Chapter 7
Informed Consent

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History

A brief review of the evolution of informed consent law will provide an understanding of the current status of the physician’s duties with respect to disclosure. The writings of Hippocrates, one of the earliest to discuss professional conduct, include phrases such as “concealing most things from the patient” and “revealing nothing of the patient’s future or present condition.” In that authoritarian age patients were expected to be obeisant, and the purpose of physician–patient communication was solely to persuade the patient to accept therapy. de Mondeville, a medieval physician, believed hope to be of sufficient therapeutic benefit to justify avoiding the truth. He advised, “Promise a cure to the patient but tell parents or friends of any danger.” In the nineteenth century, Benjamin Rush wrote, “Educate the patient about his condition.” His purpose for patient education was to motivate compliance with the advice of the physician. Although Rush thus proposed an informed patient decision, he was not an advocate of consent.

“Courts very much tend to rule on the basis of precedent or previous decisions. This is called ‘stare decisis.’ Generally it takes either a most unusual case or a growing amount of social dissatisfaction with existing law for courts to consider overruling the present law.” Actual legal doctrine evolving from court cases pertaining to present day informed consent requirements occurred mainly in the twentieth century. A patient consented to an examination under anesthesia and requested no surgery be performed. The physician found a fibroid tumor of the uterus and removed it. In 1914 the patient sued (Schloendorff v. Society of New York Hospitals) and Justice Benjamin Cardozo wrote in his opinion, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.” As of this date the law required consent but not informed consent. There was an additional problem for physicians in this ruling insofar as assault is a criminal offense as opposed to a civil offense. A patient undergoing translumbar aortography was left with a permanent paralysis. He sued his physicians (Salgo v. Leland Stanford Jr. University Board of Trustees) and claimed they failed to warn him of the risk of paralysis, and had he known of
this risk he would not have consented to the procedure. In 1957, the court ruled that “physicians have the duty to disclose any facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment” and thus created the doctrine of informed consent.

A patient sued her physician (Natanson v. Kline8) because of severe burns from radiation therapy and claimed she had not been informed of this risk. In 1960 the court ruled in her behalf and, fortunately for physicians, also established that informed consent liability was negligence, a civil offense rather than battery, a criminal offense. A patient sued his physician (Canterbury v. Spence9) after suffering paralysis following a laminectomy and claimed he had not been warned of the possibility of this risk and would not have consented to the procedure had he been so warned. In 1972, the court ruled it is the physician’s duty to warn patients of “risks and alternatives” to treatment. This phrase, “risks and alternatives,” should be part of the vocabulary of any physician with knowledge of risk prevention. The children of a woman who died from cervical cancer sued her physician (Truman v. Thomas10). She had refused a Pap smear more than once and claimed she would have consented to the test if she had been warned of the risks of not having it. In 1980, the court found in her behalf and ruled the patient must be warned of “the risks of a decision not to undergo the treatment.” This is the doctrine of informed refusal.

According to Faden and Beauchamp,11

It was case law that introduced the concept of informed consent to medicine in the twentieth century using the language of “self-determination.” Shortly thereafter informed consent was transformed into a social context beyond the law from a malpractice issue to a moral duty incumbent on physicians.

**Definition**

Performing an invasive diagnostic or surgical procedure with improper consent or no consent in most instances is actually battery. Battery is intentional (not accidental or careless) physical contact for which the patient has not given permission. It is a criminal offense that can be punishable by incarceration, although incarceration is extremely rare. However, an intentional tort such as battery may allow plaintiffs to recover punitive damages that are not covered by malpractice insurance. Negligence is an unintentional act or omission and is a tort, a civil offense for which there may be monetary consideration.

Patients rarely sue for only informed consent problems, but allegations regarding improper informed consent are included in almost every medical malpractice claim. “Courts are allowing consent cases to go forward in cases where they are suspicious that there really was negligence but it can’t be proven.”12 Members of the medical and legal professions are faced with many problems when considering the critical question of whether the appropriate legal standard has been satisfied in any given
instance. The inherent difficulty of securing a definition of “informed consent” that satisfies both legal and medical requirements is but one of these. It is no longer enough to equate consent with the mere completion of a form; rather, it is the process of communication between health care provider and patient upon which subsequent judgments as to the extent and validity of consent must be made. Informed consent is a continuum and not a single event and should be viewed by the patient and the physician as collaborative and not paternalistic. The process begins at the first encounter and continues through treatment and follow up.

Physicians tend to regard the process as a legal requirement to protect themselves rather than as an ethical process to involve the patient. Consideration must be given to the fact that patients and physicians often have different models of illness. While physicians may think of diabetes as a disease of blood vessels, many patients regard it as simply a lot of injections. Likewise, patients and physicians may have different treatment goals. It is common for patients to expect a cure with as little of their own input as possible, and it thus falls to the physician to encourage the patient to be an active participant.

The criteria for truly “informed” consent include the fact that there must be understanding by the patient of relevant information. This is often idealistic in those instances of patients with a language problem regardless of whether an interpreter is present or in the case of many elderly patients with early dementia as well as in other circumstances. The consent must be autonomous with no coercion, manipulation, or persuasion. The patient must understand the process as giving of permission. The consent is not truly “informed” unless the patient understands it as an act of authorization regardless of how well he or she understands the medical information, risks, benefits, alternatives, and so forth.

**Purposes**

There are four purposes to obtaining informed consent.

1. The informed consent process enables the physician to comply with the legal requirement to “disclose sufficient facts and information which are necessary to form the basis of an intelligent consent by the patient” (Salgo v. Leland Stanford Jr. University Board of Trustees). Unfortunately this is too often the only reason physicians become involved with informed consent.
2. Many studies have shown that patient involvement in decision making improves patient compliance, thus increasing the chance for a better result.
3. Patient education regarding risks is perhaps the most powerful risk prevention tool available to physicians. The typical patient comes to the physician expecting a cure. Patient expectations in our society are so high that to most people anything less than a perfect cure will be an unexpected event. “Surprise produces anger and anger produces lawsuits.” Negligence attorneys agree that their angriest clients are medical malpractice plaintiffs. Studies in several specialties have shown that explaining the possibility
of complications reduces patient expectations and results in greater satisfaction with whatever result is achieved. There are also studies in several specialties that show that patient retention of facts is less than optimal. Priluk et al. had a 15-minute prepared preoperative informed consent discussion with detached retina patients on admission to the hospital and tested their recall prior to their discharge from their inpatient hospital stay (range 2–11 days). Forty-three percent of the patients, none of whom had yet been discharged, were unable to recall all the material in the preoperative informed consent discussion. Furthermore, 54% of the patients with incomplete recall actually denied they were ever given the information. The authors’ conclusion was that patients understandably tend to remember favorable facts and suppress threatening facts. A more recent study of cataract patients questioned as early as the first postoperative day had similar results. Studies in cardiovascular surgery and plastic surgery were equally discouraging. Despite the results of these studies, it still makes good sense that physicians do their best to educate patients regarding the possibility of complications and less than perfect results for the purpose of risk prevention and to document these efforts. There are both videotape and computer website services available to help physicians document that they have obtained an informed consent.

4. Going through the process of informed consent gives the physician the opportunity to document having done so. Although patients have certainly been known to lie or exaggerate on the witness stand, on occasion some may honestly lose recall of the conversation. To refute the allegations of the plaintiff it becomes the responsibility of the physician to establish that the process did in fact occur. The options for documentation are discussed later in this chapter.

Indications

The indications for informed consent include any diagnostic, therapeutic, or surgical procedure with an element of risk. As a rule the more elective the nature of the procedure (e.g., LASIK) the greater is the indication for informed consent.

Exceptions

In specific circumstances it may be permissible to intentionally disregard the requirement for informed consent.

1. Public health emergency actions such as quarantine or vaccination are often required by law.
2. Medical emergencies in which delay might be harmful are also an exception provided there is no evidence to indicate the patient would refuse the procedure (e.g., blood transfusion for a Jehovah’s Witness).
3. An incompetent person, such as a minor when no parent or legal guardian is available or a person with diminished capacity, can in the appropriate circumstances receive treatment without informed consent.

4. The concept of therapeutic privilege enables a physician to withhold all or part of the informed consent discussion if it is judged that there would be harmful effects from the disclosure. This is a nebulous concept that presents a slippery slope and should be avoided whenever possible.

5. Waiver of informed consent by the patient can release the physician from the requirement of informed consent. Such a patient may say, “I trust you and I don’t need to have you explain it to me.” This situation is a “catch 22” because this waiver is in and of itself an actual consent and must also be informed. The physician should not allow the patient to waive the process for two reasons. First, defending this admittedly unclear concept in court is a tenuous situation at best. Second, failure to use the informed consent process deprives the physician of the opportunity for patient education regarding risks, one of the strongest risk prevention tools available.

The Standard for a Lawsuit

To recover damages for lack of informed consent the patient must prove the treatment carried a known risk of which he or she was not advised, the risk occurred as the result of the treatment, and a reasonable person in the patient’s place would not have undergone the treatment if advised of the risk.

The Process

Presentation of Consent Material

The environment for the discussion should be leisurely and unhurried, and privacy should be respected. The concerns of the patient should be elicited, and he or she should be encouraged to ask questions. The discussion should occur within “reasonable proximity to the procedure” (an admittedly nebulous phrase). Problems include balancing information overload versus underdisclosure. When in doubt it is advisable to give more rather than less information. The material should be well organized, unfamiliar terms should be avoided, and lay terms should be used when possible. It is easy to lose sight of the reality that information that is too complex and not easily understandable will not have the desired impact on the patient’s decision making. It may also cause the patient to feel that his or her participation is not truly desired by the physician. This may lead the patient to feel that the purpose of the consent form is solely to protect the physician. Early in my medical practice I
completed what I felt was a superb informed consent discussion only to have the patient’s husband say, “Okay Doctor, that takes care of you, now how about us?” Printed materials and/or audiovisual materials can not only save time but also increase patient comprehension. Distractions such as anxiety, fear, or pain should be recognized and dealt with as the situation requires.

**Setting**

The patient should be invited to ask any interested party accompanying him or her to be present in the room during the discussion. This has the added benefit of not having to repeat all of part of the process to an interested party who may have gone outdoors for a smoke. The names and relationships of all those accompanying the patient in the room where the discussion is held should be recorded. In addition, the same information for anyone who accompanied the patient to the office but is not in the room should also be recorded (e.g., brother George in waiting room). Recording this information precludes any credible testimony on behalf of the plaintiff as to what material was covered by person(s) who were not actually present at the discussion.

**Discussant and Discussion**

The discussant should optimally be the physician who will perform the procedure and not a fellow, resident, nurse, technician, or other staff. It is preferable not to delegate this task. The physician is the most qualified person and will be the one charged with the responsibility of defending any lawsuit in the courtroom. If the presentation is made by a video of the physician, by other audiovisual aids, and/or by someone else, the physician should be present at the end of the presentation to answer any questions the patient may wish to ask of a medical nature. Lay vocabulary should be used to increase patient comprehension. The nature of the problem and why it is of concern should be covered. The technique of the procedure should be described as simply as possible. The patient must be informed who will be performing the procedure and what parts, if any, will be done by someone else.

**Risks, Benefits, and Alternatives**

The discussion of risks is of paramount importance because of the opportunity for patient education. Patients rarely refuse a procedure even after learning of serious risks. Fear that a patient will refuse a necessary procedure after hearing of a serious risk is not usually a sufficient defense for withholding full disclosure. Do not make
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the mistake of assuming just because you tell the patient he or she might die or lose an eye it is not necessary to make full disclosure of lesser risks. This will not usually impress a jury favorably. Furthermore, incomplete disclosure deprives the physician of the opportunity for better risk prevention by means of patient education regarding risks.

Until recently the criterion for which risks should be disclosed was any risk that a “reasonable physician” judged significant. With the passing of the authoritarian age of medicine into the present day environment of self-determination, the standard has shifted in most states to any risk that would affect the decision of the “prudent patient.” Despite the evolution of the informed consent doctrine over the years there is presently no definitive legal guideline as to what risks or what type of risk must be disclosed. A continuing conundrum is the lack of a workable definition of a “material” risk. The courts have stated that a material risk is one that the average patient would feel is significant when deciding whether to agree to a diagnostic, therapeutic, or surgical procedure. Exactly how the courts expect physicians to know what specific risk will affect the decision of a given patient in a given situation is unclear. Basically, the more remote a risk is, the less likely a patient will consider it material. Likewise, the more severe the risk, the more likely a patient will consider it material even if it is remote. It is neither necessary nor possible to include every risk in the discussion. The physician must convince the jury that he or she made a bona fide attempt to include those risks that would influence the decision of a “prudent patient.” When it is applicable, do not forget to include the risks of failure to improve vision as well as decreased or total loss of vision.

Frankness and complete honesty are essential to the discussion of benefits. Be certain not to say anything that might be considered a guarantee. Angry patients frequently claim a better result was guaranteed. I recall a plaintiff who swore he was guaranteed to improve from 20/400 to 20/20 vision following panretinal photocoagulation for neovascular glaucoma secondary to a severely ischemic central retinal vein obstruction.

The discussion of reasonable alternatives should include those choices that might affect the decision of the “prudent patient” with an explanation of your opinion of the appropriateness of each and why you have chosen the procedure you are recommending. The alternative of no treatment must be included with mention of the likely consequences.

**Questions for and by the Patient**

Presentation of all the above material by the physician is optimal. At this point of the process, regardless of whether the physician has personally made the presentation, it is essential that he or she be present to ask whether the patient has understood the presentation and to answer any questions of a medical nature. Even if there are no questions for the physician, his or her presence adds the personal touch and demonstrates caring. It is the physician’s responsibility to answer if asked how
many times he or she has performed the procedure. When physicians misrepresent their experience or success rates with new or established procedures, many states view this as a “deceptive and unconscionable act” and allow patients to sue under their consumer protection laws.

There is no obligation for the physician to volunteer information regarding his or her malpractice litigation history. If asked, the physician may decline to answer. However, if there is a complication and the physician had lawsuits arising from a similar complication, the patient may claim the physician deprived them of informed consent because disclosure of this information would have caused them to choose another physician. If the physician chooses to answer he or she may not misrepresent their claims history. Questions of a nonmedical nature such as time of surgery, place, and so forth, can be answered by a nurse, technician, or other staff.

**The Consent Form**

At such time as the patient and anyone else in attendance with him or her have no further questions it is time to present the consent form. There are three types of written consent documentation. The first is the long, detailed consent form, which is the traditional means. The short form states that the patient has been informed but does not list specific risks, benefits, and so forth. The third method is a detailed note in the patient’s record. There is still controversy as to the relative values of each type. The long form and the detailed note in the record are basically the most appropriate. Many physicians make their own forms with or without consulting an attorney or medical society. Some states, such as Texas, have mandatory forms that if executed properly are a very strong defense for physicians. The American Academy of Ophthalmology has consent forms that are excellent, and several are procedure specific.

By no means should a physician rely on only the consent form given to patients on arrival at the hospital or ambulatory surgery center registration desk. Any jury can rightfully be expected to feel sympathy toward a patient who claims, “The clerk didn’t explain much to me and I was so nervous about the procedure I signed the form in order not to make trouble.” After the patient has had sufficient time to read the consent form and after all his or her additional questions have been answered, it is time for the signature. The signature can be witnessed by a patient’s family member. I prefer to also have someone from my staff act as a witness. I do not have any of my staff in the room during the informed consent conversation. My staff witness is called in at the time the form is to be signed by the patient. It will not be the responsibility of my witness to testify as to what was or was not discussed. If litigation ensues I want someone loyal to me to be able to testify only that it was the patient who signed the form and it was signed on the date written on the form and not 3 months after the complication had already occurred, as I have seen patients allege. After the consent form is signed and witnessed, I impress upon the patient that “what you have just signed is permission for me to do the procedure. It
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is not an irrevocable contract and you can change your mind at any time.” This is intended to reinforce the concept of patient authorization.

**Documentation**

At this point the consent has been documented. “Any number of experts can testify as to the competency of whatever medical or surgical treatment may be in question. However no-one who was not actually present in the room throughout the discussion can testify accurately in behalf of either the physician or the patient as to exactly what was or was not discussed.” For this reason I have tape recorded all my informed consent conversations in my offices since 1980. I keep the recorder on the desk in the room where the discussion occurs. Before starting the discussion I say to the patient, “The conversation we are about to have is rather lengthy and instead of having someone take notes I am going to make a recording so I have a copy.” I have not had a single patient ever refuse the recording. I use a double-sided 2-hour tape on which I can typically record a dozen or more conversations per side (the average time is approximately 7–10 minutes). The name and date are written in a small spiral notebook kept on the recorder. I store the tapes and notebook pages with my yearly income tax returns. The act of recording takes practically no extra time. Begin the recording by stating, “This is (date) and this is Dr. (name) explaining informed consent to (the patient and the name and relationship to the patient of anyone else present in the room).”

While the process of recording may appear cumbersome and/or over the top (some physicians use videotaping) it can be a powerful and effective defense tool. If the plaintiff has in fact suffered a bad result, regardless of whether there has been malpractice, a jury will often be more prone to accord greater credibility to his testimony. I strongly urge that you seriously consider the following rationale of an experienced negligence attorney:

The key to understanding what must be done to defeat a claim for lack of informed consent is this: The injured plaintiff need only testify that you did not tell him about the risk of the terrible complication that happened to him and that, if you had done so, he never would have agreed to the treatment; in order to defeat the claim, you cannot merely take the stand and assert the contrary. It will merely be your word against his—and he has the injuries, not you. You must produce corroboration of your testimony that you disclosed the risk. Your evidence must be as strong as possible, since the plaintiff is saying that the injuries from which he is suffering would never have occurred if you had disclosed everything to him, because he would never have agreed to the treatment. When you produce a tape recording of your explanation of the risk to the patient and the patient’s statement that he understands all the risks you have explained and agrees to the treatment, you destroy the plaintiff’s claim of lack of informed consent and go a long way toward destroying any other claims of malpractice he may be making.

A recording would have been powerful support for the physician alleged to have promised return of 20/20 vision following panretinal laser to the patient with 20/400 vision from neovascular glaucoma secondary to severely ischemic central retinal vein obstruction.
Informed Refusal

In 1980, *Truman v. Thomas* established the doctrine of informed refusal. Unfortunately relatively few physicians are familiar with this concept, and the need for appropriate action is usually overlooked. The court holds the position that the physician is the expert and the patient is ignorant with respect to most medical situations. When a patient refuses any recommended diagnostic, therapeutic, or surgical procedure, the physician may not assume the refusal was an informed decision. The patient must be warned of the risks of refusal. Most physicians are unaware of the many situations to which this concept can be applicable. In the average medical practice informed refusal situations arise far more frequently than do situations involving informed consent. Failure to keep a postoperative appointment, missing a follow-up appointment for continuing treatment, or a glaucoma patient missing an appointment for a visual field examination requires documented notification of the patient with mention of the risk of delayed examination or treatment. A patient you have never seen calls complaining of the recent onset of flashes and floaters. The receptionist gives the patient an appointment for the same day but the patient fails to appear and 3 weeks later is diagnosed with a retinal detachment by another ophthalmologist. Technically your office has not established a relationship with the patient but under some circumstances a clever attorney can bring a lawsuit claiming your office failed to warn the patient of the risk of not being seen promptly. Other examples include refusal of routine tonometry, bilateral pupillary dilation, and poor compliance in taking glaucoma medication.

To provide adequate protection for the physician, the conversation regarding risks of refusal should be documented and signed by the patient with a witness as it would be for informed consent. This situation can involve anxiety for the patient and occasionally resentment or anger as well and may thus make the atmosphere inappropriate for suggesting a formal discussion with tape recording. This is nonetheless a potentially litigious situation and should not be taken lightly. The physician must sublimate any personal feelings of anger or resentment toward the patient who has questioned and/or disregarded his or her judgment and advice. Physician demeanor should be calm and understanding in order to maintain a good physician–patient relationship in the hope that the patient will eventually acquiesce. If the problem arises without a physician–patient encounter (e.g., missed appointment), a return receipt letter is called for as is chart documentation of any phone calls.

Conclusion

Although it the physician’s duty to inform, it is the patient’s right to consent. The process can be neither complete nor utilitarian unless both parties recognize and comprehend their respective obligations. “Professionals would do well to end their traditional preoccupation with disclosure and instead ask questions, elicit the
concerns and interests of the patient, and establish a climate that encourages the patient to ask questions.”

References

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