Ethics in the intensive care unit: Informed consent

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INTRODUCTION — Informed consent is a process of communication between a clinician and a patient or surrogate decision-maker that results in the patient agreeing to undergo a specific medical intervention. Consent for specific aspects of medical treatment is a relatively new concept in medical ethics, having evolved over the last century. Society previously accepted the notion that clinicians had the detailed technical knowledge required to make medical decisions on behalf of the patient and that clinicians were guided by an overriding desire to do the right thing (ie, beneficence). Most clinicians and patients believed that medical decisions should be made by the clinician without participation from the patient, thereby sparing the patient and family from the burdens associated with these difficult choices. This paternalism emphasized beneficence to the exclusion of autonomy and failed to consider that biases are unavoidable and clinicians are not always able to determine what is in their patients' best interests [1-3].

Acceptance of paternalistic clinician beneficence was replaced by an emphasis on patient autonomy during the mid-1980s. This was probably the consequence of two main factors: society began to embrace the idea of patient autonomy and the assumption of clinician beneficence began to be questioned once it was recognized that the economic pressures exerted upon clinicians by outside forces can be great. Clinicians began to act as impartial agents for their patients who, in the extreme, were considered clients with the power to choose any therapy they desired. Giving advice was considered taboo by some who argued that this was equivalent to exerting inappropriate influence on the patient or family. Patients or family members were often made to feel that they have to "make the decision" regarding whether to attempt resuscitation. A common scenario was one in which poorly informed patients were confronted with an open-ended request to tell the medical team what "they want to have done." Often their response was to have "everything done" and this was accepted by the clinician as a request for cardiopulmonary resuscitation even if the clinician thought it would be a mistake.

Although autonomy is still emphasized in many ways, it is increasingly recognized that overemphasis of autonomy deprives patients of expert advice and may cause the clinician to abandon his or her responsibility to protect the patient against inappropriate therapy. As a result, the pendulum has begun to swing back from absolute autonomy toward a more balanced approach. This has been termed "enhanced autonomy" or the "fiduciary role", but in reality it is recognition that an approach based solely upon one principle (such as autonomy) is no better than one based solely on another (eg, beneficence) [4,5].
Ethical issues related to informed consent in the intensive care unit (ICU) are reviewed here. Our emphasis is on informed consent for a medical intervention. Although most principles also apply to informed consent for participation in clinical research, this area is vastly more complex and is beyond the scope of our review. Ethical issues related to withholding life support, withdrawing life support, and requests for futile or inappropriate therapy are discussed separately. (See "Withholding and withdrawing ventilatory support in adults in the intensive care unit" and "Ethics in the intensive care unit: Responding to requests for potentially inappropriate therapies in adults").

**INDICATIONS FOR INFORMED CONSENT** — Generally speaking, all invasive procedures require informed consent. Those that are considered routine ICU procedures (eg, central line insertion) may be covered by a “blanket consent”, which broadly covers almost everything a doctor or hospital might do without mentioning anything specific [6]. Blanket consent is typically obtained from the patient or a surrogate decision-maker upon admission to the hospital or ICU. It is the responsibility of individual units and institutions to establish guidelines for which procedures require formal written informed consent and which are covered by the blanket consent [7]. An exception to the requirement for informed consent occurs when an emergent, life-saving procedure is required (eg, endotracheal intubation).

**PROCESS OF INFORMED CONSENT** — The clinician who will perform the intervention should obtain informed consent from either the patient or a surrogate decision-maker. Informed consent consists of providing information about the intervention, ensuring adequate understanding of the information, and then obtaining permission to perform the intervention.

**Provide information** — It is generally accepted that informed consent should include a description of the following: the intervention (including the personnel who will be participating), the potential benefits and risks of the intervention, and the potential benefits and risks of any alternative courses of action (including no intervention). This information should be communicated concisely and using terminology that the patient or surrogate can understand.

There is no single widely accepted standard for how much detail should be provided in the informed consent process. The goal is to be informative, but communicating every detail is neither possible nor practical. This is particularly relevant to communicating the risks of an intervention; generally speaking, adverse events that are either frequent or severe should be described.

Concern for the quality of informed consent has increased in recent years [8]. One study of informed consent in cardiology found that current consent forms were complex, incomplete, and unreadable for the average patient [9]. Another study of patients providing informed consent for elective cardiac catheterization found that 88 percent of the patients had mistaken beliefs about the benefits of the procedure [10]. Reducing the amount of information conveyed while focusing on how and when the information is delivered, and perhaps using newer technology to improve traditional consent discussions, has the potential to “move informed consent away from a meaningless piece of required paperwork and toward a focus on patient autonomy and well-being” [8].

The law provides three different standards by which the adequacy of the information provided may be judged: the professional community standard, the reasonable person standard, and the subjective standard. It is often useful to consider if the information provided would pass all three standards if judged by an outside observer:

- The professional community standard compares the information provided with that provided by other physicians who are faced with the same or a very similar clinical situation. Such comparisons
had previously been made to physicians in the local community; however, these standards are increasingly being established by national professional organizations.

- The reasonable person standard compares the information provided with that desired by a well-reasoning individual who is free of mental or physical illness and who has no conflicting interests in the outcome of the case. This standard varies based upon a number of factors, such as the cultural and educational background of the individual receiving the information.
- The subjective standard requires the clinician to use experience and judgment to decide what information is required. This standard allows information to be tailored to a specific clinical situation by the clinician; however, it is subject to criticism by those who, on retrospective review, believe that the information provided was inadequate.

While it is important that the pertinent medical information be provided to the patient or surrogate when obtaining informed consent, it is equally important that the clinician encourage and listen carefully to the questions and opinions of the patient or surrogate. Occasionally, patients or their surrogate will ask the clinician how many similar interventions he or she has performed and their success rate. Such questions should be answered truthfully. Complete and open communication between the clinician and the patient or surrogate promotes trust and cooperation.

Clinicians with potential financial conflicts of interest should disclose those conflicts to the patient or surrogate. As an example, a clinician who is seeking permission to use a medical device on a patient and owns the patent for the device (or stock in the company that makes it) should disclose the financial relationship. Failure to disclose such conflicts of interest leaves the clinician susceptible to accusations of impropriety.

**Assess comprehension** — The clinician must ensure that the information that was provided was understood by the patient or surrogate. A useful technique to assess understanding is to ask the patient or surrogate to summarize the information that has been conveyed and to clarify any misunderstandings that occur with the patient (or surrogate).

**Obtaining the consent** — Once the appropriate information has been provided, questions have been answered, and comprehension has been confirmed, the clinician should ask the patient or surrogate whether they grant permission for the intervention to be performed. Patients or surrogates usually ask for the clinician’s opinion before giving final consent, in which case the clinician should render their opinion regarding the proper course of action. Decisions of this magnitude are best made jointly by those who have in-depth knowledge of the patient's values and wishes, and those who understand the pertinent medical issues [11]. A set of facts should not be presented to the patient or surrogate without professional input and advice. The emphasis on patient autonomy has created the temptation for clinicians to shift the burden of decision-making entirely to patients or surrogates; we believe that this is an incorrect approach and that obtaining informed consent requires both the clinician and the patient or surrogate.

A number of improvements in the informed consent process are under investigation. A systematic review identified 44 controlled trials of a wide range of interventions designed to improve patient comprehension in informed consent for medical and surgical procedures [12]. The main lessons from these studies are: (1) more is not always better, (2) discussions should take place well before the decision to undertake the intervention, and (3) informing patients using a variety of methods will improve the quality of the discussion with the physician [8,12].
Occasionally, the decision made by a surrogate that seems contrary to the patient’s best interests and/or the clinician’s expectation. In such cases, the clinician must be certain that no outside influences have caused the surrogate to deviate from the patient’s true wishes. This can be difficult to assess and requires that the clinician explore the motivation for the surrogate’s decision. As an example, the clinician might say, “can you tell me a little about why you believe that your father would not want the procedure?” Ongoing communication with family members usually allows clinicians to identify situations in which the patient’s well-being is not the surrogate’s primary concern. In such cases, clinicians will need to involve the hospital ethics committee and, in extreme cases, involve legal action to ensure that the patient’s best interests are the primary driver of clinical decision making.

**Documentation** — Clinicians should carefully document any informed consent discussions, regardless of whether consent was ultimately obtained. Documentation should include the date and time of the conversation, the identity of individuals who participated in the discussion, and the benefits and risks of the intervention and alternative interventions that were described. Finally, the clinician should document that the patient or surrogate understood the information, was given the opportunity to ask questions, and either agreed to proceed with the intervention or declined the intervention. If the patient declined the intervention, it should also be documented that the risks of not undergoing the intervention were described. If the intervention is performed without informed consent due to an emergent situation, the precise circumstances for the intervention should be documented in detail.

**INCAPACITATED PATIENTS** — Patients who lack the capacity to make an informed decision are unable to participate in medical decision-making because they cannot understand the choices available or the potential consequences of their medical decisions [13]. Such patients are frequently called incompetent but, strictly speaking, incompetence is a legal term and patients can only be deemed incompetent by the legal system. The incapacity to make informed decisions may not be obvious and psychiatric consultation should be sought if there is uncertainty.

Although we strive to respect patient autonomy even if their capacity to make an informed decision becomes impaired, we can only truly do so when the patient has already made a choice. Written advanced directives may be available for this purpose. However, in the absence of an advanced directive, ethicists, caregivers, and the legal system all mandate that the medical team and persons who are most acquainted with the patient (eg, family) attempt to construct the patient’s judgment by analyzing their prior statements, values, and beliefs. Although the goal is to determine what the patient would say if they were able to do so, this “substituted judgment” does not actually preserve patient autonomy, but rather serves to allow for decisions that are “authentic” to the patient [14]. Importantly, the evidence suggests that >90 percent of patients prefer family members to work with the clinician to make medical decisions for them if they are ever incapacitated [15].

It is important to recognize that patients without the capacity to make an informed decision may regain capacity as their illness improves and the effects of medications wears off. Thus, patients who have been deemed incapable of making informed decisions should be reassessed daily. Once the patient regains the capacity to make decisions, his or her wishes supersede the wishes of any surrogate or family members.

**FOREIGN LANGUAGE SPEAKERS** — Informed consent should be obtained in the patient’s native language using an interpreter, preferably one who is familiar with medical terminology. This is necessary to insure that the patient understands the information being conveyed by the clinician and is able to ask questions in the way that he or she intends. Family members should not be used to interpret information
because they may filter the information in order to protect the patient and this may impede the patient’s ability to make an informed judgment.

SUMMARY AND RECOMMENDATIONS

● Informed consent is a process of communication between a clinician and a patient or surrogate decision-maker that results in the patient agreeing to undergo a specific medical intervention. (See ‘Introduction’ above.)

● All invasive procedures require informed consent, although those that are considered routine intensive care unit (ICU) procedures may be covered by the “blanket consent” that is typically obtained at the time of admission. It is the responsibility of individual units and institutions to establish guidelines for which procedures require formal written informed consent and which are covered by the blanket consent. An exception to the requirement for informed consent occurs when an emergent, life-saving procedure is required. (See ‘Indications for informed consent’ above.)

● Informed consent consists of providing information about the intervention, ensuring adequate understanding of the information, and then obtaining permission to perform the intervention. Clinicians should carefully document any informed consent discussions, regardless of whether consent was ultimately obtained. (See ‘Process of informed consent’ above.)

● Patients who lack the capacity to make an informed decision (eg, due to the critical illness or medications) are unable to participate in medical decision-making because they cannot understand the choices available or the potential consequences of their medical decisions. Patients do not lose their autonomy if their capacity to make an informed decision becomes impaired. Instead, the medical team and persons who are most acquainted with the patient (eg, family) must attempt to reconstruct the patient's judgment by analyzing their prior statements, values, and beliefs. This is referred to as "substituted judgment." (See ‘Incapacitated patients’ above.)

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REFERENCES


