A Comprehensive Primer of Surgical Informed Consent

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The clinical skills required in the informed consent process tend not to be taught to fellows, residents, and medical students within the formal curriculum \cite{1}. Furthermore, surgical residents are seldom supervised during their communication with patients. As a result, faculty and trainees alike forego an opportunity to identify, evaluate, and address weaknesses in the resident’s interpersonal skills with patients generally, and during the informed consent dialogue in particular. Surgical practice is distinct from nonsurgical medical practice in a number of regards, primarily because of the operation. Surgical therapy occurs as a specific event, usually requiring entry into the patient’s body; the therapeutic event can be timed exactly (assigning culpability); the emotional stress on the patient is greater; and the surgical patient plays a more passive role than patients of other medical specialties once anesthesia is induced. The patient then becomes incapable of participatory intraoperative decision-making; and surgeon assumes full control of the decision-making process. Surgeons may consequently have a less fully developed sense of an active physician-patient partnership in the healing process than colleagues in other specialties, and this can affect their approach to informed consent. The surgeon may also assume that the referring physician has already made the necessary intellectual and emotional preparations and effectively has obtained the patient’s consent for surgical resolution of the clinical problem. In combination, these factors can lead the unwitting...
surgeon to underestimate the capacity and willingness of the patient to par-
ticipate in the informed consent process that should precede induction of
anesthesia. As a consequence, the surgeon can lose the opportunity to
form an effective therapeutic alliance with the patient.

The informed consent process

Historical development

The traditional debate over the requirement that physicians involve pa-
tients in therapeutic decisions was transformed by the ethical and legal anal-
ysis of several important legal cases involving surgical treatment. The
starting point is the common law of informed consent as a patient’s right,
a twentieth century concept. Two key features of the legal history of in-
formed consent are relevant here: simple consent and informed consent.

Simple consent involves one question: “Did the patient agree to be
treated”? If the answer is yes, then the conditions of consent are thought
to be satisfied. If the answer is no, then the conditions are not satisfied
and the surgeon cannot operate.

In 1914, Judge Benjamin Cardozo wrote a landmark opinion in the case
Schloendorff v The Society of New York Hospital, which legally defined sim-
ple consent and changed the history of American medical ethics [2]. Cardozo
wrote that, “every human being of adult years and sound mind has a right to
determine what shall be done with his body; and a surgeon who performs
an operation without his patient’s consent commits an assault, for which
he is liable in damages, ... except in cases of emergency, where the patient
is unconscious, and where it is necessary to operate before consent can be
obtained” [2]. The patient’s autonomy was at least equally important. Re-
spect for autonomy obligates the physician to seek for the patient the greater
balance of goods over harms, as those goods and harms are understood and
balanced from the patient’s perspective. The surgeon no longer possessed
authority to act unilaterally on clinical judgments.

Although many surgeons today practice as though simple consent is still
the ethical standard, the subsequent legal history of informed consent fo-
cused on the nature and quality of the physician’s disclosure and obligation.
Instead of one question, two questions must be asked: “Did the physician
provide the patient with an adequate amount of information?”, and “On
the basis of this information, did the patient consent?” As the common
law developed from the late 1950s through the early 1970s, two standards
of adequacy emerged. The first is the professional community or profes-
sional practice standard [3,4]. Under this physician-oriented standard of dis-
losure, the patient should be told what an appropriately experienced
physician in the community would tell the patient about the patient’s condi-
tion, alternatives available for managing the condition, and generalize the
benefits and risks of each alternative.
The courts gradually came to regard the professional community standard as inadequate, largely because of growing skepticism about the integrity of a solely physician-based standard. A major event in the development of an alternative standard was the case of *Canterbury v Spence*, decided in 1972 but occurring in 1958 [5]. This court rejected the professional community standard as inadequate and replaced it with the reasonable person standard. Informed consent involves meeting the needs of the “reasonable patient.” This legal construct means that the informational needs of a patient should be identified on the basis of what a reasonable patient, not a particular patient in a particular, subjective circumstance, needs to know to make a meaningful decision. The patient needs to know material information (i.e., what the nonprofessional patient is unlikely to encounter in daily life). The discussion need not be a disquisition, and surely the physician is not compelled to give his or her patient a short medical education; the disclosure role summons the physician only to a reasonable explanation. This means generally informing the patient in nontechnical terms what is at stake.

Patients may need, and often welcome, an offer to help think through their options. Because the decisions often involve subtle tradeoffs that are best understood and judged only by the patient, the surgeon should monitor himself or herself against coercing the patient, overtly or subtly. He or she may, and should, present the best case for surgical treatment if it is professionally considered to be the safest and most effective course, but the detriments of other alternatives or the benefits of surgery should not be exaggerated. In explaining the risks and discomforts attendant to any course, surgeons should be wary of making these sound so frightening that the patient rejects all varieties of crucial treatment.

In addition to the obligation to obtain consent or refusal, the patient’s “yes” or “no” to intervention, the reasonable person standard includes a duty to explain clinical judgments and recommendations that enable the patient to make an independent, informed decision. The patient’s perspective of his or her own interests should be respected by the surgeon. The ethical principle of respect for autonomy captures what is at stake clinically. The surgeon should acknowledge and accept the integrity of the competent patient’s values and beliefs, whether or not the surgeon agrees with them, and should provide the patient with an adequate amount of information. A physician’s disclosure is adequate when it includes the salient features of the physician’s clinical thinking in arriving at the recommended therapy and explains to the patient the basic thought process that brought the surgeon to the conclusion that surgical management is a reasonable course of therapeutic action for this patient in this case [1].

**The process**

Surgeons should conceptualize and practice informed consent as a continuing process, rather than as a static event. Properly used, informed
consent provides the basis for a strong and enduring professional alliance between the surgeon and patient, with shared responsibility for decision making [4]. Thus understood, informed consent is not simply the signature on the authorization form. This is legal documentation, and whereas documentation is important in satisfying the legal component of the consent process, documentation does not constitute the most important ethical element of informed consent. The patient’s signature on the informed consent form is far less crucial than the process that it serves to document.

The concept of informed consent includes three elements, each of which presumes and builds on its predecessor [4]. The first is disclosure by the surgeon to the patient of adequate clear information about the patient’s diagnosis; the alternatives available to treat the patient’s problem, including surgical and nonsurgical management; the benefits and risks of each alternative, including nonintervention (ie, allowing the natural history of the disease to continue); and a frank explanation of those factors about which the medical profession, and the individual surgeon in particular, are uncertain and cannot provide guarantees. This disclosure should be individually tailored in its presentation to the intellectual and emotional capacity of each patient to understand, absorb, and retain information and make decisions. The second of the three elements is the patient’s understanding of this clinical information. The third element is the patient’s process of decision, based not only on what the surgeon has told them, but information they have been exposed to from other sources, including other physicians, family and friends, and perhaps an acquaintance who has had a similar procedure; what they have read by independently researching the problem; and their own emotional response to illness and all that it changes in one’s life. The ethical requirements of each of these three elements are now considered in greater clinical detail.

Disclosure obligations

No surgeon wants to be sued, lose patients’ confidence, or undergo the humiliation of admitting errors; all are among the distinct dangers of full disclosure. The spirit of informed consent, however, has ethically and legally replaced paternalism in surgery. Informed consent does not stop with the agreement to accept therapy [6]. Mutual decision-making by the physician and patient (or family, when the patient agrees or cannot participate) about treatment has the same ethical obligations throughout the course of therapy.

Kantian ethics suggest that although one must avoid deception, truth may be selectively told. Selective truth telling is the way personal lives are lived; one chooses to whom one discloses information or not, and the sensitivity or completeness of information disclosed. This ethical axiom does not apply in the surgeon-patient relationship concerning specifics of the patient’s condition and therapy. The physician must help the patient to understand both what is planned preoperatively and how treatment is proceeding.
The extent of disclosure is generally based on the physician’s identification of information that should influence diagnosis, treatment planning, and outcomes. This includes knowledge that the average layperson cannot be expected to have, but needs to know to participate meaningfully in treatment decisions and planning for the future.

The patient’s understanding

McKneally and Martin [7] examined the consent process before major surgery from the patient’s perspective. Several recurrent themes of patient’s mental processes were learned: a belief in surgical cure, enhancement of trust through the referral process, idealization of the specialist surgeon, belief in expertise rather than medical information, resignation to risks of treatment, and acceptance of an expert recommendation as consent to treatment. Those patients with serious illnesses, being sent to a specific surgeon or a specific institution, had already firmly committed to operative therapy and the consent process was a formality. Patients constructed their belief systems through faith before the informed consent process took place. Informed consent in surgical practice must respond to these ethical challenges and opportunities. The surgeon should consider informed consent as an ethically essential course of action that can be used to strengthen the surgeon-patient alliance with mutual benefits. Although surgeons hesitate to mention it and its real effect is unquantified, there is a noteworthy placebo effect in surgery [8] that should not be overlooked.

Apart from legal considerations that are minimal by professional moral standards, surgeons must always remember that having major surgery is one of the most stressful and fearful events of patients’ lives. The law emphasizes the physician’s role in the informed consent process. This is not surprising; patients bring tort actions against the physicians, not vice versa. The courts have not been asked to address the patient’s role in the informed consent process. Ethics addresses both the physician’s and the patient’s roles and responsibilities in the informed consent transaction. Ethical consideration goes on to evaluate what the surgeon has explained and what the patient has understood, the second substantive element in informed consent. Patients need to understand what surgeons tell them about a proposed surgical procedure.

More substantively, patients need to understand that they are being asked to authorize surgical management. Faden and Beauchamp [4] point out that this means that the patient must understand that by consenting to surgical management the patient authorizes the surgeon and surgical team to perform the procedure that the surgeon has described to the patient. The patient must also understand that the surgery cannot proceed without the patient’s permission.

Finally, the patient should understand what is being authorized [4,9]. The patient needs to grasp the nature of the procedure, its goals, its expected
duration, and what can be expected during the near- and long-term recovery process. Sequelae of surgery, particularly functional changes that affect job performance, valued activities, or sexuality, and aesthetic changes, such as the length and appearance of scar tissue, must be understood.

Documentation in the medical record

A well-crafted note in the medical record can be a valuable clinical aid to the surgeon, as a checklist and record of the information exchanged. The consent note should include a listing of the people in attendance, the description of the procedure in lay terms, the goal of the procedure as described (with any figures about failure rates), the major aspects or steps of the procedure that were discussed, the benefits and risks of the procedure which were discussed and the pertinent questions asked, as well as expectations for the course of both near- and long-term recovery. The note should specify that the patient authorizes the surgeon and surgical team to perform the procedure. The contents of the note can be reviewed with the patient and the patient encouraged to identify what is still unclear or confusing, so that these matters can be addressed.

The process of deciding

Patient’s psychology during consent

McKneally and Martin [7] found that many patients have already determined the absolute necessity of surgical therapy before seeing the surgeon and are focused on obtaining operations; the informed consent process should both supply the necessary information and serve to qualify the patient’s belief system.

The process of making an explicit decision by the patient on the surgeon’s recommendation is importantly placed as the third and culminating element of the informed consent process. In making their decisions about surgery, patients should appreciate that present conditions and actions have future consequences. The patient should be able to reason from present events to future consequences and have an adequately developed sense of the probabilities that these projected outcomes, called cognitive understanding, may indeed occur. The surgeon’s important role in the development of cognitive understanding includes correcting errors in the patient’s information, helping to augment the patient’s fund of knowledge, and helping patients grasp the nature and likelihood of the future consequences attendant on each of the therapeutic choices available to them.

In response to patients who desire only a small role in the decision-making process but want surgical management of their problem, the surgeon should nonetheless provide an explanation of the surgical procedure by reviewing the major issues, such as contents of the consent form. The surgeon should also prepare the patient for the immediate postoperative period with
a brief explanation of what this entails so that the patient is not surprised or alarmed when they wake up in the recovery area or surgical intensive care unit.

Patients considering surgery should also evaluate benefits and risks of the alternatives available to them. These are value judgments and concern how much worth to attach to potential favorable and unfavorable outcomes associated with each available option. Making such value judgments involves evaluative understanding, a clinical consideration overlooked altogether in the law governing informed consent. In making decisions about surgery, each patient needs to make value judgments about the benefits, risks, and discomforts of surgery; of other available medical interventions; and whether surgery or other invention is less dire than living with the risks and discomforts of untreated illness. Evaluative understanding is just as essential to the patient’s decision-making as cognitive understanding.

The surgeon can help the patient to develop evaluative understanding of available alternatives. Asking a patient, “What is important to you as you consider …,” with the ellipsis completed with each alternative, is effective in eliciting the patient’s values [10]. The surgeon should discern patterns of values in conversation with the patient and identify them for patients who are struggling to articulate what is important to them. Patients do not make decisions on the basis of isolated values, and helping patients to connect otherwise unarticulated concerns promotes individual autonomy. They might consider job performance, sexual activity, mental function, physical appearance, and, particularly important, hobbies of the retired to define their values. For example, it does not respect the values of a patient who is an avid hunter to place a pacemaker on the side of the chest from which the patient fires a shotgun while dove hunting. Such assistance also directs the surgeon’s relationship to the patient’s most fundamental values and beliefs because they give meaning to the alternative possible futures the patient must contemplate. Evaluative understanding is the area that may depart most radically from the surgeon’s own value system, requiring a nondirective approach. Once the patient has identified his or her relevant values and evaluated the alternatives on this basis, it is time for the surgeon to offer a recommendation.

The patient should not only feel free to ask questions, but should be encouraged to do so. The meaning of questions from the patient and the patient’s family is not always readily apparent. The first question of many patients is often, “How long will this operation take?”, and the surgeon should respond with an estimate of the customary range of time it has taken them to complete this procedure in the past. The surgeon should also understand that the real question being asked usually is, “When should my family begin to worry that things aren’t going well?”. To help patients with questions they have difficulty articulating, the surgeon may direct the conversation to questions that earlier patients have asked about this procedure, and invite the patient to discuss these questions in the context of their personal
concerns. Patients usually become relaxed enough to start asking their own questions and genuinely begin to seek information about the operation.

Respect for the autonomy of the patient means that the patient’s decision should be free of substantially controlling influences [4,11]. The physician should make a recommendation only after the patient has developed evaluative understanding without fear of bringing undue influence to bear on the patient’s autonomy. Most patients highly value the surgeon’s recommendation as they struggle to reach their own decisions. Appropriately timed recommendations play an important role in the informed consent process, and may even support the independent nature of the patient’s decision.

The ethics of the informed consent process emphasizes the role of this process in developing solid rapport with the patient. Such a rapport has a number of clinical advantages. First, the surgeon does not function as a disinterested and unbiased source of information, consulted as one might consult a book as a noninteractive source. Instead, the surgeon has important experiences and opinions with which to assist the patient in the decision-making process, not the least important of which are the technical information and knowledge of the patient’s personal medical history. Failure by surgeons to provide patients with the full range of their knowledge for fear of violating a patient’s autonomy could mean that the patient does not become genuinely informed, and ultimately defeats the high-minded principle the surgeon is seeking to protect the patient. Ultimately, no one knows more or is more intimately concerned about the details of the patient’s surgical treatment than the surgeon and the patient, which makes their mutually respectful cooperation essential to the process of genuine informed consent. Second, forming a therapeutic alliance with the patient through the informed consent process results in a more informed, prepared patient, who has developed a sense of individual responsibility in the transaction. Patient compliance may increase, leading to a smoother, more effective postoperative course. In an era of managed care, this outcome helps to promote the valued goal of the more economically efficient use of expensive medical resources, like surgery. Third, the open and honest two-way communication called for by the ethics of the informed consent process should increase the patient’s confidence and trust in the surgeon. This goes a long way toward establishing good rapport with patients, and advance the value of surgery for both surgeon and patient.

Definition of the process

Formed by this ethical analysis, the informed consent process becomes a process of mutual decision-making. The surgeon and the patient both have active and important roles in this process, and responsibilities to discharge. The surgeon, as the patient’s fiduciary, should share beneficence-based clinical judgment with the patient. As the patient’s fiduciary (ie, as someone who acts primarily to protect the patient’s interests), the surgeon
should also be committed to doing the right thing for the patient, but the ultimate decision about what is right for the patient rests with the patient. For this reason, the ethics of the informed consent process places strong emphasis on the surgeon’s respect for the patient’s autonomy.

Initiation of the consent process in the surgical holding area just before the operation is scheduled to begin should be avoided in all but the most urgent or most minor procedures. Instead, the discussion should be initiated well in advance of surgery because decisions should be made without added tension and with the time necessary to a major life decision. Outpatient visits for preoperative work-up provide an ideal opportunity to conduct the informed consent process.

Extent of the surgeon’s influence

The surgeon’s recommendations have a proper role in the informed consent process. Most patients value their surgeon’s recommendations and customarily give them considerable weight in their own decision-making process about whether to accept surgical management of their condition. In principle, surgeons exercise permissible influence through their recommendations.

Altering the frame of reference to influence the patient’s decision by excessively emphasizing either benefits or risks, a process termed “framing” [1], poses clinical ethical challenges. Framing is inconsistent with both the surgeon’s fiduciary role and with respect for patient autonomy, and should be avoided. For example, the surgeon may describe surgical risks as merely routine, as they may seem to the surgeon, and the benefits as certain. These descriptions may be consistent with the individual surgeon’s experience, but they are incorrect in terms of predicting the outcome for the specific operative patient and are deceptive. Inadvertently, a surgeon may seek to reassure a patient by making such statements as “I cannot remember the last time we lost a patient from this operation.” Framing in this manner before the patient decides to have surgery is ethically questionable, because the characterization can discourage development of the patient’s own critical evaluation.

Surgeons should also avoid a particularly corrupt and common type of framing commonly termed “crepe hanging.” This involves exaggerating the gravity of the patient’s situation, and of the operation, to increase the patient’s estimation of and gratitude toward the surgeon when things go well, as they were expected to by the surgeon in the first place. Should the surgery have a poor outcome, the surgeon has only to say that this is as he predicted and the patient nevertheless agreed to proceed.

Surgeons should also be especially aware of subtle framing effects that can occur when substituting descriptive terms for quantitative terms, especially in the characterization of risks. For example, the surgeon might tell the patient facing surgery for glaucoma, “You will lose your eyesight without the procedure.” The more truthful statement, however, is that a certain percentage
of people in this circumstance, perhaps 15% in this hypothetical case, lose
eyesight without the corrective procedure. Surgeons should adhere to quan-
titative descriptions whenever possible in the early steps of the informed
consent process and then help the patient to evaluate this information in
the steps concerned with cognitive and evaluative understanding.

Special circumstances during informed consent

Conflicting professional opinions

Patients occasionally encounter conflicting opinions among surgeons or
between the referring physician and the referral surgeon. Everyone in the
medical profession understands, but may not readily acknowledge, that clin-
ical judgment can vary widely among the specialties and even among prac-
titioners within the same specialty. For example, the referring physician may
focus on the operation’s morbidity risks, whereas the surgeon may be most
concerned about reducing disease-related mortality and so may discount, to
some extent, the inconvenience, cost, morbidity, and discomfort of the pro-
cedure [12]. The guiding principle when differences of judgment occur was
articulated two centuries ago by the Scottish physician John Gregory
(1724–1773). He emphasized that the surgeons and physicians should man-
age such disagreements with a view always toward protecting the interests of
the patient [12].

Consent with multiple physicians

The typical surgical patient receives ongoing care from physicians in several
specialties, including surgery, before, during, and after procedures. The ten-
dency exists in these team contexts to assume that others have already spoken
with the patient, have explained what is happening, and have taken the patient
through the informed consent process. This assumption can lead to a defective
informed consent process, especially regarding the surgical procedure being
contemplated. The operating surgeon should take a preventive ethics ap-
proach to this potential problem by accepting responsibility for taking the pa-
tient through the consent process for the operation. The anesthesiologist
should participate in this process with reference to the alternatives, benefits,
and effects of anesthesia options. All physicians, especially those in training,
should avoid giving answers to questions outside their specialty and about
which they are uncertain, and avoid areas apart from their expertise.

When multiple surgeons are involved, the surgical specialist who per-
forms the most essential and most complication-prone parts of the opera-
tion has the greatest responsibility regarding informed consent. This
physician should tell the patient who the other participants are and what
their roles will be in the patient’s care. This preventive ethics approach min-
imizes the chance that the patient will become confused or concerned about
the involvement of multiple surgeons.
**Patients who are undecided or refuse surgery**

Some patients may refuse surgical intervention after an adequate informed consent process because they are in a state of indecision. If the consent process has gone well, this indecision usually results from a patient’s ambivalence over similarly attractive alternatives. The patient may often also be frightened about having an operation and understandably may resolve indecision in favor of nonsurgical management of the condition.

In this case the surgeon should explain that the patient has caused no offense by being undecided. Such a decision, after all, does not preclude a decision for surgery later. In elective surgeries, the patient should be encouraged to think matters through and to determine if the decision will become more apparent with time. The surgeon should explain, however, that the postponement of surgical treatment, as cases of cancers, for example, may change the nature of benefits and risks. If the surgeon decides to remain on such a patient’s case, the patient should be so informed, and told that the surgeon will discuss the patient’s decision at any time. The canons of medical ethics and common courtesy are violated if the surgeon vocalizes disappointment, anger, or threatens to refuse future treatment toward the patient for not affirming trust in the consulting surgeon.

A patient’s refusal to have surgery is not itself evidence of the patient’s diminished decision-making capacity. Nonetheless, refusal when surgery is clearly indicated does raise a “red flag” and prompts any thoughtful surgeon to question the patient’s decision-making capacity, especially in potentially life-threatening circumstances. A patient who refuses such surgery without attaching importance to mortality, morbidity, or reduced quality of life causes a surgeon frustration and concern. Recent studies of noncompliance confirm that failure in communication can result in patient refusal of the physician’s recommendation, or noncooperation with a treatment plan [13].

The surgeon’s first response to refusal of surgery should be to review with the patient his or her understanding of the condition, the nature of the surgical procedure, and its benefits and risks. The patient’s cognitive understanding may be incomplete, and the patient may reconsider when more complete understanding has been developed. The surgeon’s second response should be to explore the patient’s evaluative understanding. Of particular concern should be possible mistrust of physicians (perhaps based on some prior experience); pressing obligations; or emotional factors like anxiety, depression, or fear. The surgeon’s third response should be to acknowledge value conflicts when they occur, and work with the patient to identify a management plan that accords with the patient’s values. If the surgeon believes that the patient’s values are supported by surgery, the surgeon should point this out and ask the patient to reconsider. The preventive ethics approach to refusal of surgery should be respectful exploration of the patient’s reasoning, on the assumption that patients, by their own lights, have good reasons for refusal but may, with additional information and reflection, reconsider.
and accept surgery. Surgeons should not assume that the patient’s competence is somehow diminished or compromised just because he withholds consent.

One very helpful response to refusals when surgery’s value in averting mortality is unclear is to offer the patient the alternative of a trial of nonsurgical management. Nonsurgical management may be supported by patient values that emerge during the consent process. The patient should be informed of this possibility and a mutual plan developed to monitor the nonsurgical trial of management. The goal should be to identify mutually acceptable criteria for evaluating the nonsurgical management and for reconsidering it. Should a patient be disinclined to accept surgery or any other invasive management as the first option, the surgeon could propose a trial of medical management and agree with the patient on the conditions under which the surgeon initiates surgical intervention. Such circumstances could include recurrent and worsening pathology, even on a regular schedule of medication, unacceptable side effects of medication, or increasing risk of mortality.

Problems with the patient’s decision-making capacity

Some patients may still experience difficulty making decisions, regardless of how ethically, astutely, and carefully the surgeon has attended to the informed consent process. The hospital’s consultation-liaison psychiatrist, a physician who has the expertise to evaluate patients’ decision-making capacity, can be a valuable advisor and ally. The patient should be told of the role of the psychiatrist to the extent that this is possible. The surgeon should make the following request. First, the psychiatrist should evaluate the patient for a formal cognitive or objective disorder or other psychiatric disturbance that might significantly affect the patient’s ability to make decisions, and then determine whether the condition is susceptible to treatment. Second, the psychiatrist and the surgeon should agree on a clear delineation of boundaries in their treatment of the patient. Each should understand what the other will do to restore the patient’s decision-making capacity and cooperate with one another. Third, the psychiatrist and surgeon should develop a plan for improving the patient’s decision-making capacity so that the patient is able to participate in the informed consent process. In all cases, the surgeon should not use consultation-liaison psychiatry simply to declare a patient incompetent [13], thereby enabling others to make decisions for the patient, or discharging the patient to the management of other specialties. Patients with waxing and waning decisional capacity often experience periods of lucidity, and may choose to provide informed consent for surgery during such a period, specifying that statements they may subsequently make while confused should not supersede decisions made during a period of lucidity. These have been called “Ulysses contracts” in the bioethics literature [1,14].
**Surrogate decisions**

Working up the patient who exhibits problems with decision-making capacity with the aid of consultation-liaison psychiatry should lead to the reliable identification of patients who have irreversibly lost the capacity to participate in the decision-making process. By common law and now in many states by statutory law, family members are asked to make decisions for such patients [15]. There is a stable consensus in the bioethics literature for how this process should occur [14].

Family members should not be asked, "What would you do?" or "What do you want to do?", because these questions invite family members inadvertently to mix up their own concerns and values with those of the patient. Family members should be asked what they believe is important to the patient at this time and in these circumstances. The goal is to try to construct what the patient's evaluative understanding is as closely as possible. On this basis, the remaining steps of the consent process should be completed. This leads to what is known as "substituted judgment" [14].

Sometimes, for a variety of reasons, family members cannot achieve substituted judgment. In such cases they should be asked to make the decision that in their view protects and promotes their loved one's interests. The best way to assist family members in these circumstances is to encourage patients to take a preventive ethics approach on their own. All patients in their geriatric years, those with chronic diseases, and those in the early stages of dementia should be encouraged to express their values and preferences in advance. Advance directives have legal standing in most states.

Surrogate decisions that inaccurately represent the patient's wishes are not ethically binding on the surgeon, provided the surgeon has a basis for reasonable certainty that the surrogate is mistaken before acting contrary to the surrogate's instructions [14]. When the disputed decision is important enough, the court can be petitioned for appointment of a conservator. Surrogate decision-making fails to reflect the patient's wishes accurately in 70% of important treatment issues [16]. If the surgeon chooses to override the faulty surrogate decision when the surrogate is otherwise entitled to control an important decision, surgeon-family conflicts are likely. It is wise to notify the institutional ethics committee or chief of staff in such cases.

**Pediatric consent**

As a matter of law, parents are in authority over their minor children and are empowered to engage in the informed consent process on their child's behalf. Minor children, however, are not mere objects; they have their own values and preferences for how they want to receive health care. The American Academy of Pediatrics supports the view that children should participate in decision-making commensurate with their developmental capacity [17]. Pediatric surgeons confront conceptual and clinical challenges regarding pediatric assent. Adolescent patients, particularly those with
chronic diseases about which the patient has become quite knowledgeable and mature, may be able to complete the steps of the informed consent process as well as adults. When this is the case, the patient’s autonomy should be respected by the surgeon and by the adolescent’s parents. In these circumstances the surgeon’s responsibilities include pointing out to the parents that their child is capable of making an adult decision that deserves respect. When there are differences between parent and child, the surgeon should offer his or her services as a good-faith negotiator. The goal should be to reach a commonly accepted decision rather than to decide whose decision wins.

Not all adolescents can complete the informed consent process, nor can younger children. Nonetheless, children are capable of understanding to a degree appropriate to their age and emotional development that they have a disease, what parts of the body the disease involves, and that surgery can help. These matters should be explained to the patient, when the goal is not so much to obtain the patient’s consent as to provide information about the clinical course to which the patient’s parents have already consented. This concept has led to such practices as familiarizing children with the hospital, including operative and postoperative areas, before elective surgery.

*When supervised trainees do the surgery*

The medical profession has an ethical and social obligation to educate physicians and surgeons to meet the needs of future generations of patients. The first teaching hospitals in America were modeled on the British infirmaries and funded from public and private sources. These hospitals provided free care to the poor, and were seen by academic physicians as training sites where a presumed sense of reciprocity obligates indigent patients to serve willingly as teaching material in exchange for their care [18]. This assumption is now considered incompatible with the process of informed consent, which is understood to include the patient’s awareness and agreement that trainees may participate in the treatment process. The American Medical Association Council on Ethical and Judicial Affairs has established a clear position on the relationship between patients and trainees on clinical rotations: “Patients should be informed of the identity and training status of individuals involved in their care, and all health care professionals share the responsibility for properly identifying themselves” [19]. Before patients can accept the role of teaching subject, they must be made aware that they have been offered the part.

*Informed consent in research*

Some ethical constructs, particularly those involving informed consent and the conduct of research, have been so uniformly accepted as necessary to the rights of patients and the integrity of scientific method that they have
been codified into international declarations and federal law. Sade [20] summarized the various historical proclamations and their ethical implications in scientific publication. Once surgery embarks into research, surgical autonomy has compelling ethical limits. When the selection process for a medication, graft, or implant is randomized or preassigned, when the choice is not primarily determined or influenced by the patient’s individual clinical characteristics, or when the clinical outcome cannot be predicted and alternatives exist, the procedure must be considered clinical research rather than clinical care, and the laws, customs, restrictions, and ethical considerations specific to research become applicable. Surgeons must modify their own behavior accordingly, and observe the legal and ethical conventions that ensure integrity of scientific investigation and the safety of research subjects. Institutional approval must be sought and received before initiation of a research study to ensure the soundness of the science and the safety of patients.

References

