Medical informed consent is essential to the physician’s ability to diagnose and treat patients as well as the patient’s right to accept or reject clinical evaluation, treatment, or both. Medical informed consent should be an exchange of ideas that buttresses the patient-physician relationship. The consent process should be the foundation of the fiduciary relationship between a patient and a physician. Physicians must recognize that informed medical choice is an educational process and has the potential to affect the patient-physician alliance to their mutual benefit. Physicians must give patients equality in the covenant by educating them to make informed choices. When physicians and patients take medical informed consent seriously, the patient-physician relationship becomes a true partnership with shared decision-making authority and responsibility for outcomes. Physicians need to understand informed medical consent from an ethical foundation, as codified by statutory law in many states, and from a generalized common-law perspective requiring medical practice consistent with the standard of care. It is fundamental to the patient-physician relationship that each partner understands and accepts the degree of autonomy the patient desires in the decision-making process.


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.

Justice Benjamin Cardozo, 1914

Medical informed consent is ethically, morally, and legally mandated by the fiduciary responsibilities flowing from the patient-physician relationship. Negligence per se occurs when an actor’s violation of a statute or regulation causes the kind of harm the statute was intended to prevent. Ethically, physicians engaged in patient-physician relationships involving medical informed consent have a moral responsibility to identify the best treatments for each patient on the basis of available medical evidence and to discuss with patients the hoped-for benefits and the potential risks. Physicians must allow for patients’ questions about the proposed treatments, benefits, and risks and must answer those questions from the available medical literature and their professional experience. This exchange of information and ideas is the foundation of the patient-physician partnership and promotes informed decision making in the most complex medical situations.

Legally, a physician must understand that many states have codified medical informed consent into statutory law, and lack of adherence to the statute can lead to negligence for the physician. The jurisdictions vary, and violation of the statute can be considered intrinsically negligent or merely a rebuttable presumption of negligence. Several states have codified medical informed consent to varying degrees (Table 1). All physicians would be prudent to educate themselves regarding their states’ statutory laws concerning medical informed consent. Further, every practicing physician should understand the underpinnings of the common-law analysis of medical informed consent and negligence. The common law and statutory law create a burden on physicians that varies in different jurisdictions.

Ethically and legally, all physicians have a mandatory obligation to understand the medical informed consent process. Understanding this process allows for the exchange of ideas in medical practice that will yield informed decisions and will lead to the best outcomes on the basis of shared information. Further, informed consent limits the potential for negligence cases brought for lack of informed consent. Table 2 provides an outline of teaching points that should be followed in the informed consent process.

**GENERAL CONSIDERATIONS IN INFORMED CONSENT**

Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her health. It is generally accepted that patients should consider the potential risks and benefits flowing from their medical decisions. Patients must acknowledge those potential risks and benefits to make informed decisions. Generally, the law protects the patient’s right to informed consent by requiring physicians to disclose all pertinent information about risks and benefits of the procedure to the patient. Medical informed consent law requires disclosure of the risks of the suggested medical procedure and the risks of the alternatives to enable patients to make knowledgeable decisions. A patient’s understanding of the

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Risk can be defined as exposure to a chance of injury or loss. This definition contains 2 distinct components: (1) chance related to uncertain events—those that are unpredictable in any single case, but for which a probability that an event will occur in any 1 case can be estimated through statistical pooling of large databases, and (2) injury or loss, including any consequences for which the patient sustains a disability. The law places a positive obligation on physicians to disclose information about the risks to any patient who is at risk of an adverse event, that is, who will suffer injury if a chance event occurs.  

**DEVELOPMENT OF INFORMED CONSENT LAW**

Medical informed consent law developed from the intentional tort of battery, which protects individuals from an unwanted physical touching of the body by others having neither express nor implied consent of the person touched. Battery occurs in medicine when a physician performs a treatment without the patient’s consent, performs a substantially different procedure than the one for which consent was given, or exceeds the scope of the consent, or when a physician other than the one to whom consent was given carries out the procedure.  

The legal analysis of medical informed consent has evolved over the years from an allegation of battery to an allegation of negligence. Currently, the courts nearly unanimously characterize lack of informed consent as a matter of negligence of the physician to disclose necessary information to patients. Negligence requires that 4 elements be established for liability of the physician-defendant: (1) a duty of the physician to meet a particular standard of care, (2) the physician’s failure to perform that duty, (3) a causal connection (proximate cause) between the physician’s failure and the patient’s injury, and

### TABLE 1. States With Statutes and Their Citations

<table>
<thead>
<tr>
<th>State</th>
<th>Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AK</td>
<td>Alaska Stat 09.55.556</td>
</tr>
<tr>
<td>AR</td>
<td>ACA §16-114-206</td>
</tr>
<tr>
<td>DE</td>
<td>18 DeC §6852</td>
</tr>
<tr>
<td>FL</td>
<td>Fla Stat §766.103</td>
</tr>
<tr>
<td>GA</td>
<td>OCGA 31-9-6.1</td>
</tr>
<tr>
<td>HI</td>
<td>HRS §671-3</td>
</tr>
<tr>
<td>IN</td>
<td>IC 34-18-12-3</td>
</tr>
<tr>
<td>IA</td>
<td>ICA §147.137</td>
</tr>
<tr>
<td>KY</td>
<td>KRS §304.40-320</td>
</tr>
<tr>
<td>LA</td>
<td>LSA-RS 40:1299.40</td>
</tr>
<tr>
<td>ME</td>
<td>24 MRSA § 2905</td>
</tr>
<tr>
<td>NE</td>
<td>Neb Rev Stat §44-2816</td>
</tr>
<tr>
<td>NV</td>
<td>NRS 41A.110</td>
</tr>
<tr>
<td>NH</td>
<td>NH Rev Stat §507-E:2</td>
</tr>
<tr>
<td>NY</td>
<td>McKinney’s Pub Health L §2805-d</td>
</tr>
<tr>
<td>NC</td>
<td>NCGSA §90-21.13</td>
</tr>
<tr>
<td>OH</td>
<td>RC §2317.54</td>
</tr>
<tr>
<td>OR</td>
<td>ORS §677.097</td>
</tr>
<tr>
<td>PA</td>
<td>40 PS §1303.504</td>
</tr>
<tr>
<td>RI</td>
<td>Tentative. Gen Laws 1956, §9-19-32 (Judge will pass informed consent question to jury only if the court finds that reasonable minds could disagree.)</td>
</tr>
<tr>
<td>SD</td>
<td>SDCL §54-23A-1.7 (skews more toward abortion than general informed consent)</td>
</tr>
<tr>
<td>TX</td>
<td>VCTA, Civil Practice &amp; Remedies Code §74.104 and 74.105</td>
</tr>
<tr>
<td>UT</td>
<td>UCA 1953 §78-14-5</td>
</tr>
<tr>
<td>VT</td>
<td>12 VSA §1909</td>
</tr>
<tr>
<td>WA</td>
<td>West’s RCWA 7.70.050</td>
</tr>
<tr>
<td>WI</td>
<td>WSA 448.30</td>
</tr>
</tbody>
</table>

### TABLE 2. Prudent Behaviors of Physicians Engaged in the Process of Medical Informed Consent

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The physician directly involved in the proposed treatment should conduct the informed consent discussion.</td>
<td>The discussion should include the treatment, the risks and benefits of treatment, and alternative therapies with associated risks and benefits.</td>
</tr>
<tr>
<td>The physician directly involved in the proposed treatment should discuss the most likely outcome with no treatment, on the basis of the best available medical or surgical evidence.</td>
<td>The physician directly involved in the proposed treatment should always discuss the severe risks, such as death, paralysis, loss of cognition, or loss of a limb, even if the probability of occurrences is negligible.</td>
</tr>
<tr>
<td>The physician involved in the proposed treatment should always disclose less severe risks that occur frequently.</td>
<td>Courts do not place emphasis solely on consequences; they recognize frequency as an important component of risk.</td>
</tr>
<tr>
<td>The physician directly involved in the proposed treatment should discuss informed consent in language the patient can understand, and treatment should not proceed until the physician believes the patient understands the risks and benefits and has made a rational decision.</td>
<td>The physician directly involved in the proposed treatment must understand that the medical consent form is not medical consent; it represents evidence that the consent process occurred. The dialogue between the patient and physician is the essence of the consent process.</td>
</tr>
<tr>
<td>The physician directly involved in the proposed treatment should document all patient-imposed restrictions in the medical record and the discussion with the patient about how the restrictions limit the physician’s ability to provide standard medical care.</td>
<td>The physician directly involved in the proposed treatment may advise the patient to seek care with an alternative health care provider if the restrictions imposed by the patient seem to inhibit good medical practice and seem likely to lead to a suboptimal medical outcome.</td>
</tr>
<tr>
<td>The physician directly involved in the proposed treatment must understand the informed consent can be withdrawn at any time. When physicians allow 24 to 48 hours for patients to reflect after consent to a treatment strategy, the period of reflection validates the notion of informed consent. Withdrawal of consent should include a discussion and documentation through a withdrawal of consent form on which time and date are noted.</td>
<td>When physicians and patients take medical informed consent seriously, the patient-physician relationship becomes a partnership, with shared authority, decision making, and responsibility for outcomes.</td>
</tr>
<tr>
<td>The physician directly involved in the proposed treatment can enhance the informed consent process through appropriate use of additional learning materials, such as pamphlets and video, and through involvement of support staff, such as physician assistants, in providing information that can be discussed by the responsible physician.</td>
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</tr>
</tbody>
</table>
A TYPICAL MEDICAL INFORMED CONSENT CASE

A typical medical informed consent case usually arises in conjunction with an underlying medical procedure. For example, if a patient suffers a stroke during an invasive vascular procedure, the patient might allege—in addition to and separate from any medical malpractice claim—that, because the physician did not discuss the risks and benefits of the procedure and reasonable alternatives to it, the patient could not make an informed decision whether to proceed. As previously noted, to establish a lack of informed consent case, a patient must first show that the physician had a duty to discuss the risks and benefits of the procedure and reasonable alternatives to it with the patient, and that discussion should have been in accordance with an accepted standard within the medical community. That is, the physician is expected only to disclose risks that might reasonably be known to occur with the particular procedure. Therefore, the discussion might vary depending on the nature of the procedure and the patient’s relevant comorbidities. States have applied different approaches in articulating the standard regarding the physician’s duty to disclose.

DEFINING THE STANDARD OF DISCLOSURE

Two dominant approaches, the “professional” standard and the “materiality” standard, define the standard of disclosure of information by which a physician’s duty to the patient is measured. The professional standard requires the physician to disclose information that other physicians possessing the same skills and practicing in the same or a similar community disclose in a similar situation. The second approach by courts is the materiality or “prudent patient” approach, allowing the jury to decide whether other information would have been considered important by a reasonable patient in making a decision and therefore requiring disclosure.

The courts recognize situations when a physician’s non-disclosure will be excused, including cases of the patient’s mental incompetence, medical emergencies, and the therapeutic privilege exception. If a patient is incompetent to make a reasoned decision, then disclosure to the patient might not be required. The physician can also withhold information under the therapeutic privilege if disclosure would interfere with treatment or would adversely affect the condition or recovery of the patient. The emergency exception to disclosure applies in situations where attempting to secure consent would delay necessary and proper treatment. Last, physicians need not disclose risks of which the patient is already aware or risks that are commonly known. Individual state law and court decisions determine which approaches and exceptions apply in an individual physician’s practice.

PHYSICIAN’S DUTY TO DISCLOSE RISK INFORMATION

Materiality jurisdiction courts have attempted to provide some guidance for physicians by suggesting that the physician’s duty to disclose risk increases as the magnitude of the risk increases. These courts uniformly fail to give explicit guidelines or to identify on what scale risks are to be measured. All severe risks (death, paralysis, loss of cognition, loss of a limb) should always be disclosed, even if the probability of occurrence is negligible. Further, even less severe risks, if frequent, should always be disclosed. Nominal risks with low probability of occurrence need not be disclosed. Courts do not place emphasis solely on consequences, recognizing frequency as an important component of risk. The professional standard asserts the doctor’s duty to disclose what a reasonably prudent physician with the same background, training, and experience would have disclosed to the patient in the same or similar circumstances. The professional standard does not give explicit guidelines regarding the disclosure of risks.

The courts stress that full disclosure is not required. Full disclosure is a slippery slope for physicians involved in medical informed consent. There are reasons full disclosure as a standard of practice should not be expected. First, the number of risks possible from even a routine procedure is large, and potential risks can span a range of consequences. For example, in a footnote, the California Supreme Court listed some of the risks of having blood drawn: “[T]he risks…are said to include hematoma, dermatitis, cellulitis, abscess, osteomyelitis, and death, to mention a few.” Second, the burden of identifying small consequences in extremely unlikely risks is too great a burden on the physician, and the resulting choice by the patient will be impaired by a litany of consequences. Despite the courts’ pronouncements that full disclosure is not required, they have failed to delineate any clear limits on what must be disclosed. The California Supreme Court articulated this uncertainty: “One cannot know with certainty which medical consent is valid until a lawsuit is filed and resolved.” There does not appear to be a standard of disclosure to which physicians can adhere to avoid liability with certitude.

DOCTRINE OF MEDICAL INFORMED CONSENT

The doctrine of medical informed consent states that, before a patient elects to proceed with a treatment that has...
risk, there must be a balanced discussion of the treatment strategy, including the potential risks and hoped-for benefits. The magnitude of the risks and their frequency should receive special emphasis. Also considered are alternative treatments and their benefits, risks, and measured utility; the likely results of no treatment; and the probability of a good outcome with the proposed strategy. A good outcome and the major anticipated problems during recovery are described as well as the estimated time to resume normal life activities. This information must be presented in language the patient can understand, and treatment should not proceed until the physician believes the patient understands the risks and benefits and decides to proceed on the foundation of that understanding.31

The legal foundation for adopting the doctrine of medical informed consent is 2-fold: (1) to establish and promote patient autonomy and (2) to promote informed, rational decisions. The courts hold that it is reasonable to require physicians to inform, educate, and partner with patients because patients are generally unable to dissect the details of medical science needed to make an educated decision about treatment.29 This educational process should inform the patient enough to allow for an informed decision. Information disclosure will not necessarily lead to an ideal patient-physician partnership, but it should promote patient autonomy in the decision-making process and achieve a foundation for an ethical and trusting relationship between a physician and patient.

To give valid informed consent, the patient must be competent and the patient’s actions must be voluntary. Voluntary means “of free mind and free will.” The patient must not be cognitively impaired by medication, personal emotional stress, or external stress by family members or physicians. For example, one case involved a patient who was given a sedative to sleep and subsequently awakened in the middle of the night to give consent for a hernia operation. The court held that the medical consent was invalid because the patient was unlikely to understand what permission he had granted after being awakened from sleep and after taking a sedative.32

Determining incompetence and competence is a matter for the court and not a question of fact for the layperson. In medical informed consent the focus should be on the capacity of the patient. Capacity means the ability to process information received and to communicate a meaningful response. An element of capacity is that the person making the decision is an adult and has not been judged incompetent or is not otherwise prohibited by law from exercising that decision-making capacity. Decision-making capacity means the ability to understand the significant benefits, risks, and alternative to proposed health care and to make and communicate a health care decision.33

The purpose of medical consent, through medical consent forms and through documentation of the informed consent discussion in the medical record, is to have evidence of the exact terms of the medical consent in case of future disagreement. If a patient sues a physician, an outpatient surgery center, a medical group, or a hospital and alleges lack of informed consent, the defendant will be able to present the written consent form or the documentation of the discussion in court as evidence that medical consent was in fact secured. If the medical consent form or documentation of the discussion in the medical record is comprehensive and specific in terms of risks and benefits, and if the medical consent was granted voluntarily by a competent patient who understood the information presented, the probability of a successful lawsuit is low.34 However, the medical consent form does not equate to medical consent. Rather, it represents evidence that the medical consent process occurred. A patient could present evidence that medical informed consent did not occur, despite a signed form,35 for example, when a nurse presented the risks to the patient and the physician signed the form as if consent had been obtained.

What should a medical consent form contain? First, a consent form is not necessary to achieve valid medically informed consent. If an entity, such as a hospital, an outpatient surgery center, or other health care organization, chooses to honor a medical informed consent form, the form should contain all the information needed to comply with the elements of medical informed consent. The form should contain an accurate description of the proposed procedure, the risks and benefits of the proposed procedure, the potential advantages and disadvantages of no treatment, alternative treatment strategies and their risks and benefits, the potential for a successful outcome, the estimated recuperation time, and the estimated time required to return to normal activity. The consent form should contain the name of the physician involved and clauses dealing with photography, disposition, and use of removed tissues, organs, and body parts. Patients should be made aware that they are allowed to strike out any part of the medical consent form with which they do not agree or to which they do not consent. If a patient does not understand details of the treatment, the patient and physician should discuss treatment and risks to reach mutual understanding.

If a physician believes the limits placed on the medical informed consent hamper standard medical practice, he or she should document all the patient-imposed restrictions in the record, with a discussion of how the limits placed on the physician limit his or her ability to proceed in a standard fashion, and that the limits were described to the patient.
Alternatively, if a physician believes the restrictions seriously inhibit good medical practice and might lead to a suboptimal clinical outcome, he or she may advise the patient to seek care with another physician.

WITHDRAWING CONSENT OR REFUSING TREATMENT

May a patient withdraw consent after signing a medical consent form? Consent must be freely given and can be freely withdrawn at any time. Whether consent was given orally or in writing does not affect the patient’s ability to change or withdraw consent. Physicians may choose to allow 24 to 48 hours for patients to reflect after consent to a treatment strategy. During this time, patients can weigh the alternatives and come to an independent conclusion either to proceed with or to withdraw from the proposed treatment. A time for patients to appraise the risks and benefits reinforces the validity of medical informed consent. If a patient orally indicates a desire to withdraw medical consent, the physician would be wise to execute a withdrawal of consent form, noting time of day and date consent was withdrawn, or to carefully document in the medical record the details of consent withdrawal including a time and date.

May a patient refuse treatment? A competent patient may decline any and all treatment. Even mentally ill patients are generally considered competent to refuse treatment. Physicians would be prudent to have a patient who has been diagnosed with mental illness and who refuses an apparently beneficial treatment evaluated by a psychiatrist. In some situations, patients can be compelled to receive treatment.36 For example, a mentally ill patient could be considered a danger to society and institutionalized against his or her will.37 Competent individuals with contagious diseases may refuse treatment, but public health officials may quarantin or involuntarily hospitalize and isolate them if they are dangerous to other people.38 This policy is based on broad “police power” that states have (and can exercise through their departments of health) to protect the health and safety of the public. The reason for refusal of treatment can be rational or irrational. Whether rational or irrational, decisions are legally binding on the physician and the hospital. Individual freedom is guaranteed only if people are given the right to make choices that would generally be regarded as irrational behavior.39 Some states also require hospitals to ensure proper consent is obtained for no treatment. This consent for no treatment should contain a release of medical responsibility and any associated liability for the hospital, nurses, and employees, together with all physicians connected in any way to the patient.39

GOOD CLINICAL PRACTICE AND INFORMED CONSENT

Are good clinical practice and informed consent inseparable? Respect for patient autonomy in clinical practice is of great moral importance in our society. The moral and legal responsibility of medical informed consent depends on the transmission of appropriate information to patients. We believe patients’ choices must not be coerced by members of the health care team or by other third parties, such as friends, family, or payers. Equally, we believe patients must be competent to consent; they must understand, remember, consider, and believe clinical information given to them about the specific treatments. The moral foundation for the requirement of medical informed consent in general is not disputed. The question arises whether in certain situations exceptions from the general requirement of medical informed consent would be acceptable. An exception to medical informed consent could be motivated by the idea that an exception is reasonable if insistence on the requirement of medical informed consent causes more harm than good.

INFORMED CONSENT IN EMERGENCIES

Is medical informed consent always necessary in emergency medical situations? Is a patient who is having an acute myocardial infarction sufficiently competent to understand what he or she is being told? In a survey of Swedish cardiologists about their perceptions of medical informed consent during acute myocardial infarction, 86% thought that patients were unable to comprehend all the information provided and so, by definition, were unable to give fully informed consent.40

What evidence is there that patients with acute illnesses themselves fail to understand all the issues in the medical informed consent process? A report from the Fourth International Study of Infarct Survival revealed that only 31% of 129 patients perceived that they had full comprehension of the trial, and 19% thought they did not understand the trial.41 A review of patients with subarachnoid hemorrhage revealed only 19% of those who had given medical informed consent themselves could remember the consent process.42 The studies suggest that during a medical emergency many of the patients were too ill to give fully informed consent. Does this mean that patients with an acute myocardial infarction or subarachnoid hemorrhage are unable to engage in the decision-making process of medical informed consent? The answer is no. Although acute myocardial infarction is a medical emergency and there is evidence that some patients do not fully comprehend all the information to make a fully informed decision, some patients do comprehend and are capable of doing so. A dia-
logue between the physician and patient is essential. This is a unique opportunity to involve appropriate family members or health care surrogates in decision making during emergencies. Patients do not need to stand alone in the patient-physician partnership.

THE PARADOX OF CHOICE

Responsibility for medical care has landed on the shoulders of patients with a resounding thud. Patients have the choice of telling physicians what to do in relation to health care decisions. The tone of medical practice has shifted from paternalistic to consultative, in which the physician lays the possibilities before the patient, with the potential pluses and minuses of each, and the patient makes a choice. This attitude has been well described by Atul Gawande: “Only a decade ago, doctors made the decisions, patients did what they were told. Doctors did not consult patients about their desires and priorities…. They were regarded as children: too fragile and simple minded to handle the truth, let alone make decisions.”

According to Gawande, The Silent World of Doctor and Patient, by physician and ethicist Jay Katz, launched us into the era of autonomous patient choice. There is little doubt that this change in the decision-making paradigm has improved the quality of medical care generally. Yet no single paradigm fits all patients. Gawande suggests the shift in responsibility has gone too far: “The new orthodoxy about patient autonomy has a hard time acknowledging an awkward truth: patients frequently don’t want the freedom that we’ve given them. That is, they’re glad to have their autonomy respected, but the exercise of that autonomy means choosing sometimes to relinquish it.”

Gawande describes a family medical emergency where his newborn daughter stopped breathing, and the family rushed her to the emergency department. The physicians on duty asked Gawande if he wanted his daughter intubated. He said that he wanted the physicians to make that decision for him; the uncertainties were savage, and he did not want to bear the responsibility of making the wrong call.

When it comes to medical treatment, patients see choice as a burden and a blessing. Physicians must evaluate each patient-physician relationship individually and identify the level of responsibility each party wants to assume in the decision-making process. This process must be documented in the medical record and must detail the assumed responsibilities of each partner in the patient-physician relationship. The art of medicine demands an ability to apply multiple paradigms to the decision-making process when guiding patients through complex medical decisions. This process requires empathy, time, mutual understanding, and courage.

CONCLUSION

Medical informed consent is essential to a true patient-physician relationship. Patients need to participate in the informed consent process to understand the risk-benefit relationship for the proposed treatment strategy; this understanding is essential because patients are often psychologically regressed secondary to the realization that they are confronting a life-preserving procedure. Physicians need to participate in the informed consent process to provide patients with the best treatment available by sharing decision making and limiting any potential for liability. Medical ethics, common law, and, in many states, codified statutory law (Table 3) mandate the informed consent process. Physicians would be prudent to be knowledgeable in these areas of medical ethics, common law, and statutory law. Physicians would be prudent also to understand that the consent process is vital to the physician-patient relation-
ship and that no single paradigm can define the ethical, medical, and legal approach a physician should undertake to achieve informed consent. The process should be individualized within the boundaries of the patient’s desires for autonomy, thus reflecting true patient autonomy.

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