Over the past third of a century, there has been a revolution in the way that health-care providers and patients make most medical decisions. Paternalism has slowly gone the way of the long-play record, and in its place has emerged a consent process in which the patient is a more fully informed and active participant. This process takes time however, and for the busy health-care provider there is often the temptation to hand the patient a consent form to sign. It is important to realize that signing a consent form does not constitute informed consent. True informed consent is a process, and, as such, it requires that the health-care provider enter into a discussion that ultimately leads to the patient understanding of their options, and the risks and benefits of the alternative courses of action. The purpose of this article was to describe, in some detail, the consent process in practical clinical terms, and to note when and how it should be obtained.

Key words: decision making; ethics; informed consent

Just as medicine has evolved over the past 200 years into a sophisticated profession that can often alleviate symptoms and cure disease, so also has the physician-patient relationship evolved from one of paternalism to one of a more equal partnership in the United States.1 A cornerstone of this new relationship is the belief that respect for patients and their values is right and essential to good medical care. From this flows the obligation to obtain a patient’s informed consent when decisions must be made about significant diagnostic and therapeutic interventions. But what is informed consent?

The concept of informed consent has been evolving over the past 100 years based largely on case law early in the last century and later influenced by the Nuremberg trials, influential articles such as those of Henry Beecher, and contemporary bioethical thought beginning in the 1960s in the United States.2–5 Informed consent in medical research will be discussed in a subsequent article in this series.

Informed consent may be defined as the autonomous act by a patient or research subject to expressly permit a professional person to perform a medical action on the patient or to include a person in a research project.2 Although much has been written about each element of this definition (eg, autonomous act, expressly permitted), and its philosophical underpinnings, it seems most important for the busy physician to understand the practical implications of this definition. Below are cases that exemplify important aspects of informed consent.

**Elements of Informed Consent**

**Case 1**

A pulmonologist, seeing a patient in the outpatient clinic for a new asymptomatic infiltrate, recommends bronchoscopy. She hands the patient a detailed consent form that describes the risks, benefits, and alternatives to bronchoscopy, and asks him to take his time reading it. Coming back a few minutes later, the pulmonologist asks the patient if he has any questions. The patient has none and signs the consent form, which is witnessed by a nurse.
Has the physician obtained informed consent? Yes and no.

Yes, from the legal and administrative perspective of a hospital the physician has obtained consent. Indeed, some hospitals have a patient sign a generic “consent-to-treat” form on admission. However, a signed consent form does not prevent a lawyer from pursuing a malpractice suit nor does it ensure a legal judgment in favor of the physician.

No, from the perspective of obtaining an ethically valid form of consent, the patient has not given consent. Informed consent is not a signed piece of paper; it is a process. What is written on a consent form is only a part of the process. A consent form gives information, but it does not give understanding, an obligation that a physician obtaining consent needs to ensure. Obtaining true informed consent consists of a number of critical elements. These include the following: (1) disclosure of the pertinent medical facts and alternative courses of action; (2) ensuring patient capacity to understand the decision to be made; (3) ensuring patient understanding of the medical information; (4) the absence of coercion or manipulation; and (5) the ability to consent.

There are no national standards enumerating which procedures or decisions require informed consent by the patient in the United States. Indeed, in one study marked variability within and between hospitals was found in obtaining informed consent for procedures among ICUs and internal medicine programs. At present, hospitals and their medical staffs are left to develop local guidelines for obtaining consent. Although there is no formally recognized threshold of risk above which we ought to obtain informed consent, one ethical guideline might be any risk that is of a greater magnitude than that which we might ordinarily encounter when carrying out normal daily activities. Future guidelines for when to obtain informed consent in gray areas may be developed by determining societal expectations. Some hospitals have attempted to amalgamate the consent process into a single blanket consent signed early in the hospital course. This may be administratively acceptable but is not ethically acceptable unless the patient waives their right to make decisions.

Disclosure: When are physicians obligated to disclose information about a treatment or test? When a physician performs a venipuncture to obtain a blood sample from an adult patient, the physician does not feel obligated to obtain written or verbal consent. Because the risks are small, and because most adults have already had a venipuncture, they know what to expect. However, when a thoracic surgeon sits down with a patient about to undergo lung transplantation, the surgeon feels obligated to carefully discuss all of the risks, benefits, and alternatives to having surgery. These two scenarios represent ends of the spectrum of the concept of proportionality with respect to disclosure. The notion of proportionality suggests that the greater the risk we are asking the patient to expose themselves to, the greater our obligation to disclose the risks, benefits, and alternatives to the procedure.

What has to be disclosed to the patient? Clearly, the physician must disclose enough information so that the patient can make an informed decision. What that entails has been evolving over the last 100 years. At the beginning of the 20th century, the standard of disclosure was the professional practice standard (whatever the physician felt should be disclosed). With the influence of case law and contemporary bioethics, the standard has become one in which the physician must disclose the information that a reasonable person would want to know before making a decision. This so-called prudent-person standard applies to information about the harms, benefits, and alternative treatment strategies.

The concepts of likelihood and magnitude of harm also assist the physician in deciding what risks to disclose when talking about diagnostic and therapeutic decisions. A reasonable guideline is to describe the complications/side effects that have a high likelihood of occurring even if they are minor in nature (e.g., nausea or transient fever), and to describe the complications/side effects that have a low but not rare likelihood of occurring but are of such a magnitude of harm that they would give the prudent person pause when making decisions (e.g., 5 to 10% chance of dying). Complications and side effects that have a moderate chance of occurring and are mild or moderate in their severity should be disclosed, dependent on the circumstances. When obtaining consent and after giving the patient information that a reasonable person would want to know, it is vital to ask the patient whether there is any other information needed to make a decision. This allows the patient to ask questions, and thus sets an even higher standard, a subjective standard of disclosure. By asking whether there is anything else the patient wishes to know, this allows the patient to ask questions that reflect their unique sense of values and concerns. For example, some patients are more risk averse than others, and want to know more about the likelihood and consequences of complications or side effects than the physician would discuss with the average patient.

Capacity and Competence: Capacity is a medical concept and implies that a patient has the ability to understand and weigh medical information and
make decisions. Capacity may fluctuate (eg, when the patient goes in and out of a delirium). Most patients have the ability to understand simple choices, but as the risks and benefits of choices increase in magnitude and complexity some with limited capacity or less formal education may be unable to give true informed consent. Again the concept of proportionality applies here. As the complexity of a decision and the magnitude of the consequences increase, so does the physician’s obligation to ensure that the patient has the capacity to make the decision. Asking the patient to describe the treatment or test and its risks, benefits, and alternatives will often allow the physician to determine whether the patient has the capacity to understand and weigh the choices at hand. If there is a concern, asking the patient questions that test mental status is appropriate. More formal cognitive testing and a psychiatric consultation may be appropriate in some instances. Even when the patient has the capacity to make a decision, the patient may not understand the words or concepts presented by the physician. For example, a 10% chance of a complication may need to be translated into “for every 100 people who have this procedure, 90 of them will not have the complication, but 10 will.”

It is important to understand that capacity and competence mean different things. Competence is a legal term. Society and the law presume all persons to be competent until legally judged otherwise. A judicial declaration of incompetence is a legal declaration that the patient can no longer manage his or her affairs. This declaration may only be made or rescinded by a judge. Guardianship generally follows when a person is declared to be legally incompetent. Physicians and families routinely make decisions for patients who have been judged to be incapacitated without subjecting the patient to a formal competence hearing. This is justifiable if the patient has been judged by the physician to be incapable of understanding the nature of the decision, its alternatives, and the accompanying risks, benefits, and consequences.

A less commonly recognized problem related to capacity is that of acceptance. A patient may understand all of the factual information that the physician gives him or her, but may not believe that some of it is true. For example, a patient in the ICU may have a life-threatening illness, be told about it, and be able to comprehend the risks and the benefits of the treatment options, but makes a decision that he or she would not otherwise make because the patient does not accept the life-threatening nature of the illness.

When it is determined that a patient does not have the capacity to make the medical decision at hand, a surrogate (ie, a substitute decision maker) should make the decision. Ideally, all persons would have named a surrogate via an advance directive. In fact, most patients have not, so that we traditionally turn to the immediate family to act in the patient’s best interest. Studies have shown that the person the patient would want to make decisions for him/her (ie, the moral surrogate) is usually the same person that state law would name as the decision maker (legal surrogate). Occasionally, the legal surrogate does not act in the patient’s best interest (ie, is not also the moral surrogate). In such instances, the physician must ensure, if necessary through an ethics committee and/or court proceedings, that someone who will act in the patient’s best interest is named.

Physicians may be asked to offer guidance to the surrogate in terms of how decisions should be made. The first suggestion is that the surrogate try to make a decision based on prior discussions with the patient (known as substituted judgment). In the absence of such discussions, the physician should suggest that the surrogate make the decision based on his or her best sense of the values and beliefs of the patient (knows as best interest judgment). If the surrogate has had little contact with the patient and does not know the values and beliefs of the patient, then the surrogate should be advised to make a decision that a prudent person would make in the circumstances.

In the absence of detailed discussions with patients about their preferences for various treatments, there is a reasonable likelihood that the family (ie, surrogates) cannot accurately predict what decision the patient would make. Is this a persuasive argument against family members (surrogates) making decisions for patients? Most who have thought about this argue that this is not a compelling reason to dismiss family decision making as being invalid. In one study, when patients were asked whose preferences should prevail when there was a conflict between the patient’s advance directive and the family’s wishes, more than half the patients said that their advance directive should be ignored and the family’s wishes followed.

Physician Decision-Making Influence: There are three ways that a physician can influence a patient’s decision making. These are rational persuasion, coercion, and manipulation. Rational persuasion implies that the patient makes the decision based on the logic of the factual information the physician has given coupled with the patient’s own values. Ideally, physicians should use only this method of influencing patient decision making.
Coercion implies that the patient is threatened in some way, such that a decision is made that the patient may not otherwise have made. For example; “Mr. Jones, if you don’t start cooperating with us, I’m going to have you committed to the psychiatric ward.” A threatening statement by someone who has the power to carry out the threat meets the criteria for coercion. Coercion is unethical and is rarely seen in chest medicine. Manipulation is exemplified in Case 2.

Case 2

A physician believes that the best decision that a patient can make related to an impending elective surgical procedure is to refuse it. The physician also knows that the patient is very risk averse. So the physician, during the process of obtaining informed consent, tells the patient (while raising her eyebrows) that he has a 5% chance of dying as a result of a complication of the surgery.

The physician could have given the patient the same information by saying that the patient had a 95% chance of a successful surgery but chose to emphasize the risks in order to influence the patient to make the decision the way that the physician wanted it to be made. This more pervasive and subtle but inappropriate form of presenting information is called manipulation. Manipulation implies that the physician gives information to the patient either selectively or through emphasizing or deemphasizing some information inappropriately so as to make attractive to the patient the decision that the physician thinks is best for the patient. A common form of manipulation is called framing. Consciously or unconsciously, physicians will often frame information, emphasizing or minimizing the risks or benefits of one of the choices so that the patient makes the decision that the physician wants them to make. The patient does not know that as we are presenting the choices to them in a seemingly objective manner, we are actually conflating the factual information of decision making with our own opinion about what is the best decision. It is better to state the facts objectively and then separately give the patient your opinion about the best course of action.

Ability to Consent: Rare instances may occur in which a patient fulfills all of the other criteria for informed consent but cannot give consent. For example, a patient may be in a “locked-in” state and may literally be unable to convey the decision to the health-care providers, even though they may have made an informed decision.

Who Should Give Informed Consent

Case 3

The condition of an 81-year-old retired janitor, who was not previously your patient but is now under your care, is deteriorating in the ICU. A decision must be made about resuscitation. The patient is alert, cooperative, and, in your judgment, appears to have the capacity to make any necessary decisions. You discuss the treatment options, risks, and benefits with the patient, and, after much discussion, you ask him what he would prefer that you do. Is this the right question to ask?

No, because this question presumes that he wants to make the decision. Additionally, the patient may have assumed that he must make the decision because you asked. It is widely recognized that patients have the right to make decisions for themselves. But many mistakenly believe that because this right exists, patients must and will always choose to exercise it. There is a growing body of empirical evidence suggesting that in a variety of circumstances patients would prefer not to make decisions by themselves. Rather, they often want to share decision making with family and/or their physician or want others to make decisions on their behalf. These observations suggest that, when obtaining informed consent, we ask first who and how they want to make decisions, rather than what decision they want to make.

Cultural Diversity and Informed Consent

Sensitivity to cultural values must always be an important consideration when obtaining informed consent, and the United States, which is a country of immigrants, is increasingly a multicultural society. Importantly, many cultures place family values above those of the individual and do not value the individual decision making that has become common practice in the past half century. For example, it is considered an insult in some Arabic cultures if the physician asks the patient to sign a consent document. It is essential to understand the culture of a patient and, if necessary, meet the patient privately, perhaps with the help of an interpreter, to determine what information the patient wishes to know and how the patient wishes the consent process to proceed. Do not use family as interpreters because they may not accurately express the patient’s wishes. If patients choose to allow their spouses, family, or elders to make decisions on their behalf, then they have expressed their autonomous wish to allow others to make these decisions.
When Consent Is Unnecessary

Case 4

A young woman in your ICU is in shock secondary to massive pulmonary emboli. Because of the small, isolated nature of the hospital, there are no surgical or transport options available. You have the capacity to give the patient a thrombolytic agent but wish to obtain informed consent from her next-of-kin because of the significant risks associated with its use. After many frantic attempts to contact a family member, none is found. Should you give her the agent without obtaining consent?

It is not necessary to obtain informed consent in emergency circumstances if delay will increase the risk of significant harm and there is a reasonable likelihood that the patient will benefit from the treatment. The challenge is in defining what we mean by the terms significant harm and benefit. The meaning of harm and benefit must be determined by the physician in the clinical context. In the case cited in previous sections, most would agree that death is a likely significant harm without treatment. Most physicians would agree that there is significant chance of benefit from the use of the thrombolytic agent. But there may be disagreement as to whether the likelihood of an intracranial bleed secondary to therapy constitutes a significant risk.

Another circumstance in which it is not necessary to obtain informed consent occurs when a patient waives the right to go through the informed consent process. Some patients trust their physician or family implicitly, do not wish to know certain information related to decision making, and may waive their right to give consent. This is ethically and legally acceptable, but may be psychologically burdensome to the family/physician and has the potential to expose the patient to abuse. Alternatively, some patients wish to know and understand the choices before them, but choose to let the physician make decisions on their behalf.

A rarely invoked reason not to obtain informed consent is what is known as the therapeutic privilege. Some states legally allow a physician to withhold information needed by the patient to give informed consent if there is a reasonable likelihood that the patient would be harmed by hearing the information. An example might be the withholding of information from a severely depressed patient who has attempted suicide in the past when given similar information. This does not mean that the patient should never be given important information in such circumstance; rather, if they are told, the physician must make preparations in advance to reduce the patient’s risk of self-harm by involving psychiatry and the patient’s family in the disclosure process.

Conclusion

Informed consent is a cornerstone of patient-physician interactions. Even the most mundane of patient-physician interactions, that of writing a prescription, is an opportunity to practice informed consent and may even enhance patient adherence. It can be time consuming and frustrating, especially when the patient makes a choice with which the physician does not agree. But as physicians we must be cautious not to inject our own sense of values into decision making unless it is clear to the patient what part of the discussion is factual and what part reflects our values and opinion. We must continually remind ourselves that it is our responsibility to give the patient the information they need to make a decision and to ensure that they understand it. Informed consent exists to allow the patient to pursue their life plan by safeguarding their values and facilitating a rational decision-making process.

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A 16-year-old person may have the capacity to give ethical consent (called assent) but cannot sign the hospital consent form because of age restrictions on the definition of an adult. At progressively younger ages, the ability of a child to reason becomes questionable, but it remains incumbent on the physician to help minors understand, as much as possible, the decision that must made by their parents and to obtain their assent to the decision.

Assent

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