

INFORMED CONSENT

*Guidelines from the Maine Board of Licensure in Medicine*¹

Obtaining and recording informed consent before major diagnostic, therapeutic, and invasive procedures is a physician's professional and legal obligation. Patients have the legal right to grant or withhold informed consent, either personally or through lawful representatives.

The term "informed consent" first appeared in an *amicus curiae* brief filed by the American College of Surgeons in the case of *Salgo v. Leland Stanford University* in 1957.² While not all physicians and not all patients desire to be involved in a shared decision making process, prevailing negligence law and the legal right to self-determination now require some documentation of informed consent for most major treatments and procedures. Physicians therefore have a legal motivation for obtaining and recording informed consent for major treatments and procedures, subject to recognized legal exceptions such as in providing emergency medical care to incapacitated patients. In addition to this legal motivation, the Board believes physicians ought to be motivated by a commitment to the ethical value of patient self-determination, or personal autonomy. Therefore, the Board offers these guidelines for physicians practicing in Maine.

The Goal

The goal of offering these guidelines is to help physicians move beyond a limited consent model that emphasizes primarily the physician's legal obligation to disclose information and the patient's legal right to make independent decisions. The Board advocates a different model that emphasizes communication and encourages a certain kind of transaction between patient and physician. The norms that govern such transactions are clarity, relevance, accuracy, and sincerity. There is no standard form, nor any uniform procedure that will fit all cases calling for informed consent in this model, but there is an underlying ethical obligation to make it possible for the patient and the physician to participate together in a transaction that takes into account the norms of clarity, relevance, accuracy, and sincerity.

The Board is concerned here with major diagnostic, therapeutic, and invasive procedures, and not so much with routine decisions about minor medical problems. In certain cases, physicians may simply explain that they see many people with a particular problem and regularly with success treat the problem in a particular way, then ask if the patient has any questions about the problem or the treatment. In these cases, if the patient

¹ Title 32 M.R.S.A. § 3269(3) authorizes the Board to "license and set standards of practice for physicians and surgeon practicing medicine in Maine." However, nothing in this document is intended to affect the definition of "informed consent" for civil medical malpractice actions as defined by Title 24 M.R.S.A. § 2905.

² 154 *Cal.App.2d* 564.

makes statements or asks questions indicating discomfort, lack of understanding, or continuing uncertainty, then the following guidelines apply.

Shared Decision Making

The primary value of documented informed consent is that it represents the existence of a relationship between physician and patient that is based upon, or at least includes, an element of shared decision making. Shared decision making for the patient is not the same as mere acquiescence, or compliance based on partial or slanted information, or indifference due to habit or apathy, nor is it the same as conformity to custom – such as the custom of “following doctor’s orders.”

Shared decision making is a process for reaching a shared conclusion through informed judgment. Such a process is an educational ideal in the field of medical care, as it is throughout most institutions in a democratic society. The heart of the matter is the control of information: to the extent information about a problem can be shared, decisions about potential solutions can be shared. Physicians have privileged access to medical information through their education, experience, and expertise. This privilege carries with it the duty to disclose *clearly* such information as is *relevant* and is supported by *accurate* scientific information in a *sincere* manner for consideration by the patient. Furthermore, this duty is itself governed by the physician’s fiduciary obligation to protect the patient’s best interests.

Generally, physicians control the medically relevant information patients need in order to ask the questions they may want to ask but might not be able to formulate on their own. Successfully sharing that information is a matter of 1) the physician’s willingness to do so, and 2) the physician’s ability to apply the skills of communication required to do so. It is also a matter of 3) the patient’s willingness to participate in the process, and 4) the patient’s ability to understand the information, apply it to his or her situation, and then express a reasoned judgment based on the relevant medical information as well as on personal values, wishes, and goals. If there is any doubt about the patient’s ability in this regard, the physician should arrange an evaluation of the patient’s capacity by a qualified colleague.

The physician personally initiates the process of informing the patient by presenting the medically reasonable options relevant to the patient’s condition. The medical reasonableness of these options is tied to the available and reliable evidence base of expected benefit and risk for each alternative. The physician’s judgment about these options should be free of personal self-interest, and religious, political, racial, and gender bias.

The Board encourages physicians to remind patients of their right to have someone with them (an advocate of some kind) during these discussions, as patients can be overwhelmed, frightened, and confused when confronting an important medical decision.

Skills for Eliciting Informed Consent

By far the most important skill is **empathetic listening**, which is the capacity for acquiring objective knowledge about the perspective taken by another person. It is a way of listening that requires temporary suspension of one's personal point of view while trying to assume another's point of view. It is a means for gathering data. It is not synonymous with being compassionate or sympathetic, even though its mere presence can have a beneficial effect. The primary purpose of empathy in this sense is to become well informed about the patient's point of view. It is important for the physician to find out what and how much the patient already knows and what more the patient wishes or needs to know, and to what extent the patient desires to participate in the decision making process. In disclosing medical information the physician can err in two ways – excess and deficiency. Empathetic understanding can help guard against going wrong in either of these ways.

Next is skill in **disclosing and explaining**. In trying to establish the basis for shared decision making, the physician discloses medical information relevant to the case at hand, and provides explanations of what that information means, in language that is intelligible to the patient.

It is important to distinguish between two useful but distinct kinds of explanation. The first is *scientific* explanation, which is making a case for why certain events are the way they are and for predicting future events. The second is *semantic* explanation, which by contrast is making the meaning of something clear to the listener. Semantic explanation is like translation or paraphrase, using different words and terms until the intended meaning is revealed and understood.

An explanation can be *satisfactory* from a formal (scientific) point of view, while at the same time failing to be *satisfying* from the patient's point of view. Another way to put this point is that while a medical explanation of risks and benefits associated with treatment options can be scientifically sound, the listener may find it to be unintelligible, and therefore not useful as information upon which to grant or withhold consent. Informed consent depends on the physician's success in providing both kinds of explanation.

Third is **framing**. Anything that can be said, can be said another way. Decisions are often influenced by the way alternatives are presented. For example, the outcome statistics for 100 middle-aged men undergoing surgery for lung cancer can be described as “90 survive the surgery . . . and of those 90, 34 are alive at the end of 5 years.” An alternative way of expressing (framing) the same results might be: “10 die from surgery. . . and 66 more die within 5 years.” Typically, for a patient choosing between surgery and radiation, surgery appears much less attractive when described using mortality rather than survival statistics. The difference between 10% mortality (for surgery) and 0% mortality (for radiation) is more impressive than the difference between 90% survival (for surgery) and 100% survival (for radiation). A physician may knowingly or unwittingly nudge a patient toward one option simply by the way the range of options is described, or framed. (Note that 5-year mortality statistics for radiation only have not been mentioned.)

Definition of Informed Consent

In conclusion, the Board recommends the following definition of informed consent be adopted and applied by Maine physicians.

Informed consent for treatment has been obtained when: 1) the physician has disclosed and explained *to the patient's satisfaction* the process used to arrive at the medically reasonable and recommended intervention(s), which is based on reliable evidence of expected benefit and risk of each alternative, and which is free of any impermissible bias; 2) the patient, who has demonstrated capacity, has been given ample opportunity to ask questions about the process and the recommended intervention(s), *to the extent the patient wishes*, all questions then having been answered *to the patient's satisfaction*; and 3) the patient gives consent in writing to major intervention(s) agreed to jointly with the physician.

Nota bene:

Obtaining informed consent is the physician's personal responsibility. This responsibility cannot be *wholly* delegated. Other medical staff (PA's, NP's, Physicians in training and others) may usefully participate in the process, but no amount of shared videos, questionnaires, and pamphlets can substitute *entirely* for personal communicative transaction with the responsible physician. Finally, proof of informed consent cannot be reduced merely to a signature on a form. A note from the physician about the process of gaining that signature should be attached to the form.

When a Physician Assistant, with proper delegation, performs a diagnostic, therapeutic, or invasive procedure for which the standard of care indicates informed consent is required, the Board expects the Physician Assistant to take the same actions as are described in this document for the physician.

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