

Legal and Ethical Myths About Informed Consent

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Informed consent is a foundational concept of medical ethics. Since its enunciation almost 4 decades ago, it has engendered, and continues to engender, a great deal of debate and opposition from practicing physicians. We believe that much of the negative reaction to informed consent stems from some fundamental misunderstandings about what informed consent requires. This article discusses and refutes several myths about informed consent that have acquired some currency among physicians.

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Informed consent has been at the heart of medical ethics in the modern era. In fact, one could argue that the emergence of informed consent is the hallmark of the modern era in medical ethics. Informed consent first guided the evolution of the ethics of biomedical research that arose from the horrors of Nazi medical experimentation.^{1(p153)} Informed consent came of age in clinical medicine only a few years later.^{1(pp56-60),2(pp35-41)} Moreover, the idea of informed consent has provided the foundation for an evolving ethical and legal consensus in perhaps the best-known area of medical ethics, forgoing life-sustaining treatment.³ Yet, even though informed consent seems to be well established, strong reactions have continued to surround it.

The purpose of requiring informed consent is to promote autonomy of the individual in medical decision making. The modern concept of autonomy has its philosophical roots in 17th-century political philosophy and its legal roots in even older English legal principles that American democracy has inherited from English law. However, patient autonomy lay dormant in the physician-patient relationship until the beginning of the present century and only developed into full-blown form in the last 4 decades.

The origins of informed consent in medicine are somewhat murky. Its antecedents can be traced to early 20th-

century American law.⁴ The requirement of *simple* consent to medical treatment was well established in the United States before World War II, and the Nuremberg trials of Nazi physicians made this a requirement of international law. But the *elaboration* of the requirement of consent to medical treatment and its transformation into informed consent, according to Katz,^{5(p60)} one of the leading authorities on informed consent, "surfaced, seemingly out of nowhere." In attempting to ascertain the origins of the phrase "informed consent," first used in a 1957 California case, he could unearth no antecedent cases. The entire informed consent paragraph (in the first informed consent case) was adopted verbatim, and without attribution, from the *amicus curiae* brief submitted by the American College of Surgeons. It is an ironic twist of history that informed consent was dreamed up by lawyers in the employ of physicians.^{5(p60)}

Some physicians are still mistrustful of the doctrine of informed consent. It has been condemned in the medical literature as a myth and as bad medicine.⁶ It has been the subject of numerous parodies intended to illustrate the absurdities to which it can be carried.⁷ Most of these attacks are based on the idea that there is a fundamental incompatibility between the patient autonomy that informed consent is intended to promote and physician responsibility for a patient's well-being and on the fear that well-being will be severely compromised.

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Recently, more subtle attacks on informed consent have come from well-intentioned medical ethicists. For instance, Veatch⁸ argues that modern medicine has too many treatments available for many conditions for a physician to be able to disclose relevant information about all of them—as would need to be done if the letter of the law were to be observed—and therefore, physicians should disclose only information about those treatments that are consistent with their own values. Veatch somewhat overoptimistically advocates delivery-of-care arrangements that pair physicians and patients who have similar values and treatment dispositions as the solution to this problem.

We think that these critics of informed consent exhibit a variety of misunderstandings. Rather than confuse matters further by analyzing their arguments point by point, we first outline the 2 major approaches to informed consent and the ideals behind them. Then, we examine the most common misunderstandings of informed consent, ie, myths, and suggest more productive conceptions.

APPROACHES TO INFORMED CONSENT: RIGHTS VS SHARED PROCESS

Patient autonomy began to grow as an antidote to physician paternalism—the supposed tendency of physicians to assume almost complete responsibility for determining what treatment patients would have—and in recognition of the fact that what treatment patients should have is a normative as well as a scientific determination. Its function in preserving a patient's liberties is probably responsible for the enthusiastic response lawyers have given to informed consent. However, too strong an emphasis on its legal origins and function eclipses the fact that informed consent is not merely a legal concept.

Informed consent is a legal doctrine that also supports many of our cherished ideals about the rights of the individual. The law's rights-oriented approach to informed consent assumes that the individual pa-

tient is characterized by a set of personal values that no one but that patient can know. In deciding what treatment, if any, a patient is to receive, the physician is viewed as an expert who should leave his or her values aside and only bring technical expertise into play. In the standard rendition of informed consent, the physician's role is to explain the various possibilities for the diagnosis or treatment of a particular patient's condition, and the patient is to consider this information in the context of his or her own values and then choose a course of treatment suited to him or her.

This approach fits certain cases nicely, for example, religiously based treatment refusals by a competent adult patient. However, mindless application of this approach to all medical decision making is responsible for many of the myths that have developed about informed consent. In the clinical setting, rights often recede into the background, and it is more helpful to approach informed consent as a *shared process* of decision making. A shared process approach does not restrict the physician to providing facts and insists that the patient supply all the values. The physician and patient each have access to interrelated facts and values. The values and thinking of the physician and patient should gradually take shape. They should mutually monitor⁹ each other so that their goals, thoughts, and evaluations become transparent to each other.¹⁰

Conceived as a process of shared decision making, informed consent can accommodate both patient autonomy and the physician's responsibility for the well-being of the patient.¹¹ As we explore some of the myths about informed consent, we highlight how a balance should be struck to accommodate both autonomy and beneficence.

MYTH 1: A SIGNED CONSENT FORM IS INFORMED CONSENT

Perhaps the most fundamental and pervasive myth about informed consent is that informed consent has been obtained when a patient signs a consent form. Nothing could be

further from the truth, as many courts have pointed out to physicians who were only too willing to believe this myth. Consent forms are used as a matter of routine in both treatment and research settings because many hospital administrators, physicians, and their attorneys see these forms as providing protection against liability, despite the fact that they actually provide little protection.

Consent forms do have some value. They create an inference that the patient at least had an opportunity to read the information on it. If the information presented in the consent form contains a description of the risk that actually came to pass and contains other information that is adequate for a patient to make a decision, it will probably be helpful to a physician in the defense of a lawsuit.

On the other hand, if the information on the form is not adequate or is overly complex, the form may provide evidence to support the *patient's* case. If the form merely acknowledges that disclosure was made, but fails to recite the *content* of what should have been disclosed, it is unlikely to provide the physician with any advantage with respect to the main issue in a lawsuit: what was disclosed and whether it was adequate. Contemporary consent forms—often optimistically referred to as “informed consent forms” as if wishing would make it so—provide a false sense of security to physicians and hospital administrators who are led to believe that a signed consent form constitutes informed consent.

MYTH 2: INFORMED CONSENT IS A MEDICAL MIRANDA WARNING

As practiced, and certainly as symbolized by consent forms, informed consent is often no more than a medical Miranda warning. Just as police are required to tell criminal suspects that “you have a right to remain silent, you have a right to a lawyer, and if you choose to speak, anything you say can be used against you,” some physicians believe that informed consent has

been obtained if they warn patients of the risks of treatment.

Certainly, patients should be told about the risks of treatment. Admittedly, it is difficult to know what risks must be disclosed, but the approach to informed consent that we advocate makes this less important. Rather than focusing on risks, the focus needs to be on therapeutic options. For example, patients with ulcers need to know about medical treatment and surgical treatment. Patients with breast cancer need to know about different kinds and combinations of surgery, radiation, and chemotherapy. All patients always need to know that one of their options is to do nothing.

Knowledge of one's options alone, however, is not meaningful unless one also knows the range of consequences is choosing each option. One facet of information about consequences is the risks of treatment, but there are others such as information about the likely outcomes, including information about mortality, morbidity, and functioning.

MYTH 3: INFORMED CONSENT REQUIRES THAT PHYSICIANS OPERATE A MEDICAL CAFETERIA

A myth that contradicts the previous one, yet is sometimes held simultaneously with it, is that informed consent requires physicians to operate a medical cafeteria, in which they must set out all the therapeutic options and let patients choose, each according to his or her own appetite. The law clearly does not require this.

Some physicians feel that their ability to practice medicine "the way we used to in the good old days" has been impinged on not only by courts and lawyers but also by third-party payers, health facility administrators, Congress, the state legislature, governmental bureaucrats, and patients incited by Ralph Nader, the consumer advocate. In a sense, this myth about informed consent has arisen as an antidote to the previous one. It is not hard to envision a physician, who has been continually told to provide patients with information about medical options and

their consequences, wringing his or her hands in disgust or discouragement and responding with,

Well, damn it, if informed consent is all about letting patients chart their own course in medical matters, then let *them* do it. And if things go wrong, well it's their own fault—both because *they* did the choosing, and because *they* didn't listen to us.

When this attitude is at work, there is a serious sin of omission. What is being omitted is a central part of the physician-patient relationship as both physicians and patients view it—namely, the physician's role as medical adviser.

Patients usually want more than information. They also want advice. They say, "Doctor, if you were in my position, what would you do?" That does not mean they are going to do what their physician would do, nor does it mean that they should have just let the physician decide from the outset. It does not mean that informed consent is a charade. What it means is that informed consent is a process and part of the process is human interaction. Rather than thinking of informed consent as an abstract ideal, what we call informed consent should take the form of a conversation in which patients get information, ask questions, give information, and say "I want to think about it" or "I've thought about it and I can't decide. What do you think I should do?" Thus viewed, informed consent is a process of *shared* or *collaborative* decision making.⁵

Another way of looking at the process of informed consent is that it must mix together treatment goals and particular treatments. Most of the confusion surrounding the cafeteria approach to informed consent assumes that patients wish to micromanage their care. This is rarely the case.¹² However, patients are entitled to know the goals of therapeutic options and when that goal has changed. Too often, treatments are discussed in detail but patients are not really sure what the treatment is ultimately meant to do. Similarly, when new treatments are introduced and discussed, it is not

always clear to the patient that the old goal is no longer realistic, eg, cure is no longer possible, and that this new treatment is directed at a different goal such as minimizing disability or relieving pain. Patients are not experts at treatments; physicians are. However, patients' preferences are central to the choice of treatment goals. Thus, in selecting and revising treatment goals, physicians and patients need to form a partnership.

MYTH 4: PATIENTS MUST BE TOLD EVERYTHING ABOUT TREATMENT

Some believe that the law requires patients be told everything about treatment—the equivalent of giving them the *Physicians' Desk Reference*. Actually, the law requires only that patients be given a *reasonable* amount of information. In about half the states, the adequacy of disclosure is measured by customary professional practice, which means that patients must be given the information that a reasonable physician would disclose. In the remaining states, the adequacy of disclosure is measured by a so-called legal standard, which requires the provision of that amount and kind of information that a reasonable *patient* would find material to making a decision about treatment.

Because those rules are vague, lawyers cannot provide physicians with specific guidance about how to comply. Therefore, physicians sometimes feel driven back into the corner of disclosing everything, which is unnecessary. Further, it is unwise from a legal perspective because physicians could be held liable (though it is not likely) for intentionally inflicting emotional distress on patients by giving them *too much* information.¹³

Our previous discussions of goals and treatments should provide a minimal checklist. Once a physician and patient have explored all the relatively realistic goals of treatment, the number of therapeutic options and amount of information about those options frequently become relatively minor issues.

MYTH 5: PATIENTS NEED FULL DISCLOSURE ABOUT TREATMENT ONLY IF THEY CONSENT

Information about therapeutic options and their consequences to be used by patients in making decisions needs to be provided before, not after, decisions are made. In practice, this is not always the case. One reason is the nature of the process by which physicians conceptualize and solve problems and formulate recommendations. Physicians acquire information about patients through examination, history, medical records, laboratory tests, and similar processes and then formulate a diagnosis. The physician makes a treatment recommendation to the patient in the form of, "Here's what's wrong with you and this is what we need to do."

Patients are expected to comply with the recommendation although some patients will ask questions, take some time to think about it, seek a second opinion, or even refuse the recommendation or any further medical attention. If the patient decides to follow the recommendation (ie, consents), and especially if the physician has not yet provided much in the way of information, he or she might then receive more information because this decision provides an occasion to discuss the medical malady and its treatment. In other words, much of the information relevant to making a decision actually comes after the decision is made. There is nothing wrong with continuing to provide, reiterate, or recast information at the time the patient consents to treatment. In fact, we recommend it. However, if informed consent was conceived of by physicians as a process of shared decision making, information might more readily flow earlier and more frequently.

The failure to make information available to patients before they decide whether to accept or reject a physician's recommendations is based on the premise that if the patient refuses treatment, it is unnecessary, if not paradoxical, to obtain informed consent. This illustrates how the use of the term *informed consent* is unfortunate, if not dan-

gerous, for it assumes that the process of informing is to eventuate in *consent*. Physicians also assume that if in fact consent is not forthcoming, information need not be given to patients or if the patient refuses the recommended treatment and settles on an alternative treatment, no information need be provided about the rejected treatment.

In fact, physicians are obligated to obtain not only informed consent but also informed refusal.¹⁴ This is not as silly as it might at first appear, when one recalls that the most important part of informed consent is information about options and their consequences and a refusal of treatment is a choice to do nothing, which has predictable consequences too. This is not a resurrection of the cafeteria approach, nor are we recommending that the physician present the entire treatment menu. What we are saying is that when the physician examines the patient and says, for example, "We'll have to do bypass surgery," and omitted discussion of the choice of goals, he or she has assumed that the patient would agree about the treatment to meet that goal.

MYTH 6: PATIENTS CANNOT GIVE INFORMED CONSENT BECAUSE THEY CANNOT UNDERSTAND COMPLEX MEDICAL INFORMATION

The notion that informed consent is a myth and bad medicine is premised in part on the assumption that providing information to patients frightens them.^{1(pp74-76)} These characterizations are also based on the assumed difficulty of transmitting technical information to patients. A typical unspoken thought might go,

Patients can't understand all this medical stuff. Why I have trouble keeping up with my own subspecialty, I've forgotten 95% of what I learned in medical school, and the 5% I remember is now outdated. Even worse, what about all those empirical studies that show that patients who have been given information don't remember it 6 months, 6 days, or even 6 hours or 6 minutes later?

There are at least 2 errors in this reasoning. The first is the equation of recall with understanding. While it

might be true that someone who cannot retain information for a few seconds might not be said to understand it, people often make reasonable decisions but cannot later recall the premises that supported the reasoning or the process that led to the conclusion. Nevertheless, they might well have understood it at the time.

The second error is the assumption that patients must understand information in the same way and to the same extent as the physician. It is true that a patient who is totally bereft of understanding lacks decision-making capacity and would be considered legally incompetent. In such a case, decision making would need to take place with a surrogate decision maker acting on the patient's behalf. The fact that a patient might put an odd gloss on information or might not have a completely accurate factual understanding of the information does not disqualify that patient as a decision maker. To have decision-making capacity, patients do not need to be Jonas Salk.^{2(pp81-111),15,16} They merely need to be able to understand their options and the potential risks and benefits of these options. Most assuredly the fact that the patient reaches a decision different from the one that the physician would have made does not mean that the patient does not understand the information.

What is critical is that patients be given information and that they have a chance to use it in formulating a decision, to ask questions about it, and to gather further information. It is essential that they be given the context for the proposed treatments, ie, they must be told the physician's goals in making this treatment recommendation. However, within broad limits, patients have the right to set their own goals and to make their own decisions in their own way and for their own reasons, which includes the right *not* to use information that others might think relevant, rational, and even necessary to decision making.

We are steering a course between extremes. One extreme assumes that a patient just cannot understand medical information, and so we should give up on informed

consent. On the other end of the spectrum resides the extreme rights-oriented view that a patient's treatment choices should not be challenged. We advocate the middle path: patients' choices should make sense in terms of their values and way of making sense of the world and these decisions should be made in the manner patients normally make similar choices. However, to require "understanding" in the same way and to the same extent that a physician understands the information is as paternalistic as not permitting patients to participate in decision making at all.

MYTH 7: PATIENTS MUST BE GIVEN INFORMATION WHETHER THEY WANT IT OR NOT

Some patients choose not to participate in the decision-making process at all or may wish to participate on a reduced basis. Withholding information from patients when they request that it not be given respects their autonomy as much as providing information to patients who want it. Enabling and permitting patients to make medical decisions is one way of fostering self-determination; respecting their wish not to participate is another. *Compelling* patients to receive information that they do not want or to make decisions that they do not wish to make is to fail to respect their dignity.

Withholding information from patients at their request is a legally recognized exception to informed consent referred to as waiver.¹⁷ Usually, only by initiating a conversation with a patient can a physician determine that a patient wishes to participate in only a limited way, or not at all, in the decision-making process. In some instances, patients may fully engage in such a conversation and only at the end declare that they do not know what to do and wish to leave the decision to a family member, the physician, or someone else. In such a case, a patient can be said to have waived the right to decide though not the right to be informed. Sometimes patients make it clear that they do not even

want to talk about therapeutic options and consequences. They may be willing to make a decision on less, rather than more, information. In such a case, a patient can be said to have waived the right to be informed, though not necessarily the right to decide. Or patients may want neither information nor to decide, again preferring to leave it all to someone else.

Thus, the waiver exception parallels the 2 distinct but related rights that informed consent embodies, the right to be given information and the right to decide. Patients who waive their right to decide do not automatically waive their right to information. There may be good reasons to continue to provide information to such patients. One is that just because patients do not want to make a particular treatment decision does not mean that they will not wish to participate in the future. Furthermore, there are reasons to provide information other than for decision making. Patients also need information to facilitate compliance with treatment decisions. They deserve information about their treatment as a sign of respect and so that they can be prepared for what is to happen to them.

MYTH 8: INFORMATION MAY BE WITHHELD IF IT WILL CAUSE THE PATIENT TO REFUSE TREATMENT

It is ironic that physicians who profess not to know much about informed consent sometimes do know about the therapeutic privilege, which, like the waiver exception, allows information to be withheld from patients. When information is withheld under the waiver exception, *patients* decide that having information would not serve their ends. By contrast, when the therapeutic privilege is invoked to withhold information, the *physician* determines that providing the patient with information would undermine, rather than promote, the goals of informed consent.

The purpose of the therapeutic privilege is to allow physicians to honor their "primary duties" to do

what is beneficial for the patients and to avoid inflicting harm on them.¹⁸ However, it is far less clear what circumstances justify the physician in withholding information. In general, physicians are permitted to withhold information when its disclosure would seriously harm the patient.

In practice, the therapeutic privilege may legitimate a physician's natural aversion to providing unpleasant information to patients—indeed, almost everyone's natural aversion to providing unpleasant information to anyone else. However, the therapeutic privilege is not a license for physicians to withhold information when they fear, rightly or wrongly, that providing it to patients will lead them to refuse recommended treatment. Such a view of the privilege is paternalistic in the extreme; it threatens to devour any obligation to provide information and would permit physicians to substitute their judgment for the patient's. The more appropriate formulation of the privilege permits physicians to tailor (and even withhold) information when, but only when, its disclosure would so upset a patient that he or she could not rationally engage in a conversation about therapeutic options and consequences.

CONCLUSION

A number of myths about what the law requires impede the practice of obtaining informed consent. If informed consent is viewed as a process of shared decision making, some of the seeming absurdities and excesses that can be associated with it disappear. In so doing, it might make the practice of medicine more rewarding for physicians. The doctrine of informed consent does not analogize physicians to waiters who take orders from customers. Rather, it recognizes the responsibility of the physician for the patient's well-being.

We are a litigious society, and physicians must be concerned with avoiding lawsuits. The best advice we can give is to treat patients like people, act sensitively and compassionately, and most of all, talk to pa-

tients. Have a conversation, have several; remember that this is a process. In this process, you will gradually come to know your patient's decision-making style. Furthermore, do not press patients to decide quickly. Do not make them think that you do not have time for them. Because if you do, regardless of how much information they are given, they are going to be angry, and another name for an angry patient is plaintiff.

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