

# THE RIGHT AND RITE OF INFORMED CONSENT

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Charles W. Lidz, Alan Meisel, Eviatar Zerubavel, Mary Carter, Regina M. Sestak, and Loren H. Roth. *Informed Consent: A Study of Decisionmaking in Psychiatry*. (New York: Guilford Press, 1984). xv + 365 pp. Notes, appendix, index. \$30.00.

Ruth R. Faden, Tom L. Beauchamp and Nancy M. P. King. *A History and Theory of Informed Consent*. (Oxford: Oxford University Press, 1986). xv + 392 pp. Notes, index. \$29.95.

A clinician in a mental hospital admission center explains to a patient that before he can see a physician, he must listen to his rights. While she is reading the list of rights drafted by the department of welfare, the patient pleads with her: "Stop!" She continues to read to him, over his objections. When this incident is described to Jay Katz, the leading theorist on informed consent, he remarks, "What was originally intended as a right has become a rite" (quoted in Lidz *et al.*, p. 94). These two recent books, *A History and Theory of Informed Consent* by Faden *et al.* and *Informed Consent* by Lidz *et al.*, explore how informed consent became a right—and a rite.

The legal term "informed consent" was introduced in a 1957 California court case, *Salgo v. Leland Stanford Jr. University Board of Trustees* (154 Cal. App. 3d 560, 317 P.2d 170 (1957)). The doctrine of informed consent has developed to require physicians to disclose to their patients information about the patients' condition and the availability, benefits, and risks of diagnostic and treatment procedures<sup>1</sup> as well as alternatives.<sup>2</sup> This doctrine has been described as "the legal model of the medical decisionmaking process" (Meisel and Roth, 1983: 272). These two books evaluate how adequately that model reflects medical practices of the past and present.

Faden *et al.* seek the historical roots of informed consent.

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<sup>1</sup> In addition to *Salgo*, see *Gates v. Jenson*, 92 Wash. 2d 246, 595 P.2d 919 (1979); and *Keogan v. Holy Family Hospital*, 95 Wash. 2d 306, 622 P.2d 1246 (1980).

<sup>2</sup> See *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979); *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977).

They begin by developing a definition of informed consent as follows:

- (1) a patient or subject must *agree* to an intervention based on an *understanding* of (usually disclosed) relevant *information*, (2) consent must *not be controlled* by influences that would engineer the outcome, and (3) the consent must involve the intentional giving of *permission* for an intervention (p. 54).

They then undertake a rich and impressive intellectual history of the concept to determine how, if at all, informed consent has manifested itself in classical and contemporary medical oaths, codes, treatises, and published lectures. However, they acknowledge the limitations of these data sources, since “it is not always clear whether the statements made in these documents were primarily exhortatory, descriptive or self-protective” (p. 55). For a better sense of the role of informed consent in medical practice, Faden *et al.* turn to a source rarely tapped by social scientists or medical ethicists—detailed medical case reports from the nineteenth century—which provide a better view of actual practices than do the codes.

In their quest for early sightings of informed consent, the authors are entering the cross fire between psychiatrist Jay Katz and historian Martin Pernick. Katz has argued that when courts first articulated the requirement of informed consent thirty years ago, the concept was completely foreign to medical practice. He likens the legal doctrine of informed consent to the *deus ex machina* in Greek plays, which surfaces seemingly out of nowhere (Katz, 1984: 60). “The history of the physician-patient relationship from ancient times to the present . . . bears testimony to physicians’ inattention to their patients’ rights and needs to make their own decisions” (*ibid.*, p. 28). Physicians “have not, except inadvertently, employed words to invite patients’ participation in sharing the burden of making joint decisions” (*ibid.*, p. 4).

In making such a statement, Katz can find support from the most influential figure in medical ethics, Hippocrates. Not only did Hippocrates ignore the idea of patient choice, he also advised against even disclosure to patients. The *Corpus Hippocraticum* recommends “‘concealing most things from the patient, while you are attending to him . . . turning his attention away from what is being done to him; . . . revealing nothing of the patient’s future or present condition’” (Faden *et al.*, p. 61).<sup>3</sup>

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<sup>3</sup> According to Faden *et al.* (p. 3), the Hippocratic view of medical practice did not have an extensive influence in the ancient period. Medical practice at the time was less authoritarian than what Hippocrates advocated. It was not until several centuries later that the Hippocratic Oath and practices gained serious attention. In medieval times, the Christian monastic physicians resurrected the Hippocratic traditions, perhaps because the emphasis on authoritarianism and patient’s obedience was compatible with Christian religious doctrine.

In contrast to Katz's approach, Pernick (1982: 3) argues that "truth-telling and consent-seeking have long been part of an indigenuous medical tradition, based on medical theories that taught that knowledge and autonomy had demonstrably beneficial effects on most patients' health."

The findings of Faden *et al.* tend to favor Katz's position that informed consent has not been a part of tradition in medical practice, but the authors nonetheless dispute his argument that "the doctrine of informed consent surfaced, seemingly out of nowhere."<sup>4</sup> In their close analysis of nineteenth-century medical case reports, Faden and her collaborators uncover cases in which informed consent was present in its modern form, with the physicians discussing the nature, risks, and benefits of the proposed treatments as well as possible alternatives.

Even when informed consent did not manifest itself in its entirety, the cases (as well as the works of some nineteenth-century medical commentators) evince more of an emphasis on disclosure than Katz seems to acknowledge. The findings of Faden *et al.* serve to reconcile the theories of Katz and Pernick by demonstrating that although disclosure and consent-seeking were historically only rarely undertaken to facilitate patient autonomy (the central tenet of the modern legal requirement of informed consent), in the past disclosure and to a certain extent consent-seeking have been undertaken when they were thought to be beneficial to the patient.

The withholding and granting of information have themselves been used as therapeutic agents. Because in earlier centuries disease etiology was not understood and therapies were few, disclosure necessarily meant the relaying of bad news (rather than potential options and choices). During those times, much of what medicine offered was a placebo effect. Silence and even deception were justified by physicians as a way to provide a medical benefit by maintaining hope. Such an approach was taken by Thomas Percival, who saw the role of the physician primarily to "be the minister of hope and comfort" (Faden *et al.*, p. 67). His 1803 book, *Medical Ethics*, claimed that truthful disclosure was detrimental to a patient's health. This book served as the basis for the American Medical Association's 1847 Code of Medical Ethics, which did not acknowledge a duty of disclosure to patients. The AMA Code was revised numerous times over the next century, but it did not depart significantly from Percival's influence until 1980.

Those commentators who broke from the Percival tradition believed that patients had a right to receive information or to reject their physicians' recommendation. Some advocated truthful

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<sup>4</sup> They emphasize "how inadequately and with what measure of hostility and insularity, problems of truthfulness, disclosure, and consent were framed and discussed prior to the twentieth century" (p. 60).

disclosure because it would help persuade patients to follow doctor's orders. In that way, disclosure was seen as providing a medical benefit. For example, Benjamin Rush, a physician and signer of the Declaration of Independence, advocated disclosure to patients so that they would more fully understand and comply with physicians' recommendations (Faden *et al.*, p. 65).

Worthington Hooker was less sanguine about medical therapy and thus believed that patients might benefit from being informed about and refusing some medical interventions. In his 1849 book, *Physician and Patient*, Hooker declared that "the good, which may be done by deception in a few cases, is almost as nothing, compared with the evil which it does in many cases . . ." (Faden *et al.*, p. 71). He also recommended truthful disclosure to protect patients against ineffective remedies. But, once again, his recommendations were based on beneficence, rather than autonomy.

Even today, some commentators argue in favor of informed consent on beneficence grounds. Disclosure is advocated as being psychologically beneficial to patients,<sup>5</sup> as giving patients the opportunity to refuse overly risky procedures,<sup>6</sup> and as protecting patients from procedures advocated for physicians' self-interest.<sup>7</sup> Nevertheless, the heart of the legal doctrine of informed consent is not the protection of the patient's body but rather the protection of the patient's autonomy. As a 1971 case summarized, the "primary interest" of informed consent is "having the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment, regardless of whether he in fact chooses rationally" (*Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647, 650 (1971)).

The only major shortcoming of the book by Faden *et al.* is the authors' failure to explain satisfactorily why, in the mid-twentieth century, courts began to attempt to protect patients' autonomy by requiring physicians to disclose information. In two short paragraphs, they speculate that the Nazi atrocities and some American incidents of experimentation on unconsenting subjects raised suspicions about physicians' abilities to act in patients' best interests, as did the increasingly technological and impersonal medical care, and that this loss of faith led to stricter legal oversight.

Although deficient in an analysis of why courts introduced the concept of informed consent, Faden and her coauthors do provide

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<sup>5</sup> Research has indicated that advance disclosure about the risks of a medical procedure can serve, in Janis' terms, as an "emotional inoculation" so that informed patients need fewer painkillers afterward (as compared to uninformed patients) (see, e.g., Janis and Mann, 1977; Egbert *et al.*, 1964; Schmidt and Wooldridge, 1973; Wilson, 1981).

<sup>6</sup> Lidz *et al.* (p. 7) point out that some statutes requiring informed consent for particular procedures (such as electroshock therapy) were adopted to discourage their use. (See also Faden *et al.*, p. 140).

<sup>7</sup> See Schneyer, 1976: 124, 137-138.

an explanation for why the idea caught on. They postulate that the “increased legal interest in the right of self-determination and increased philosophical interest in the principle of respect for autonomy were but instances of the new rights orientation that various social movements of the last 30 years introduced into society” (p. 87). They point, for example, to the wide range of disclosure-type legislation passed by Congress during this time, such as the Freedom of Information Act (5 U.S.C. § 552 (Supp. 1987), enacted 1966), the Truth-in-Lending Act (15 U.S.C. § 1601 (Supp. 1987), enacted 1968), the Consumer Product Safety Act (15 U.S.C. § 2051 (Supp. 1987), enacted 1972), and the Toxic Substances Control Act (15 U.S.C. § 2601 (Supp. 1987), enacted 1976). In the area of health care per se, patients’ rights became such a celebrated cause that the American Hospital Association adopted a “Patient’s Bill of Rights” in 1972.

Faden *et al.* (p. 92) also identify a change in medical ethics itself, with a greater amount of writing and teaching being done by individuals outside of the medical profession, which resulted in such a radical change in conceptualizing medical ethics in the decade between 1962 and 1972 that the field itself took a new name: bioethics. By the late 1970s, nearly all medical schools had ethics courses. According to Faden *et al.* (p. 93), “informed consent became a major moral problem when it did because it was swept along with a tide of interest in morals and medicine. . . .” While only nine articles on consent appeared in the medical literature between 1930 and 1956, the issue was addressed in over one thousand articles between 1970 and 1982 (pp. 86, 91, 95).

Informed consent flourished within the law because it rested comfortably with a legal framework that emphasized autonomy in a variety of realms.<sup>8</sup> In contrast, “in medicine, there was no ready set of internal principles that paralleled those of law” (p. 142). Medicine did not have a framework within which to assimilate informed consent. Facilitating patient autonomy had never been viewed by physicians as part of their moral responsibilities.

The disjunction between the moral emphasis of the legal doctrine of informed consent (autonomy) and the moral emphasis of medical practice (beneficence) has influenced the way in which informed consent is operationalized. In *Informed Consent*, Lidz *et al.* report on the most ambitious research project to date analyzing informed consent in a clinical setting. The authors spent thousands of hours observing mental health professionals and patients in three settings within a hospital—an evaluation center, a research ward, and an outpatient clinic treating schizophrenia. The

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<sup>8</sup> According to the authors (p. 142), “for decades legal theory has possessed principles that could give expression to concerns about consent. Civil liberties, self-determination, fraud, bodily integrity, battery, trespass, the fiduciary relationship, contract, and the like were all staples of the law.” This quotation appears in a chapter written primarily by attorney Nancy King.

purpose was to study information disclosure, understanding, voluntariness, competency, and decision making. Every interaction was observed by two researchers—one who focused on the staff member and one who focused on the patient.

The Lidz study demonstrates the enormous difficulty health care professionals have in moving from a beneficence model of disclosure to an autonomy model.<sup>9</sup> At the end of their four-year project, Lidz and his colleagues (p. 36) concluded that “nowhere in the Hospital did we see decisionmaking and communication patterns look the way they were supposed to look under the ethical doctrine of informed consent.”<sup>10</sup> The clinicians seemed to feel that they had the right to make health care choices for patients (p. 133). Information was withheld or disclosed to encourage patients to follow the clinicians’ recommendations.

The process of information disclosure in the hospital did not resemble the legal model of informed consent in which a patient is to be told the nature of the condition and the risks and benefits of a proposed procedure or treatment and of alternatives (see Andrews, 1984). “One of the most remarkable findings of our study,” write Lidz *et al.* (p. 76), “has been that patients rarely were explicitly informed about the findings of the initial evaluation; that is about ‘what was wrong with them.’” One patient, for example, felt that her problem was that she lacked skills for a job. She wanted to enter the hospital to get a rest, to get away from her family, and to see her friends on the ward. She was never told that she was being hospitalized because she had been diagnosed as having schizophrenia.

Patients in the evaluation center, who were deciding whether to commit themselves voluntarily, were provided with little information upon which to make that choice. For example, they were generally not told how long they might be hospitalized or what tests or treatments might be used. They were not told what ward they would be on, even though the wards differed in the treatments employed (for example, behavior modification versus medication) and length of stay. Nor were patients given information about the advantages or disadvantages of inpatient versus outpatient treatment. Of the forty-eight patients the researchers observed making decisions in the evaluation center, only one was

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<sup>9</sup> The health care professional’s use of the beneficence model rather than the autonomy model is illustrated by the following exchange observed by the researchers (p. 152):

PATIENT: I have humanistic rights that were taken away from me.

HEAD NURSE: Our duty towards you is to keep you alive.

<sup>10</sup> They note that “although we attempted to perform a study of how informed consent is obtained in a variety of psychiatric treatment set-ups, this goal was impeded by the fact that the entire constellation of behavior that ought to constitute informed consent was rarely observed” (p. 322).



given a description of the tests he would be given after admission (pp. 74–90).<sup>11</sup>

Inpatients on the research ward often were not given adequate information in order to make a choice of whether to participate in the research. The staff frequently made it appear that one of the benefits of research was that the patient would get diagnostic studies; they neglected to say that patients who did not participate in the research protocol also received the same diagnostic tests.<sup>12</sup> Moreover, the staff did not discuss the disadvantages of research participation.

Neither inpatients in the research ward nor outpatients were given information about the risks of the medications prescribed for them.<sup>13</sup> In particular, none was told of the substantial risk of tardive dyskinesia, a neurological disorder characterized by involuntary movements that affects 10 percent to 20 percent of all patients treated for long periods with psychotropic drugs. Even when patients actually developed the disorder, they were not told of its origin (p. 276).

When information was provided, it was often disclosed to the patient (or in many instances, relatives) for the express purposes of persuading the patient to follow the clinician's recommendation, rather than for providing the patient with alternatives and risk assessments to facilitate true choice.<sup>14</sup> Clinicians allowed the patient to harbor misconceptions about the nature of their condition or a treatment if it meant that the patient would acquiesce in the clinicians' recommendations.

In addition, information was often presented later than the informed consent doctrine envisioned. Rather than receiving it when it could be used to evaluate alternatives, patients were given information after they had agreed to the staff member's recommendations or a particular treatment had been embarked upon. For instance, patients were often given new drugs and then told about the change only after they had begun taking them. In one case, the patient protested, specifically saying that her psychiatrist had not discussed the medication change with her, but the nurse

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<sup>11</sup> That description itself was very vague: "I think you should come in for some tests so that we can check your memory and concentration." (p. 89).

<sup>12</sup> Outpatients were given more details about the side effects of drugs than were inpatients, in order to be able to monitor themselves to determine if the side effects materialized. However, even the outpatients were not told that they might have to continue taking the medications for the rest of their lives (pp. 271, 273).

<sup>13</sup> In addition, of the inpatients on the research ward, only one was told of alternative medications (p. 184).

<sup>14</sup> In many cases, Lidz *et al.* (p. 98) found that "the staff informed patients not to facilitate their independent decisionmaking, but rather in order to overcome their resistance to cooperating." In that way, the clinicians' approach was similar to that advocated two centuries earlier by Benjamin Rush (see Faden *et al.*, p. 65).

dispensing the drug pressured her to take it. The researchers observed that when patients did object to a medication change, “they were typically told to take the medications now and to discuss it with the doctor the next morning” (p. 232).

Because clinicians operated on a beneficence model—and felt that they generally knew what was best for their patients—they gave low priority and low status to efforts to enhance patients’ autonomy. For example, welfare regulations require that patients be told of their rights. With one exception, it was always a nurse rather than a psychiatrist who performed this task. “Informing patients was not regarded as a duty of enough importance to justify the use of the most highly trained and highest status professionals” (p. 96). Rather than being a right, it was a ritual, in which the staff member either droned on through an oral presentation of printed information or rushed the patient through the forms by saying, “‘It’s not necessary to read to the end’” (p. 92).

The staff’s feeling that informed consent lacked importance was conveyed to patients in other ways as well. For example, the patients were not even given privacy to consider the forms; they were presented in a common area (p. 123). When a provisional treatment plan was presented for patients to sign, “the tone and manner in which the material was sometimes presented to the patient . . . conveyed the impression that to engage in any kind of discussion on the issue would have been peculiar or unusual” (p. 124). Clinicians were effective at achieving compliance and averting questions. Patients were willing to sign the statement that treatment had been explained to them even if it had not been. In addition, in the forty-eight presentations of consent forms that the researchers witnessed, twenty-one were not read and five were only skimmed or glanced at (p. 109).

Why was the informed consent procedure so rarely followed? Lidz and his colleagues blame medical training, which stresses that it is the physician’s role to find the one best treatment for the patient, and the institutional setting of medicine, which distributes responsibility for disclosure vaguely over a large number of people.

The beneficence values that characterize medicine may be appropriate in some aspects of mental health care since, if a patient is mentally incompetent to make treatment decisions, there might be a justification for providing treatment without consent in order to restore the patient to the point at which autonomy could be exercised. Yet few of the patients in the study were judged to be incompetent. Moreover, most understood whatever information was presented, and the provision of information in no way harmed them. Thus even though the patients were seemingly capable of making autonomous choices, they were not allowed to do so.

In substituting their judgments for those of the patients, the clinicians felt that they were doing what was medically best for patients. Not only did their actions compromise patient autonomy,



they arguably fell short of their intended goal of beneficence as well. The outpatient clinic, for example, adopted a particular treatment strategy: medication. By not informing patients of alternative therapies, the staff may have prevented certain patients from trying a treatment that might have been better suited for them. Failure to inform patients about the risks of the proposed treatment (particularly of tardive dyskinesia) might also have impeded them from undertaking treatment strategies that were best for them. For example, to the extent that some patients saw their problems as rooted in their lifestyles, they might have made changes in their lives or sought group or individual therapy if they had been told about the side effects of the drugs.

Lidz and his colleagues also claim that the law's model of medical decision making is rarely encountered "because patients seem little interested in exercising their right to informed consent" (p. 322). This latter conclusion is far more broad than the study itself would support. The researchers did not actually test whether patients were interested in exercising informed consent. It is likely that most were unaware that they had this right. Those who felt they had a right to information they needed to make their own decisions had difficulty in both obtaining information and having their choices respected. For example, Lidz and his coauthors report that in the research ward, "in no case did a patient's objection prevent a test that the doctor or another staff member wanted from being carried out" (p. 208).

Even patients' failure to ask questions cannot be taken as an indication of a lack of interest in directing the course of their own health care. The Lidz study itself found that "the staff was seldom receptive to questions" (p. 97). In some interchanges, the patients' questions were ignored<sup>15</sup> or only vaguely answered. For example, when a patient asked the resident what medications he would be getting, the reply was, "'Pills'" (p. 283). In other instances, it seemed that the clinician was not listening to the patient's responses to the physician's questions,<sup>16</sup> thus making it unlikely that the patient would feel that she had the clinician's attention sufficiently to make an inquiry. The researchers observed that most

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<sup>15</sup> For example, in response to one patient's question, the psychiatrist replied, "That's a good question," but did not answer it. In another instance, a resident ignored the patient's questions but kept asking his own (pp. 97, 283).

<sup>16</sup> This is evident in the following exchange that occurred in the evaluation center (pp. 64–65):

CLINICIAN: Are you working?

Ms. G.: No.

CLINICIAN: What made you come here today?

Ms. G.: I was feeling depressed and upset.

CLINICIAN: About what?

Ms. G.: A lot of things.

CLINICIAN: I have to ask you to sign here to give authorization for us to send the bills to Medical Assistance.

inpatients “found it hard to question the doctors in any detail, because they saw the doctors as being very busy and too important to be concerned with their troubles” (p. 170). Asking questions was so disvalued that one patient who asked questions was diagnosed as schizophrenic. Lidz *et al.* observed that “her asking questions was taken as contributory evidence of her paranoia” (p. 97). However, although questioning was made extremely difficult, the patients who asked the most questions received the most information.

In their analysis of outpatient decision making, the authors note that in only fifteen of sixty treatment decisions did patients weigh risks against benefits (p. 289). Yet considering how little information was given to patients about proposed treatments, the 25 percent of the patients who engaged in the decision-making process envisioned by the law might actually be cause for optimism rather than pessimism about the potential for informed consent.<sup>17</sup>

Lidz and his colleagues also conclude that “the patients seem to have substantial difficulty in distinguishing research from treatment” (p. 235). The authors imply that this is due to a cognitive deficit in the patients. They never relate it to their finding that, in order to get patients to consent to participate in research, the staff itself blurred the distinction.

Rather than showing patients’ disinterest in exercising their right to informed consent (as Lidz *et al.* claim), the findings suggest that many patients did not realize they had this right and that those who tried to exercise it were thwarted either by not receiving the information they requested, by receiving misleading information, or by having their decisions overruled by staff members. The value that patients would put on informed consent cannot be adequately tested until a situation exists in which the practitioners respect informed consent. This means respecting both the value of the concept and the decision of the patient. It would require vast practical changes, such as giving higher status and priority to disclosure and telling patients in a supportive way that they have a right to receive information and to reject the practitioners’ recommendations.

The Lidz group (p. 323), like Faden and her coauthors, conclude that “the values of the healing profession are substantially at odds with the values that underlie the informed consent doctrine.” Nevertheless, they believe that informed consent is worth pursu-

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<sup>17</sup> The authors also report that one-quarter of the outpatients changed their medication dosage themselves between visits (p. 297). The authors do not provide information about whether these people are the same 25% who considered the risks and benefits. If they are, there might be a consistent minority of patients who exhibit autonomy in health care decisions. If the latter group includes people who are not among the quarter who initially weighed risks and benefits, the percentage of patients who engaged in at least one autonomous decision-making action is even greater.

ing and suggest various methods for doing so, including hiring an individual to educate patients, placing greater emphasis in medical education on communicating with patients, and expanding legal remedies, such as making the failure to inform and/or obtain consent the basis for professional discipline (pp. 331–333). Yet they provide no explanation for what might motivate medical facilities, medical education, or medical practitioners to adopt these changes. Medicine has not identified the furtherance of patient autonomy as a goal. And the external mechanisms for change the authors suggest, such as disciplinary proceedings, are apt to be invoked even less frequently and with less effect than torts suits for lack of informed consent are now. Thus, informed consent may continue to be a rarely attained ideal—more a rite than a right.

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