

AMA Journal of Ethics

March 2015, Volume 17, Number 3: 236-242

STATE OF THE ART AND SCIENCE

Is Informed Consent for Extracorporeal Life Support Even Possible?

Allan B. Peetz, MD, Nicholas Sadovnikoff, MD, and Michael F. O'Connor, MD

Extracorporeal membrane oxygenation (ECMO), the most common form of extracorporeal life support (ECLS) technology, is an increasingly common way of providing life support to patients in severe cardiac or respiratory failure. In the vast majority of instances, informed consent, as it is commonly understood, cannot be obtained from either the patient or a proxy agent. The obstacles to obtaining informed consent are multiple and include the following: informed consent cannot be obtained from a patient who is unconscious; time pressure prevents the obtaining of informed consent from a patient with severe respiratory failure and dyspnea; and, in almost all cases involving ECLS, time pressure precludes the kind of education and conversation that are integral to the informed consent process.

During the twentieth century, the practice of medicine in the United States changed from physician decision making to reliance on patients' informed consent. Prior to the modern era, physicians decided what evaluation and treatment were appropriate for a patient and rendered it. Patients were expected to accept whatever treatment their physicians provided without question. As might be expected, this practice led to rare but sometimes spectacular abuses and has been supplanted by the contemporary approach, in which informed consent is obtained from an autonomous patient or surrogate [1].

Autonomous Informed Consent and its Conditions

The informed consent process is an exercise of a person's autonomy. In the ideal scenario, a physician proposing an intervention has a detailed discussion with the patient in which the following requisites are met: "threshold elements" of patient voluntariness and competence, "informational elements" of physician disclosure and recommendation and patient understanding, and "consent elements" of patient decision and authorization [2]. In both clinical medicine and medical research, the medical team must educate the patient about his or her medical problems, options for treatment, and the risks and benefits of each option. The more complex the medical condition or treatment, the longer and more complex the education and conversation have to be.

Any physician or researcher who has obtained informed consent knows that the actual process of informed consent is far more complicated in practice than in theory. How much education is enough? How much explanation is enough? Do all possible alternatives need to be identified? How well does the patient need to understand his or her condition and treatment to be competent to offer consent? In practice, obtaining informed consent in medicine often devolves into explaining the patient's condition and the proposed treatment, and, in almost all instances, the practice falls far short of the ideal, even for the

most simple of medical conditions and treatments. When the decision pertains to an intervention like ECLS, there are additional barriers to model informed consent.

Problems with Informed Consent in General

Several factors affect informed consent in most or all medical decisions.

Misunderstanding. A problem affecting many instances of informed consent, in a variety of circumstances, has to do with inadequate understanding on the patient's part. More than 20 years ago, Paul Stuart Appelbaum and his colleagues described the process of "consenting" research subjects for a trial. Their description revealed how the process falls short of the ideal (a fully informed person exercising perfectly free agency) [3].

Nevertheless, the narrative and scenario were typical then and now. When Appelbaum et al. evaluated the subjects' comprehension of what they had consented to, they discovered that most subjects lacked even a basic understanding of the study to which they had consented. The body of the literature that evaluates informed consent supports that misunderstanding is the rule rather than the exception [4, 5].

Emotional distortion. Emotion and intellect have an enormous impact on the process of informed consent and its outcome. Acute illness typically provokes anxiety or other strong emotions in patients that can significantly degrade their cognitive function, leading to misinterpretation of information that would be included in an informed consent process. Appelbaum and colleagues describe patients whose understanding of their consent is compromised by these emotions and their attendant disruption of cognition [3].

Patient beliefs about expertise. Another relevant misconception that distances actual informed consent from theoretical informed consent may exist in the form of patient beliefs about expertise. In 2000, McKneally and Martin [6] surveyed a cohort of 36 patients who opted to undergo an esophagectomy for esophageal cancer after (ostensibly) a normal surgical informed consent process. The researchers combined ethnography with more conventional social science research approaches to define and categorize the beliefs and experiences involved in the patients' decisions to proceed with invasive surgery for a life-threatening condition. Their findings are surprising: rather than a standard ethical or legal framework of informed consent, the patients' responses seem to describe something else entirely. The authors write, "Patients did not perceive themselves to be making an informed decision"—giving consent as it is commonly theorized—but instead "viewed themselves as accepting an expert recommendation"—that is, "entrusting" their welfare to their surgeons [7]. They explain,

The patients in our study universally described their trust in the competence and willingness of their surgeons to make good treatment decisions on their behalf and to care for them with vigilance. Trust has been defined as the "reliance on others' competence and willingness to look after rather than harm things one cares about which are entrusted to their care"; trust provides an "alternative to vigilance and rational calculation of risks, benefits, and alternatives" [7].

A likely explanation for the gap between models of consent and the experience of opting to proceed with a treatment is the central role of cultural and socialized beliefs that McKneally and Martin identified as part of the concept of entrustment. These include:

1. cultural belief in surgical cure for cancer (which may also apply to invasive life-saving procedures like ECLS),
2. "enhancement of trust through the referral process" (i.e., the "understand[ing] that their specialist surgeon embodied the highest available level of skill and expertise" [8]),
3. idealization of their surgeons,
4. belief that they (the patients) possessed insufficient expertise to make good decisions based on medical information,
5. resignation to risks of (the particular) treatment, and
6. belief that they were not so much making an informed decision as accepting an expert recommendation [6].

These beliefs about expertise were not only a part of the informed consent process; they were essential parts of it.

All this suggests that theoretical models of consent may not apply in the making of many medical decisions, and that ECLS in particular is so complex that understanding of what is being proposed may not be possible.

Condition-Dependent Factors that Interfere with Informed Consent

Situational factors more specific to ECLS and other acute, life-threatening conditions can also cause problems with informed consent.

Time pressure. When patients are in cardiac arrest or circulatory collapse, they are dead. Those patients cannot be educated about either their condition or their options for treatment. In most instances, consent is assumed. Even when a competent proxy agent is available for a consent discussion, time pressure compels it to be dramatically foreshortened. In this context, a practitioner explaining and obtaining consent is almost certain to convey a sense of urgency to a patient's proxy agent, who is almost certain to sense that the choices are ECLS or nothing. In the setting of severe respiratory failure, more time may be available for a consent discussion—in most instances, the patient, usually sedated to the point of incompetence to give consent, will already be on life support, attached to a ventilator—but the proxy agent is still likely to sense both urgency and a lack of alternatives.

In most instances, physicians proposing monumental interventions to patients take great care to educate the patient about the implications of consenting to the treatment. Patients contemplating bone marrow transplants, liver transplants, lung transplants, and artificial hearts may be introduced to patients who have undergone these interventions and learn a great deal about both the benefits and the complications of these procedures from their peers. These experiences may allow patients in these settings to come far closer to realizing the ideal informed consent of an autonomous patient. Contrarily, absent these encounters, it is reasonable to suppose that it would be difficult or impossible for patients undergoing these procedures or others like them to truly understand the benefits and complications of the procedure and "how it feels."

Life-threatening emergencies and saving life at all costs. When delaying action to engage in such a discussion—or even to find the right person(s) with whom to have such a discussion—would seriously threaten the patient’s life through inaction, choosing the course that favors preserving life is considered ethically appropriate. So-called emergency consent takes this approach, with the assumption that once the clinical situation has been stabilized, a formal, if retrospective, consent discussion can then be held, with the option of withdrawing the life-sustaining interventions or therapies being given full consideration if consistent with the patient’s previously expressed preferences. Complicating this approach, however, is the fact that, once it is started, the withdrawal of a life-sustaining therapy may be psychologically more difficult to endorse than withholding it in the first place, despite the widely accepted ethical equivalence of withholding and withdrawing life-sustaining therapies in accordance with the patient’s preferences and values.

What the patient considers material and relevant to the decision in the context of duress/anxiety/stress (i.e., “save my life at all costs”) may not be what he or she would consider material in a calmer frame of mind. The type of emotion (e.g., anger, anxiety, terror, depression) and its intensity influence the prioritizing of facts and the processing of knowledge in ways that can compromise understanding or comprehension [9, 10]. Furthermore, the duress experienced during an emergency (such as in indications for ECLS) presents special challenges to the informed consent process [11]. The aim of “saving life” has strong emotional appeal and appears obviously preferable to the alternative. It isn’t natural under duress (or perhaps practical, depending on the nature of the emergency) for the patient to ask deeper questions about the quality of the life being preserved.

Complexity. When interventions are complex, patients may be especially likely not to understand what they are consenting to. A classic example of a complex and ultimately misunderstood intervention is the first artificial heart placed in a heart transplant patient by Denton Cooley [11]. The resultant legal battle exemplified how problematic explaining and understanding highly complex medical interventions can be. Most practitioners have met well-educated patients who underwent any of a number of monumental interventions but indicated that they had no idea of what they had consented to and regretted having done so. Patients may not understand that, at the simplest level, consent for ECLS entails consent for the insertion of at least one large-bore venous cannula, and most often a large-bore arterial cannula. Consent for ECLS in the setting of cardiac arrest is implicit consent for all of the associated life support measures, which include intubation and mechanical ventilation, vasoactive support, and often renal replacement therapy. These therapies may all be required to allow sufficient time for a patient to demonstrate some recovery, which can take days or weeks.

Lack of information. Deepening the difficulty of ensuring adequately informed consent is the lack of prognostic certainty associated with the institution of such rescue interventions. Depending on the cause of the patient’s decline, the outlook may be grim indeed, but there is almost always a small, difficult-to-identify subset of patients who will make a substantial and meaningful recovery. This uncertainty leads to great challenges when attempting to conduct an informed consent discussion with patients or (much more

commonly) their health care (proxy) agents regarding continuing versus withdrawing the very intervention that has already rescued the patients from nearly certain death.

In addition, these “extreme” therapies are often done within a research context. Lack of knowledge regarding the prognosis, risks, and likelihoods of success or failure is a natural part of the conditions under which these treatments are employed. This also creates additional problems with understanding.

Therapeutic misconception. In consent for research studies, a misunderstanding that often invalidates consent arises from a basic tension between the goals of the scientific method and the duties of a physician to the patient. Patients often presume that their physicians will choose what is best for them even when the research and scientific method demand otherwise—a phenomenon termed the therapeutic misconception [3].

Appelbaum points out the importance of socialization in this problem of therapeutic misconception:

Most people have been socialized to believe that physicians (at least ethical ones) always provide personal care. It may therefore be very difficult, perhaps nearly impossible to persuade subjects that this encounter is different, particularly if the researcher is also the treating physician, who has previously satisfied the subject’s expectations of personal care [3].

It is reasonable to regard the therapeutic misconception as a consequence of the history of paternalism in medicine.

All these problems interfere with creating the conditions for the adequately informed and freely made decision that is supposed to constitute informed consent, and all of them are present when using ECLS.

Informed Consent and ECLS

The world of medicine has long accepted that standard informed consent is not possible in many emergency situations. When the concepts of autonomy and informed consent were first advocated, emergency interventions were few and fairly simple. Modern technology has created emergency care that is invasive, complex, expensive, and might continue for days or weeks. Informed consent, as it is classically understood, cannot be realistically obtained from patients being considered for ECLS for cardiac arrest and could be problematic even in respiratory failure. Extracorporeal life support for cardiac arrest has created a new set of quandaries that may require years of deliberation to fully understand.

The recent resurgence in enthusiasm for ECLS technologies has led to the widespread adoption of an intervention that throws the concept of informed consent into even greater confusion. Extracorporeal life support therapies are generally called upon in the context of severe, life-threatening conditions, and, like other life-sustaining therapies, the initial decision to use them is frequently emergent and does not allow for a robust informed consent discussion.

And, while interventions such as conventional mechanical ventilation can be followed by an informed consent discussion guided by the known statistical outcomes of patients who had these interventions, such is not the case with ECLS, the clinical applications of which are still in their infancy and the outcomes of which are uncertain. It is abundantly clear that these therapies can be instituted to forestall certain death in cases of both respiratory and circulatory failure, but the prognosis once they are in place cannot be guided by the minimal experience with these therapies to date.

Conclusion

To summarize, robust informed consent is regarded as the ideal mechanism by which to protect patient autonomy when deciding upon medical interventions. Emergent conditions limit timely informed consent, and the use of a drastic, experimental, and complex intervention such as ECLS makes it difficult for practitioners to prognosticate and patients to understand what they are agreeing to. Informed consent for ECLS is not realistically possible; the ethical implications of this fact should be taken into account as its use becomes yet more widespread.

An argument can be made that the results of the employment of ECLS are so uncertain that the technology should be regarded entirely as experimental and used exclusively as research. In this context, informed consent would in some ways be more straightforward, as the expected outcomes of experimental therapies are by definition unknown.

References

1. Meisel A, Roth LH, Lidz CW. Toward a model of the legal doctrine of informed consent. *Am J Psychiatry*. 1977;134(3):285-289.
2. Beauchamp TL. Respect for autonomy. In: Beauchamp TL, Childress JF, eds. *Principles of Biomedical Ethics*. 7th ed. New York: Oxford University Press; 2013:99-148.
3. Appelbaum PS, Roth LH, Lidz CW, Benson P, Winslade W. False hopes and best data: consent to research and the therapeutic misconception. *Hastings Cent Rep*. 1987;17(2):20-24.
4. Sudore RL, Landefeld CS, Williams BA, Barnes DE, Lindquist K, Schillinger D. Use of a modified informed consent process among vulnerable patients: a descriptive study. *J Gen Intern Med*. 21(8):867-873.
5. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet*. 2001;358(9295):1772-1777.
6. McKneally MF, Martin DK. An entrustment model of consent for surgical treatment of life-threatening illness: perspective of patients requiring esophagectomy. *J Thorac Cardiovasc Surg*. 2000;120(2):264-269.
7. McKneally, 267.
8. McNeally, 266.
9. Antrobus JH. Anxiety and informed consent. Does anxiety influence consent for inclusion in a study of anxiolytic premedication? *Anaesthesia*. 1988;43(4):267-269.
10. Merckaert I, Libert Y, Bron D, et al. Impact of life-threatening risk information on the evolution of patients' anxiety and risk recall: the specific context of informed

consent for experimental stem cell transplant. *Patient Educ Couns.* 2009;75(2):192-198.

11. Capron AM. Informed consent in catastrophic disease research and treatment. *Univ PA Law Rev.* 1974;123(2):340-438.

Allan B. Peetz, MD, is a surgical critical care fellow at Brigham and Women's Hospital and an instructor of surgery at Harvard Medical School in Boston. He is also completing a fellowship in medical ethics at Harvard's Center for Bioethics. His research interests include ethical issues in trauma surgery and in vulnerable surgical populations.

Nicholas Sadovnikoff, MD, is an assistant professor of anaesthesia at Harvard Medical School in Boston. He is also an intensivist at Brigham and Women's Hospital, where he is co-director of the surgical intensive care units, director of the fellowship in anesthesia-critical care medicine, and co-chair of the hospital ethics committee.

Michael F. O'Connor, MD, is the section head of critical care medicine and a professor of anesthesia and critical care at the University of Chicago Pritzker School of Medicine. His practice as an intensivist has routinely included the management of patients undergoing extracorporeal life support.

Related in AMA Journal of Ethics

[The Appropriate Use of Increasingly Sophisticated Life-Sustaining Technology](#), December 2013

[The Evolution of Surrogates' Right to Terminate Life-Sustaining Treatment](#), September 2006

[Withholding Information from an Anxiety-Prone Patient?](#) March 2015

[Perioperative Do-Not-Resuscitate Orders](#), March 2015

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

Copyright 2015 American Medical Association. All rights reserved.
ISSN 2376-6980