

EDITORIAL

First, We Do Harm: Obtaining Informed Consent for Surgical Procedures

Curt Tribble, MD, Walker Julliard, MD

Division of Cardiac Surgery, University of Virginia Health System, Charlottesville, Virginia, USA

INTRODUCTION

The informed consent process is the place where the surgeon and patient arrive at an acceptance by the patient that authorizes the surgeon to risk harm to the patient in order to be helped and trusts the surgeon's skill to accomplish the healing.—James Jones and Laurence McCullough [Jones 2015b]

Although many believe that the phrase “First, do no harm” was part of the Hippocratic Oath, in fact it was not. This phrase, often written in Latin (“Primum non Nocere”), seems to have first appeared in medical writing in the 17th century. However, it is obvious that many therapeutic interventions do cause at least some harm with hopes of benefitting patients in the long run. This balancing of initial harm in hope of eventual benefit is never more apparent than in the case of invasive procedures, though other examples abound, such as the administration of chemotherapy. The ethical concept of nonmaleficence, which traces its origins to the concept of *primum non nocere*, accurately acknowledges the concept of the need to strive to do more good than harm. Thus, it is apparent that, in a surgical operation, the surgeon is proposing to cause harm, initially, to the patient in hopes of creating an outcome that results in more good than harm. Therefore, the process of obtaining consent from the patient for a surgical operation acknowledges the fact that harm will, in fact, be inflicted on that patient, with the hope that, on balance, this harm will result in a greater overall good for the patient. It is for this reason that the modern concepts of informed consent have developed.

The clinical skills required in the informed consent process tend not to be taught to fellows, residents, and medical students within the formal curriculum.—Laurence McCullough, James Jones, and Baruch Brody [McCullough 1998]

Although every surgeon must understand the process of obtaining consent for invasive procedures, the background, principles, and strategies necessary for accomplishing this crucial aspect of caring for patients are rarely taught in an organized manner. It is essential that both the surgeon and the

patient clearly understand that the consent process will authorize the surgeon to cause at least some harm while attempting to help the patient. Therefore, we will attempt to outline the basic concepts involved in obtaining informed consent from patients for surgical procedures and to offer some specific suggestions to facilitate and optimize the consent process.

There are many challenges in understanding the various aspects of obtaining informed consent. These challenges include legal issues, ethical considerations, and the relative lack of experience that many patients have with complex decision making. Though the focus of this treatise will be on the basics of obtaining consent for surgical procedures, there are many ancillary issues that must frequently be taken into account, such as religious beliefs, ethical issues, legal considerations, work-flow challenges, and the nearly all-inclusive aspects of obtaining consent for surgery, such as the often underemphasized fact that some form of anesthesia will be part of most procedures and, therefore, consent to receive anesthesia or sedation will generally be assumed to be part of the consent process. Finally, we will not attempt to cover more complex situations involving informed consent, such as obtaining consent for end-of-life care, participating in research protocols, or other special situations, such as care involving minors.

LEGAL CONCEPTS OF CONSENT

The foundation of the informed-consent process is the surgeon's deliberative judgment that a technically possible procedure is expected to result in net clinical benefit.—Jones and McCullough [Jones 2015a]

“Simple consent” revolves around the most basic of questions, which is: did the patient agree to be treated in the manner described by the practitioner who is obtaining that patient's consent? In recent years, this legal concept has been divided into 2 questions, which are:

- Did the physician provide the patient with adequate information?
- On the basis of that information, did the patient give consent?

There have been 2 standards used when describing the adequacy of informed consent, and these standards are called “the professional practice standard” and “the reasonable person standard.” The professional practice standard has, relatively recently, been replaced by the reasonable person standard, which places the obligation on the practitioner to

Correspondence: Curt Tribble, MD, Professor of Cardiothoracic Surgery, University of Virginia Health System, Division of Cardiac Surgery, Box 800679, Charlottesville, VA 22908; 434-243-9250 (e-mail: ctribble@virginia.edu).

provide clinically relevant information to the patient, including the expected benefits of the recommended treatment, the potential discomfort and risks, as well as the possible limits of the effectiveness of the proposed therapy, in a manner that a reasonable patient would consider appropriate for making a decision on whether or not to accept the physician's recommendations. This approach is considered to create a shared responsibility between the physician and the patient. However, it has also been acknowledged that the physician cannot generally be expected to provide the patient with the depth and breadth of information that would be provided to another medical practitioner.

Informed consent consists of 3 general elements, which include:

- Disclosure by the surgeon,
- Facilitating understanding by the patient, and
- Assuring that the patient has given voluntary consent.

These 3 elements will be described in more detail below.

DISCLOSURE AND OTHER ETHICAL ISSUES IN OBTAINING CONSENT

While the courts seem satisfied when the patient is educated to the point that she or he has a "rough understanding" of what is being proposed, as a matter of ethics, the conscientious surgeon should not be.—McCullough, Jones, and Brody [McCullough 1998]

The disclosure expected of the surgeon entails educating the patient about his or her diagnosis, the therapeutic alternatives available (including both surgical and nonsurgical therapies), the benefits and risks of each alternative (including the natural history of the condition if left untreated), and, crucially, an honest explanation of the degree of uncertainty that exists for each course of action.

It is also commonly understood that practitioners must disclose to the patient any conflicts of interest that might exist regarding their recommendations. These conflicts are generally thought of in economic terms, such as when a provider recommends a treatment from which that practitioner might benefit financially. However, a more subtle type of disclosure involves acknowledging that different providers or different clinical environments may have substantially different outcomes for a given condition or procedure, as it has been increasingly understood that "a reasonable person" would consider this information important to his or her decision making [Woo 2019] ("You Are the Perfect Age" [Tribble 2019]). Above all else, the surgeon must avoid coercing a reluctant patient to agree to a recommendation, either overtly or subtly.

FACILITATING UNDERSTANDING BY THE CONSENTING PATIENT

The good physician treats the disease. The great physician treats the patient who has the disease.—Sir William Osler

A key element of informed consent involves ensuring that the patient and the patient's family understand the clinical information being provided.

A very important aspect of optimizing these crucial conversations with a patient is that the physician must sit down when speaking with that patient (*A Little Book of Doctor Rules III* [Meador 2018]). Another important aspect of optimizing understanding in these discussions is that you must, if at all possible, have a family member of the patient present ("Grandmother Rules" [Tribble 2017a]). Another important facet of ensuring understanding is to consider the possibility of language barriers. For instance, if the patient is not a native English speaker, one must utilize an interpreter, regardless of how fluent the practitioner may be in the primary language of the patient. The need for an interpreter also applies to the deaf population. Many people assume that these patients can read English; and, although this is the case for most American Sign Language (ASL) users (especially ones who have been educated in more recent years), it is not always true. Many health care providers believe that they do not need to have an interpreter present because they assume that writing back and forth will be sufficient. However, relying on this approach can place a significant burden on the patient, since the intricacies of the surgery, risks, and postoperative expectations can be lost [Sadler 2001]. Finally, physicians must present themselves professionally. Although it is always important to act and appear as a competent physician, this issue is likely rarely more important than when discussing difficult and potentially risky procedures with patients and their families. You simply cannot show up dressed sloppily, such as having your lab coat buttons in the wrong button holes or having soiled shoes or clothing. You must do your best to present yourself in a manner that inspires confidence.

When we know something, it's difficult to recognize when someone else doesn't.—Lisa Rosenbaum, MD [Rosenbaum 2019]

Another challenge frequently facing the clinician obtaining consent is assuring that the patient understands what the physician has conveyed to them. Thus, the physician must make an assessment of the degree of comprehension of the patient. And, we must constantly remind ourselves of how daunting it can be to recognize when a patient is not grasping something that seems quite obvious to us. Thus, we must help our patients absorb, retain, and recall what we have told them.

It has been said that the level of complexity of a conversation of this sort should not exceed the understanding of someone with a 10th-grade education. It is also important for the physician to be aware of possible changes in the patient's level of attention and to help the patient be comfortable asking questions without apprehension or embarrassment. In this context, saying "now, that is a very good question" will always be well received. You should always leave time for additional questions, without making the patient or the family feel rushed. Furthermore, you must also find ways to respectfully dispel unfounded beliefs or unrealistic expectations that seem to be held by the patient (Everything Happens for a Reason [Bowler 2018]).

*Still, a man hears what he wants to hear
And disregards the rest*—"The Boxer," Simon and Garfunkel

The physician must be able to discern whether the patient is able to think through his or her current condition and to have a reasonable understanding of the future consequences of decisions about the therapeutic alternatives being discussed. The ability to assess the understanding of a wide array of patients is a clinical skill that all physicians should strive to attain.

It is worth noting that many of our patients will have quite limited experience with, or understanding of the process of, making high-stakes decisions, especially those that involve many factors, choices, and unfamiliar issues. Thus, many patients will naturally tend to try to simplify their decision-making strategies as much as they can. Some colorful examples of this sort of simplification include having the mindset of thinking in terms of a “Hobson’s choice” (a binary choice, defined as a “take it or leave it” choice) or of “Pascal’s wager” (a decision-making strategy about the existence, or lack thereof, of God, described as a “no lose” proposition) (see Endnotes for more information on Hobson’s choice and Pascal’s wager). The need for the clinician obtaining consent to understand the level of decision-making sophistication of the patient requires that practitioner “meet the patients where they are” in order to help them understand the expected benefits and the potential risks of the procedures being proposed.

Annie Duke, in a recently published book, *Thinking in Bets*, describes how humans have evolved to seek certainty and order, which leads many people to be uncomfortable acknowledging that luck plays a significant role in the outcome of the decisions that we make. In other words, people tend to resist the idea that things may not work out the way they hope [Duke 2018]. Therefore, people in general, and patients in particular, need to understand that many medical recommendations and decisions depend on choosing between “shades of gray.”

Statistics always remind me of fellow who drowned in a river where the average depth was only three feet. —Woody Hayes, former Ohio State Head Football Coach

It is also pertinent to note that most patients do not truly comprehend statistics, especially when conveyed to them in an overly granular way. It has been pointed out that the most common experience that a patient of average education has with statistics is their experience with weather forecasts. However, even when asked to describe, in plain terms, what a certain weather forecast actually means, most ordinary people cannot offer a concise explanation.

Because every surgeon performing major visceral procedures has had patients die when it was thought they would live and live when it was considered they would die, the point should be made—without “crepe hanging”—that there are no guarantees regarding major operations. —Jones and McCullough [Jones 2014]

On a similar note, it can be useful to explain to a patient the difference between likelihood and consequence. For most patients, translating statistics into stories, while describing the range of possible outcomes, will be an effective approach to

helping them understand the desired benefits and potential risks of the recommended treatment. A fairly straightforward way to convey the fact that every operation has risks, even the risk of mortality, is to note that there can be no absolute assurance of the hoped-for outcome in major surgical operations.

BEST CASE/WORST CASE: AN AID IN FACILITATING UNDERSTANDING

One of us (W.J.) had the opportunity to work with a group of physicians and surgeons at the University of Wisconsin, led by Margaret “Gretchen” Schwarze, MD, who have an interest in improving how surgeons communicate with patients and families facing decisions about high-risk procedures. This group has described its process as the “Best Case/Worst Case framework.” The process developed by this group was designed to facilitate shared decision making between patients, their families, and their care providers, particularly in high-stakes settings, with an emphasis on achieving what they describe as “value-concordant treatment decisions” while seeking to minimize unwanted care [Taylor 2017].

These authors describe the use of scenario planning and the concepts of shared decision making in the development of their Best Case/Worst Case framework. This framework utilizes narrative descriptions and hand-drawn graphic aids to facilitate communication between surgeons and their patients and their patients’ families. The authors recommend using stories to describe the various possible outcomes of different therapeutic interventions, with an emphasis on how the patients might experience these outcomes, while considering the individual patient’s goals and beliefs. More specifically, they recommend asking questions, such as: “What’s important to you? What is it that makes life worth living for you?”

This group’s research has shown that this approach can help surgeons conduct challenging conversations in a way that supports their patients and their families [Taylor 2017]. This group has also created an excellent video that illustrates this process in a very engaging and effective manner [Best Case/Worst Case 2019].

MAKING A RECOMMENDATION AND ASSURING VOLUNTARY CONSENT

No mortal condition can be treated without risk, and that risk is often substantial. —O. H. “Bud” Frazier (C. T. indicates having heard Frazier say this statement on many occasions.)

After a full disclosure and explanation, the surgeon should make a recommendation. This recommendation should include an acknowledgment that no therapy is without risk and that no one can know with certainty how circumstances will evolve in any individual case. The surgeon should be prepared, in all situations, to accept the patient’s choice of treatment, once the patient seems to have understood the therapeutic options. However, after the surgeon’s providing a full explanation of a potentially complex situation, when offered a choice that has a result of slim to none, a patient will often choose slim.

Allowing the patient to make a specific decision about the recommended treatment is, arguably, the most important part of the consent process. The patient must be able to appreciate his or her current condition and the consequences of the choices to be made by him or her about the therapeutic options being offered.

Voluntary consent refers to the decision making of the patient, who should take into account not only the information that the surgeon has provided but also information from other sources, which allows the patient to arrive at his or her personal interpretation of the benefits and the burdens of each potential therapeutic option. Ultimately, it must be clear that the patient has agreed to be treated.

THE RIGHT TO REFUSE

It must be acknowledged that the patient has the right to refuse the recommended plan if he or she is competent, even if refusal may result in disability or death. The existence of advance directives can be helpful in these settings, of course. If the patient refuses the recommended plan, that refusal does not mean that the patient is declining all care. The provider should offer the next best treatment alternative, even if that alternative is comfort care. The patient may be asked to sign an against medical advice (AMA) form, which can make it clear that the patient is refusing the recommendations being made and which may protect the provider from subsequent scrutiny of the decisions made in conjunction with the patient.

On the other hand, a patient's refusal of the recommended treatment may be ignored if the provider believes that the patient does not have adequate decision-making capacity due to injury, emotional stress, or intoxication or if there is an emergency situation in which the "average, reasonable person" would consent to the treatment. Dealing with these issues in greater detail is beyond the scope of this review.

DOCUMENTATION

Nothing so focuses the mind as the prospect of being hanged. — Mark Twain

At this point, the surgeon must obtain formal written consent from the patient. This requirement recognizes the reality that, when putting one's signature on a consent form, the patient will be as focused on his or her decision as at any point in the consent process. The physician must document that the patient has provided voluntary consent to have the treatment that has been recommended. The components of voluntary consent that must be documented in the consent document include a description of the condition that warrants the proposed treatment, the purpose and benefits of this course of therapy, the possible adverse events that could ensue, and the consequences of not accepting the recommendations being made. The consent document must then be signed by the patient, the provider, and a witness.

Although it has been common to have an associate of the surgeon, such as a nurse, supervise the signing of the consent document, in recent years some courts have held that this moment of documenting the final decision is so important that it should not be delegated to a subordinate.

It is also crucial, at the point of the signing of a consent form, to ask explicitly who will make decisions for the patient at any point that the patient is unable to provide consent, such as during an operation. Addressing this issue need not sound like an "end-of-life" discussion. Rather, it can be addressed as a routine, practical matter, given that most will acknowledge that there will almost always be at least some period of time when the patient is sedated or anesthetized and, therefore, will be unable to participate in decisions that might need to be made under those conditions. However, this can also be an appropriate time, in some situations, to allow the patient to give end-of-life instructions ("Knockin' on Heaven's Door" [Tribble 2017b]). Finally, as noted, the consent form must be witnessed, usually by a second health care provider who has participated in the consent process.

FORMING A THERAPEUTIC ALLIANCE

We consider informed consent a morally essential course of action that the surgeon should utilize to form a strong therapeutic alliance with the patient. —McCullough, Jones, and Brody [McCullough 1998]

In the process of obtaining consent for an operation or a procedure, the physician having this discussion with a patient must balance encouragement with reality. This process should allow the patient and the patient's family not only to understand the procedure, its expected benefits, and the accompanying risks, but also to understand the collaborative nature of the care to be provided. This process is almost always an ongoing one, beginning with the practitioner and the patient getting to know each other to the degree possible and then transitioning to helping the patient understand the reasons the procedure is being recommended, including the expected benefits, while describing accurately the possible risks or unexpected outcomes. This process, when handled adroitly, will help forge an alliance with the patient and the patient's family.

PREPARATION OF THE PATIENT FOR THE PROCEDURE

Anxiety does not empty tomorrow of its sorrows, but only empties today of its strength. —Charles Spurgeon, 1834–1892

As an important part of helping the patient make a decision to move forward with a procedure, the surgeon and his or her team should also prepare the patient for the postoperative period so that the patient and the family will not be surprised or alarmed by the circumstances that are likely to be encountered, as noted by David Richardson, MD, who has himself had numerous operations and has written about his experiences as a patient to enlighten his surgical

colleagues about these issues [Richardson 2018]. Descriptions of what the patient and family might expect need not, however, be overly dramatic. Discussions of this sort should be couched in terms of how the surgeon and the surgical team will strive to care for the patient in manner that will afford as much comfort, care, and pain relief as is feasible.

We must remember that, to the extent that the patient is inclined to trust the advice and competence of the surgeon and to exercise a measure of denial to prepare for the ordeal ahead, the zeal to disclose should NOT breach these emotional defenses and deprive the patient of his or her comfort [caps for emphasis added]. —McCullough, Jones, and Brody [McCullough 1998]

However, the surgeon and the surgical team need to judge how much an individual patient and that patient's family actually want to know. Sensitivity to these issues is an important clinical skill that can be learned, particularly as one gains experience with these crucial conversations.

Hope is a powerful ally, our last defense against despair. As physicians, we must never give our patients false hopes or unrealistic expectations. But neither should we deny them the comfort that hope can bring. —Roger Bone, MD [Bone 1997]

The delicate balancing of facts and feelings takes on even more importance with the highest-risk operations, as most clinicians understand the appropriateness of allowing a patient and that patient's family to retain hope in order to have the optimal mindset when preparing themselves for an operation, particularly one that all involved understand may have substantial risk. A strategy we have found particularly useful in helping shift these kinds of conversations towards a more optimistic tone is to ask the patients what they will do when they are well again (“Gimme 3 Steps” [Tribble 2016]). Virtually every patient will have an answer to that question, we have learned. Once the patient has described what he or she wants to do when well, we find it very helpful to tell the patient to keep focus on that plan, while “leaving the worry to us.”

Just give me one thing that I can hold on to. —“Angel from Montgomery,” John Prine

Finally, since parting words can frequently be the most memorable, we have found it useful to close such a conversation on a positive note, saying something like “we will hope for good things.”

CONCLUSIONS

I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel. —Maya Angelou

In summary, gaining a full understanding of the consent process, while somewhat daunting, is crucial for almost all clinicians. It is also important to recognize that this process is not

merely a formality but an opportunity to forge a “therapeutic alliance” with the patient and the patient's family. Although this process may become fairly routine for most clinicians, we should never lose sight of the fact that these discussions are likely to be among the highest-stakes discussions that a patient and that patient's family will ever have in their lives. We owe it to our patients and to their families to approach these discussions with this reality firmly in our minds.

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ENDNOTES

Things to Say or to Avoid Saying While Obtaining Consent

Noteworthy (good things to consider saying)

In surgery, first we do harm, while hoping to help patients in the long run.

There are no guarantees regarding major operations. The vast majority of our patients do well, but not by much.

What is important to you? What makes life worth living for you?

No mortal condition can be treated without risk, and that risk is often substantial.

We will hope for good things.

It's a privilege to try to be of help.

Now, that is a very good question.

We know what to do when reality goes sideways.

The rate-limiting step may be . . .

There's a lot to unpack.

We can't unoperate.

We can, and will, figure it out.

This work is not for the faint of heart.

Everything has a price, and miracles are no exception.

Surgeons know that there is no occupation where so much is on the line every day.

In high-risk operations, the surgeon is not completely in charge.

Cringeworthy (things to avoid saying)

Everything happens for a reason.

It'll be fine.

All bleeding stops.

The fault may be in your stars.

A miracle happens here every day.

It just adds to the mystery.

Trust me on this.

Hobson's Choice

Thomas Hobson kept a livery stable in Cambridge, England, in the early 17th century. He rented horses to the university students of that city. The students often had a favorite

steed, so Hobson devised a plan to keep his horses from being overworked. Thus, the students were given the choice of taking the horse nearest the stable door or none at all. This plan became known as “Hobson’s choice,” which eventually came to mean “a choice between one thing and nothing” or “no choice at all” in a wide variety of situations [Hobson’s choice 2019].

Pascal’s Wager

Blaise Pascal was a French scientist and philosopher, who is remembered for, among many reasons, writing about the existence, or lack thereof, of God. He proposed the following thought experiment:

I have a binary choice:

I believe God exists.

I do not believe God exists.

The consequence of believing God exists is:

If, indeed that is true, I will gain infinite happiness.

If, however, that is not true, I will have no payoff.

The consequence of believing God does not exist is:

If, indeed that is not true, I will gain infinite unhappiness.

If, however, that is true, I will have no payoff.

Therefore, by believing in God:

I have everything to gain.

And, I have nothing to lose.

And, by not believing in God:

I have everything to lose.

And, I have nothing to gain.

(See <https://philosophy.lander.edu/intro/pascal.html> [Philosophy 102: introduction to philosophical inquiry: Pascal’s wager].)

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