# Reconsidering the Ethical Implications of Informed Consent†

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***Abstract:***

Informed consent is a legal principle with ethical implications. The concept is usually explained as the transition from the "paternalism of doctors" to "patient self-determination." However, several problems have emerged because of this interpretation. Thus, I propose a different one.

In law, informed consent refers to the "patient's consent" reinforced by disclosure, a concept based on "assault and battery." I argue that the aspect of "negligence" is more important, which implies an expansion of the doctor's responsibility.

From this perspective, I examine the ethical implications of informed consent. Originally, medicine included two elements: (1) benefit to the patient and (2) will of the patient. The will of a patient was not ignored even in ancient times, despite being overshadowed by a focus on the benefit to the patient. In the 20th century, informed consent brought about a change: from "benefit to patient > will of patient" to "will of patient > benefit to patient." This is not an alternative selection, but a matter of prioritization.

Two ethical consequences have arisen. First, doctors must seek medical benefit to a patient according to their will. This is an improved style of benevolence. Second, doctors are not obligated to perform unethical actions unrelated to medical treatment.

***Keywords:***

informed consent, negligence, no-fault liability, expansion of doctor's responsibility, conversion of priorities, improved style of benevolence

## 1. Preface: Purpose and Problems

Informed consent is a legal principle that has been used since 1960. It was developed as the result of a series of lawsuits in the USA. However, for doctors and patients to apply the principle in medical treatment, ethical perspectives are needed. Thus, this article proposes some ethical interpretations regarding this legal principle.

One ethical interpretation of informed consent emphasizes "the patient's right of self-determination." According to this view, traditional medical ethics are distinguished by the "paternalism of doctors," and the ethical significance of informed consent is characterized as the transition from this "paternalism" to "patient self-determination."[1)]

However, patient self-determination has been criticized as excessively individualistic, sometimes even selfish, and

medical services are sometimes charged with excessive commercialization. Furthermore, it is well-known that some patients do not exercise their right to self-determination.[2)]

In consideration of these challenges, another ethical interpretation of informed consent has been proposed, viz., "the communication and accommodation model" between patients and doctors.[3)] Certainly, sufficient communication is desirable. However, strangely, medical decisions are now made by "accommodating" both sides.

In this article, I briefly reflect on the early discussions associated with the legal principle of informed consent in the USA and then consider the ethical implications. In this article, "legal" refers to social regulations, which empower certain actions. In contrast, "ethical" refers to a practical attitude toward or an evaluation of such actions.

## 2. Legal Meanings of Informed Consent in Clinical Treatment

The principle of informed consent is employed in two fields of medicine: medical research and clinical treatment. My focus in this article is on informed consent in clinical treatment. In this context, two legal principles relevant to informed consent are applied in the USA, viz.

(1) assault and battery
(2) negligence

In my view, two legal meanings of informed consent correspond to these principles:

(1) Establishing a patient's right to self-determination
(2) Expanding the scope of doctors' responsibilities

Earlier discussions on informed consent have emphasized "assault and battery" and the "self-determination of patients." I contemplate that the other aspects of "negligence" and "expansion of a doctor's responsibility" contribute towards resolving the challenges of informed consent. Now, I briefly outline the development of the principle of informed consent in the USA and then substantiate my argument.

### The Mohr Case (1905)

Mohr had experienced problems with her right ear. While the patient was under anesthesia during surgery, the doctor diagnosed a problem with her left ear, consequently removing a small bone in the left ear without the patient's consent. The doctor caused irrevocable damage. The court ruled that the patient's consent was needed to perform the surgery, and it was the patient's right to make this decision during medical treatment.[4)]

This lawsuit argued the legal principle of "assault and battery," which describes medical surgery as an invasion of a patient's private body. Without the patient's consent, surgery becomes an injury. This is a natural argument that stems from the essence of medicine. Following this case, the patient's right to make decisions regarding the own body was acknowledged as the "patient's right to self-determination."[5)]

### The Salgo Case (1957)

The next important lawsuit was the Salgo case. The plaintiff, Salgo, complained of pains in the right side of his abdomen. The doctor noted a serious problem with his circulatory system and prescribed an abdominal aorta examination. The doctor proposed an aortography, which involves injecting a substance into the aorta, without explaining the possible risks. The procedure left the patient's lower extremities paralyzed.[6)]

The verdict examined whether the doctor was guilty of negligence from the perspective of *Res Ipas Loquitur* (Latin for "the thing speaks for itself"), "a doctrine of law that one is presumed to be negligent if he/she/it had exclusive control of whatever caused the injury even though there is no specific evidence of an act of negligence, and without negligence, the accident would not have happened."[7)] After examining the doctor's actions one by one, the court did not acknowledge them to be technically negligent. The uncertainty of the medical field means that applying *Res Ipas Loquitur* to medical practice places excessive demands on doctors unless there is apparent evidence. However, the verdict placed another demand on doctors,

namely "the full disclosure of facts necessary to gain informed consent." [8] This was the first case in which informed consent was used in court.[9]

This verdict comprised two factors, which are related to two aspects of informed consent. One factor was the intensification of the consent principle in the Mohr case. If the patient is not provided with sufficient information, the patient's consent is not legally valid. This is the reinforcement of "assault and battery" and the establishment of the patient's "right to self-determination" and is the commonly accepted view of informed consent. However, in this case, the plaintiff did not win the lawsuit.

The second factor, in this case, was a social trend of expanding responsibility for damages. This is evident in the application of *Res Ipas Loquitur* in cases of medical malpractice. This emerged from the consumer movement demanding the application of no-fault liability (strict liability) to companies in the USA. Although the verdict did not acknowledge doctors' technical responsibilities, it added to their duties by mandating that they provide patients with sufficient information. The significant implication of this duty was clarified in the Nathanson case, discussed next. We must remember that informed consent is contextualized within a milieu of expanding provider responsibilities.

The Nathanson Case (1960)

The plaintiff Nathanson underwent a mammectomy. To prevent a relapse of cancer, she was exposed to cobalt radiation without any explanation of the risks. The procedure resulted in severe radiation burns.

While the court did not recognize the doctor's technical negligence, it did acknowledge another form of negligence, namely that had the doctor sufficiently explained the risk, the patient, having no emergency needs, would have had the opportunity to decline cobalt radiation and would not have suffered the burns. This illustrates the negligence doctrine in informed consent. The doctor committed negligence by not explaining the inherent risk of the treatment and thus was legally liable for compensating the patient for her injuries. In this case, the informed consent used in the Salgo case was cited and used as a presumption of negligence.[10]

According to this principle, doctors are liable for damages when they do not provide sufficient information, even if they have not committed technical negligence. This fact underlies the shock that the principle of informed consent imparted American doctors in the 1960s. To appreciate the social impact of informed consent, we must remember the principle of negligence, which holds irrefutable legal logic that translates into social impact.

To understand the revolutionary character of the principle of negligence in informed consent, responsibilities in medicine must be reviewed. In modern civil law, "the principle of liability arising from negligence" generally prevails. This principle is expressed as "without negligence, no responsibility" (in German: *Ohne Schuld, keine Strafe*). In medical practice, doctors have the responsibility to take due care according to standard criteria accepted by medical professionals. Unless doctors perform unwarranted care and are deemed negligent (at fault) according to these criteria, they are not legally responsible for patient injuries.

However, another direction emerged from the American consumer movement regarding this responsibility, namely the concept of "no-fault liability" (strict liability). For example, a private person is unable to demonstrate a company's technical negligence if the company's products harmed the person. Here, no-fault liability means that the company is responsible for damages caused by its acts and omissions regardless of negligence (PL law: product liability law).

This movement was introduced into medical malpractice lawsuits as *Res Ipas Loquitur*. However, medicine is an uncertain field; thus, we cannot make doctors liable for negative results of treatment provided, as long as they practice with due care according to accepted criteria. In this way, *Res Ipas Loquitur* was not generalized to the medical field. In the Salgo case, the verdict denied the use of *Res Ipas Loquitur*. However, in return, judges stipulated that doctors inform patients of the risks of prescribed treatment before obtaining their consent to undergo it. The

Nathanson case reveals the profound influence of disclosure. If doctors did not disclose sufficient information regarding a prescribed treatment to a patient, they committed negligence. They were liable for damages arising from the treatment, even if they had not technically committed negligence.

This meant an expansion of the scope of doctors' responsibilities. Previously, doctors were responsible only for technical treatment, without further responsibility to patients, unless they performed undue medical care according to the accepted standard criteria. However, following the Nathanson case, doctors became responsible for the entire process, which includes providing patients with sufficient information, obtaining their consent, and performing medical treatment. This meant a structural change in medicine and a redefinition of the doctor-patient relationship. The expansion of doctors' obligations and the change in the character of medical practice was a revolution. In the realm of clinical ethics, the issue of informed consent has become a new dimension of doctors' responsibilities.

Here, the concepts of informed consent and no-fault liability (or strict liability) are parallel in the same direction of liability expansion; however, they are not the same. Although some disputants argue that informed consent and strict liability are the same thing, their views are not valid.[11)]

Consequently, the meaning of informed consent must be interpreted according to the perspective mentioned above.[12)] Importantly, the structural change in medicine is another consequence of the USA consumer movement for strict liability.[13)]

Structural Change in Medicine

Former: medicine = treatment →

Present: medicine = explanation + obtaining consent + treatment

Informed consent has two legal meanings. The first is complementary to the principle of consent based on "assault and battery." If doctors do not provide sufficient information to patients, the consent provided by them is deemed invalid, and treatment provided by doctors becomes battery. The second meaning of informed consent is an expansion of doctors' responsibilities, which is confirmed by the legal principle of negligence and liability for patients.

Within the first context, informed consent has often been discussed as a developed form of "assault and battery" and is said to be fundamental to the patient's right to self-determination. In fact, an excessive and unconditional emphasis on the patient's right to self-determination is derived from this perspective.

However, to understand the social impact of informed consent, the second context, negligence, must be considered. As a frame for compensation for damages, a doctor's duty to disclose information to patients was shaped within traditional "Tort Law."[14)] Without this perspective, the great influence on societies, which informed consent has exerted, cannot be understood. It is no accident that a dramatic increase in medical malpractice lawsuits in the USA occurred at the same time as the negligence principle of informed consent was created. Furthermore, the principle of negligence highlights the patient's right to self-determination, although this is emphasized only within the medical treatment and never beyond the medical context. From this perspective, in the following sections, I consider the ethical implications of informed consent.

The principle of negligence in informed consent is sometimes criticized. One criticism, that of "hindsight"[15)] emphasizes that if medical treatment is successful, a patient will not accuse doctors of providing insufficient information. Only when treatment fails will a patient accuse doctors of not providing adequate information. In this case, an accusation based on the principle of negligence in informed consent could be said to use "hindsight." However, this criticism is based on the old view of medical practice, which has been discredited by the principle of negligence in informed consent. Critics suppose that medicine is equivalent to treatment in practice (medicine = treatment).

Such a supposition is now just questioned. Today, conversely, when treatments are successful, doctors merely escape accusations for not disclosing sufficient information.

Another criticism is referred to as a "paper tiger."[16] Here, the principle of negligence in informed consent at first appears to be a powerful argument; however, in fact, patients hardly ever win lawsuits by using it. Thus, it is a paper tiger. Several circumstantial factors are relevant in cases of medical malpractice. In medical lawsuits based on informed consent, two arise.

(1) Criteria pertaining to the extent to which doctors must disclose inherent treatment risks. Three criteria are important, namely the "professional practices standard," the "reasonable person standard," and the "subjective standard." In lawsuits after the Nathanson case, the choice of an appropriate criterion to adopt was frequently debated.[17]

(2) Demonstration of causal relations, whereby a doctor's negligence in disclosure harms the patient.[18] For example, in the Nathanson case, as the patient had already undergone a mammectomy as a treatment for lung cancer, it was assumed she would not have agreed to such risky treatment had the doctor explained the risks. In this case, a causal relationship was evident between the doctor's negligence in disclosure and the patient's injuries.

To be sure, patients cannot always win lawsuits by appealing to this principle. However, the point is that there are such clear-cut cases as Nathanson, which demonstrates that patients can win lawsuits through its application. This fact serves as a strong caution to doctors. The problem with the principle of negligence in informed consent is that it formulates an undeniable legal logic, which urges a structural change in medicine.

Historically, informed consent has transitioned into a "social norm" by becoming a doctor's duty and a patient's right as codified in the American Hospital Association's "A Patient's Bill of Rights" (1973) and the World Medical Association's "Declaration of Lisbon on the Rights of the Patient" (1981), amongst others. Based on my perspective, this movement is understandable. Informed consent in medicine has made way for a new horizon of responsibility, which can be generalized as accountability. It has become a new legal and ethical norm and internalized as a practical principle. Thus, informed consent must be interpreted from an ethical perspective.

## 3. The Ethical Implications of Informed Consent

Informed consent is a newer legal doctrine applied in medical malpractice lawsuits. However, doctors and patients need an ethical interpretation of this doctrine to apply it as a practical principle in clinical medicine. As explained in the preface, "ethical" refers to a practical attitude toward or evaluation of actions. As such, what are the ethical implications of informed consent?

Informed consent is often considered fundamental to a patient's right to self-determination. This interpretation derives from the "assault and battery" principle. But, what are the ethical interpretations of informed consent informed by the legal principle of negligence? I address this question based on the preceding discussion. To consider this problem, we need to come back to the original ethical meanings of medical practices. Initially, two elements are included in medicine[19]:

(1) Improving the patient's health [Benefit to Patient], and

(2) The patient's consent to medical intervention [Will of Patient].

Doctors must treat patients so that patients are benefited. The patient's improved health is the essence of medical practice. Naturally, patients must pay doctors for their services. However, if doctors treated medical services as commercial trade, patients' lives and health would become only a means of making money. Consequently, medicine would be immoral and exploit people's weaknesses.[20] Therefore, the main purpose of medicine should not be to make money but to improve patients' health.

There is another component of medicine. Even in ancient times, doctors could not cut a patient's wounded leg without consent, which is necessary for the practice of

medicine.[21] If this argument is true, the necessity of a patient's consent is not the essence of informed consent. The element of a patient's will was included in medicine from the beginning.

Even before the 20th century, a patient implicitly expressed his/her will for treatment by visiting a doctor, and doctors often treated patients for their benefit without specifically confirming their will. While patients had a will, this was superseded by the potential benefits of treatment. This can be better expressed as follows:

"Benefit to Patient > Will of Patient" (">" means a priority relation)

However, these dynamics changed in the 20th century. Medical intervention has become risky, and the probability of harming patients has become high because of the development of medical technology. Furthermore, people's awareness of medical treatment has gradually increased, allowing them to make their own decisions.[22] In addition, the legal principle of informed consent has emerged, specifically the principle of negligence, which has burdened doctors with the legal obligation to respect a patient's will as a form of liability. Thus, doctors must now explicitly and specifically obtain a patient's informed consent. We can express this situation in the same way as the former:

"Will of Patient > Benefit to Patient"

Therefore, we can express this change as follows:

"Benefit to Patient > Will of Patient" →
"Will of Patient > Benefit to Patient"

Considering this formulation, the issue is not a problem of selecting either the "Benefit to Patient" or the "Will of Patient." Rather, it is a problem of prioritization. Consideration of both the "Benefit to Patient" and the "Will of Patient" is necessary in medicine, although prioritization has shifted. Here, my interpretation of informed consent differs from the following popular interpretation:

"Paternalism of Doctors" [Benefit to Patient] →
"Patients' Rights of Self-Determination" [Will of Patient]

The popular interpretation of informed consent emphasizes the principle of "assault and battery," which means a doctor's treatment becomes an injury without patient consent. This has been thought to be fundamental to "patients' rights to self-determination." However, as previously mentioned, the concept of the "Will of the Patient" has been included in medicine from the beginning. Thus, doctors requiring patient consent [Will of Patient] to practice medicine is not new. The issue is positioning a patient's will within medicine. Here, the principle of negligence becomes more significant.

The principle of negligence indicates that doctors must provide a patient with the necessary information, so that they have an opportunity to choose and make decisions regarding treatment. Medical treatment is premised on informing patients and obtaining consent. If doctors do not live up to the premises, and treatment fails, they bear the liability for negative consequences through negligence. This implies that medical practice prioritizes a patient's will. Informed consent based on the principle of negligence is a powerful legal logic to assure that the patient's will is prioritized.

At the same time, the principle of negligence in informed consent only applies to clinical treatment. In other words, the patient's right to make decisions based on this principle is a right in clinical treatment, not a right in every possible context. Accepted interpretations of informed consent consider the patient's right of self-determination as valid in every possible context, such as positive euthanasia and abortion. This is a misunderstanding of informed consent.

Medical practice is a socialized action in which multiple persons—the patient, doctors, and nurses—participate. Socialized actions cannot be performed without sharing a common value. In medicine, this value is to promote the benefit to a patient, which is a presupposition of medical

practice. Without this supposition, medicine cannot be performed as a social practice. Based on this clarification, many misunderstandings concerning informed consent are dispelled in the next section.

The core ethical reason for prioritizing a patient's will is that patients must live with the results of treatment all their lives. On the other hand, no matter how sincere doctors are, they cannot shoulder the results of their treatment in their lives. Doctors also have consciences, which must be respected. However, there is an overwhelming difference in the degree to which doctors and patients are involved in their interests. The will of those who are more closely related to their interests must be more deeply respected. This can be called "the interest principle" in ethics.[23] As such, the patient's will and values must be respected in the decision to undergo or conduct medical treatment.

## 4. Several Ethical Consequences of This Interpretation

What ethical consequences emerge from this interpretation of informed consent?

(1) In medicine, while the benefit to and will of a patient are both necessary, doctors should prioritize a patient's will in the practice of medicine. Obviously, doctors explain circumstances, propose medical treatment, and advise patients as medical professionals. However, they should also consider the medical benefit of treatment to patients while taking their will and values into consideration. In other words, doctors must respect patients as people and support and assist them as medical professionals. This is not a mere emphasis for patient self-determination, rather a conversion in priorities.

(2) Doctors are not obligated to perform actions unrelated to medicine, even with the patient's consent. For example, if a man came to a hospital and said, "Cut off my arm, I agree with this action," doctors cannot amputate his arm, because that action has nothing to do with medicine. Thus, medical benefit is essential for medical practice.

Similarly, doctors are not obligated to perform unethical actions that are not related to medicine, such as performing positive euthanasia or abortion, even if patients request these procedures. Informed consent or the principle of negligence applies only in the context of medical practice.

Certainly, in medical practice, several difficult problems arise, which are debated in the field of bioethics. I cannot conduct a debate about these problems in this article. To resolve such complicated problems, a method to analyze their complicatedness is needed. In a previous article, I proposed a method to solve them by applying and prioritizing four principles,[24] which include "Benefit to" and "Will of a Patient."[25] However, even this method cannot, for example, justify positive euthanasia based only on the patient's will.

(3) In medical practice, what should doctors do if patients are reluctant to express their will? In Japan, many elderly people entrust doctors to make judgments related to treatment. In the USA, some people are reported not to exercise opportunities to make decisions about treatment.[26] In these cases, doctors may confirm a family's will, and based on this, seek the patient's best interests. In medical ethics, "best interests" refers to what is considered in the patient's best interest, based on best practice guidelines.

(4) The discipline of medical ethics, which concerns the morality of doctors, has developed throughout the Eastern and Western worlds. In the course of medical history, many doctors have performed good deeds for disadvantaged people.[27] In the commonly accepted view of informed consent, these positive attributes of doctors are ignored with the sweeping terminology of the "paternalism of doctors." However, in my interpretation, doctors' attention to morality, decency, and fitting pride in their work should not be denied. Rather, informed consent implies an improved style of the benevolence associated with the physician role. Doctors are expected to respect patients as persons and assist or support them as medical professionals.

With consideration of these ideas, informed consent is

possible in Japanese and American societies. An excessive focus on the individualism of patients and the commercialization of medicine are not necessarily consequences of informed consent. Medicine, based on informed consent is possible in most countries. The principle seems universal, and different optimal forms or systems of medicine will emerge in different countries and cultures.

### *Notes*

1) Ruth R. Faden, Tom L. Beauchamp (1986), *A History and Theory of Informed Consent*, Oxford University Press, p.13-14, 74-76, 96-100

2) President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982), *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* [MHCD]. Part I, p.17–18

3) The President's Commission in the USA considered the "paternalism of doctors" and "sovereignty of patients" as two extreme views of informed consent, and proposed a middle position, viz., "mutual participation" and "accommodation" (shared decision making), and then took them as their own position. See: *MHCD*. Part I, p.36-39

4) *Mohr v. Williams* (104 N. W. 12), 1905

5) The words of Judge Cardozo are well known. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages." See: *Schloendorff v. Society of New York Hospital.* 211 N.Y. 125, 105 N.E. 92, 1914

6) *Salgo v. Leland Stanford Jr. University Board of Trustees,* 154 Cal. App. 2d 560, 1957, p. 564-568

7) *http://dictionary.law.com/Default.aspx?selected=1823*. Referenced on June 4, 2020.

8) *Salgo v. Leland Stanford*, p. 568-573, 578

9) Several months before the Salgo verdict, Mc Coid published his research, which influenced the Salgo decision. In this article, the explanation before treatment was highlighted. See: Allan H. Mc Coid (1957), A Reappraisal of Liability for Unauthorized Medical Treatment, *Minnesota Law Review*, vol.41, No.4, p.426-427

10) *NATANSON v. KLINE 186 Kan. 393* (1960) 350 P.2d 1093, p.402-404

11) See: Meisel, A. (1977), The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability By Way of Informed Consent. *Nebraska Law Review*, 56(1): p. 51-152. Jose E. Maldonado (1976), Strict Liability and Informed Consent: "Don't Say I Didn't Tell You So!", *Akron Law Review,* 9 (4), p. 609-628.

12) Yoshiro MAEDA (2014), The Significance of Informed Consent: focus on the legal principle of "negligence" (Japanese), *Annals of the Japanese Association for Philosophical and Ethical Researches in Medicine,* vol. 32, p. 1-10

13) Jay Katz (1977), Informed Consent - A fairy Tale – Law's Vision, *Yale Law School Legal Scholarship Repository,* p. 147-148

14) Mc Coid argued that in medical malpractice cases, the charge of assault and battery is inappropriate, because doctors have no "intent" to harm patients. See: A. H. Mc Coid (1957), *op. cit*. p.422-434

15) *MHCD*, part I, p. 26-28

16) Meisel A. (1977), *op. cit.* p. 90-93

17) R. R. Faden, T. L. Beauchamp (1986), *op. cit*. p.129-139

18) R. R. Faden, T. L. Beauchamp (1986), *op. cit.* p. 34-35

19) In addition, the President's Commission in USA enumerated two values—"personal well-being" and "self-determination of patients"—as essences of informed consent in clinical medicine. See: *MHCD*, Part1, p.2

20) The following are the words of Chinese physician Kou Zongshi; "when the physician is not guided by compassion and humaneness, the patient begins to doubt and despise the physician." See: Albert R. Jonsen (2000), *A Short History of Medical Ethics*, Oxford University Press, p.38

21) Importantly, Jonsen reported that "in medieval times, physicians were admonished never to come unbidden to the patient's bedside. The custom of requiring permission for medical touching entered English common law in the 15th century; touching a patient without permission was trespassing." See: Albert R. Jonsen (1998), *The Birth of Bioethics,* Oxford

University Press, p. 354–355

22) A. R. Jonsen (2000), *op. cit.*, p.59, 72, 87

23) J. Feinberg (1974), The Rights of Animals and Unborn Generations, in Blackstone, William T. ed. *Philosophy and Environmental Crisis*, University of Georgia Press, pp. 43-68

24) Yoshiro MAEDA (2012), A Method to Solve Ethical Dilemmas in Medicine, *Journal of Philosophy and Ethics in Health Care and Medicine*, Vol. 6, p. 9–28

25) The four principles are "Respect for Autonomy" [Will of Patient], "No Self-impairment," "No Harm," and "Benevolence" [includes Benefits of a Patient].

27) See note 2.

28) A. R. Jonsen (2000), *op. cit.* p. 7, 9-10, 37, 56, 126-127

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