seriousness of their illness.[198]

2. *Illness and Anxiety*

Whether or not it is true that doctors could avoid the use of technical information, there are still other reasons why patients have difficulty understanding what they are told. Among the most significant may be the anxiety engendered by illness, by dependency, and (even when well) by being placed in the position of having to make a decision. There has been, however, little empirical investigation of these issues in the informed consent studies.

Leonard *et al.*, in their study of genetic counseling, suggest that the reason that patients may not understand is that the information with which they have been presented is often unpleasant at best, and that the psychological defense mechanism of denial is responsible for their not understanding.[199] Bergler *et al.* claim that their finding that prospective research subjects who demonstrate poor recall of the side effects of a drug for the treatment of their hypertension can be explained by "the theory of individual personal denial of unpleasant realities."[200] The implication of this hypothesis, if true, is that no matter how simple and nontechnical the language doctors use in making disclosure, a high level of understanding

195. Benson, *supra* note 57, at 448.

196. *See* Fisher, Rowley & Lipkin, *Predicting Immediate Outcome of Genetic Counseling Following Genetic Screening*, 26 SOC. BIOLOGY 289, 298-99 (1979); Howard, *supra* note 111, at 297-98.

197. Riecken & Ravich, *supra* note 173, at 348.

198. *Id.* at 347-48. This factor of seriousness of illness was thought by the authors to be indicative of the fact that subjects' participation in the research may have been a relatively minor aspect of their hospitalization. *Id.* at 346. The authors further distinguish between the "unaware" and the "poorly informed." *Id.* at 348. The "poorly informed" were those with a limited understanding of the treatment regimen to which they were exposed. This latter group of patients was said to be much more likely to have had less than high school education, and, accordingly to be much less well prepared to absorb and retain the information than were patients who, though unaware of their participation in research, understood their treatment regimen. Thus, the distinction made by the authors clarifies the independent significance of factors in the consent process which inhibit physicians from obtaining informed consent to research participation, regardless of the patient's personal characteristics.

199. Leonard, *supra* note 118, at 438.

200. Bergler, *supra* note 123, at 438.

will be difficult to achieve in a large number of people if the information being transmitted deals with an unpleasant issue.

Golden and Johnston place the responsibility more squarely in the lap of the doctor, who they claim "in every instance except one [n=20], without being asked to do so, . . . left the patient's bedside without hearing whether the patient understood him clearly."[201] This occurred despite "massive amounts of anxiety experienced by the patients."[202] Thus, it is anxiety in the first instance which causes patients not to understand, and it is the doctor's failure to ascertain whether patients understand, and presumably to reexplain, which perpetuates the initial misunderstanding.

There is, in the case of psychiatric patients, yet another reason offered for poor comprehension. Palmer and Wohl state, in their study of patients' understanding of voluntary admission forms, that "[a]n obvious conjecture is that their poor comprehension is due to some combination of the degree of their disturbance at admission and the inadequacy of the institution's procedures for explaining the provisions [of voluntary admissions forms]."[203] Olin and Olin in their study of the same subject come to a similar conclusion: "Our original hypothesis that newly admitted confused patients would show a shift toward increased understanding in a relatively short time was proved by our finding."[204]

D. *Understanding and "Special" Groups: Studies Involving Psychiatric Patients and Research Subjects*

1. *Psychiatric Patients*[205]

Psychiatric patients' level of understanding of information that they have been given is not significantly worse (nor better) than that of medical patients generally. One study found that in a group of patients whose commitment status was changed from involuntary to voluntary, only thirty-five percent indicated some awareness of the matter involved.[206] Another study found that among patients who were initially admitted to a psychiatric hospital as voluntary patients, almost a fourth had severe misconceptions about information relevant to their admission.[207] Recall was also low in a group of patients whose hospitalization status was changed from involuntary to voluntary.[208] None of the patients was able to recall the content of the voluntary admision form, and even after it was reread to

201. Golden & Johnston, *Problems of Distortion in Doctor-Patient Communications*, 1 PSYCHIATRY IN MED. 127, 130 (1970). This was not a study of informed consent per se.

202. *Id.*

203. Palmer & Wohl, *supra* note 93, at 252.

204. Olin & Olin, *supra* note 92, at 940.

205. *See also supra* section IV(C)(2), at p. 301 (illness and anxiety).

206. Klatte, *supra* note 119, at 201.

207. Only 8% had a "complete" understanding of the information they had been given about voluntary admission, 24% were responsive to questions but had erroneous information, 18% were responsive to questions but answered that they did not know, and 13% gave an "irrelevant" response (that is, one with no apparent logical meaning). Olin & Olin, *supra* note 92, at 939.

208. Sixty-five percent of this group recalled signing some form. Klatte, *supra* note 119, at 31. Similarly, in a group of patients who signed a "release of information" form at the time of admission, 70% could recall having signed the form when interviewed several days later. Palmer & Wohl, *supra* note 93, at 251.

them, one-third could not even repeat a single provision. The investigators concluded that the patients' comprehension was "minimal."[209]

Other studies of informed consent in psychiatric patients involve understanding of information about medications the patients are taking. In a study of understanding of the purpose of the medication, Soskis reports that only four percent (n=25) of schizophrenic patients mentioned that their drugs were for treatment of schizophrenia, compared with forty percent (n=15) of medical patients who mentioned their diagnoses in connection with the purpose of their medication.[210] By contrast, schizophrenic patients were significantly better informed about side effects and risks than were medical patients.[211]

Findings in a later study by Soskis and Jaffe are not entirely consistent with Soskis' earlier findings. In a group of twenty-five schizophenic inpatients, eighty percent knew the reasons for taking their prescribed medication, compared with four percent in the earlier study.[212] Knowledge of side effects was again high (eighty-four percent answered correctly) as was knowledge of the risks of the medication (sixty percent).[213] The authors do not acknowledge any discrepancy between these studies.[214]

2. *Research Subjects*

One of the topics that investigators have studied relatively frequently is the nature and extent of understanding of what it means to be a subject in a clinical research protocol.[215] Several aspects of being a research sub-

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209. Palmer & Wohl, *supra* note 93, at 252.

210. Soskis, *Schizophrenic and Medical Inpatients As Informed Drug Consumers*, 35 ARCHIVES GEN. PSYCHIATRY 645, 646 (1978).

211. Eight-four percent of the psychiatric patients could name one side effect, and 60% one or more risks, while 73% of the medical patients were unaware of any side effects, and only 13% could name one or more side effects. *Id.*

212. Soskis & Jaffe, *supra* note 81, at 128.

213. *Id.*

214. The findings in the second study parallel those of Grossman and Summers who report that among 20 schizophrenic patients in an after-care center, 15% were "fully" informed, 45% were "partially" informed, and 40% were "not" informed, on the basis of oral questions administered to them about a fictitious drug which had been explained to them. Grossman & Summers, *A Study of the Capacity of Schizophrenic Patients To Give Informed Consent*, 31 HOSP. & COMMUNITY PSYCHIATRY 205,206 (1980). The investigators do not explain what they mean by "fully," "partially," and "not" informed, nor do they report what the patients were told.

Jaffe conducted a study of the recall of family members who had given consent to the administration of neuroleptics for a developmentally disabled family member. Jaffe, *Informed Consent: Recall About Tardive Dyskinesia*, 22 COMPREHENSIVE PSYCHIATRY 434 (1981). Mean overall recall of these family members in regard to side effects, treatment benefits, and risks was only 33% when tested 5 to 10 weeks after the original consent was obtained. *Id.* at 436. The author found these results "consistent with results of most previous experiments: patients (and their potential guardians) remember discouragingly little, even when giving written consent." *Id.*

215. The common-law informed consent doctrine does not expressly require that research subjects be informed that they are participating in a research protocol, at least not where the research is therapeutic, although there is limited authority that where the research is not therapeutic, such disclosure must be made. *Cf.* Halushka v. University of Saskatchewan [1965] 52 W.W.R. 608. It is not, however, stretching the doctrine too far to find such a requirement implied by the more general requirement that patients be informed of the "purpose" of a medical procedure. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 25, at 8389-8390 (to be codified 45 C.F.R. § 46.116(a)(1)). Certainly such information is "material" and should therefore be disclosed. In any event, research subjects are required to be informed, pursuant to federal regulations, of the investigative nature of any procedures to which they are subjected. *Id.*

ject are important for subjects to understand.

First, subjects should understand that they *are* research subjects. In the research project that Gray studied "only 19 of 49 . . . subjects knew before the admission that they were to take part in a research project," despite the fact that they had signed a consent form approved by an institutional review board.[216] Twenty subjects did not learn of the research until after it had begun, usually during their interviews with Gray.[217]

If subjects are to understand the import of their status as research subjects, they must also understand that the procedure is being performed exclusively or in part for the pursuit of knowledge and that the procedure may not be intended to yield any direct benefit to them.[218] One study designed principally to determine the meaning to research subjects of nonbeneficial clinical research found that, overall, subjects' understanding that participation was not intended to be beneficial was poor.[219] Of 140 mothers of research subjects, only six mothers properly understood that it was not the purpose of the research to benefit their children.[220] Similarly, Park *et al.* found that "[a]lmost all . . . patients had only a vague idea of what 'research' or 'experiment' could mean. The majority [76%] . . . did not acknowledge any awareness that research was involved at all,"[221] and only four percent were "sure" that research was involved in their treatment.[222]

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216. B. GRAY, *supra* note 13, at 66.

217. *Id.* Although Gray's methods did not allow him to determine whether many subjects' lack of knowledge resulted from their not having been informed or from inadequate efforts to communicate with patients, *Id.* at 69, he is one of the few, if not the only investigator to have acknowledged this methodologic deficiency.

218. It is important from the perspective of self-determination that patients know they are involved in research. However, when the research is therapeutic it may not be beneficial from a medical perspective for patients to know that they are involved in research. There is substantial evidence that even inert medications (that is, inactive placebos) provide therapeutic benefit to patients if patients believe that they are being treated with active medications. *See, e.g.*, Park, *supra* note 86, at 199 (quoting Fisher, Cole, Rickels & Uhlenhuth, *Drug-Set Interaction Effect of Expectations on Drug Response in Outpatients*, 3 NEURO-PYSCHOPHARMACOLOGY 149 (1964): "[P]atients . . . more often see themselves as being 'treated rather than researched and this may provide a highly favorable setting for a drug action.' "

219. McCollum & Schwartz, *supra* note 111, at 199. Actually the research subjects were children, and it was the meaning to parents of "research" that was investigated. *Id.*

220. Sixty-one mothers "thought the purpose of hospitalization [of their child] to be diagnostic and/or therapeutic. These parents had failed to understand why the medical care of their children would be undertaken in a research center." McCollum & Schwartz, *supra* note 111, at 200. Another 60 mothers partially misunderstood the meaning of being a subject in a nonbeneficial research protocol. They believed that hospitalization was both for the acquisition of knowledge *and* for the clinical benefit of their children, when in fact the investigators did not view the research as having any benefit for the children. *Id.* at 201. Mothers of nine patients viewed hospitalization as "primarily for research purposes, with little chance of direct benefit to their children." *Id.* Four other maternal responses were listed as "unclassified." *Id.*

221. Park, *supra* note 86, at 201.

222. *Id.* It is essential to realize two things about these findings, however. First, it is clear that the subjects were deliberately not informed that they were involved in a research protocol, so that there is no issue here of misunderstanding on their part. Second, this research was performed in the early 1960's, before there was any positive law requiring investigators to obtain informed consent from research subjects, though there was some common-law precedent for the requirement.

Fletcher reports similar results, namely, that subjects of nontherapeutic research "tend to confuse research and treatment." Fletcher, *Realities of Patient Consent to Medical Research*, I(1) HASTINGS CENTER STUD. 39, 46 (1973). *See also* Howard, *supra* note 111, at 290 (eight percent of

Research subjects should also know that participation in a research protocol may mean that they will be assigned to a control group receiving no treatment or only a placebo, if that is part of the experimental design.[223] Assignment to such a group means that patient-subjects, without their knowledge and permission, may be denied a procedure, usually a medication, about which there is substantial (but unsubstantiated) belief in its efficacy and safety. According to the little evidence that is available, subjects' understanding of the difference between active medications and placebos is deficient. Gray found that at least nine of the forty-nine subjects receiving placebos assumed that they were receiving an active drug.[224] "Perhaps some," he postulates, "could not divorce the idea of being in research from the idea of getting the new [active] drug."[225] In another study, the great majority of the research subjects questioned were well informed about the study's design and purposes.[226] "Eighty-nine percent knew that BHAT was a research program involving experimental drugs and a control substance."[227] But subjects did not do so well describing the assignment process or specific risks of participation.

Assignment to active treatment versus placebo is usually made on a random basis. Patients should be informed of this and should have some understanding of what random assignment is.[228] Flanery *et al.* report that only a little more than one-half of subjects in an experimental study even

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the sample of a clinical drug trial appeared to believe they were involved in a therapeutic program rather than a research project).

One study which sought to determine whether subjects in a clinical drug trial understood the investigators' reasons for doing the study reports that 16 of 17 subjects indicated that the purpose of the research was "to help the patient's arthritis" and 15 subjects also indicated that the purpose was "to help other patients." Hassar & Weintraub, *supra* note 110, at 381. This indicates that they had at least a rough understanding that research was not exclusively intended to benefit them directly. Unfortunately, the authors of this study did not ask the subjects to rank the order of importance of the investigators' reasons for conducting the study.

Another study reports that two-thirds of a group of 58 prison inmates who were subjects in a nontherapeutic drug research protocol understood the experimental nature of the study, its use of placebos, the purpose of the experiment, and the name of the drug being used. Marini, *supra* note 148, at 434. Almost all subjects identified financial remuneration as the principal benefit to them. *Id.* at 435.

223. From the perspective of self-determination, it is important that patients know they are receiving placebos. However, from the perspective of medical benefit to the patient, it may not be beneficial. *See supra* note 218. The traditional medical view is that knowledge of placebo administration " 'would engender suspicion and perhaps hostility in subjects . . . .' " Park, *supra* note 86, at 199 (quoting Liberman, *An Experimental Study of the Placebo Response Under Three Different Situations of Pain*, 2 J. PSYCHIATRIC RESEARCH 233 (1964)). This view is supported by the findings of Brownell & Stunkard, *supra* note 84, at 1487, who report that in 70% of the cases of patients receiving placebos, both the patients and the clinicians were able to determine correctly that the patients were in fact on placebos. Thus, informing patients that they may be receiving placebos in conjunction with informing them of the side-effect of active medications may influence the integrity of double-blind, controlled clinical trials of drugs. *Id.* at 1488-89.

224. B. GRAY, *supra* note 13, at 111.

225. *Id.*

226. Howard, *supra* note 111, at 300.

227. *Id.*

228. Of course, when informing subjects that assignment to treatment will be done by randomization, that term must either be explained or avoided. "[A] medical doctor has a duty to . . . explain in lay terms . . . ." Cobbs v. Grant, 8 Cal. 3d 229, 244, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972). *See, e.g.*, McLean, *supra* note 42, at 131, who told subjects "that they had been assigned to one of four different types of treatment on a purely chance basis before any personal information whatsoever was available."

recalled that the consent form contained a statement that random assignment would be used.[229] McLean took this idea one step further and found that no subject who was told that his treatment would be determined by randomization was deterred from participating in the research protocol.[230] This may well be because subjects did not know what "random assignment" meant. Use of terminology without a descriptive explanation of its meaning—namely, that the choice of therapy will not be made by the doctor in the exercise of his professional judgment as to what is best for the particular patient—will enlighten few if any subjects.

Gray, who made similar findings about research subjects' lack of understanding that their procedures were primarily for investigative and not therapeutic purposes,[231] suggests that this misunderstanding occurred in many cases because "[t]he role of patient is a familiar one, and the role of research subject is not."[232] The "invention" of benefits "makes it possible for the subject to understand the situation in terms of the familiar doctor-patient relationship."[233]

E. *Summary*

All of the findings dealing with understanding must be viewed with a great deal of skepticism. Because of the conceptual, methodological, and possibly even ideological difficulties mentioned earlier in this section,[234] it is impossible to conclude *that* patients do or do not understand, *what* they do or do not understand, or their level of understanding relative to other sectors of the population.

It is not unlikely that the data on understanding, especially on recall, will be marshalled to demonstrate that patients do not understand. This could arise in a variety of contexts, for example, by defendants in right-to-refuse psychiatric treatment cases[235] or by patients in ordinary informed consent cases.[236]

At the present time, there is absolutely no warrant for using the studies to demonstrate that patients do not understand, nor that they do under-

229. Flanery, *supra* note 109, at 36.

230. McLean, *supra* note 42, at 132. *But see* Lacher, *Physicians and Patients As Obstacles to a Randomized Trial*, 26 CLINICAL RESEARCH 375, 379 (1978), where the author found informed consent to be a major barrier to randomization in a clinical trial. He concluded that patients could not readily accept their physician's acknowledgment that he did not know the "right" therapy, and that patients found it difficult to consent to having their treatment decision made by a mathematical formula.

231. Thirty-four of 48 subjects gave as the reason for the procedure their clinical condition; only 14 correctly realized that they were receiving the procedure for research purposes. B. GRAY, *supra* note 13, at 72. *See also* Howard, *supra* note 111, at 292 (47% of subjects aware of random assignment).

232. B. GRAY, *supra* note 13, at 14.

233. *Id. See also* Appelbaum, Roth & Lidz, *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, 5 INT'L J.L. & PSYCHIATRY 319-29 (1982).

234. *See supra* section IV(A), at p. 289.

235. *See, e.g.*, Rennie v. Klein, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 102 S. Ct. 3506 (1982); Rogers v. Okin, 834 F.2d 650 (1st Cir. 1980), *vacated and remanded*, 102 S. Ct. 2442 (1982); Davis v. Hubbard, 506 F. Supp. 915 (N.D. Ohio 1980); Colyar v. Third Judicial Dist. Court, 469 F. Supp. 424 (D. Utah 1979); *In re* K.K.B., 609 P.2d 747 (Okla. 1980).

236. A patient might claim that he did not understand what the doctor told him, and thus that his "consent" is not valid.

stand. Before any such claims may be made on the basis of empirical studies, certain elementary precautions must be taken. First, investigators must be certain that patients have been properly informed. This means that the right kind of information must be given in an understandable manner. If patients are found not to understand very much of what they have been told, it is just as plausible that the reason lies in the manner of communication as it does in the qualities or the condition of the recipient.[237] Second, efforts should be made to determine what nonpatients understand of the same information. Indeed, patients could be used as their own "controls," perhaps by testing their understanding pre- or post-hospitalization and comparing it with their understanding while in the hospital.[238] Effort should be made to determine why patients understand less than do "normal" subjects, if that is in fact the finding. We need to know if there is something about being a patient—for instance, being in pain, having an illness, being in a subservient position—that impedes understanding, which might explain why an individual understands less when he is a patient than when he is not.

Finally and most important conceptually, we must arrive at some operational definition of what it means to "understand." To say that patients do not understand, or worse, that informed consent is impossible because patients do not remember is to commit the gravest of errors. The law does not, and should not, require patients to remember what they have been told, except long enough for a determination to be made as to whether they understand.

V. COMPETENCY: PATIENTS' CAPACITIES FOR MAKING DECISIONS

For reasons described elsewhere,[239] "competency" may be thought of either as a separate element of informed consent or may be coterminous with the "understanding" element of informed consent.[240] In any event, there have been, to our knowledge, only two empirical investigations which focus on competency to make medical decisions.[241]

237. *See* Morrow, *How Readable Are Subject Consent Forms?* 244 J.A.M.A. 56 (1980); Grundner, *supra* note 177; U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *supra* note 175, at 56,189.

238. Obviously, the patients would have to be tested on different material in the pre- or post-hospitalization test in order not to bias the results of the second in the series of two tests.

239. Meisel, *supra* note 151, at 42-45; Meisel, *supra* note 16; Meisel, *supra* note 1, at 446-47.

240. *See supra* section IV, at p. 284.

241. In addition to these two studies, there is one other which derives from our own larger study of informed consent in a psychiatric hospital. *See* C. LIDZ, *supra* note 13. This study sought to determine the extent to which hospitalized, depressed patients understand information provided to them about electroconvulsive therapy and psychiatric research studies, whether such patients are competent to give informed consent, and what distinguishes patients whose understanding is good from those whose understanding is not. *See* Roth, Lidz, Meisel, Soloff, Kaufman, Spiker & Foster, *Competency to Decide About Treatment or Research: An Overview of Some Empirical Data*, 5 INT' J. L. & PSYCHIATRY 29 (1982). The study found that a substantial minority of patients failed to understand significant amounts of information contained in consent forms, *id.* at 37, that approximately 75% of patients were evaluated as competent when careful efforts were made to educate them, *id.* at 40, and whether or not patients were able to understand correlated strongly with their age and the severity of their mental illness. *Id.* at 43. An important predictor of whether or not a patient would be determined to be competent was whether or not that patient required assistance in reading and understanding the consent form. *Id.*

Appelbaum and Mirkin administered fifteen questions to fifty psychiatric patients shortly after admission to an inpatient unit and then analyzed the answers to the questions according to differing concepts of incompetency. The investigators found that regardless of the definition of incompetency that they applied, over sixty percent of the patients scored less than one-third correct answers.[242] Although this study is a significant first step in the investigation of an area that is particularly difficult, primarily because of the imprecise manner in which the concept of incompetency is defined in law,[243] the study exhibits flaws which future investigators should try to avoid.

First, some of the questions asked of the subjects to determine their competency were unnecessarily value-laden. For instance, one question was, "Do you think that you have psychiatric problems?"—a negative answer to which detracted from the subject's competency score.[244] A more neutral way of phrasing this question would have been to ask, "Do you think that the authorities [or doctors] believe that you have psychiatric problems?" The investigators found that "50% of the patients [n=50] did not acknowledge their need to be in a psychiatric hospital, the vast majority of these denied it outright."[245] If this answer is to be taken as evidence of incompetency, as it was in the study, it suggests that the authors define as incompetent any patient who disagrees with the doctor. Such a definition is not only circular, but also paternalistic, and threatens to undermine the right of self-determination.[246]

The problem of incompetency to participate in medical decisionmaking looms large not only in psychiatry, where it has already generated significant litigation,[247] but also in geriatric and pediatric medicine. The threshold research question is just how significant a problem incompetency is in these three subareas of medical practice, as well as in medicine more generally. Second, it is important to determine how decisions are currently made about medical care when patients are incompetent or of dubious competency. Finally, we need to know what kinds of standards are being applied to determine incompetency; whether the standards are being applied consciously or whether the issue is largely unarticulated; what difference it makes, if any, what standards of incompetency are applied in determining whether or not an individual is incompetent; and what difference it makes, if any, as to who judges competency.

Kaufman and Roth examined some of these issues in a preliminary way by studying the determinations of psychiatrists regarding the ability of

242. Appelbaum, Mirkin & Bateman, *Empirical Assessment of Competency to Consent to Psychiatric Hospitalization*, 138 AM. J. PSYCHIATRY 1170, 1174 (1981) [hereinafter cited as Appelbaum].

243. Meisel, *supra* note 1, at 440; Roth, *supra* note 19.

244. Appelbaum, *supra* note 242, at 1172.

245. *Id.* at 1173.

246. Roth, *supra* note 19; Meisel, *supra* note 1, at 445-46. By contrast, had the authors found that 50% of the patients believed that the authorities did not believe that they had psychiatric problems, this would have been evidence either of a delusion or of a deficiency in their reasoning process, either of which is more closely related to definitions of incompetency consistent with values that reflect the individual interest in autonomy.

247. Meisel, *supra* note 16.

psychiatric patients to make decisions about undergoing electro-convulsive therapy (ECT).[248] Each psychiatrist was given the same information on which to base his decision through the use of videotaped psychiatric interviews with three hospitalized patients who had been referred for ECT. These videotapes were edited for use in the study. The content of the interviews included the nature of the patients' condition and the patients' understanding of the recommended treatment. Psychiatrists were then asked who should make the final decision as to whether the patient should receive ECT, the reason why the psychiatrists chose as they did, which of eight decisionmakers they would prefer as a proxy decisionmaker for the patient should this be necessary, and the reason for this preference. In two of three cases presented on videotape, the psychiatrists rejected the patient as the final decisionmaker about treatment. They most often preferred the patient's doctor, a team of doctors, or the patient's relatives.[249]

At least among this group of psychiatrists, the decision to accept or reject the patient as decisionmaker was not a function of whether the patient had been voluntarily or involuntarily admitted or whether the patient consented to or refused treatment.[250] Rather, psychiatrists in this study appeared to employ two main criteria in making their evaluations: (1) a clinical assessment of the nature and severity of the patient's illness, and (2) the patient's understanding of the treatment, specifically its risks, benefits, and alternatives.[251] Thus, psychiatric patients who are thought to be most gravely ill would be less likely to be permitted to make the final decision about treatment. However, this may be mitigated in some circumstances by the study's alternate finding that the greater the patient's apparent understanding of treatment the more likely it is that the psychiatrist will accept the patient's right to make the treatment decision.[252]

VI. VOLUNTARINESS: THE PRESSURES THAT COME TO BEAR ON PATIENTS

All human behavior is subject to a variety of pressures, some of which are so extreme as to deprive the behavior of some of the legal consequences that it might otherwise have had. Wills are voided if the testator was subjected to "undue influence";[253] criminal confessions are voided if "coerced";[254] and contracts entered into under "duress" are voidable.[255] So too with consent to medical care. While it is difficult to specify exhaustively the kinds of conduct that will render consent nugatory, there can be

248. Kaufmann & Roth, *Psychiatric Evaluation of Patient Decision-Making: Informed Consent to ECT*, 16 SOC. PSYCHIATRY 11 (1981).

249. *Id.* at 18.

250. *Id.* at 15.

251. *Id.* at 18. *But see* Stanley, Stanley, Peselow, Wolkin, Deutsch, Platt, Speicher, Golash & Kaufman, *The Effects of Psychotropic Drugs on Informed Consent*, 18 PSYCHOPHARMACOLOGY BULL. 102, 104 (1982) (reporting that although psychiatric patients' conditions significantly improved from drug treatment, their competency did not) [hereinafter cited as Stanley].

252. Kaufmann & Roth, *supra* note 248, at 18.

253. 1 A. CORBIN, CONTRACTS § 6 (1951); J. MURRAY, CONTRACTS § 8 (1974); 1 W. PAGE, WILLS §§ 5.7, 15.11 (W. Bowe & D. Parker eds. 1960).

254. Spano v. New York, 360 U.S. 315 (1959); Brown v. Mississippi, 297 U.S. 278 (1936).

255. RESTATEMENT (SECOND) OF CONTRACTS § 175 (1979).

no doubt as to the general rule.[256]

For present purposes, we will not attempt to determine what kinds of conduct ought to render consent involuntary and thus ineffectual.[257] Instead, we will provide an overview of the kinds and sources of pressures that may come to bear on patients in the process of making medical decisions. There is very little data addressing the central empirical[258] question about voluntariness in medical decisionmaking, namely, "What pressures from what sources come to bear on patients in the process of medical decisionmaking?" The dearth of data on voluntariness probably is a result in large part of the extraordinary difficulty of investigating this aspect of informed consent. As is the case with understanding, conceptual problems abound. But assuming either that these problems can be resolved, which is unlikely, or that operational definitions can be devised, there are still serious impediments to empirical inquiry.[259]

These pressures fall into two general categories: structural and situational. Structural pressures inhere in the roles, statutes, and institutions involved in the medical decisionmaking process. Situational pressures, by contrast, arise from transitory aspects of medical decisionmaking.

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256. "Consent is not effective if it is given under duress." RESTATEMENT (SECOND) OF TORTS § 892B(3) (1977).

> Although the term "voluntary" is nowhere defined in the statutes under consideration, it is frequently encountered in the law. Even its dictionary definition assumes an exercise of free will and clearly precludes the existence of coercion or force . . . . And its use in the statutory and decisional law, at least when important human rights are at stake, entails a requirement that the individual have at his disposal the information necessary to make his decision and the mental competency to appreciate the significance of that information.

Relf v. Weinberger, 372 F. Supp. 1196, 1202 (D.D.C. 1974) (citations omitted).

257. For a discussion of this problem, see generally 1 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE & BIOMEDICAL & BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP (1982).

258. The central legal question which cannot be answered by empirical investigation is, "Which of these pressures should be considered legitimate and which illegitimate?"

259. We are keenly aware of these problems from one of our own unpublished pilot studies in which we attempted to ascertain what sorts of influences are felt by patients to compromise their freedom of choice and the relative effect which each influence exerts. Lippo, Roth, Meisel & Lidz, *Voluntariness of Consent to Psychiatric Therapy* (unpublished 1976). This study used outpatients (n=60) in group psychotherapy in an experimental design. Subjects were asked, in a written exercise, to imagine that they were a "very badly depressed patient on an inpatient ward." A treatment was then recommended to them.

In making the recommendation, different kinds of language were used, and the subjects were asked which language was more likely to cause them to consent to or refuse treatment. We referred to these different types of language as "influence variables," as they placed different kinds of influences on the patient. The influence variables are: (1) reminding the patient that he is a voluntary patient; (2) reminding the patient that he is an involuntary patient; (3) informing the patient that he may refuse the treatment being recommended; (4) informing the patient that his family agrees with the recommended treatment; (5) threatening the patient with frightening, though real, alternatives for failing to accept the treatment; and (6) no influence variable (as a control). The hypothesis was that these "influence variables" exert differing amounts of influence on a subject, which would account for a differential rate of consent to treatment associated with each variable.

The results were quite different from our expectations. The willingness of subjects to say that they would consent to treatment depended not upon the influence variables, but upon the nature of the treatment. Thus, subjects were hypothetically more willing to consent to psychotherapy than to electroconvulsive treatment.

A. *Structural Pressures*

The fact that patients are ill or injured and often in pain is a dominant structural feature. As a result of the pain and discomfort of illness, whether physical or psychic, patients may feel that they have to do something, which may make them more willing to do that which a doctor most favors. Pain and discomfort may make a patient less aggressive in seeking alternatives, asking questions, and otherwise acting to the fullest extent of that capacity for autonomy which he manifests in other areas of daily activity. Patients may make decisions to undergo the treatment that the doctor recommends because they feel that they have no choice; they are, in effect, "pressured" by their illness. Among mothers who sought admission of their improperly developing children to a hospital to be subjects in a research protocol holding out no direct benefits to the children, McCollum and Schwartz found when the lack of benefits was explained, only three of 140 mothers refused to admit their children. "A clue to [the mothers'] conscious motivation," they contend, "is contained in the recurrent statement, 'I have no choice.' "[260]

Another phenomenon influencing decisionmaking is what might be referred to as "inertia." Patients seem to get caught up in events that involve so many other persons and so much technical information that they feel powerless to play a volitional role in decisionmaking. Instead, a recommendation is made by medical personnel, and at best patients are consulted as to whether or not they wish to go along with it, thus transforming the "recommendation" into a "decision," though one made by someone other than the patient. At least this appears to be the case in the two studies of persons asked to be tested to determine if they were suitable kidney donors.[261] Once it is determined that a person is a suitable candidate for a kidney transplant, donors are sought from among the potential recipient's close family members. Before a donor can be selected, however, tests must be performed to determine whether his kidney is suitable for removal. In one study, four of twelve potential donors said "they just went along with the tests hoping it would be someone else [who actually was found to be compatible with the prospective kidney recipient]. They could not recall ever really having made a clear decision yet they never considered refusing to go along either . . . ."[262]

B. *Situational Pressures*

The conditions under which patients are requested to make decisions are one significant situational factor which may impose constraints on their free choice. That is, a patient may be presented with the need to make a decision and then be informed that the decision must be made

260. McCollum & Schwartz, *supra* note 111, at 203; *see also* Lankton, *supra* note 44, at 295.

261. Fellner & Marshall, *Kidney Donors—The Myth of Informed Consent*, 126 AM. J. PSYCHIATRY 1245 (1970) [hereinafter cited as *Fellner & Marshall I*]; Fellner & Marshall, *Twelve Kidney Donors*, 206 J.A.M.A. 2703 (1968) [hereinafter cited as *Fellner & Marshall II*].

262. *Fellner & Marshall II*, *supra* note 261, at 2704.

now, very soon, or within a brief period of time. Thus, to all the other pressures are added the pressures of time and isolation.

To provide more breathing space within which to make a decision, Silberstein permitted prospective subjects in a clinical research protocol to take their two-part consent forms home to discuss with "friends, family, lawyers, etc."[263] To further mitigate the pressure being exerted by the investigator or by the need to make a decision per se, each patient was accompanied by a family member or other patient advocate on the second visit with the investigator. "Then, and only then, [was] a signature indicating informed consent requested."[264] Unfortunately, this study presents no comparative data as to the consent and refusal rates for patients approached in this manner as compared with the ordinary procedure for obtaining informed consent; thus, we cannot know what effect, if any, this procedure produced.

Pressures from other persons may also come to bear on the patient. Besides pressure from doctors, nurses, and other members of the hospital staff, the patient may be subjected to pressure from family, friends, employers, and other patients. The only empirical evidence that we have deals with pressure from family members.[265] How this pressure comes to bear, how strong it is, and how it operates in different circumstances are all topics which need to be, but have not been, investigated. Rather, all we know at this point is that "there appears to be a . . . family system, which also tends to influence [decisionmaking] but which is very difficult to demonstrate."[266]

C. *Voluntariness and "Special" Groups: Studies Involving Psychiatric Patients and Research Subjects*

1. *Psychiatric Patients*

When the decisions to be made involve psychiatric patients, the pressures that come to bear are permeated, if not overshadowed, by one other structural feature, namely involuntary civil commitment statutes, regulations, and procedures. Unlike the vast majority of medical decisions of a nonpsychiatric nature, persons can be hospitalized against their will for mental illness.[267] Whether, once confined, they can be treated against their will is a hotly disputed legal controversy.[268] As a matter of practice, however, some voluntary psychiatric patients do receive at least some

263. Silberstein, *supra* note 114, at 156.
264. *Id.*
265. *See* C. LIDZ, *supra* note 13, at ch. 11.
266. *Fellner & Marshall I*, *supra* note 261, at 1246. *See also* Lidz & Meisel, *supra* note 13, at 363-68.
267. *See* S. BRAKEL & R. ROCK, THE MENTALLY DISABLED & THE LAW 34-132 (rev. ed. 1971).
268. Several courts have held that there is, in one form or another, a right of involuntarily civilly committed psychiatric patients to refuse treatment. *See* Rennie v. Klein, 653 F.2d 836 (3d Cir. 1981), *vacated and remanded*, 102 S. Ct. 3506 (1982); Rogers v. Okin, 634 F.2d 650 (1st Cir. 1980), *vacated and remanded*, 102 S. Ct. 2442 (1982); Davis v. Hubbard, 506 F. Supp. 915 (N.D. Ohio, 1980); Colyar v. Third Judicial Dist. Court, 469 F. Supp. 424 (D. Utah 1979); *In re* K.K.B., 609 P.2d 747 (Okla. 1980).

treatment without their consent or acquiescence, and sometimes against their affirmatively manifested will.[269] Subject' willingness to consent to psychiatric treatment varies significantly with the type of therapy offered, but not with the persuasive tactic or type of influence used by the psychiatrist in order to obtain consent.[270]

Psychiatric patients who are involuntarily hospitalized are coerced to the extreme; they are not, *ex hypothesi*, voluntary. Yet because of the existence of an involuntary system, even patients who enter the hospital or outpatient treatment on what is denominated a "voluntary" basis[271] are not entering voluntarily in the same sense as persons who, for example, seek nonpsychiatric kinds of medical care. The very existence of a system of involuntary psychiatric hospitalization hangs like the sword of Damocles over the entire psychiatric decisionmaking process.[272] Based on their own experience, chronic patients probably know that if they refuse treatment altogether, legal process may be used to compel them to undergo treatment; certainly doctors and other hospital staff are aware that involuntary commitment proceedings may be instituted. Even if such proceedings are ultimately unsuccessful, the possibility of their being instituted may subtly or expressly affect the conduct of the parties in the "voluntary" decisionmaking process.

A study by Gilboy and Schmidt of the operation of the civil commitment process in a St. Louis hospital bears this out.[273] One of the most coercive aspects of so-called voluntary hospitalization is the involvement of the police in the process, although the degree of involvement varies both among and (despite the uniformity of law within a given state) within jurisdictions. Gilboy and Schmidt report that "about 40% of all voluntarily admitted patients are brought to the mental hospital by the police and in about 55% of the[se] cases . . ., voluntary admission results."[274]

Another important finding of this study is that there is a substantial amount of overlap between the "information" and "voluntariness" aspects of informed consent. That is, the way in which information is disclosed or withheld can exert pressures on patients in making decisions. In the Gilboy and Schmidt study, patients often operated under the mistaken belief that there were only two choices available: voluntary hospitalization or involuntary hospitalization, and if they did not choose the former, the latter would be imposed.[275]

In addition to the primary structural pressure, involuntary civil com-

269. *See* C. LIDZ, *supra* note 13, at ch. 11.

270. *See supra* note 262.

271. Aden v. Younger, 57 Cal. App.3d 662, 680, 129 Cal. Rptr. 535, 547 (1976); Gilboy & Schmidt, *supra* note 89.

272. *See, e.g.*, Marcus v. Leibman, 59 Ill. App.3d 337, 375 N.E.2d 486 (1978).

273. Gilboy & Schmidt, *supra* note 89.

274. *Id.* at 433. There is probably great variation in police involvement in the commitment process among jurisdictions and over time. In our study, the incidence of police involvement was insubstantial, though when it did occur, its effects could be substantial. *See* C. LIDZ, *supra* note 13, at ch. 7.

275. "The typical practice . . . is to explain voluntary admission to the patient in a very cursory manner, describing it as a desirable alternative to involuntary commitment." Gilboy & Schmidt, *supra* note 89, at 440. *See also id.* at 448-49.

mitment, there are other structural pressures. For many persons, especially those who are less affluent, psychiatric care can be obtained free or at a low cost only if obtained from a particular community mental health center determined by one's place of residence (referred to as a "catchment" area).[276] That is, there is little or no choice as to where the care will be obtained, thus placing additional pressure on the patient to cooperate with the recommendations of the staff. Pressure arises from the knowledge that the patient's alternatives are limited or nonexistent. As with the pressure exerted by knowledge of the existence of an involuntary civil commitment system, it is likely that the staff is even more aware than is the patient of the limitation on the patient's choice. Such awareness may act as an incentive to the staff to be less flexible in offering choices to the patient.

2. *Research Subjects*

From extensive interviews of eighteen patient-volunteers in nontherapeutic medical research, Fletcher concluded that although the subjects were not "coerced" into being research subjects, they gave "signs of having to defend themselves against their consent being 'engineered' . . . ."[277] Research subjects who are also patients are vulnerable to pressure, as is the case with all patients, because "serious illness is threatening and limiting."[278] Additionally, the imposing nature of the clinical research center, the expectations of the investigator, and the failure to understand the distinction between nontherapeutic research and treatment conspire to impel the patient to consent. Where, however, the patient is aware of his right not to be a research subject or to withdraw from research procedures, the same sense of pressure may not exist.[279]

D. *Summary*

Little empirical investigation has been made of the problem of the voluntariness of patient participation in the medical decisionmaking process. Before any determination can be made intelligently about what sorts of pressures are illegitimate, a catalog is needed of the kinds of pressures

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276. 42 C.F.R. §§ 54.102-103 (1981).

277. Fletcher, *supra* note 222, at 42.

> Thirty-nine percent of elderly persons who agreed to participate in a research study did not know they were free to withdraw at any time after they signed up, and among the subgroup of elderly who had the lowest vocabulary level, 23% indicated that someone else had submitted their name. Social pressure from peers and leaders of their senior center was thought to influence the elderly to "volunteer."

Taub I, *supra* note 115, at 689. *Accord Taub II*, *supra* note 115, at 144.

278. Fletcher, *supra* note 222, at 46.

279. *Id.* at 47. There are also some preliminary indications that family and peer pressures may operate to enhance patients' awareness of their right to refuse to participate in research. In addition to mitigating other influences in the decisionmaking process, family and friends may themselves be powerful and perhaps compelling factors in patients' decisionmaking. *See* Ratzan, *The Experiment That Wasn't: A Case Report in Clinical Geriatric Research*, 21 GERONTOLOGIST 297, 300 (1981); Howard, *supra* note 111; *Taub I*, *supra* note 115. Subjects of federally sponsored research are required to be told of their rights not to participate in research and to discontinue participation. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 25, at 8389-8390 (to be codified at 45 C.F.R. § 46.116(a)(8)). Whether or not this information is communicated other than in writing and whether or not subjects understand it are matters for further investigation.

that come to bear on patients making medical decisions. Only then can efforts be addressed to alleviating those pressures believed to be undesirable.

VII. DECISION: THE RELATIONSHIP AMONG THE COMPONENTS OF INFORMED CONSENT

The judicial cases discussing the informed consent doctrine implicitly conceive of informed consent as a simple stimulus-response process in which a doctor feeds certain information to a patient, and the patient responds with a simple consent to treatment. Informed consent in practice, as distinguished from law, is not quite so simple. As one commentator states, "Consenting must be defined dynamically to include all of those encounters between investigator and subject in which the expectations of the research agreement are being built, maintained or repaired."[280] More to the point, informed consent is not a highly structured event, but a complex and often amorphous process.

Before discussing the relevant studies, a few matters of definition must be addressed. First, although the process of medical decisionmaking is often complex, eventually some identifiable decision is made either to undergo or to forego treatment, though sometimes the decision is made more by default than by active effort. Thus, the process does eventuate in a "decision" as the simple, linear model of informed consent derived from the case law postulates.[281] We use the term "decision" to refer to the static concept, and the term "decisionmaking process" to refer to the larger process of which "decision"—along with disclosure of information, competency, understanding, and voluntariness—is a component. Included under the rubric of "decision" are such concerns as (1) whether the patient gave or withheld permission, (2) when, where, and under what circumstances the patient gave or withheld permission, (3) whether it was the patient or a proxy who gave or withheld permission, (4) in what manner permission was given or withheld, (5) why permission was given or withheld, and (6) how decisions are made. Thus, in this section, we will review findings that shed light on the "decision" component of the decisionmaking process as well as studies about the process as a whole or the interrelationship of two or more of the component parts.

The second matter of definition is that we use the term "decision" rather than "consent" because "consent" denotes a decision in favor of treatment, when in fact the decision may be to decline treatment.[282] Further, since at common law the term "consent" denotes knowledge of the nature of the act to which consent is given, we use the term "decision" to avoid conceptual overlap with "understanding" and "competency."[283] Thus, by using the term "decision," we are referring to whether the patient (or a surrogate) gives or withholds permission for a particular procedure to

280. Fletcher, *supra* note 222, at 40; *see also* Lidz & Meisel, *supra* note 13.
281. *See supra* notes 16-21 and accompanying text.
282. Goldstein, *supra* note 97, at 691.
283. *See supra* pp. 284-86.

be performed.[284]

A. *What Patients Decide*

The most fundamental inquiry involving the "decision" aspect of informed consent is the nature of the decision that patients make. More simply put, in what proportions do patients *consent* or *refuse* to undergo procedures? This inquiry is, however, almost meaningless without relating it to the precedent issues of information, understanding, and voluntariness. That is, knowledge of the proportion of consenting and refusing patients, by itself, is of little or no value without knowing what patients were told, what they understood, and to what pressures, if any, they were subjected. Taken together, the relationship among these components of informed consent constitutes the crux of the process of informed consent.

One illustration of why the answer to the question "what do patients decide," standing alone, is meaningless is provided by a study purporting to investigate the ability of patients to give "valid" consent to psychiatric hospitalization.[285] The investigators report that sixty-five percent of the patients consented to admission, that twenty-five percent did not consent, and in the remaining ten percent of the cases, it was not possible to ascertain whether patients had consented or refused.[286] If the investigators had looked at the relationship between patients who had consented to hospitalization (or refused it) and the information they had been given, what they had understood, and how if at all they had been influenced by others in making a decision, perhaps we would have some data of significance. The bald findings simply provide no useful information.

B. *Information and Understanding*

Surely one of the most important issues raised by the informed consent doctrine is the relationship between the disclosure and understanding of information. In light of the rather uniform belief, if not findings, that patients do not understand as much as doctors would like them to, it is essential to attempt to ascertain the reasons for inadequate understanding. One of the most likely reasons is that patients do not understand because they have not been adequately or properly informed.

One of the reasons that patients have difficulty understanding information that doctors give them has to do with the way in which disclosure is made. A study by Fisher *et al.* provides results that strongly suggest that a

284. When speaking of authorization given on behalf of an incapacitated person by a surrogate decisionmaker, the term " 'permission' [is used] rather than 'consent,' to distinguish what a person may do autonomously (consent) from what one may do on behalf of another (grant permission)." U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *Protection of Human Subjects—Research Involving Children: Report and Recommendations of the Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research*, 43 Fed. Reg. 2084, 2087 (1978) (comment to recommendation 7), *amended and adopted*, 43 Fed. Reg. 31,787 (1978). *See also* U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *Protection of Human Subjects—Research Involving Those Institutionalized As Mentally Infirm: Report and Recommendations of the Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research*, 43 Fed. Reg. 11,328, 11,341 (1978).

285. Dabrowski, *supra* note 145.

286. *Id.* at 440.

physician's presentation of the information to be disclosed will directly affect patients' apprehension of its importance to them.[287] The results showed a high agreement (85%) between what health care professionals and the "public" generally believe a patient should know.[288] However, these results were, as the authors point out, confounded by the way in which the study was conducted.[289] The authors conclude that "the public tends to rely heavily on professional judgment, particularly when the experts are expressing concern about dangers and risks in taking medications."[290]

According to Epstein and Lasagna, the comprehension of information decreases as the amount of information given increases.[291] Therefore, they suggest that the use of longer, more detailed "consent forms" impedes understanding. Second, limited findings indicate that the medium of disclosure does not affect patients' understanding of information,[292] but rather the complex language often used by doctors to make disclosure inhibits understanding.[293] Finally, the use of written forms—consent forms or "informed consent forms" as they are sometimes misleadingly titled[294]—does not assure either that disclosure in fact occurs or that patients understand the information contained in them. Hospital staff members develop routines for evading the use of forms which were designed in part to assure that disclosure is in fact made.[295] Even where the use of forms is not evaded, patients do not seem to get very much out of them, in part, because the staff also develops devices for undercutting the significance of the information, such as by saying to the patient about signing the form, "this is just a formality."[296]

The relationship between disclosure and understanding is fundamental to informed consent theory. There is a clear need for research aimed at learning how different methods of disclosure affect patient understanding and how disclosure can be modified to increase comprehension.

C. *Information and Decision*

A relatively large number of studies reports findings which shed some light on the relationship between the nature and extent of disclosure that doctors make to patients and the decision that patients ultimately render, that is, whether patients consent to or refuse treatment. Although most of

287. Fisher, Mansbridge & Lankford, *Public Judgments of Information in a Diazepam Patient Package Insert*, 39 ARCHIEVES GEN. PSYCHIATRY 707, 711 (1982).

288. *Id.* at 709.

289. *Id.* at 711. The facts presented to the public were first reworded and assigned priority by the experts. They were then broken down into individual fact units and placed on cards for the subjects to rank. The subjects chose 16 of the 17 facts that were stated in the imperative. *Id.* at 710.

290. *Id.* at 711.

291. Epstein & Lasagna, *supra* note 50, at 684.

292. Faden, *supra* note 187, at 204.

293. Garnham, *supra* note 120; *see also supra* section IV(A)(1), at p. 286.

294. Goldstein, *supra* note 97, at 692.

295. Lidz & Roth, *The Signed Form—Informed Consent?*, in SOLUTIONS TO LEGAL AND ETHICAL PROBLEMS IN APPLIED SOCIAL RESEARCH 144 (R. BORUCH & J. CECIL eds. 1983).

296. *Id.*

the studies containing such findings did not actually set out to investigate this aspect of informed consent per se, a few studies have.

There is evidence that disclosure to patients of unpleasant information about contemplated procedures does not lead to their declining the procedure.[297] However, none of the studies on which this evidence is based used a control group, so that we do not know what the consent and refusal rates would have been in the absence of such disclosure. Alfidi found that making full disclosure to patients about the risks of angiograms resulted in only four refusals out of 232 patients.[298] Similarly, Leydecker *et al.* report that no patients refused cataract surgery after detailed disclosure of the risks.[299] Furthermore, providing psychiatric patients in a research protocol with information about "an experimental manipulation of medicine—in their own interests—did not appear to result in dropouts . . . ,"[300] nor did "a more detailed, informative and truthful introduction [of a study of sexual behavior and drug use] adversely affect either overall response rate or responses to individual questions . . . ."[301] Also, Hershey and Bushkoff found that, contrary to physicians' fears, detailed disclosure of the procedures and risks involved in surgery did not make patients so apprehensive that they would become sick or refuse the procedure.[302] Finally, all 100 patients in a study consented to peroral endoscopy despite the fact that thirty-four percent felt that full disclosure had increased their apprehension about the procedure.[303]

As is the case with so many other aspects of informed consent, there are data to support a contrary conclusion as well. For instance, in an experimental design in which 100 subjects were given a hypothetical case of a man with a suspected brain tumor faced with the decision whether to undergo a cerebral arteriogram, fifty percent of the subjects would have refused the procedure because of one complication or another about which they had been informed.[304] "Sixty percent of those who have refused did so only because of specific, detailed knowledge of stroke syndromes, and the highest rates of refusal were for the most sinister complications."[305] Similar results are reported in another study also using an experimental design in which willingness to participate was "inversely related to the subjects' belief that participation would be dangerous."[306] Perhaps the discrepancy between these two groups of findings can be explained by the difference in design. Subjects in an experimental design who are not actu-

297. *But see* text accompanying note 413.

298. Alfidi, *supra* note 53, at 1328.

299. Leydhecker, *supra* note 57, at 244.

300. Park, *supra* note 94, at 350. *See also* Park & Covi, *supra* note 87. Disclosure of the inert contents of placebo pills did not adversely affect patients' willingness to consent. Of the 15 patients who started the study, only one did not agree to take the "sugar pills" at the conclusion of the first interview. *Id.* at 337-38.

301. Singer, *Informed Consent: Consequences for Response Rate and Response Quality in Social Surveys*, 43 AM. SOC. REV. 144, 159 (1978).

302. N. HERSHEY & S. BUSHKOFF, *supra* note 26, at 26, 43.

303. Roling, *supra* note 57, at 70; *see also* B. GRAY, *supra* note 13, at 97.

304. Rosenberg, *supra* note 57, at 67.

305. *Id.*

306. Stuart, *supra* note 113, at 78.

ally suffering from an illness may be more inclined to state that they would refuse a procedure because of its risks than would be persons who are actually suffering from that illness.[307]

Not surprisingly, the variations in the way information is presented have an effect on patient decisionmaking. McNeil *et al.* instructed subjects to assume that they had operable lung cancer and were made to choose between two alternative therapies, either radiation or surgery.[308] Patients chose radiation therapy less often when it was specifically identified than when the same information was given as to its treatment effects, but it was referred to as treatment "B."[309] In addition, patients chose surgery more often when information regarding the possible treatment outcomes was framed in terms of the probability of survival rather than in terms of dying.[310] The authors suggest that a "cognitive illusion" is created by explaining the same results using different terminology, and that a bias toward one or the other treatment alternative may be reduced by awareness of the effects of presentation on decisionmaking.[311] They note, however, that their findings also illustrate the difficulty of selecting appropriate "summary data" for presentation to the patient.[312]

The manner in which disclosure is made may also affect the decision that the patient renders. Barbour and Blumenkrantz found that supplementing oral disclosure with an explanatory videotape caused many patients to change the decision that they had made based on oral disclosure alone.[313] However, change was in both directions. That is, many patients who had decided not to participate as subjects in a research protocol agreed to join the study after seeing the videotape, and some patients who initially volunteered changed their minds later.[314] Boria and Gordon report similar results involving patients seeking sterilization operations.[315] Approximately fifty percent of those who initially sought sterilization concluded, after obtaining more information about the procedure, that they were "not ready" for it. In the other half of the cases, the receipt of information confirmed the patients' original intentions.[316]

In a study of consent by psychiatric patients to release of information to a state mental health department, there were no refusals among patients who were merely given an opportunity to read the release form and sign it.

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307. There is also some evidence in the "voluntariness" literature that this is the case. *See infra* section VI, at p. 309.

308. McNeil, Pauker, Sox & Tversky, *On the Elicitation of Preferences for Alternative Therapies*, 306 NEW ENG. J. MED. 1259 (1982).

309. *Id.* at 1261.

310. *Id.* at 1262. The risks involved in this type of lung surgery are greater than with radiation (10 out of 100 patients die in surgery; no one dies from radiation), but those who survive surgery have a greater life expectancy (6.8 years versus 4.7 years for those who receive radiation). *Id.* at 1260-61.

311. *Id.* at 1262.

312. *Id.*

313. Barbour & Blumenkrantz, *Videotape Aids Informed Consent Decision*, 240 J.A.M.A. 2741 (1978).

314. *Id.* at 2742.

315. Boria & Gordon, *Legislation or Education? A Practical, Effective Approach to the Problem of Informed Consent in Elective Sterilization*, 13 ADVANCES IN PLANNED PARENTHOOD 21 (1978).

316. *Id.* at 22-23.

However, when this procedure was supplemented by an oral statement assuring the patient that "if you don't sign you will get the same services from us as if you did sign,"[317] patients refused to sign the release form in eighty percent of the cases in one clinic and in fifty-nine percent in another.[318] That the content of the information alone is not determinative of the patient's decision is clear from the differential release rates in these two clinics and from the investigator's explanation that "[t]he discrepancy in the compliance rates [in the two clinics] . . . was probably influenced by the status or power of the worker who presented the forms to the client. In Clinic A, a clerk stated the option, whereas in Clinic D, the professional stated the option."[319] Although it is not possible to be certain and there is evidence to the contrary,[320] a plausible explanation for these findings is that different or supplemental modes of disclosure lead to greater understanding of the disclosed information, which then affects the decision that the patient makes. Investigation of the disclosure-understanding decision nexus is high on the list of priorities for further study.[321]

The absolute amount of information that patients receive may play a determinative role in whether they consent or refuse. Epstein and Lasagna gave an experimental group different length consent forms containing information about a mock research protocol.[322] They found that the longer the consent form, that is, the more information a subject was given, the greater the likelihood of refusal to participate in the research protocol.[323] One doubt about the validity of this result, however, arises from the fact that the longer consent forms do not only present more information, but also present it in a different way. Specifically, with the shorter forms the risks of the procedure are played down and the language is more conversational than in the longer forms.

The most ambitious of the studies of the decisionmaking process is one conducted by Michaels and Oetting which illuminates the relationship between the risk/benefit ratio and the nature of a patient's decision.[324] One hundred and fifty college students were asked to indicate which of a list of possible procedures (some "physical" and some "psychological") they would and would not allow to be done to them as part of an experi-

317. Rosen, *Why Clients Relinquish Their Rights to Privacy Under Sign-Away Pressures*, 8 PROF. PSYCHOLOGY 17, 19 (1977).

318. *Id.* at 20.

319. *Id.* at 22.

320. Faden, *supra* note 187; *see also* text accompanying note 187.

321. One study which does not involve informed consent still presents some interesting findings on the effect of information on the decision that patients make. Bunker & Brown report in a study of the utilization of surgical services by physicians and their families that operation rates were higher than those of other "well-informed" professional groups, and that the rates for all professional groups were about 25-30% higher than for the country as a whole. They conclude that "as the public becomes more fully informed, the demand for surgical services will increase." Bunker & Brown, *The Physician-Patient As an Informed Consumer of Surgical Services*, 290 NEW ENG. J. MED. 1051, 1051 (1974). The implication of this study for informed consent are somewhat unclear since we do not know what information the patients had and to what extent the information may have emphasized benefits of the expense of risks.

322. Epstein & Lasagna, *supra* note 50, at 682.

323. *Id.* at 684.

324. Michaels & Oetting, *The Informed Consent Dilemma: An Empirical Approach*, 109 J. SOC. PSYCHOLOGY 223 (1979).

ment. They were then told what the benefit of the experiment would be and asked to sign the consent form. The subjects were divided into five groups, each of which was told that its members would receive a different benefit, denominated as "low personal," "high personal," "low societal," "high societal," and "no stated benefit."[325] The investigators concluded that "the benefits offered had no significant effect" on the willingness of the subjects to participate in the hypothetical experiment.[326] Rather, subjects seemed only to be concerned with the nature of the risk or discomfort involved and not with the benefit that would accrue by virtue of their assuming that risk.[327] What this suggests is that decisionmaking does not involve a simple weighing of risks against benefits.[328]

Although Stanley *et al.* did not set about to study the relationship between the risk/benefit ratio and the "sign" of decision (that is, whether the patient consents or refuses), their study of the relative willingness of psychiatric and medical patients to consent to hypothetical research studies provides incidental findings on this topic.[329] Roughly three-fourths of the subjects (n=65) consented to participate in studies involving low risks and high benefits in contrast to about one-fourth to one-third who agreed to participate in studies with high risk and low benefit.[330] Not surprisingly, in a hypothetical study involving moderate risk and high benefit, about forty-five percent of the subjects agreed to participate.[331] This means that there is a roughly linear relationship between the risk/benefit ratio and the refusal/consent ratio.

While the disclosure of information may not induce refusals, there is some evidence that neither does nondisclosure. In other words, disclosure or withholding or information may not be related to whether one consents or refuses. Bergler *et al.* report that

> [o]f the 39 entering participants [in a clinical trial of hypertension medication] only 7 indicated . . . that they would not have participated without having received the associated information, and 2 indicated that they probably would not have. Seven said they probably would have agreed to participate without having been informed, and 23 indicated they definitely would have agreed to participate without the information.[332]

Data from the survey by Singer and Frankel suggests that researchers do not "pay a price by giving respondents more information ahead of time:

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325. *Id.* at 226-27.

326. *Id.* at 228.

327. *Id.* The finding may account for Berscheid, et al.'s results which indicated that the greater the amount of information provided in a hypothetical context, the greater the refusal rates to participation in a stressful experiment. Berscheid, Baron, Dermer & Libman, *Anticipating Informed Consent: An Empirical Approach*, 28 AM. PSYCHOLOGIST 913, 920 (1973) [hereinafter cited as Berscheid].

328. The problem with this is that the investigators did not standardize the risks involved. That is, each subject was asked to state which risks were acceptable to him, and it must have been those acceptable risks which were weighed against the proposed benefits.

329. Stanley, *supra* note 122.

330. *Id.* at 671 (table 1).

331. *Id.*

332. Bergler, *supra* note 123, at 437 (patients saying what they would have done, not what they actually did).

on the contrary, they may benefit from such a procedure."[333] In a study that specifically experimented with different ways of informing subjects who were being asked to participate in a survey, researchers who provided the greatest detail about the content as well as the purpose of the questionnaire achieved the highest response rates and encountered the fewest refusals.[334] Some elements of the disclosure were believed to affect the subjects' initial decision to participate in the research, while other elements were believed to have an impact on other aspects of the decisionmaking process. A variety of factors, such as qualities associated with the interviewer, the nature of the topic disclosed, or the announced length of the interview, affected primarily the subjects' initial decisions to participate. On the other hand, the assurance of confidentiality and the description of the study's purpose appear more likely to affect the quality of the response made by those who decide to participate, that is, how willing subjects are to share information about themselves which they consider sensitive.

All of the foregoing studies shed light on the disclosure/decision nexus and suggest, but do not establish, a causal connection between what is told and what is decided. The studies simply draw this inference from the correlation that is found between the two variables. However, Faden and Beauchamp have explicitly attempted to study the causal link. They report that in 284 patients considering which, if any, nonsurgical contraceptive techniques to employ, there was no evidence that the patients' decisions were based exclusively, or even primarily, on information given to them about the techniques.[335] The overwhelming majority (eighty-eight percent) did not identify disclosed information as the most important factor in making their decision,[336] and one-third said that disclosure had *no* effect on their decision.[337] In fact, a startling ninety-three percent reported making their decision before disclosure was made and only four percent of this group changed their minds as a result of the disclosed information.[338] The investigators correctly caution that in other medical settings where patients may have less familiarity with treatment options prior to disclosure, disclosed information may have a greater influence on decisionmaking.[339]

The studies do not suggest, as the informed consent cases implicitly prescribe, that patients engage in a utilitarian process of weighing, at least not one of which patients are conscious or which investigators are able to discern. The only study that even mentions the possibility of patients making decisions in this way concludes that they do not do so.[340] Rather, the consensus is that it is doctors, not patients, who in effect make decisions. The studies suggest, though they do not expressly focus on this issue, that

333. Singer & Frankel, *Informed Consent Procedures in Telephone Interviews*, 47 AMER. SOC. REV. 416, 421 (1982).
334. *Id.* None of the differences were statistically significant.
335. Faden & Beauchamp, *supra* note 78, at 326.
336. *Id.*
337. *Id.* at 327.
338. *Id.*
339. *Id.* at 328.
340. *Fellner & Marshall I*, *supra* note 261, at 1247.

doctors make recommendations and give patients some information about the recommended procedures, and patients go along with the decisions.[341] Fellner and Marshall, in one of their two studies of kidney donation, report that donors "could not recall ever really having made a clear decision yet they never considered refusing to go along either . . . ."[342]

Patients may go along with doctors' recommendations simply because of the trust that patients place in doctors.[343] One study found that seventy-five percent of patients studied (n=39) stated that they would have been willing to participate in the clinical trial of a hypertension medication without having received any information about it.[344] The investigators concluded that although patients desire information, "the most important factor motivating most of them to give their consent appears to be their confidence and trust in the physician and nurse rather than in their understanding of the information provided in the consent procedure."[345]

Although information provided by doctors may not be a prime ingredient in decisionmaking, decisions are not necessarily made blindly by patients, relying only on trust in a particular doctor or in the status of the medical profession generally. Patients sometimes obtain information about a particular treatment from their own prior experience with that treatment[346] and may request their doctor to provide the same treatment again.[347] In some cases, patients even ask for drugs about which they know but which they have never taken. The doctor will prescribe the requested drug despite knowledge of common and undesirable side-effects or despite the doctor's belief "that he did not see what [a particular] injection could possibly do to alleviate that particular condition . . . ."[348]

In an effort to test the belief of many investigators that disclosure to research subjects that their treatment will be selected by randomization deters participation in research, McLean divided a group of potential subjects in a research protocol for the treatment of depression into two groups, only one of which was informed that assignment was by randomization.[349] Since none of the subjects (n=104) who received information about randomization refused to participate in the research, there is a strong temptation to conclude, as McLean does, that informing patients of random assignment to treatment does not affect their decisions.[350] However, since none of the subjects who were not informed of randomization (n=22) refused to participate in the research, it is possible that there was something about the subjects, the nature of the research protocol, or the way in

341. *See Fellner & Marshall II*, *supra* note 261, at 2706; McCollum & Schwartz, *supra* note 111, at 204. Our own research supports these findings. *See also* C. LIDZ, *supra* note 13; Lidz & Meisel, *supra* note 13.
342. *Fellner & Marshall II*, *supra* note 261, at 2704.
343. Roling, *supra* note 57, at 70; Garnham, *supra* note 120, at 141; *see also* Beecher, *supra* note 145.
344. Bergler, *supra* note 123, at 438.
345. *Id.* at 439.
346. *See supra* section III(C.), at p. 276.
347. Boreham & Gibson, *supra* note 31, at 413.
348. *Id.*
349. McLean, *supra* note 42, at 130.
350. *Id.* at 132.

which they were informed about the protocol that accounts for the 100% consent rate. Under other circumstances, disclosure of the fact and implications of randomization might induce some subjects to refuse.[351]

In summary, the findings on the relationship between the nature and extent of disclosure and patient consent or refusal are far from clear. Some researchers claim that risk-disclosure leads to refusals; others claim it makes no difference. It may be that the overall amount of information provided affects the decision, with consent decreasing as information increases. This suggests that too much information may confuse patients and cause them to opt for doing nothing. The problem with the studies as a group is that they do not clearly separate the different variables that may be at work, including (1) amount of information, (2) nature of information (about risks, benefits, nature of the procedure, alternatives), (3) manner of disclosure, and (4) the effect of using "normal" subjects as compared with patient-subjects. The actual relationship is probably far more complex than the simple linear relationships hypothesized and tested in these studies.

D. *Understanding and Decision*

The informed consent doctrine presumes that when disclosure is made to a patient, the patient will understand the information and make a decision on the basis of a weighing of that information.[352] The foregoing studies of the disclosure/decision nexus implicitly make the same assumption. Both in fact and in theory, however, there are grounds for belief that not all patients will understand all information, which is reflected in law in the notion of "incompetency" to consent to (or to refuse) medical treatment.

We have already indicated that we believe that the term "informed consent" is unfortunate, for it assumes implicitly that the medical decisionmaking process eventuates necessarily in "consent" to treatment when, more properly, we should be speaking about an informed "decision." The primary purpose of the informed consent doctrine is to assure that patients have adequate information to allow them to make rational decisions about medical treatment, not to assure that they choose a particular, or even any, treatment. That is, the informed decision that the patient makes may certainly be a consent, but may equally well be a refusal.

Some, though not many, of the empirical studies of informed consent have investigated the relationship between understanding and the "sign" of decision—that is, whether it is positive (consent) or negative (refusal). The issue in which we are interested, more specifically stated, is whether or not a greater (or lesser) level of understanding is likely to result in a patient consenting to treatment or participation as a research subject or refusing it. A few studies have yielded some findings on this issue.

Epstein and Lasagna divided their subjects in an experimental design

351. *See* Lacher, *supra* note 230, at 377 (7 out of 12 subjects approached for consent to a clinical trial refused randomization after full disclosure).

352. *See* Meisel, *supra* note 16. In a sense, this is what the "presumption of competency" means, at least in the context of medical decisionmaking.

into three groups.[353] Each group was given a different consent form about the same mock research protocol. Although each description of the protocol contained in lay terminology the same basic information about the purpose and duration of the study and risks and dosage of the drug under "study," there was a varying degree of "elaboration" of the information in the three forms (referred to as the "short" form, "medium" form, and "long" form).[354] After reading the descriptions, all subjects were administered the same questionnaire testing their comprehension of the material and asking whether they would consent to participate in the study.[355] The investigators claim that the questionnaires were constructed so that it was possible to get a perfect score regardless of the particular description of the study read by a subject.[356] The willingness of patients to consent to participation in the study was found to be inversely related to the length of the form, as was comprehension of the information in the form.[357] Thus, we might conclude that the better the subjects understood the form, the more willing they were to consent; the less well they understood the information, the more likely they would refuse.

Another experimental study which looked both at comprehension and willingness to participate in a mock research protocol came to a contrary conclusion. Flanery *et al.* found that subjects who misunderstood the consent form were more likely to be willing to consent than were subjects who understood it.[358]

It may be that these findings clearly contradict those of Epstein and Lasagna. On the other hand, it may be that the differential findings reflect some other variable for which neither group of investigators has accounted, most likely the nature of the information which was understood or not understood, and/or the manner in which information was misunderstood. If the information that was understood was essentially benign, it is plausible both that subjects understood it and that they consented to participate in the study. By contrast, if the information that was understood was frightening, such as information about risks of the study, it is plausible that the subjects would both understand it and would refuse to participate in the study. Still another possibility is that the information was actually frightening but misunderstood to be benign, and hence subjects who misunderstood would be more likely to consent to participate. Without a better idea of what information was understood and misunderstood, it is difficult either to reconcile the findings of these two studies or to determine the relationship between level of understanding and the sign of decision.

Stuart's study illuminates this problem somewhat.[359] He distributed to five groups of subjects different descriptions of the same mock research

353. Epstein & Lasagna, *supra* note 50, at 683.
354. *Id.* at 682-83.
355. *Id.* at 683.
356. *Id.* at 683.
357. *Id.* at 684.
358. Flanery, *supra* note 109, at 36 (table 3).
359. Stuart, *supra* note 113.

protocol. However, instead of merely giving increasingly more detailed descriptions of the same basic information, as did Epstein and Lasagna, certain of the versions of Stuart's forms contained different information.[360] Stuart found that "subjects . . . show[ed] a statistically significant decrease in their willingness to participate as the experiment was described in increasing detail."[361] However, the design of the experiment was such that subjects were not merely given more detailed or more comprehensible versions of the same information in the different forms, but were actually given information about risks that not all other subjects received.[362] Stuart concludes "that a specific awareness of aversion was the only condition that led a majority of subjects to decline participation . . . ."[363] There is little doubt that while quantity of information may bear an inverse relationship with comprehension, as Epstein and Lasagna claim, comprehension per se does not fully explain whether a patient will consent to or refuse a procedure. Rather, the nature of the information understood or misunderstood must also be taken into account.

E. *Patients' Attitudes Toward Their Participation in Decisionmaking*

One study focused on patient preferences about the roles of physicians and patients in making decisions about a hypothetical, but common, medical situation involving a continuing sore throat.[364] Subjects were asked to rate the importance of the physician alone making decisions versus that of letting the patient decide. The majority of subjects did not want the entire responsibility for making their own medical decisions. However, neither did they desire to be entirely passive in the physician-patient relationship.[365]

F. *Information and Voluntariness*

In theory, there is some overlap between voluntariness and other elements of informed consent: between voluntariness and information on the one hand, and voluntariness and decision on the other. The overlap or interplay between voluntariness and information results from the fact that

360. *Id.* at 75-76. Forms 2-4 gave additional information about risks or gave it in a more comprehensible fashion. Forms 4 and 5 contained information giving contraindications to participation—that is, advising persons with certain kinds of illnesses not to participate. Form 5 also offered $20 for participation, whereas all the others offered only $5. Form 5 was otherwise identical to Form 4, with its greater disclosure of risks, inconveniences, and contraindications to participation.

361. *Id.* at 76.

362. For example, Form 2 explains that one of the procedures "involve[s] the use of aversive stimulation." Form 3 uses the phrase "moderately painful electric stimulation." Thus, Form 3 does not merely provide more detailed information, but more comprehensible information and in a manner which may affect the subject's decision. *See id.* at 76.

363. *Id.* at 76-78.

364. Vertinsky, Thompson & Uyeno, *Measuring Consumer Desire for Participation in Clinical Decisionmaking*, 9 HEALTH SERVICES RESEARCH 121 (1974).

365. *Id.* at 121. Further, certain subgroups of patients may have a greater desire for participation than others. Older patients, those who frequently visit the physician or who have had lengthy hospital stays, were found to have had a lessened desire to participate, *id.* at 130, while those who have had their family physician for less than one year scored above average on patient involvement in decisionmaking. *Id.* at 131.

providing patients with information shapes the decision that they will make, as indeed the informed consent doctrine contemplates. However, there may be a point at which the amount of information actually provided exceeds the amount required to be provided by the legal standard of disclosure and "pressures" the patient into making a decision, or a point at which the manner of disclosure, for example, playing down risks and alternatives, and stressing benefits, affects decisionmaking. What little empirical evidence there is about the effect of coercive information on the outcome of patients' decisions suggests that when such information is in the gray area of legitimacy, that is, when the content of the information threatens sanctions which would not be illegal if actually applied, it has little or no effect on the outcome of decisions.[366]

By contrast, inadequate information about important aspects of a particular decision may play an important role in making a choice different from that which would have been made had more relevant information been available.[367] This is a particularly acute problem in the hospitalization of the mentally ill, as the study conducted by Gilboy and Schmidt substantiates.[368] For one thing, individuals facing involuntary commitment, especially when brought to the hospital by the police, often believe that the only alternative to involuntary hospitalization is voluntary hospitalization.[369] Such individuals are unaware that there may be other options (in the form of outpatient treatment) or that they may not meet the legal criteria for involuntary commitment.[370] They may also be mistaken in the belief that there are advantages to voluntary hospitalization that will not accrue from involuntary hospitalization,[371] when the fact is that involuntary patients sometimes enjoy greater rights than do voluntary patients.[372]

G. *Manner of Obtaining Consent: Oral Versus Written*

Asking a research subject to consent in writing rather than orally seems to prompt refusals.[373] There is, however, no evidence as to whether or not doctors usually obtain consent in writing or orally, except in the case of experimental procedures. Where patients are requested to participate in medical research protocols, the only data available indicates that "usually" consent is obtained in writing.[374] No doubt this finding reflects

366. *See* note 259 *supra*; *see also supra* section VI, at p. 309.

367. This assumption is one of the bases of the informed consent doctrine and dictates some of the rules of recovery in informed consent litigation, for example, the requirement that the plaintiff prove that the undisclosed risk was the legal cause of his injury. *See generally* Meisel & Kabnick, *supra* note 11, at 438-41.

368. Although the findings are based on data in St. Louis in 1969-70 and no doubt vary in frequency and intensity from place to place and over time, especially in light of the increased concern with the rights of persons in the mental health process, the nature of the problems which Gilboy & Schmidt document is probably universal.

369. Gilboy & Schmidt, *supra* note 89, at 439-40, 452.

370. *Id.*

371. *See generally* A. BROOKS, LAW, PSYCHIATRY AND THE MENTAL HEALTH SYSTEM 736-39 (1974).

372. *See, e.g.*, *In re* Buttonow, 23 N.Y.2d 385, 244 N.E.2d 667, 297 N.Y.S.2d 97 (1968).

373. Singer, *supra* note 301, at 159.

374. U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *supra* note 175, at 56,188.

the fact that federal law requires consent to be in writing;[375] however, there is no such requirement in nonexperimental procedures.[376] When research subjects are to be asked questions about highly sensitive subjects, an assurance that their answers will remain completely confidential "appear[s] to affect the rate of nonresponse to individual questions,"[377] but does not affect subjects' willingness merely to be interviewed.[378]

H. *When Decisions Are Made*

Both empirical and anecdotal literature on informed consent and case law[379] hint at another significant issue which has not been studied directly: the timing of obtaining informed consent. Occasionally, studies indicate that informed consent was obtained just prior to surgery. It is important to investigate the relationship between the proximity of informed consent to performance of the procedure and whether or not the patient consents or refuses. To the extent that patients decide to undergo procedures and are informed of risks only just prior to their performance, we anticipate that the patients are psychologically committed to the procedure and that the disclosure of risks is unlikely to change their minds. However, if patients receive the information before the decision is made, and certainly if some time in advance of the procedure, it is possible that risk-disclosure will make it more likely that they will refuse treatment. This hypothesis is supported by Gray's finding that subjects who learned for the first time in the labor room that they were research subjects undergoing a procedure not for their benefit, but purely for the discovery of new knowledge, were less likely to report giving "serious consideration" to their decision to participate in the research than were persons informed at an earlier time.[380]

I. *Proxy Decisionmaking*

A large number of issues, almost none of which have been addressed in the empirical literature, involve proxy decisionmaking. Most important among them are (1) the frequency of use of proxy decisionmakers, (2) the conditions under which proxies are used, (3) the identity of the proxy, (4) the frequency of proxy-consent as opposed to proxy-refusal, and (5) the willingness of doctors to rely upon on proxy decisions (most likely refusals) which do not concur with the doctors' own recommendations. In

375. Prior to the 1981 revision of the federal regulations governing research with human subjects, *see* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 25 (to be codified at 45 C.F.R. Part 46), it was unclear whether or not it was permissible to obtain consent orally. The regulations contained two provisions for obtaining written informed consent. *See* 45 C.F.R. § 46.110(a), (b) (1979). A third provision stated that "[m]odifications of either of the" other two procedures could be made if permission were obtained from the Institutional Review Board, *id.* § 46.110(c), but did not explicitly state whether dispensing with written documentation altogether constituted such a "modification."

376. Meisel & Kabnick, *supra* note 11, at 477.

377. Singer, *supra* note 301, at 151. *See also* Singer & Frankel, *supra* note 334, at 425.

378. *Id.* at 159.

379. Sard v. Hardy, 281 Md. 432, 437-38, 379 A.2d 1014, 1019 (1977).

380. B. GRAY, *supra* note 13, at 96. *See also* Leydhecker, *supra* note 57, at 243 (36% of the cataract patients questioned indicated that they would have preferred to have been given the detailed disclosure information earlier, that is, prior to admittance to the hospital for surgery).

Pryce's study of the value of a particular drug for the treatment of chronic schizophrenia, twenty-nine of fifty subjects "seemed unable to understand the explanation given" and were therefore thought to be incompetent.[381] Consent was then sought from relatives, but the study does not indicate which relatives. Of the seventeen cases in which a relative responded, fifteen consented and two refused to permit the patient's inclusion in the study.[382] Of the relatives who refused, one did so "because she did not wish to prejudice the patient's present state of improvement, and the other after a period of painful doubts as to whether she should give consent or not."[383] Of those who consented, "some [did so] with expressions of interest and approval because something new was being tried."[384] In another study, nineteen of twenty relatives asked, on behalf of developmentally disabled adults, to give consent to the administration of neuroloptic medication agreed to the proposed treatment plan and signed the consent form.[385] The one who refused felt that the possible side effects of tardive dyskinesia should not be risked.

Often, decisions are made by physicians for patients whose competency is questionable. Ratzan complains that thirteen of twenty-four elderly potential research subjects were eliminated from participating in a research protocol by their personal physicians, without consultation with the patients.[386] He notes that legitimate physical problems may have been at issue in some cases, but seven of the patients were excluded solely on physician speculation about some inconvenience to the patients.[387]

Spohn noted a similar phenomenon where 225 of 558 patients selected for a research project involving the withdrawal of anti-psychotic drugs were never approached directly for their consent.[388] In this case, it was the ward team that refused to allow their participation. The reasons given for the refusal included the belief that without drugs the patient might become homicidal or suicidal, or that the patients were too disorganized to understand, or too well adjusted on drugs to risk a setback.[389] The ward team's refusals, permitted as part of the informed consent screening process, actually biased the sample of patients who consented to the research. The patients approved for the study were somewhat older, with a shorter duration

381. Pryce, *Clinical Research upon Mentally Ill Subjects Who Cannot Give Informed Consent*, 133 BRIT. J. PSYCHIATRY 366, 367 (1978).

382. *Id.* at 367.

383. *Id.*

384. *Id.*

385. Jaffe, *supra* note 214, at 435. Most of the relatives in this study were parents or others close enough and likely to be appointed guardians if there were to have been judicial proceedings.

386. Ratzan, *supra* note 279. *See also* Sorensen, *A Sociological Study of Informed Consent in a University Hospital: Problems with the Institutional Review Board*, 26 CLINICAL RESEARCH 1, 4 (1978).

387. Ratzan, *supra* note 279, at 299. *Accord* Lacher, *supra* note 230, at 377 ("[p]hysicians turned out to be a major obstacle to randomization with informed consent" by advising their patients not to participate). Buchwald believes that risks and benefits to the individual may not be weighed at all, but rather the physician may decide based on his or her own prejudgments. Buchwald, *supra* note 37.

388. Spohn & Fitzpatrick, *Informed Consent and Bias in Samples of Schizophrenic Subjects at Risk for Drug Withdrawal*, 89 J. ABNORMAL PSYCHOLOGY 79 (1980).

389. *Id.* at 82.

of illness and fewer hospitalizations, and consisted of a proportionately larger number of blacks and a smaller number of females.[390]

J. *Decision and "Special" Groups: Studies Involving Psychiatric Patients and Research Subjects*

1. *Psychiatric Patients*

There is a small but growing number of studies of the "decision" component of informed consent in the context of psychiatric treatment. Not surprisingly, there is some evidence that psychiatric patients make decisions about treatment for irrational reasons. Appelbaum and Gutheil report seventh-two episodes of refusal of psychiatric medications by twenty-three patients over a three-month period.[391] Some patients refused medication a small number of times; others always refused for a short time and then relented and took the medication; still others refused medication consistently for extended periods.[392] Among the patients who always refused for a short time, some gave as a reason the desire to discuss with their doctor the side effects of the medication.[393] The final group of patients uniformly "maintained as a reason for refusal that it was their legal right to decline medication," as well as providing a variety of other reasons.[394] One problem with this study is that there is no indication as to what information, if any, patients had been provided about their medications.[395] Another is that data about the patients' reasons for refusing medications were obtained by investigators not by questioning or observing patients, but by asking the nurses who administered medications to the patients what the reasons for refusal were. Since the staff reporting this information was the same staff involved in medicating the patients and since the study indicates that the "nurse-patient alliance" was a pivotal variable in the patients' decisions to resume taking medication,[396] the validity of the data is open to question. What is important about their findings for present purposes is that a significant proportion of the refusers did not identify the side effects of medications as one of their reasons for refusal.[397] Again, however, without knowing what patients were told about the medications, it is difficult to determine what proportion of patients would refuse medication if adequately informed of risks and other relevant information.

What would be useful to know is not so much rates of refusal of medication (or other treatment) or even articulated reasons for refusal (since it is possible that a patient's stated reason might not be his actual reason)[398]

390. *Id.* at 87.

391. Appelbaum & Gutheil, *Drug Refusal: A Study of Psychiatric Inpatients*, 137 AM. J. PSYCHIATRY 340, 342 (1980).

392. *Id.*

393. *Id.* at 343.

394. *Id.*

395. A more serious problem is that the study results are presented in a somewhat polemical fashion.

396. Appelbaum & Gutheil, *supra* note 391, at 344.

397. *Id.* at 342-43. Twenty-three patients refused medication, accounting for the 72 individual episodes of refusal of a given medication on which data was collected. *Id.* at 342.

398. We are not suggesting the psychiatric patients' stated reasons for refusal of treatment

but whether or not the rate of refusal differs significantly from that of other hospitalized medical (that is, nonpsychiatric) patients. This would be a first step in determining whether the reasons for refusal in psychiatric patients are traceable in large part to their particular illnesses or whether they arise from the conditions of illness and hospitalization more generally.

By contrast, another study concludes that there is no significant difference between medical patients' and psychiatric patients' expressed willingness to participate in hypothetical "research" studies.[399] The authors go even further and conclude that the "[d]egree of psychopathology [is] . . . a poor indicator of ability to evaluate research risks."[400] These conclusions and findings are inconsistent with those of Appelbaum and Gutheil.

In an experimental study, sixty percent of schizophrenic outpatients (n=20) consented to take a fictitious drug which had been explained to them, twenty-five percent refused the medication, and fifteen percent were ambivalent.[401] Only fifteen percent of the patients "fully" understood the information they had been given, and all of these patients consented.[402] The investigators conclude that the more "informed" subjects were more likely to consent, that the less "informed" subjects were more likely to refuse treatment,[403] and that "only a small portion of schizophrenics may be able to give fully informed consent . . . ."[404] The investigators correctly recognize, however, that their findings are "seriously limited" by the lack of a comparison group.[405]

As noted earlier in the discussion of proxy decisionmaking, Pryce conducted a study of a drug used in the treatment of chronic schizophrenia. He found that of fifty subjects, twelve gave "true consent," nine refused to participate, "some for delusional reasons," and twenty-nine "seemed unable to understand the explanation given."[406] Since he does not indicate how "true consent" was defined or determined, we can only infer that it was the response of those patients who did not refuse to participate and who did not seem unable to understand the explanation given. A more precise and operational definition of "true consent" would aid greatly in evaluating the findings.

Stanley *et al.* examined the effect of drug treatment on the decisionmaking of thirty-nine psychiatric inpatients, all but one of whom were diagnosed as severely mentally ill.[407] They found that patients did not become more or less reasonable in their decisions as a result of drug treatment. A series of four hypothetical vignettes were administered prior to

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should not be taken at face value because psychiatrists know better than the patients what the patients' reasons are. Our point is the more general one that an explanation given by an actor for his actions in response to a question asking for an explanation may be generated in order to accomplish the particular goal at hand: namely, answering the question.

399. Stanley, *supra* note 122.
400. *Id.* at 671.
401. Grossman & Summers, *supra* note 214, at 206.
402. *Id.*
403. *Id.*
404. *Id.*
405. *Id.*
406. Pryce, *supra* note 381.
407. Stanley, *supra* note 251, at 103.

and following drug treatment. Two-thirds of the patients did not change their minds at all, and when patients did change their minds, about an equal percentage of them moved in either direction.[408] In comparing the drug-treated group with the group that received no medication, no significant differences in their willingness to participate in the hypothetical studies emerged, given standardized disclosure procedures.[409] Evaluation of the finding of this and other studies and comparisons among studies are also complicated by the fact that we cannot be sure that the nature and degree of mental impairment in the subjects are comparable.

2. *Research Subjects*

Gray reports that "many . . . subjects [in a protocol involving induced labor] had not made a decision to be in research because they did not understand that research was involved."[410] Yet, even among those who did understand that they would be research subjects, "the decision to receive an experimental drug was made quite lightly."[411] In some cases, in explaining the lack of gravity with which they decided, "subjects often emphasized their eagerness to have their baby; many said that the *only* thing they considered was that the research might hasten this event."[412]

In studies using elderly subjects, Ratzan claims that "comfort often supersedes risk."[413] Of the subjects who were asked to participate in a research experiment to refine methods of monitoring compliance with digoxin therapy, all refused. Most indicated their decision not to participate was made because of the discomfort of venipuncture as part of the research protocol.[414]

In recognition of the problems of obtaining an informed decision in the research setting, particularly in regard to research involving deception, Berscheid *et al.* propose the possibility of finding alternative means of "anticipating" informed consent.[415] That is, in lieu of relying on the judgment of the principal investigator or a specially convened committee, a sample of subjects from the potential research population could be used to predict more accurately the decision of that population.

K. *Summary*

It is unfortunate that so many of the studies of informed consent are merely limited investigations of the relationship between only two of the

408. *Id.* at 104.
409. *Id.*
410. B. GRAY, *supra* note 13, at 89.
411. *Id.* at 90.
412. *Id.* at 93 (emphasis in original).
413. Ratzan, *supra* note 279, at 300.
414. *Id.*
415. Berscheid, *supra* note 327, at 914. The ethical standards of the American Psychological Association state that when the research is of great importance and the research objectives cannot be realized without deception, the use of deception methodology *may* be made more acceptable when, among other considerations, there is sufficient reason for concealment that a research participant who is later informed would find it reasonable. AM. PSYCHOLOGICAL ASSOC., ETHICAL PRINCIPLES IN THE CONDUCT OF RESEARCH WITH HUMAN PARTICIPANTS 37 (1973).

components of informed consent. Few have viewed the entire decision-making process as a subject of study. To do so would involve (1) acquiring data on what information patients are given, by whom, and under what circumstances; (2) what information patients already have or acquire on their own; (3) the extent to which patients understand the information they are given; (4) the basis for the decision a patient makes, including the extent to which the patient uses the information disclosed in arriving at a decision; and (5) the pressures that come to bear on patients in the process of making medical decisions, the source of such pressures, and the extent to which they affect the decision the patient makes.

Merely cataloging these issues makes it apparent why there are few comprehensive studies of informed consent. Such studies require a considerable amount of resources. They must employ several different research techniques, such as observation, questionnaires, and interviews. They require that study personnel be available to gather data on a continuous basis for long periods of time to assure that important transactions between staff and patients, among staff members, and between patients and families and staff and families are not overlooked. Finally, the analysis of such data is even more time-consuming than its collection.[416] Yet, in the absence of such studies, we have only piecemeal findings, the validity of which are uncertain, and which thus prove to be uncertain guides for policymaking.

VIII. SUMMARY OF FINDINGS

Probably the most important general finding of our review of the studies of informed consent is how little is actually known about how informed consent operates in the clinic and how much doubt there is about the validity of what is thought to be known. It is not our purpose either to disparage the work that has been done or to imply that nothing can be known unless it has been studied in a scientifically rigorous way.[417] Many of the studies are important; about that there can be no doubt. Rather, what concerns us is that because of the conceptual, methodologic, and pragmatic deficiencies of so many of the studies, their validity and certainly their generalizability are open to substantial question. This does not mean that the findings of these studies are incorrect reflections of reality, but only that we cannot be sure how accurately they depict reality.

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416. C. LIDZ, *supra* note 13, at ch. 4.

417. We are in general agreement with Lindblom & Cohen's belief that

> [i]nformation and analysis are not a universal or categorical prescription for social problem solving . . . . Information and analysis constitute only one route among several to social problem solving. And PSI [professional social inquiry] is one method among several of providing information and analysis to the extent that they are required . . . . PSI is only one among several analytical methods, because other forms of information and analysis—ordinary knowledge and casual analysis foremost among them—are often sufficient or better than PSI for social problem solving . . . .
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> . . . .
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> By "ordinary knowledge," we mean knowledge that does not owe its origin, testing, degree of verification, truth status, or currency to distinctive PSI professional techniques but rather to common sense, casual empiricism, or thoughtful speculation and analysis.

C. LINDBLOM & D. COHEN, USABLE KNOWLEDGE 10, 12 (1979).

In part, the uncertainty about their portrayal of reality arises from the fact that there is no single reality about medical practice. It is not a monolithic enterprise. Thus, what may be valid in the circumstances in which it occurred may not be in other situations. The nature of the procedure and its attendant risks, the personal qualities of the doctor and the patient, the seriousness of the patient's illness and the urgency of the need for medical care, and the patient's status as an inpatient or outpatient may be among the more significant variables in determining how medical decisions are made.

One of the most significant conclusions about informed consent does not come out of the studies that we have reviewed but has emerged from our own studies.[418] It is that informed consent as envisioned by the courts is a relatively rare phenomenon in the clinical settings that we have examined. Patients receive information; consent forms get signed. But rarely do doctors sit down with patients and provide them with thorough explanations of treatment options and then seek their consent to one or another. Instead, information is often given to patients not to enable them to choose, but to encourage them to cooperate with doctors and to comply with decisions that have already been made, not by patients as law envisions, but by doctors.

Thus the linear model of informed consent, in which it is assumed that a doctor provides a competent patient with information about treatment options, and the patient understands the information, and voluntarily renders a decision about treatment, rarely predicts what happens in practice. Instead, doctors make recommendations in which patients are expected to acquiesce, but which they occasionally resist. Information is given to acquiescent patients to obtain their compliance with treatment, and to resistant patients to overcome their opposition. The resistant patient may persist and ultimately veto treatment, but neither he nor the compliant patient has actually made a choice in the sense contemplated by law. Rather, patients either go along with or refuse to go along with doctors' recommendations.

Having made these disclaimers, we come to what it is that we do know about informed consent on the basis of empirical investigation.

A. *Disclosure*

The picture of the disclosure process that emerges is that information is not very actively provided by doctors to patients, nor do patients actively solicit information. Although doctors do not volunteer much information, when patients ask questions doctors tend to answer them, although it is not clear how fully and forthrightly. There are mixed findings on whether patients want information. This is not surprising if "information" is viewed monolithically. Patients probably do want information about some aspects of treatment and not about others. Their expressed desires for information may depend on whether they are asked before or after they have actually

418. *See* C. LIDZ, *supra* note 13, Appelbaum & Roth, *supra* note 13; Lidz & Meisel, *supra* note 13.

been given information, and even this may depend as much on the manner in which information was provided as on its content.

B. *Understanding*

According to almost all of the studies of patient recall, patients do not remember much of what they have been told. However, these studies are not controlled, and we do not know how patients' memories of such events compare to the ordinary forgetting process. Although there has been little investigation of what patients actually understand contemporaneous with the time they have received information, there is not much reason on the basis of the studies to assume very high levels of understanding here either. Patients have low levels of knowledge about two of the most significant aspects of treatment: alternatives and risks. Finally, the conditions inherent in being a patient make it difficult to understand information relevant to decisionmaking. As a result, greater efforts must be used to assure that patients understand. Most important in achieving this goal, perhaps, is that the task of communicating must be undertaken more self-consciously and less reflexively. Like the technical practice of medicine, it probably requires training and practice to perfect.

C. *Competency*

Very little research has been done on competency, and what has been done involves psychiatric patients. Research needs to address the question whether it makes any difference, in terms of whether or not people are determined to be incompetent, what test of incompetency is applied and who applies it. An even more basic issue is the determination of the dimensions of the problem of incompetency—that is, what is the prevalence of incompetency in medical populations generally and in specific subsets (for example, geriatric patients)?

D. *Voluntariness*

Here, too, there is only the scantest information available. There is a need to catalog, as to nature, source and intensity, the kinds of pressures that come to bear on patients in making medical decisions. Patients' perceptions of whether or not some factor has influenced their decision should be compared with detached evaluations to determine whether patients are unaware of certain pressures or perhaps even more sensitive to them. Finally, we need to know what, if anything, can be done to minimize significant pressures without seriously impeding the operation of health care providers, except of course where their operation includes the use of illegitimate pressures.

E. *Decision*

The studies uniformly fail to investigate the complex relationship among the components of informed consent, and focus more on simple one-to-one relationships between pairs of components such as disclosure

and understanding or understanding and decision. A plausible hypothesis is that the manner of disclosure affects the extent to which patients understand the information provided them, but "manner of disclosure" is itself composed of a number of variables which must be separated and studied in terms of their relationship to understanding. The same is likely to be true of the relationship between disclosure and decision. Simple relationships such as "the more information, the less likely the patient is to consent" are misleading because there are a variety of aspects of disclosure which probably affect how and what patients decide.

There is some evidence that patients probably do not engage in a process of weighing the risks and benefits of treatment options in the manner that the judicial decisions on informed consent contemplate. This should not be unexpected since one of the significant criticisms of utilitarian decisionmaking paradigms is that risks and benefits are noncomparable, even when they can be quantified, a difficult and uncertain task even when undertaken by those with an opportunity to engage in the process in a more reflective manner than most patients have.

Although the studies that we have reviewed do not reveal this largely because they have not set about to study the decisionmaking process as a whole, our own research suggests that decisions about medical treatment are actually made in a manner much different from that contemplated by the informed consent doctrine, with doctors making recommendations and patients acquiescing in them or occasionally objecting to or even vetoing them. Information is given for the purpose of implementing these recommendations, rather than enabling patients to select among treatment options at the outset.[419] Thus, one of the most misleading implications of the empirical studies of informed consent is that informed consent is actually obtained in the manner and to the extent required by law. This, we believe, is itself a matter for inquiry.

Finally, there has been almost no study of proxy decisionmaking, a matter closely bound up with the issue of incompetency to participate in the medical decisionmaking process. We need to know some rather elementary things, such as who makes decisions for incompetent patients and how these persons become clothed with decisional authority.

IX. CONCLUSION

Despite the tomes that have been written about informed consent, the sad conclusion is that more than a quarter-century after the birth of the doctrine we know almost nothing about its operation. To be certain, there are those who claim to know how informed consent actually operates. The anecdotal reports about informed consent are generally to the effect that it is impossible to obtain.[420] While there is no need to question their bona

419. Lidz & Meisel, *supra* note 13; *see also* C. LIDZ, *supra* note 13.

420. *See, e.g.*, Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 J.A.M.A. 34 (1966); Burnham, *Medical Experimentation on Humans*, 152 SCIENCE 448 (1966); Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MED. 465 (1972); Irvin, *"Now, Mrs. Blare, About the Complications . . .,"* 40 MED. ECON. 102 (1963); Laforet, *The Fiction of Informed Con-*

fides, the critics still have not borne the burden of coming forth with hard and persuasive evidence.[421] As of this time, what evidence there is does not support the conclusion that informed consent is impracticable. Because of the flawed ways in which the evidence has been gathered, most of it, with some sparkling exceptions, is of little use. Although some of the research may even have been motivated to demonstrate that informed consent cannot be obtained, by far the great majority has come out of the true spirit of scientific inquiry, but unfortunately that is not enough.

There is reason to believe that there are all manners of difficulities in obtaining informed consent—some inhering in patients as people, some in the condition of being ill; others in doctors as people, and still others in the socialization of doctors. The structure of delivery of medical care must also share some of the responsibility.[422]

There is no doubt that there are grave difficulties in studying the process of obtaining informed consent. The truth is that the process of obtaining informed consent can be—indeed, if done in conformance with the spirit of the doctrine, in many instances cannot help but be—a complex undertaking.[423] Obtaining informed consent—as opposed to obtaining a signature on a consent form, which is what often passes for informed consent[424]—will rarely be a discrete event, but will often take place over a period of time. Patients will obtain information from a variety of informants. Patients will misunderstand some information; they may seek clarification leading to another "round" of disclosure and questioning. Patients will make tentative decisions, discuss them with family members, friends, other patients, nurses, and others, revise and modify the decisions, reconfer with the doctors, and reconsider before the decisions can be said to have been "made."

In short, making a decision about medical treatment as envisioned by the spirit of the informed consent doctrine is a process which follows no simple, orderly, linear (or even circular) pattern as hypothesized by theorists and inferred from court decisions.[425] At its best, the decisionmaking process involves conversation, negotiation, reflection, and debate among the patient, the doctor, and possibly many other persons. At its worst, the doctor makes a recommendation and announces it to the patient in the manner of a *fait accompli* and obtains the patient's signature on a piece of paper, thus formally ratifying the decision.[426] Between these two extremes

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sent, 235 J.A.M.A. 1579 (1976); Middleton, *Informed Consent*, 233 J.A.M.A. 1049 (1975); Ravitch, *Informed Consent—Descent to Absurdity*, 101 MED. TIMES 164 (1973).

421. Perhaps it is unfair to place the burden on the critics to demonstrate that informed consent is unworkable since that involves the proof of a negative. Nonetheless, this has not deterred the critics from mustering evidence, though of questionable quality and weight.

422. *See* Lidz & Meisel, *supra* note 13.

423. One does not see even a glimpse of the complexity of obtaining informed consent from the empirical studies, which tend toward the reductionistic in their understanding of what the doctrine requires, and thus how it should be studied. *Cf.* C. LIDZ, *supra* note 13; Lidz & Meisel, *supra* note 13.

424. Lidz & Roth, *supra* note 295.

425. *See* Meisel, *supra* note 16.

426. C. LIDZ, *supra* note 13.

there are endless variations as to how informed consent might be and is obtained.

To study such a complex variety of processes is no easy task. Few have attempted it. Instead, most have dissected the process and studied only small slices. In so doing, they have produced a great store of information, the validity of which unfortunately is open to serious question.

Scientific investigators must first understand as much as possible concerning what is already known about the processes they are investigating. In fairness to the investigators, this is not always a simple task, because law-making institutions have failed to clarify just what the informed consent doctrine requires of physicians, and indeed clarification down to the last detail may be impossible or undesirable.[427] Still, few of the empirical investigators of informed consent know what the doctrine requires in those areas where there is some certainty, and few know where the ambiguities in the doctrine lie.[428]

Scientific investigators must define the concepts they are investigating or at least acknowledge the difficulties of so doing. Few, if any, have done this in studying informed consent. Admittedly, devising operational definitions of concepts like understanding, competency, and voluntariness is difficult. The studies that have done so have ordinarily erred on the side of oversimplification—for example, by equating understanding with recall. Those few studies that have not oversimplified the concept have still failed to operationalize it.

Scientific investigators should acknowledge the limits of their findings. Where, for example, a study uses an experimental design, it is incumbent upon the investigators to suggest that factors may exist in clinical situations which do not exist and cannot be replicated in the laboratory, which may substantially alter the validity of the findings. Even where a clinical population is the subject of study, it may not, for a variety of reasons, be representative (if indeed any subgroup can be representative) of medical populations generally. At the least, it is incumbent upon investigators to suggest the distinguishing features of their populations and to suggest whether and why the results may or may not be generalizable.

Scientific investigators ought to adhere to elementary rules of scientific inquiry. To suggest that a finding has a certain significance without the use of control groups often violates this requirement. Rarely, if ever, is such behavior tolerated in medical research; it should not be tolerated any more in social research on medical practice.

Many of the studies do a disservice to informed discussion of informed consent. Some should not have been published.[429] Although some

427. The legislative approach to informed consent taken by Texas, TEX. REV. CIV. STAT. ANN. art. 4590i, § 6.07(b) (Vernon Cum. Supp. 1980), entails the promulgation of complex and detailed regulations specifying the information that must be disclosed to patients. *See* 3 Tex. Reg. 4293, 4293-4296, § 301.01.03.001 (Dec. 12, 1978). This scheme is discussed in Meisel & Kabnick, *supra* note 11, at 537-41.

428. *See supra*, section III, at p. 272.

429. Perhaps the most egregious example is a study of maternal "understanding" of circumcision, in which the investigators administered a questionnaire to a large group of mothers to determine what they knew about the risks of circumcision. In some cases, the procedure had been

investigators recognize the deficiencies and limitations of their findings, more frequently investigators either do not recognize them, or do not admit recognition.

But even where deficiencies are acknowledged, it is likely that those who need data to make decisions will rely on whatever is available rather than rejecting it for its deficiencies. No less august a judicial body than the United States Supreme Court has been charged with such a practice.[430] Worse yet, those who wish to make policy about informed consent on the basis of values rather than facts (and there is certainly nothing wrong with such a practice per se) may be encouraged to buttress their value choices with deficient empirical evidence that is not known by them to be so, or to camouflage value choices in factual garb.[431] Whether intentional or not, this constitutes a misuse of empirical data, contrary to its intended purpose: "to shed light on hiterto unknown facts."[432]

There is also the danger that the findings of the empirical studies of informed consent may be generalized beyond the problem of informed consent to other areas of regulation which are based on disclosure of information. Critics or skeptics of such regulation may be tempted to conclude that it "doesn't work." Perhaps it does not, and if there are no compelling value-based reasons to utilize such regulation—that is, to provide consumers of goods and services with information about what they are buying—then it probably should not be preserved. But we cannot conclude intelligently that it does not work on the basis of studies as fundamentally flawed in the variety of ways as are the empirical studies of informed consent.

It is imperative, we believe, that social policy makers be cautious about relying upon knowledge which purports to have been discovered through "scientific" means, not only because the means may not, in fact, be particularly scientific, but also because the scientific method is not the only road to knowledge, let alone wisdom. We are in agreement with the perceptive observations of Professors Lindblom and Cohen with respect to

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performed as much as 44 years earlier; almost 75% had been performed more than 4 years earlier. The investigators report that 87% of the respondents were not aware of any of the risks. Lovell & Cox, *Maternal Attitudes Toward Circumcision*, 9 J. FAM. PRAC. 811, 812 (1979). On the basis of this fact alone, one might conclude that it makes no sense to require informed consent because of such a low level of understanding. But in light of the fact that we have no idea what, if anything, the mothers had been told about risks, we cannot even validly conclude that most people *forget* information over a long period of time.

430. Professors Zeisel and Diamond suggest that this is what the Supreme Court has done in deciding cases on the constitutionality of 6-person juries. Zeisel & Diamond, *"Convincing Empirical Evidence" on the Six Member Jury*, 41 U. CHI. L. REV. 281 (1974). *Cf.* C. LINDBLOM & D. COHEN, *supra* note 418, at 1 n.1 ("Increasingly . . . it is being noted that governmental users of social research use it in ways other than those intended by the researchers."). For a discussion of recent uses (and misuses) of empirical studies in United States Supreme Court opinions, see Schlesinger & Neese, *Justice Harry Blackmun and Empirical Jurisprudence*, 29 AM. U.L. REV. 405 (1980).

431. Zeisel & Diamond, *supra* note 430, at 281:

> The United States Supreme Court has recently been increasing its references to what it likes to call "empirical" data. A genuine issue is occasionally documented by such data . . . . In some cases, however the intent of such references is merely to ornament an already determined result . . . . The Court generally cites "empirical" studies as lawyers cite cases, treating their summary conclusions as if they were holdings in prior cases.

432. *Id.*

what should be old hat, namely that "[f]or social problem solving . . . people will always depend heavily on ordinary knowledge . . . . The most basic knowledge we use in social problem solving is ordinary."[433] And further, they point out that what they call "professional social inquiry" is "only occasionally . . . a distinctive source of information and analysis."[434]

Finally, and more fundamentally, even if social science inquiry were the only or even the "best" means of ascertaining knowledge, we do not suggest that social policy about informed consent should be made on the basis of such knowledge alone. In fact, we wish to state emphatically that informed consent policy should be based largely on values, informed but not dictated by sound social science inquiry as well as by other sources of knowledge.[435]

To the extent that policy makers wish to rely on information in making policy, we caution that much of what purports to be "scientifically" generated knowledge is far from that. Thus the studies of informed consent are, as a whole and with some notable exceptions, worse than anecdote and speculation because they are dressed up in a way that often deceives social policymakers into believing that they represent a higher form of truth than they actually do.

433. C. LINDBLOM & D. COHEN, *supra* note 417, at 12, 13.

434. *Id.* at 17.

435. The doctrine of informed consent has been justified on the basis of both deontological and utilitarian ethical theories. The findings of social science contribute little if anything of value to the analysis of of a deontological justification for or against a particular policy, since it is not the consequences of that policy, ascertained by empirical investigation, but the values sought to be promoted by the policy that are the policy's ultimate justification. The most that social science can say is that the values on which an ethical principle is based are or are not widely held within a society. However, when a policy is sought to be justified from a utilitarian ethical position, empirical studies may be relevant. Since the ultimate justification for the policy is to be found in the benefits that it confers and the costs that imposes, an effort which ascertains these benefits and costs is helpful, if not essential, to an adequate utilitarian analysis. For informed consent to be justified on utilitarian principles, we must be able to say that the doctrine produces more good than harm.

APPENDIX: BIBLIOGRAPHY OF EMPIRICAL STUDIES

1. Alfidi, *Controversy, Alternatives, and Decisions in Complying with the Legal Doctrine of Informed Consent*, 114 RADIOLOGY 231 (1975).
2. Alfidi, *Informed Consent: A Study of Patient Reaction*, 216 J.A.M.A. 1325 (1971).
3. Alfidi, *Informed Consent and Special Procedures*, 40 CLEVELAND CLINIC Q. 21 (1973).
4. Appelbaum & Gutheil, *Drug Refusal: A Study of Psychiatric Inpatients*, 137 AM. J. PSYCHIATRY 340 (1980).
5. Appelbaum, Mirkin & Bateman, *Empirical Assessment of Competency to Consent to Psychiatric Hospitalization*, 138 AM. J. PSYCHIATRY 1170 (1981).
6. Appelbaum & Roth, *Treatment Refusals in the Medical Hospital*, in 2 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE & BIOMEDICAL & BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 411-77 (1982).
7. Appelbaum, Roth & Lidz, *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, — INT'L J.L. & PSYCHIATRY — (1983).
8. Barbour & Blumenkrantz, *Videotape Aids Informed Consent Decision*, 240 J.A.M.A. 2741 (1978).
9. Benson, Gordon, Mitchell & Place, *Patient Education and Interuterine Contraception: A Study of Two Package Inserts*, 67 AM. J. PUB. HEALTH 446 (1977).
10. Bergler, Pennington, Metcalfe & Freis, *Informed Consent: How Much Does the Patient Understand?*, 27 CLINICAL PHARMACOLOGY & THERAPEUTICS 435 (1980).
11. Berscheid, Baron, Dermer & Libman, *Anticipating Informed Consent: An Empirical Approach*, 28 AM. PSYCHOLOGIST 913 (1973).
12. Blumenfield, Levy & Kaufman, *Do Patients Want To Be Told?*, 229 NEW ENG. J. MED. 1138 (1978).
13. Boreham & Gibson, *The Informative Process in Private Medical Consultations: A Preliminary Investigation*, 12 SOC. SCI. & MED. 409 (1978).
14. Boria & Gordon, *Legislation or Education? A Practical, Effective Approach to the Problem of Informed Consent in Elective Sterilization*, 13 ADVANCES IN PLANNED PARENTHOOD (1978).
15. Brownell & Stunkard, *The Double-Blind in Danger: Untoward Consequences of Informed Consent*, 139 AM. J. PSYCHIATRY 1487 (1982).
16. Buchwald, *True Informed Consent in Surgical Treatment of Morbid Obesity: The Current Case for Both Jejunoileal and Gastric Bypass*, 33 AM. J. CLINICAL NUTRITION 482 (1980).
17. Bunker & Brown, *The Physician-Patient As an Informed Consumer of Surgical Services*, 290 NEW ENG. J. MED. 1051 (1974).
18. Cassileth, Zupkis, Sutton-Smith & March, *Informed Consent—Why*

Are Its Goals Imperfectly Realized? 302 NEW ENG. J. MED. 896 (1980)
19. Chandler & Dugdale, *What Do Patients Know About Antibiotics?* THE LANCET, Aug. 21, 1976 at 422.
20. Dabrowski, Gerard, Walczak, Woronowicz & Zakowska-Dabrowska, *Inability of Patients to Give Valid Consent to Psychiatric Hospitalization*, 1 INT'L J.L. & PSYCHIATRY 437 (1978).
21. Denny, Williamson & Penn, *Informed Consent—Emotional Responses of Patients*, 60 POSTGRADUATE MEDICINE 205 (1976).
22. Epstein & Lasagna, *Obtaining Informed-Consent: Form or Substance*, 123 ARCHIVES INTERNAL MED. 682 (1969).
23. Faden, *Disclosure and Informed-Consent: Does It Matter How We Tell It?*, 5 HEALTH EDUC. MONOGRAPHS 198 (1977).
24. Faden & Beauchamp, *Decision-Making and Informed Consent: A Study of the Impact of Disclosed Information*, 7 SOC. INDICATORS RESEARCH 313 (1980).
25. Faden, Lewis, Beeker, Faden & Freeman, *Disclosure Standards and Informed Consent*, 6 J. HEALTH, POLITICS, POLICY & L. 255 (1981).
26. Fellner & Marshall, *Kidney Donors—The Myth of Informed Consent*, 126 AM. J. PSYCHIATRY 1245 (1970).
27. Fellner & Marshall, *Twelve Kidney Donors*, 206 J.A.M.A. 2703 (1968).
28. Fisher, Mansbridge & Lankford, *Public Judgments of Information in a Diazepam Patient Package Insert*, 39 ARCHIVES GEN. PSYCHIATRY 707 (1982).
29. Fisher, Rowley & Lipkin, *Predicting Immediate Outcome of Genetic Counseling Following Genetic Screening*, 26 SOC. BIOLOGY 289 (1979).
30. Flanery, Gravdal, Hendrix, Hoffman, King, May, O'Keefe, Timmerman, Waltman & Roberts, *Just Sign Here . . .*, 31 S.D. J. MED. 33 (1978).
31. Fletcher, *Realities of Patient Consent to Medical Research*, I(1) HASTINGS CENTER STUDIES 39 (1973).
32. Freeman, Richard & Smith, *Effect of Informed Consent and Educational Background on Patient Knowledge, Anxiety, and Subjective Responses to Cardiac Catheterizations*, 7 CATHETERIZATION & CARDIOVASCULAR DIAGNOSIS 119 (1981).
33. Garnham, *Some Observations on Informed Consent in Non-Therapeutic Research*, 1 J. MED. ETHICS 138 (1975).
34. Geller, *State Hospital Patients and Their Medication—Do They Know What They Take?*, 139 AM. J. PSYCHIATRY 611 (1982).
35. Gilboy & Schmidt, *"Voluntary" Hospitalization of the Mentally Ill*, 66 NW. U.L. REV. 429 (1971).
36. Goin, Burgoyne & Goin, *Face-Lift Operation: The Patient's Secret Motivations and Reactions to "Informed Consent,"* 58 PLASTIC & RECONSTRUCTIVE SURGERY 273 (1976).
37. Golden & Johnston, *Problems of Distortion in Doctor-Patient Communications*, 1 PSYCHIATRY IN MED. 127 (1970).

38. Gray, Cooke & Tannenbaum, *Research Involving Human Subjects*, 201 SCIENCE 1094 (1978).
39. B. GRAY, HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION (1975).
40. Grossman & Summers, *A Study of the Capacity of Schizophrenic Patients to Give Informed Consent*, 31 HOSPITAL & COMMUNITY PSYCHIATRY 205 (1980).
41. Grundner, *On the Readability of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900 (1980).
42. Hassar & Weintraub, *"Uninformed" Consent and the Wealthy Volunteer: An Analysis of Patient Volunteers in a Clinical Trial of a New Anti-Inflammatory Drug*, 20 CLINICAL PHARMACOLOGY & THERAPEUTICS 379 (1976).
43. Hawkins, *Patients' Reactions to Their Investigations: A Study of 504 Patients*, 2 BRIT. MED. J. 638 (1979).
44. N. HERSHEY & S. BUSHKOFF, INFORMED CONSENT STUDY: THE SURGEON'S RESPONSIBILITY FOR DISCLOSURE TO PATIENTS (1969).
45. Howard, DeMets & The BHAT Research Group, *How Informed Is Informed Consent? The BHAT Experience*, 2 CONTROLLED CLINICAL TRIALS 287 (1981).
46. Jaffe, *Informed Consent: Recall About Tardive Dyskinesia*, 22 COMPREHENSIVE PSYCHIATRY 434 (1981).
47. Joubert & Lasagna, *Patient Package Inserts: I. Nature, Notions, and Needs*, 18 CLINICAL PHARMACOLOGY & THERAPEUTICS 507 (1975).
48. Kaufmann & Roth, *Psychiatric Evaluation of Patient Decision-Making: Informed Consent to ECT*, 16 SOC. PSYCHIATRY 11 (1981).
49. Kennedy & Lillehaugen, *Patient Recall of Informed Consent*, 7 MED. & PEDIATRIC ONCOLOGY 173 (1979).
50. Klatte, Lipscomb, Rozynko & Pugh, *Changing the Legal Status of Mental Hospital Patients*, 20 HOSPITAL & COMMUNITY PSYCHIATRY 199 (1969).
51. Korsch & Negrete, *Doctor-Patient Communication*, 227 SCI. AM. 66 (1972).
52. Kottow, *When Consent Is Unbearable—A Case Report*, 4 J. MED. ETHICS 78 (1978).
53. Lacher, *Physicians and Patients as Obstacles to a Randomized Trial*, 26 CLINICAL RESEARCH 375 (1978).
54. Lankton, Batchelder & Ominsky, *Emotional Responses to Detailed Risk Disclosure for Anesthesia: A Prospective, Randomized Study*, 46 ANESTHESIOLOGY 294 (1977).
55. Leeb, Bowers & Lynch, *Observation on the Myth of "Informed Consent,"* 58 PLASTIC & RECONSTRUCTIVE SURGERY 280 (1976).
56. Leonard, Chase & Childs, *Genetic Counseling: A Consumers' View*, 287 NEW ENG. J. MED. 433 (1972).
57. Leydhecker, Gramer & Krieglstein, *Patient Information Before Cataract Surgery*, 180 OPHTHALMOLOGICA, BASEL 241 (1980).
58. Lidz & Meisel, *Informed Consent and the Structure of Medical Care*, in 2 PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS

IN MEDICINE & BIOMEDICAL & BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 317-340 (1982).

59. C. LIDZ, A. MEISEL, E. ZERUBAVEL, M. ASHLEY, R. SESTAK & L. ROTH, INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRIC TREATMENT (1983).
60. Lidz & Roth, *The Signed Form—Informed Consent?* in SOLUTIONS TO LEGAL AND ETHICAL PROBLEMS IN APPLIED SOCIAL RESEARCH (Boruch & J. Cecil eds. 1981).
61. Lippo, Roth, Meisel & Lidz, *Voluntariness of Consent to Psychiatric Therapy* (unpublished 1976).
62. Lovell & Cox, *Maternal Attitudes Toward Circumcision*, 9 J. FAM. PRACTICE 811 (1979).
63. Marini, Sheard & Bridges, *An Evaluation of "Informed Consent" with Volunteer Prisoner Subjects*, 49 YALE J. BIOLOGY & MED. 427 (1976).
64. McCollum & Schwartz, *Pediatric Research Hospitalization: Its Meaning to Parents*, 3 PEDIATRIC RESEARCH 199 (1969).
65. McLean, *The Effect of Informed Consent on the Acceptance of Random Treatment Assignment in a Clinical Population*, 11 BEHAV. THERAPY 129 (1980).
66. McNeil, Pauker, Sox & Tversky, *On the Elicitation of Preferences for Alternative Therapies*, 306 NEW ENG. J. MED. 1259 (1982).
67. Meyer & Latz, *What Open Heart Surgery Patients Want To Know*, 79 AM. J. NURSING 1558 (1979).
68. Michaels & Oetting, *The Informed Consent Dilemma: An Empirical Approach*, 109 J. SOC. PSYCHOLOGY 223 (1979).
69. Morrow, *How Readable Are Subject Consent Forms?*, 244 J.A.M.A. 56 (1980).
70. Morrow, Gootnick & Schmale, *A Simple Technique for Increasing Cancer Patients' Knowledge of Informed Consent to Treatment*, 42 CANCER 793 (1978).
71. Muss, White, Michielutte, Richards, Cooper, Williams, Stuart & Spurr, *Written Informed Consent in Patients with Breast Cancer*, 43 CANCER 1549 (1979).
72. Novack, Plumer, Smith, Ochitill, Morrow & Bennett, *Changes in Physicians Attitudes Toward Telling the Cancer Patient*, 241 J.A.M.A. 897 (1979).
73. Oken, *What To Tell Cancer Patients: A Study of Medical Attitudes*, 175 J.A.M.A. 1120 (1961).
74. Olin & Olin, *Informed Consent in Voluntary Mental Hospital Admissions*, 132 AM. J. PSYCHIATRY 938 (1975).
75. Palmer & Wohl, *Voluntary-Admission Forms: Does the Patient Know What He's Signing?* 23 HOSPITAL & COMMUNITY PSYCHIATRY 250 (1972).
76. Park & Covi, *Nonblind Placebo Trial*, 12 ARCHIVES GEN. PSYCHIATRY 336 (1965).

77. Park, Covi & Uhlenhuth, *Effects of Informed Consent on Research Patients and Study Results*, 145 J. NERVOUS & MENTAL DISEASE 349 (1967).
78. Park, Slaughter, Covi & Griffin, *The Subjective Experience of the Research Patient: An Investigation of Psychiatric Outpatients' Reactions to the Research Treatment Situation*, 143 J. NERVOUS & MENTAL DISEASE 199 (1966).
79. Priluck, Robertson & Buettern, *What Patients Recall of the Preoperative Discussion After Retinal Detachment Surgery*, 87 AM. J. OPHTHALMOLOGY 620 (1979).
80. Pryce, *Clinical Research upon Mentally Ill Subjects Who Cannot Give Informed Consent*, 133 BRIT. J. PSYCHIATRY 366 (1978).
81. Ratzan, *The Experiment That Wasn't: A Case Report in Clinical Gerictric Research*, 21 GERONTOLOGIST 297 (1981).
82. Riecken & Ravich, *Informed Consent to Biomedical Research in Veterans Administration Hospitals*, 248 J.A.M.A. 344 (1982).
83. Robinson & Merav, *Informed Consent: Recall by Patients Tested Postoperatively*, 22 ANNALS THORACIC SURGERY 209 (1976).
84. Roling, Pressgrove, Keeffe & Raffin, *An Appraisal of Patients' Reactions to "Informed Consent" for Peroral Endoscopy*, 24 GASTROINTESTINAL ENDOSCOPY 69 (1977).
85. Rosen, *Why Clients Relinquish Their Rights to Privacy Under Sign-Away Pressures*, 8 PROF. PSYCHOLOGY 17 (1977).
86. Rosenberg, *Informed Consent: A Reappraisal of Patients' Reactions*, 119 CALIF. MED. 64 (1973).
87. Roth, Lidz, Meisel, Soloff, Kaufman, Spiker & Foster, *Competency to Decide About Treatment or Research: An Overview of Some Empirical Data*, 5 INT'L J.L. & PSYCHIATRY 29 (1982).
88. Silberstein, *Extension of Two-Part Consent Form*, 291 NEW ENG. J. MED. 155 (1974).
89. Singer, *Informed Consent: Consequences for Response Rate and Response Quality in Social Surveys*, 43 AM. SOC. REV. 144 (1978).
90. Singer & Frankel, *Informed Consent Procedures in Telephone Interviews*, 47 AM. SOC. REV. 416 (1982).
91. Sorensen, *A Sociological Study of Informed Consent in a University Hospital: Problems with the Institutional Review Board*, 26 CLINICAL RESEARCH 1 (1978).
92. Soskis, *Schizophrenic and Medical Inpatients as Informed Drug Consumers*, 35 ARCHIVES GEN. PSYCHIATRY 645 (1978).
93. Soskis & Jaffe, *Communicating with Patients About Antipsychotic Drugs*, 20 COMPREHENSIVE PSYCHIATRY 126 (1979).
94. Spohn & Fitzpatrick, *Informed Consent and Bias in Samples of Schizophrenic Subjects at Risk for Drug Withdrawal*, 89 J. ABNORMAL PSYCHOLOGY 79 (1980).
95. Stanley, Stanley, Lautin, Kane & Schwartz, *Preliminary Findings on Psychiatric Patients as Research Participants: A Population at Risk?* 138 AM. J. PSYCHIATRY 669 (1981).
96. Stanley, Stanley, Peselow, Wolkin, Deutsch, Platt, Speicher, Golosh

& Kaufman, *The Effects of Psychotropic Drugs on Informed Consent*, 18 PSYCHOPHARMACOLOGY BULL. 102 (1982).

97. Stuart, *Protection of the Right to Informed Consent to Participate in Research*, 9 BEHAV. THERAPY 73 (1978).
98. Svarstad, *Physician-Patient Communication and Patient Conformity with Medical Advice*, in THE GROWTH OF BUREAUCRATIC MEDICINE 220 (D. Mechanic ed. 1976).
99. Taub, *Informed Comment, Memory and Age*, 20 GERONTOLOGIST 686 (1980).
100. Taub, Kline & Baker, *The Elderly and Informed Consent: Effects of Vocabulary Level and Corrected Feedback*, 7 EXPERIMENTAL AGING RESEARCH 137 (1981).
101. U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *Protection of Human Subjects—Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 43 Fed. Reg. 56,174 (1978).
102. Vertinsky, Thompson & Uyeno, *Measuring Consumer Desire for Participation in Clinical Decision Making*, 9 HEALTH SERVICES RESEARCH 121 (1974).
103. Walsh & Nash, *Personality Characteristics of Volunteers for Medical Research*, 5 CRIM. JUST. & BEHAV. 99 (1978).
104. Williams, Rieckmann, Trenholme, Frischer & Carson, *The Use of a Test To Determine That Consent Is Informed*, 142 MIL. MED. 542 (1977).
105. Woodward, *Informed Consent of Volunteers: A Direct Measurement of Comprehension and Retention of Information*, 27 CLINICAL RESEARCH 248 (1979).
106. Zerubavel, *Informing Patients About the Benefits of Psychiatric Treatment* (unpublished 1980).