Informed Consent: Charade or Choice

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he physicians of ancient Greece valued conversation with their patients. Conversation, however, did not apply to slaves, whose minds and opinions did not matter. More than 2000 years later, slavery has been abolished and the law has joined ethics in setting standards for the doctor-patient relationship. The most important doctrine, in both medical ethics and health law, is the doctrine of informed consent (better termed “informed choice”), including its corollary, the right to refuse treatment. Today this doctrine is under attack. The attack is direct from business models that see genuine doctor-patient conversations as inefficient (and a waste of time), and indirect from new information technologies, especially the use of computer screens during doctor-patient encounters. Even the law has helped undermine informed choice by replacing doctor-patient conversations with legal forms.

Almost all patients want to trust their physicians. Courts see the desire to trust physicians as a necessity, describing the doctor-patient relationship as a “fiduciary” relationship in which the patient must trust the physician to honestly present treatment options and their benefits and risks. Patients want their physicians to speak to them; but as important, they want their physicians to listen to them. Professor Jay Katz, probably the world’s foremost authority on informed consent, argued that the physician-patient dialogue envisioned by the doctrine is much more difficult to accomplish than judges ever seemed to realize. This is for at least two basic reasons. The first is that the doctrine, most clearly enunciated in the Nuremberg Code in the judgment of the Nazi physicians in 1947, was seen by physicians as a requirement being imposed on the profession from the outside, by lawyers and judges. Moreover, its birth at Nuremberg led many to think that it applied only to Nazi-like deadly research, not to what US physicians did. Only decades later, in the 1970s, did US courts impose the duty of informed consent on therapy as well as research. The second reason that honest conversations about treatment options are more difficult than judges might think is that they require that both doctor and patient share uncertainty. But this is very unnerving, since both the physician and patient are highly motivated to believe that medicine can provide a cure or at least make an illness or injury better.

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The reality is that the researcher is following a protocol to obtain generalizable knowledge. Katz believed the therapeutic illusion could only be dispelled, if at all, by the researcher explicitly insisting to the subject that the proposed intervention was not for the subject’s benefit. (2) Katz, the psychoanalyst, knew that the subject would resist hearing this message, and that the researcher would also resist delivering it. Institutional Review Boards were adopted to help encourage information sharing, but they have become counterproductive. The attempt at dialogue has been replaced by a complex research “consent form” (approved by the IRB) which contains the information the institution’s lawyer and IRB believe is necessary to avoid liability, or at least to fulfill a risk management function. And even in research, informed consent is often explicitly ignored by the adoption of incoherent concepts such as “broad consent” and the oxymoron, “standard of care research.”

Informed consent has historically been described as critical in theory, but incapable of realization in practice, a superficial charade rather than an autonomous choice. This observation should help inspire us to reform our practice to make sure that informed choice actually upholds patient dignity, promotes rational decision-making, and protects self-determination. These goals are critical to a human rights-based medical practice, and the informed choice doctrine is central to the ethical practice of medicine and the dignity of all patients. Here are a few suggestions that could help us make it more meaningful in practice.

First, informed consent should be referred to by its more functional designation: informed choice. This puts the emphasis on the process rather than the outcome, and states more precisely what is at stake. It should also help insure that physicians and researchers grasp that the doctrine applies equally to therapy and research (although additional requirements, such as IRB review, may apply to research as well). Waivers of informed choice should not be permitted — it is your life and future and you have an obligation to yourself and your family to participate in decisions that could radically alter your life.

Second, we need to do a better job of educating patients and research subjects about their rights, and why they matter. People should be able to do more than complain about their physicians not listening or talking to them; the doctrine of informed choice gives patients the right to demand a dialogue, rather than beg for it as a luxury. And the right to refuse treatment altogether can also be used to insist on conversation before making a treatment decision, and also to insist on being left alone.

Third, in the research setting, we should eliminate written consent forms and reform IRBs. At least two-thirds of IRB members should be non-researchers; and, at this point, the only way to encourage informed choice as a process rather than a form is to replace forms with a discussion (which should be audiotaped or videotaped for review by the subject and documentation for the researcher and institution).

The public eagerly supports the trendy “personalized medicine” movement because it seems to hold out the prospect of more personal attention, and at least some conversation, from their physicians. The public’s hope that medicine will reverse its current trend and become less impersonal will be dashed unless strong steps are taken to promote conversation and informed choice. Without public resistance to the attack on informed choice medicine is in danger of relapsing to the very efficient and inhuman silence of the Greek slave doctor.

References