Opinion

Informed Consent: Right or Rite?

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The last few years have witnessed a dramatic growth of the doctrine of "Informed Consent"—the full disclosure of the risks, benefits, and options associated with any experimental procedure. Yet proponents of this concept have generally failed to consider harmful reactions that might result from the information provided during an informed consent discussion. The issues are more complex than they seem initially, and the informed consent coin certainly has two sides.

Although the legal concept of "consent" has been well established since the turn of the century, perhaps the earliest use of the phrase "informed consent" arose in the case of Salgo versus Leland Stanford, Jr. University Board of Trustees in 1957. In this case the plaintiff's primary claim was negligent performance of translumbar aortography, resulting in a paralysis of his lower extremities. The assertion was that the physician negligently failed to warn the plaintiff that the risk of paralysis was inherent in the procedure. The Court of Appeals reversed a judgment for the plaintiff—but it recognized for the first time that a physician might be held liable for failure to provide important information beyond the traditional requirement of revealing the nature of the procedure. The court strongly implied that a physician is obligated not only to disclose what he or she intends to do, but also to address other issues such as potential risks.

Since Salgo the doctrine of informed consent has flourished. To paraphrase Yale professor Jay Katz, the phrase "informed consent" now evokes the same sort of magic expectations one sees in fairy tales, where uttering magic words or performing magic deeds transforms frogs into princes. The proponents of "informed consent" seem to believe that once kissed by the doctrine, frog-patients will be autonomous princes. However, a new current of thinking worries that informed consent can, on the contrary, turn prince-patients into sickly frogs. We here examine briefly this facet of the two-sided coin.

July 1974 marked the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the Commission's charges was to identify the basic ethical principles that should guide the conduct of research involving human beings, and a recent document—the Belmont Report—summarizes the Commission's deliberations. Three fundamental principles were put forth: 1) "respect for persons," referring to the right to autonomy, the right of an individual to

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determine what will be done to his or her mind and body; 2) “beneficence,” referring to the right to have harm minimized as far as possible according to the Hippocratic maxim “primum non nocere;” and 3) “justice,” meaning that the experimental risks and benefits are not to be preferentially allocated to particular segments of society. While these underlying principles remain inviolate, the informed consent “rituals” that have been advanced in their name may cause dilemmas; in many instances the rituals may conflict with the principles or they may increase a conflict among the principles. Thus, for example, a dilemma exists if the process of providing information increases the potential harm to the individual.

The responses of human beings to information are intricate. Words can carry strong implications, and they can carry different implications for different people. In an anxiety-laden situation, in which individuals may be more suggestible than otherwise, words can have special force. Transmitting information devoid of nuance is a tricky business. This is due in part to the inaccurate ideas that many individuals have about their bodies’ functions. In a recent editorial, Dr. Mack Lipkin, Professor Emeritus at the University of Oregon Medical School, used cancer as an example: “Patients seldom know that while some cancers are rapidly fatal, others never amount to much; some have a cure rate of 99 percent, others less than one percent . . . Thus, one patient thinks of cancer as curable, the next thinks it means certain death.” Clearly the four words, “This is a carcinoma” will be frightening to some but not to others.

A different problem arises when, after the diagnosis is made, an experimental protocol is suggested. What information should accompany the experimental treatment? A vast body of psychological and medical evidence indicates that the suggestion produced by a combination of an informed consent discussion and a placebo can cause symptoms that are truly physiologically unlikely. A compelling example comes from a Los Angeles physician who told a patient during an informed consent discussion that nausea and vomiting might occur postoperatively. The next day sleep was induced by diazepam, but shortly afterward the operation was cancelled. Upon awakening, the patient complained of extreme nausea and vomited continuously for 20 minutes. Then, when the patient was told that the operation had not taken place and the diazepam does not produce nausea and vomiting, the retching immediately disappeared. Oncologists have reported to us an instance in which explanation of the hazards inherent in a combination chemotherapeutic protocol caused a subject to leave the medical center in favor of a local and more hopeful Laetrile practitioner, and another in which discussion of the hazards of a MOPP protocol appeared the proximate cause of a suicide in a Hodgkin’s disease subject. In addition to such anecdotal experiences, many experimental studies provide data that explicit suggestion of possible adverse effects may cause individuals to experience these effects. The possible consequences of suggested symptoms range from minor annoyance to, in extreme cases, death.

If protection of individuals is the reason for obtaining informed consent, the possibility of harm as a direct result of the consent ritual must be considered. This ethical dilemma is relevant to many areas of medicine; perhaps especially so when treatment of unknown efficacy is administered both for the possible benefit of the patient and for a potential increase in medical knowledge. This situation exists, of course, with new chemotherapeutic agents for treatment of carcinoma. The investigator is concerned with maximizing the “good time” remaining to the protocol patient; unnecessary nausea, vomiting or other physical symptoms, or unnecessary anxiety or depression, are manifestly detrimental.

Fortunately, the same literature that indicates a need for concern about the negative placebo effect describes factors that should be part of a rationally developed consent ritual. From these consid-
erations we offer the following suggestions: First, all subjects should be provided a clear, direct, accurate, brief statement of the procedure and the general level of risk. Phrases like "The risk of death is one in one hundred," and "The risk for this operation is about the same as for an appendectomy" are appropriate. But predicting specific side effects will increase their frequency, and such information should not be forced upon a subject. Second, all information, specific or not, should be available to all subjects at all times, should they desire the information. Nothing should be withheld. We suggest that the back of the consent form, a copy to be retained by the subject, is a good place for these facts. Most subjects will not want to access this information; it resembles the "fine print" of an insurance policy. But some will, and they must have access. Finally, where these specific risks and symptoms are discussed in detail, they should be presented in the context of placebo effects in general: why they occur, and how to guard against them. The discussion should include an explanation of how a person's expectations can actually cause negative experiences. Just as knowledge of possible negative effects can cause people to experience them, so this additional knowledge can be used to defend against the negative effects. Preliminary data suggest that many induced symptoms may be eliminated or at least minimized by this tactic.

Human beings may have a right to information that will affect their minds and bodies, just as they have other rights—for example, the right to free speech. Yet this constitutional bulwark has been specifically held to deny the right to cry "Fire!" in a crowded theater. That is, one does not have the right to utter words that will evoke anxiety reactions that can lead to physical harm. A recognition of this dilemma may have prompted L. J. Henderson, the great Harvard physicist-philosopher of decades ago, to comment: "To speak of telling the truth, the whole truth and nothing but the truth to a patient is absurd. Like absurdity in mathematics, it is absurd simply because it is impossible." The sometimes morally obtuse advocates of full information un-failingly argue that "more is better;" they argue for the autonomy of the subject even as their rituals increase that subject's peril. Human beings have the right to information that will affect them, but they simultaneously have the right to choose when they have had enough.

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