Published in final edited form as:

Surgery. 2016 June ; 159(6): 1684–1688. doi:10.1016/j.surg.2016.02.006.

Ethical challenges of reconsidered informed consent in trauma

Ema Zubovic, BA^a, Ira J. Kodner, MD, FACS^b, Douglas Brown, PhD^b, Grant M. Kleiber, MD^a, Thomas H. Tung, MD^a, and Jennifer Yu, MD^b

^aDivision of Plastic and Reconstructive Surgery, Washington University School of Medicine, St. Louis, MO

^bDepartment of Surgery, Washington University School of Medicine, St. Louis, MO

CASE

A 27-year-old, right hand–dominant man with partial amputation of 4 digits of his dominant hand from a machinery accident was transferred by helicopter for possible replantation. He had a sharp, guillotine-style, near-amputation of his right index through ring fingers at the level of the middle phalanges and a near-complete amputation of the tip of his small finger. Five hours of warm ischemia time had passed. Three of the 4 fingers were deemed suitable for replantation, and urgent operative intervention was recommended.

Risks and benefits of attempted replantation were explained to the patient (including the prolonged duration of operation and hospital stay, possible inability to revascularize any of the 3 fingers, requirement for intensive postoperative hand therapy, need for additional operations secondarily to maximize finger mobility and function, a total recovery and rehabilitation process lasting one year or more, possibility of multiple returns to the operating room acutely, blood loss requiring transfusions and blood products, and the possibility of failed revascularization and need for revision amputation). The patient expressed regret that his wife was not present for this discussion (she was 1.5 hours away by car), but he confirmed his understanding of the risks, gave verbal consent, and signed the consent forms. In the process of obtaining informed consent, however, the operative team realized that the patient had received substantial doses of narcotic pain medication prior to arrival.

In the interval between the consent discussion and transfer to the operating room, the patient developed concerns about his postoperative course, specifically commenting on the duration of hospital stay and the inability to smoke cigarettes after the revascularization. He expressed concerns about losing his house for inability to pay rent, not having sufficient childcare for his 6 stepchildren, and being expected to go without cigarettes postoperatively. He then requested completion amputation of his fingers instead of proceeding with the revascularization.

Reprint requests: Jennifer Yu, MD, Department of Surgery, Washington University School of Medicine, St. Louis, MO 63110. j.yu@wustl.edu.

The authors report no conflicts of interest.

THE ETHICAL DILEMMA

The operative team considered 4 clinical options:

- 1) Proceed with the operation based on the patient's original consent.
- 2) Cancel the planned procedure and proceed with revision amputation instead.
- 3) Repeat the discussion of risks, benefits, and postoperative care to clarify the patient's understanding and reasons for refusal, and give the patient the option of consulting a family member or other decision-making assistant.
- 4) Conclude that the patient does not have decisional capacity and search for a surrogate decision-maker.

DISCUSSION

Option 1: Proceed with the operation based on the patient's original consent

Replantation is a time-sensitive, limb-threatening emergency. The patient's life is not at risk, but his dominant hand will be essentially nonfunctional with a 4-finger amputation, which will impact his functional capabilities, especially considering that this is his dominant hand. The generally accepted indications for proceeding with replantation are (1) amputation of the thumb at any level, (2) amputation of multiple digits, (3) amputation of any digit in a child, and (4) proximal amputations at the midhand, wrist, or forearm level. With the exception of pediatric replantations, which generally have a high level of resultant function, the criteria are based on the high degree of functional impairment with each listed amputation. The patient fulfills the criteria of the second category, with a multidigit amputation considered favorable for attempted salvage given the sharp mechanism of injury.

The investment (time, effort, financial) in finger replantation is considerable and more extensive than most realize. Months of intensive hand therapy are required, usually followed by additional operations to release scar tissue and maximize finger mobility and function. The additional operations are followed by even more months of aggressive hand therapy. Any complications, such as infection or bony nonunion, require additional procedures. Despite the surgeon's and patient's best efforts and diligence, there are no guarantees on the final level of function. At best, a mildly stiff, shortened but moderately functional finger is realistic. At worst, a completely stiff, painful, nonfunctional finger is not uncommon, with the patient ultimately desiring a completion amputation, because the finger actually impairs overall hand function.

If there is any doubt about the patient's capacity to give informed consent, performing a revision amputation precludes any further attempts at digit salvage. Replantation, however, can be converted to amputation at any time. Alternatively, a revision amputation of a single noncritical digit may have minimal effect on overall hand function and is often the preferred choice by those who are well informed and have a priority to minimize their recovery time, return to work, and resume their normal routines as quickly as possible. Many of these patients will return to work the next day with only restrictions on the injured hand. No further operative intervention is usually required, and the duration of hand therapy and the

recovery process by comparison are minimal. In this case, a 4-finger amputation is clearly debilitating and would result in substantial permanent impairment and disability.

The ethical justification for proceeding with the patient's operation rests on the judgment that he had decisional capacity at the time he consented to the operation. His subsequent reservations conflicted with his previous consent. Should the operative team pause and attend to his concerns, given the likelihood of benefit from attempted revascularization? The patient meets medical indications for proceeding with replantation, and the surgeon's prerogative is to attempt to salvage the severed digits. In the surgeon's experience, the vast majority of patients would choose to proceed with replantation in a comparable situation, and the surgeon's motivation to operate may be strong enough that the patient's concerns are not given sufficient weight to alter the management plan.

The patient had clearly consented. His subsequent hesitations could be viewed as common expressions of anxiety and fear in anticipation of the planned procedure and postoperative course. Consent, however, is not given just by signing a form.¹ The consent form itself has no legal bearing---it must be present in the medical record, but it is not binding to the patient, and he may choose to exit the agreement at any time. It is not the consent form but rather a detailed note in the medical record---preferably by the attending surgeon---documenting the consent discussion (including risks, benefits, and alternatives; the recommended plan; and importantly, the patient's stated understanding of the conversation) that serves to uphold an appropriate and ethical preoperative consent process.

Schwarze et al² define the complex patient-surgeon relationship, termed "surgical buy-in," as a mutual informal agreement in which the surgeon commits to perform a given operation, and the patient in return commits to participate in the anticipated postoperative care. The surgeon's and the patient's responsibilities in this buy-in are different: the surgeon commits to performing the operation to his/her best abilities, and the patient commits to participating in a possibly arduous postoperative period. To ensure the best possible outcome, these responsibilities should be established prior to embarking on any such operative intervention. Nonetheless, a surgeon should never use the signed consent form to transfer responsibility for a poor outcome to the patient. The patient's signature represents his agreement to the procedure, but the surgeon maintains responsibility for all consequences of the operation.

Consideration of patient autonomy, however, makes it difficult ethically to justify operating on a patient who has decisional capacity and is explicitly refusing operation. Furthermore, operating on a patient who has not bought into the postoperative care necessary for a successful outcome is questionable ethically.

Option 2: Cancel the planned procedure and proceed with revision amputation out of respect for patient's self-determination

A patient's decision not to proceed with a medically indicated operation conflicts with a surgeon's desire to operate for the patient's benefit. The patient in this case meets criteria for replantation, with a guillotine-style injury to 4 fingers and favorable ischemia time.³ Because the situation is urgent but not a life-threatening emergency, the decision to proceed to the operating room should rest with the patient's choices in guiding his care.

This case presents a conflict between medical indications and patient autonomy. Prioritizing beneficence argues for attempted replantation of the severed digits---ie, doing good for the patient and giving him the best chance at achieving an intact and possibly usable hand. In contrast, amputation would provide a more rapid return to work and home, which may be more meaningful to him. Though replantation may be highly successful in achieving tissue viability, there is a substantial risk of poor functional outcome, need for future amputation, and requirement for prolonged postoperative therapy.³

Educating the patient about these risks and benefits in the discussion of informed consent allows him to make a choice about the direction of his care, which may not be the surgeon's recommended course of action. The patient's decision not to proceed with replantation should be honored if the patient demonstrates sufficient understanding of the consequences of his choices. McCabe et al⁴ note that "differentiating irrational choices from those based on different but rational values and beliefs might be difficult," but this is a crucial distinction when a patient's wishes differ from the recommended course of action.

This patient gave specific, coherent reasons (eg, loss of salary, possible inability to pay rent, and lack of sufficient childcare) for refusing the procedure that should be considered a sign of intact decision-making capacity. He also indicated he would not abstain from cigarettes postoperatively, which would compromise the viability of the replanted digits. Operating on a patient unwilling to accept the burden of postoperative care also impacts the resources of the health care system. Choosing amputation may be the most favored option from both the patient's and the operative team's perspective. The reason for the noted decline in the number of finger replantations performed nationwide is that the potential and sometimes theoretic benefits of replantation do not always clearly outweigh the long rehabilitation process or cost to the health care system, nor do they always justify the final functional outcomes.

Option 3: Repeat the discussion of risks, benefits, and postoperative care to clarify the patient's understanding, and give the patient the option of consulting a family member or other decision-making assistant

Truly informed consent requires that the patient has a sufficient understanding of the proposed procedure to agree to or refuse the procedure.⁵ It is the physician's responsibility to explain the nature of the intervention, its associated risks, benefits, and possible alternatives and to give a medical recommendation. The patient's comprehension depends on multiple factors, including his literacy, the adequacy of the physician's explanation, and the patient's mental state and decision-making capacity at the time of the discussion. In the setting of an acute injury, a patient's comprehension may be compromised by pain, drugs, fear, and anxiety, creating a potential for selective hearing and unreliable decision-making.

If the patient's comprehension of any of the elements of the discussion of informed consent is in question, the physician should take the time necessary to revisit any and all subjects to ensure the patient has a sufficiently sound foundation for his decision. Informed consent discussions are often hasty and abbreviated in the acute setting. It is often appropriate to repeat the discussion with the patient in a more methodical manner. Rather than categorically accepting the patient's decision or conversely, dismissing the patient as lacking decisional capacity, the physician should "diagnose and treat the patient's decision-making

problem”⁶ to help the patient make a reasonable decision. If that decision is still to decline the recommended operation, the physician should defer to the patient's wishes.

Given the consequences, the physician and patient may involve someone from the patient's support network to assist the patient in considering the decision of whether to proceed with the operation. This step does not amount to naming this person (ie, the wife in this case) a surrogate decision-maker, as long as the patient is still considered to have at least minimally reliable decisional capacity, but rather to involve her as an intermediary trusted by both the patient and physician.⁶ A family member or friend is likely to have a better understanding of the patient's point of view, to provide ancillary support for sound decision-making, and to serve as a bridge between the patient and the operative team. In the initial encounter, the patient expressed a desire to have his wife present for the preoperative discussion. With the patient's consent, the physician may contact the patient's wife by phone to speak with her about the risks and benefits previously presented to the patient. Encouraging the patient to consult with trusted family or others can strengthen rather than diminish a patient's self-determination. In the end, however, the decision to proceed with the operation rests with the patient.

It must be noted that the chances for success decrease dramatically with additional warm ischemia time. If replantation is to be attempted, it must be done as soon as possible. When presented with an intoxicated patient, it is usually not feasible to delay operation until the patient is no longer intoxicated or until the effects of medications that impair mental status have worn off.

Option 4: Determine that the patient does not have decisional capacity and search for a surrogate decision-maker

Based on the patient's ability to understand the necessary information and make a coherent decision, the treating physician determines whether a patient has decisional capacity.⁵ It is important to distinguish the determination of decisional capacity from the legal determination of competency. In a time-sensitive setting, such as replantation of a digit, it would be impractical to proceed with formal psychiatric evaluation for legal competency.

The treating physician should assume that decision-making capacity is present, not absent.⁷ It would be ethically inappropriate to dismiss this patient as decisionally incapacitated on the basis of his wavering consent. Decision-making abilities can vacillate, and choices can change. The treating physician has to determine whether the patient's capacity is sufficient for a given situation.⁶

When the patient is deemed to be decisionally incapacitated, a surrogate decision-maker is required. In an ideal circumstance, a patient has an advance directive that names a chosen surrogate, but currently, most patients do not have advance directives. A surrogate decision-maker needs to be accessible and know the patient well. The surrogate must have intact decisional capacity. Each state has varying laws governing determination and implementation of surrogacy, and physicians should be familiar with this legislation. Turning to a surrogate, however, would also present challenges given the time constraints of this urgent case.

In a case such as this one, if the treating physician concludes the patient lacks decisional capacity and begins to search for an alternate decision-maker, a consultation with the hospital ethics committee is advisable and can be helpful, provided the consultation can be accomplished quickly and efficiently. The medical team should be familiar with how an ethics consultation occurs in its hospital prior to an acute event.

ETHICAL BOTTOM LINE

This patient presents in acute stress and is faced with the possibility of losing adequate function of his dominant hand. His decision-making appears to waver.

The effects of pain medication, fear, or anxiety should not argue categorically against the patient's decisional capacity. Decisional capacity is too often dichotomized: a patient either has full autonomy or requires a surrogate.⁶ Feinberg's⁸ description of a "fully voluntary" decision requires "calmness and deliberateness" and the absence of any "distracting or unsettling emotions," "clouded judgment," or "immature or defective faculties of reasoning." By this standard, few patients in an acute situation in an emergency room are able to make reliable medical decisions.⁶

This case represents a difficult scenario of a favorable injury for which salvage is indicated (multidigit, sharp amputation) in an unfavorable patient (a smoker, not motivated to stay in hospital or participate in postoperative therapy). Because this situation does not constitute a life-threatening emergency, informed consent is required for any operative intervention. When the informed consent discussion results in discord between the patient's wishes and medical recommendations, the patient's decisional capacity is brought into question.

Particularly in the acute setting, many patients fall into a potentially gray zone between capacity and incapacity.⁵ Effects of pain, anxiety, fear, and medication can be difficult to quantify. The patient's capacity to make medical decisions should be part of a global assessment that takes into account the patient's demonstrated understanding of the proposed interventions. The treating physician should hold in equal regard the ethical obligations of beneficence and respect for patient autonomy.

Repeated discussions with the patient, if time permits, may be critical to establishing sound judgment. The patient's decisional capacity must be assumed to be intact unless explicitly proven otherwise. The patient should be provided any necessary assistance by family members and medical staff in understanding the options and coming to a decision. If an extended decision-making process is necessary, however, the medical team must remain aware of the critical time sensitivity of an ischemic limb if replantation is to be attempted.

Adequate disclosure of information by the treating physician is essential to the ethical soundness of seeking informed consent. In an academic training center, the process of informed consent may be delegated to junior residents who are frequently less well supervised in this essential communication with a patient. What is meant to be a meaningful conversation between physician and patient may be reduced to a "please go consent the patient," with the end goal of obtaining a signature. A patient may be confused by a hurried discussion. It is imperative that appropriate attention is given to providing the patient with

the necessary information in a comprehensible way. Residents, who are often implicitly trained to convince the patient to want operative intervention, often gloss over possible complications and may feel a sense of failure if the patient does not consent. Because both replantation and amputation of severely injured digits will result in substantial morbidity and postoperative challenges, the goal should be to achieve a mutual buy-in with the patient and not simply to obtain a signature.

REFERENCES

1. Jones JW, McCullough LB, Richman BW. Informed consent: it's not just signing a form. *Thorac Surg Clin.* 2005; 15:451–60. [PubMed: 16276809]
2. Schwarze ML, Bradley CT, Brasel KJ. Surgical “buy-in”: the contractual relationship between surgeons and patients that influences decisions regarding life-supporting therapy. *Crit Care Med.* 2010; 36:843–8. [PubMed: 20048678]
3. Goldner, RD.; Urbaniak, JR. Replantation.. In: Wolfe, SW., editor. *Green's operative hand surgery.* 6th ed.. Churchill Livingstone; New York: 2011. p. 1585-644.
4. McCabe SJ. Patient participation in the decision for replantation. *Hand Clin.* 2001; 17:351–5. [PubMed: 11599205]
5. Jonsen, AR.; Siegler, M.; Winslade, WJ. *Clinical ethics: a practical approach to ethical decisions in clinical medicine.* 7th ed.. McGraw-Hill; New York: 2010.
6. Morreim EH. Impairments and impediments in patients' decision making: reframing the competence question. *J Clin Ethics.* 1993; 4:294–307. [PubMed: 7803824]
7. DeBosch BJ, Brown D, Tse G, Hua M, Kodner IJ. Fetus-saving Caesarian rejection by pregnant woman: a case study. *Surgery.* 2009; 145:6–8. [PubMed: 19093328]
8. Feinberg J. Legal paternalism. *Can J Philos.* 1:105–124.