The term informed consent is relatively new to the lexicon of medicine, coming into popular use only in the last half century [1]. The establishment of bioethics as a unique scholarly discipline promoted the importance of informed consent within medical practice and clinical research [1]. Medical ethicists served to advance the concept of patient civil rights in health care, furthering the notion of informed consent for both the lay public and the medical profession itself. In 1981, the American Medical Association recognized informed consent as “a basic social policy” that acknowledged a patient’s right to make his or her own health care choices, even if those choices conflicted with a physician’s recommendations [2].

The process of obtaining informed consent demonstrates physician respect for patient autonomy in medical decision making [3]. To apply this ethical concept in practice, the physician must be knowledgeable and skilled in the key elements of the informed consent process. This process can be difficult for residents new to the critical care environment, as it is challenging to obtain truly informed consent from an acutely ill patient [4]. Physicians in the emergency department (ED) or intensive care unit frequently encounter such patients, whose decision-making capacity may be impaired by great emotional or physical stress [5]. The need for rapid interventions can further complicate the consent process in emergency care, as patients or their surrogates may have limited time to ask relevant questions and gain an understanding of the decisions before them. By understanding the principles of fully informed consent and following a systematic approach, physicians will be better able to overcome the challenges to obtaining consent in the acute care setting.

Although the Accreditation Council for Graduate Medical Education has mandated professionalism as a general competency for residency graduates in all specialties [6], specific content areas such as informed consent have not been standardized in all curricula. This represents a critical gap in contemporary medical education. Not only do residents need experience confronting issues of consent in practice, they require a firm understanding of the basic ethical principles that guide the process of obtaining informed consent. This article examines these principles and highlights the challenges to obtaining informed consent in the acute care environment. We define the key elements of the consent process and provide a stepwise approach to obtaining informed consent for risk-inherent therapies. A fictitious patient scenario demonstrates the process steps for obtaining consent in an acute care setting, providing an introductory framework for the application of the ethical principles discussed.

An Intervention Requiring Informed Consent

Mr. Baros, a 55-year-old man, presents to the ED with a chief complaint of generalized weakness. He describes several weeks of worsening fatigue, stating that he came to the ED because he “couldn’t get out of bed today.” His medical history is significant for untreated hypertension and reflux disease, a 40 pack-year smoking history, and alcohol intake of 3 to 4 beers per day. He has no primary care physician and takes no medications. He is employed full-time in a local factory and is upset that he had to miss work today because he was “just too weak.”

Dr. Gerard, the senior emergency medicine resident, enters the room and finds Mr. Baros resting comfortably and in no acute distress, although he notices that the patient appears very pale. Dr. Gerard skims the chart for initial vital signs recorded at triage: oral temperature, 97.0°F; heart rate, 115 bpm; blood pressure, 105/70 mm Hg; respiratory rate, 22 breaths/min; and oxygen saturation, 95% on room air. Upon questioning, he learns that Mr. Baros has been having dark black stools for about 3 weeks and now feels lightheaded when rising from a sitting position.

On physical examination, the patient’s conjunctivae...
appear pale, his heart is tachycardic and regular with no murmurs, his lungs are clear, and his abdomen is soft, nondistended, and nontender, with normal bowel sounds. Rectal examination reveals guaiac-positive dark stool. After completing the examination, Dr. Gerard explains his concerns.

“Mr. Baros, I’m worried that you may be bleeding from somewhere in your stomach or intestines. We’ll check your blood counts and see if you need a transfusion, although we can discuss this in more detail when the tests come back.”

About an hour later, Mr. Baros’ laboratory results return and reveal a hemoglobin of 8 g/dL. This finding convinces Dr. Gerard that active gastrointestinal (GI) bleeding has caused Mr. Baros to become symptomatically anemic. As a result, Dr. Gerard anticipates that Mr. Baros will require a blood transfusion.

As Dr. Gerard is about to go speak with Mr. Baros, a paramedic call comes in. A severely injured trauma patient is being brought to the ED, and Dr. Gerard must prepare the resuscitation bay. He asks the third-year medical student working in the ED to review Mr. Baros’ blood test results with him, discuss the potential need for a transfusion, and answer any questions he may have.

“After you’re done, come help out with the trauma.”

The medical student quickly agrees as Dr. Gerard heads to the trauma bay. She obtains a transfusion consent form and approaches Mr. Baros for the first time.

“Where’s Dr. Gerard?” asks Mr. Baros.

“He was needed in the trauma suite for a very sick patient who is coming in by ambulance. He asked me to discuss your tests results with you. Mr. Baros, your hemoglobin was found to be 8. You will likely need a blood transfusion soon.”

The student then pauses, realizing she is not sure she can provide accurate answers to questions Mr. Baros may have. She hesitates to invite any inquiries.

“Here’s a consent form that provides information about transfusions, in case you have any questions. Please read through this form and sign it at the bottom. This gives us permission to give you a transfusion.”

“Do I really need this right away?”

“Well, Dr. Gerard tells me that you do, and I guess if he feels that it’s necessary, we should do it.”

Mr. Baros signs the form, and the medical student quickly proceeds to the trauma bay. She realizes she has not done exactly what Dr. Gerard asked, and she worries about what to tell him.

The Dilemma

The medical student successfully obtained Mr. Baros’ signature on the consent form but did not explain any details about the transfusion itself. She also did not give Mr. Baros the opportunity to ask any questions about blood transfusions. Instead, she gave the patient the option of reading over a consent form that explains the risks and benefits associated with receiving a transfusion. She now wonders:

- Was it appropriate to have Mr. Baros sign the form, consenting to a transfusion, without discussing the procedure and making sure the patient had no questions?
- Is the patient’s signature enough to satisfy the requirements for informed consent?

What Is Informed Consent?

Informed consent is the process by which a patient makes an autonomous decision to undergo a medical procedure or treatment or to participate in medical research [7]. The main goal is to foster patient control over decisions pertaining to his or her health care by providing an opportunity for informed participation in such decisions. Although the process typically involves obtaining a patient signature as proof of authorization of a medical intervention, it is not the signature but the patient’s fully informed participation in the decision that constitutes informed consent.

Inherent to this process are the assumptions that the patient is capable of making autonomous health care decisions and that the physician has fully explained the nature and rationale for a proposed intervention, all reasonable alternatives to the intervention, and the relevant risks, benefits, and uncertainties of each option [8]. To be informed, the patient must possess an understanding of the requisite information necessary to make an authentic choice.

Although beyond the scope of this article, brief mention of another concept related to enhancing patient choice is warranted at this point. Shared decision making refers to a collaboration between physician and patient on medical decisions, wherein both parties share ideas, beliefs, and values and, together, weigh the pros and cons of available choices to arrive at a shared decision regarding the course of action. A shared decision-making approach is most appropriate for medical decisions involving greater uncertainty, in which 2 or more medically reasonable choices exist [9]. Whitney et al [9] have developed a conceptual model for classifying medical decisions according to
degrees of risk and certainty, which physicians may find useful for determining whether a decision requires informed consent, shared decision making, neither, or both (Figure 1).

As suggested by the model in Figure 1, risk assessment is a primary determinant of the need for informed consent [9]. If a treatment or procedure has minimal risk, patients may be asked to give their consent without a formal discussion of the intervention. For instance, a patient presenting to the ED will be asked for his or her general consent to be examined by a physician and to have routine medical tests performed. Such tests could include radiographs or venipunctures, which carry only minimal risk to the patient’s health. A process of informed consent is not necessary for these tests, which are routine in nature and therefore included in the initial consent to treatment [10].

Conversely, some high-risk interventions may also be performed without obtaining informed consent, when such heroic treatments are considered to be lifesaving for an altered or unconscious patient [11]. This exception to informed consent reflects the societal assumption that most unconscious patients would want to be resuscitated to the point that they were again capable of making their own decisions. The American College of Emergency Physicians endorses this concept in its Code of Ethics, stating that, “emergency physicians may treat without securing informed consent when immediate intervention is necessary to prevent death or serious harm to the patient” [11].

Although lifesaving interventions for unconscious patients may be performed without explicit consent, most patients seen in the acute care setting are still alert and capable of making health care decisions. Many require some risk-inherent treatment that mandates informed consent. In these instances, physicians must be able to efficiently discuss interventional risks, providing patients with a thorough understanding of their health care options. Swift treatment decisions can be facilitated by physicians skilled in the process elements of informed consent, ensuring timely care that maintains respect for patient autonomy.

### Elements of the Informed Consent Process

Five distinct process elements have been defined for obtaining informed consent: 1) assessment of decision-making capacity, 2) disclosure of information, 3) assessment of understanding, 4) assurance of authenticity of choice, and 5) confirmation of consent [7]. Figure 2 outlines a conceptual approach to the informed consent process, and Table 1 provides a useful checklist to ensure that all essential process steps are taken.
Assessment of Decision-Making Capacity

The process of informed consent begins with the assessment of decision-making capacity, defined as “the ability to receive, process, and understand information; the ability to deliberate; the ability to make choices; and the ability to communicate those preferences” [12]. Capacity is task-specific and a function of the individual patient when placed in a particular environment at a particular time [12]. It is a dynamic ability that can be influenced by a variety of internal and external stressors, such that an individual may be capable of making decisions in one setting but not in another. This medical notion of decision-making capacity differs from the legal definition of competence, which is an assessment of an individual that is made by a judge [13].

It is generally accepted that all adults, unless delirious or unresponsive, possess decision-making capacity [8]. Common reasons for temporary impairments in decision making are listed in Table 2. The ability to process information and make decisions should be fairly obvious during a brief interview with an alert patient [12]. If cognitive ability is in question, the physician should simply ask the patient to communicate his or her understanding of the situation and proposed medical decision at hand. For instance, patients who have received narcotic analgesia for severe pain are often thought to have impaired cognition. Although such medication may alter sensation of pain, it does not always effect one’s ability to process new information; for such patients, decision-making capacity should be assessed in the same manner as for other patients. Similarly, some patients who may be considered legally incompetent, such as a demented patient who cannot manage his finances, may still possess the capacity to make decisions that affect health and well-being.

If it is determined that a patient lacks the decision-making capacity for a needed treatment, an available surrogate decision-maker or health care directive should be consulted. For situations in which neither is available, the physician may make treatment decisions in the best interest of the patient [7].

Disclosure of Information

Physicians must provide a reasonable amount of detailed information regarding treatments or procedures for which they seek consent. This includes the name of the intervention and method of performing it, the name of the physician performing the intervention, the risks and benefits of the intervention, and a list of potential alternatives. Indications for the intervention should be included in the discussion of potential benefits, while alternatives to treatment...
should include the option of no intervention. It is important to avoid the use of medical jargon in these discussions. Repetition of new facts may be appropriate and often is necessary. The use of a translator may facilitate optimal communication. Adequate time should be reserved to address any questions or concerns. The supervising physician should be identified and made available for questions.

The focus of the discussion must center on risk disclosure, the most important step in the informed consent process. Physicians should list all common potential side effects or complications for any recommended intervention. Rare but serious complications should be briefly discussed as well. Research suggests that although patients may not fully understand pertinent risks, they prefer to be informed of them [14]. Lawsuits may result from a misunderstanding about or discontent with risk disclosure, rather than from complications or medical errors themselves [14].

Physical and emotional stressors can make acutely ill patients vulnerable to a discussion of potential treatment risks, sometimes rendering them unable to make any decision at all [15]. A compassionate approach to this difficult situation may facilitate patient understanding. Bioethicists suggest several methods for dealing with such a challenge, including the professional practice standard (physicians should employ any known professional society standards of disclosure for a particular procedure), the reasonable person standard (physicians should be thoughtful of what a reasonable person would want to know when faced with such a decision), and the subjective standard (physicians should tailor any discussions based on the patient’s situation, cultural norms, and any known value systems) [7].

### Assessment of Understanding

An individual can assimilate only a limited amount of new information in a given amount of time. When a patient is ill or in pain, the ability to retain information can be further impaired. Once the pertinent details of an intervention have been discussed, it is important to confirm that the patient understands the necessary information. Patients should be asked to explain their understanding of the decision in their own words, without repeating the medical terms used by the physician. The following is a time-sensitive, practical approach to ensuring patients have ample opportunity to discuss a proposed intervention, generate questions, and demonstrate understanding:

<table>
<thead>
<tr>
<th>Did the physician:</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>Assess the patient’s decision-making capacity?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Identify a surrogate decision-maker, if needed?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Provide the name and details of the proposed intervention?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Discuss all common risks?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Discuss the potential benefits of the intervention?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Discuss treatment alternatives?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Provide the alternative of “no intervention”?</td>
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<td>☐</td>
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<tr>
<td>Solicit and answer any questions?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Confirm that the decision-maker understood the information?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Not pressure or coerce the decision-maker?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Properly document a confirmation of consent?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Document the process steps of obtaining informed consent?</td>
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### Factors that Commonly Impair Patient Decision-Making Capacity

<table>
<thead>
<tr>
<th>Pharmaceutical effects</th>
<th>Dementia</th>
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<tr>
<td>Intoxication</td>
<td>Delirium</td>
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<td>Pain</td>
<td>Psychosis</td>
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<td>Stress</td>
<td>Organic disease</td>
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<tr>
<td>Metabolic disturbances</td>
<td>Communication barriers</td>
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<tr>
<td>Infection</td>
<td>Cultural differences</td>
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<tr>
<td>Malignancy</td>
<td>Incarceration</td>
</tr>
</tbody>
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Table 1. Checklist of Steps for Informed Consent

Table 2. Factors that Commonly Impair Patient Decision-Making Capacity
• Inform the patient of the need for a treatment intervention
• Leave to attend to other tasks, allowing the patient to absorb the information
• Return to answer any questions and assess patient understanding
• Leave to gather the necessary equipment and/or personnel for the proposed intervention
• Return to answer any remaining questions and obtain final consent

Ensuring Authenticity of Choice
When obtaining informed consent, it is vital that the patient’s decision be voluntary and free of coercion, manipulation, or duress. Physicians may overemphasize treatment benefits, deliberately or inadvertently, in an attempt to help patients decide on a “best” course of action. Such paternalism can be too influential for very ill patients, and physicians should be cautious with their style of presentation. The patient’s choice must be considered authentic—a true representation of his or her usual preferences and free will.

Some patients will seek their physician’s opinion as part of the decision-making process, asking, “What would you do, doctor?” If the patient voluntarily requests the physician’s opinion, this viewpoint may be freely provided without worry of coercion or manipulation. A physician who is concerned that he or she is being too persuasive should ask if the patient feels pressured to make a decision. Such an open inquiry will help patients express any further concerns they may have.

Confirming Consent
After the patient has made a decision about a treatment option, the physician should document the consent process. Informed consent requires the participation of the health care organization, via the physician, as the “institutionally or legally effective authorization” that confirms the choice of the patient [7]. This authorization is reflected through the use of a consent form, a document signed by a patient to acknowledge his or her consent for medical intervention, in agreement with a physician or hospital. Although necessary in the legal documentation of the decision process, the consent form is not considered the limiting step. Patient signature alone does not confirm that the physician obtained informed consent, although it does reflect that the patient was queried about the intervention in question. Legal action has been sought by patients who alleged that their physicians neglected to fully inform them of interventional risks, despite the fact that they signed a consent form [16].

In addition to using a patient consent form, physicians should document the informed consent process in the medical record. Progress notes should state that the patient was capable of making a health care decision and understood the risks, benefits, and alternatives to treatment. If a patient consulted his or her primary care physician or a family member to assist in the decision process, this discussion should be documented as well. Surrogates who consent on behalf of altered or unconscious patients should sign consent forms, and their involvement should be noted in the patient chart.

Informed consent should be obtained by a member of the health care team who is able to address any patient questions or concerns [17]. As in our case example, students or junior residents at teaching hospitals are often asked to obtain consent in lieu of busy supervising physicians (ie, attendings or senior residents). Unfortunately, this is a common occurrence in academic medical centers. In one study, more than one third of junior doctors were asked to obtain consent for unfamiliar procedures [17]. It is unfair and unethical to leave such a job to someone who, by lack of training and experience, cannot adequately fulfill the task. Junior physicians should not confirm patient consent for a procedure unless they are convinced that they have adequately disclosed all pertinent information and answered all patient concerns. Supervising physicians should confirm the steps of the informed consent process and sign pertinent consent forms prior to initiating a treatment protocol [17].

Demonstration of the Informed Consent Process
After successfully resuscitating the injured trauma patient, Dr. Gerard asks the medical student if she obtained consent from Mr. Baros for his needed transfusion. The medical student admits that she did not adequately explain the treatment or its potential complications to Mr. Baros.

“It’s important that we take care of this,” says Dr. Gerard. “Let’s go see Mr. Baros right now.”

“Mr. Baros,” begins Dr. Gerard, “the student doctor on our team is concerned you may have some questions regarding the transfusion.”

“Oh yes, doctor. I don’t really know what’s happening, to tell you the truth.”

“I apologize for the confusion. I’d be happy to explain the reasons for the transfusion in more detail and to answer any questions you may have.”

Dr. Gerard pulls up a chair next to the patient and continues. “After hearing of your symptoms, examining you, and reviewing your blood tests, I believe you have a source of significant bleeding somewhere
along your GI tract. When we tested your blood, we saw that your hemoglobin was much lower than it should be for a man of your age.”

“Excuse me, but what’s hemoglobin?”

Your hemoglobin level tells us how well your blood is supplying oxygen throughout your body. Adequate blood supply and oxygen is very important for our organs, particularly our heart and brain. Many things can cause a low hemoglobin or low blood level. In your case, I believe it is due to ongoing bleeding in your stomach or intestines.”

“I think I may have had an ulcer in the past,” says Mr. Baros.

“That’s important, as it may be the cause of your bleeding today.”

“Do I need a transfusion right now? Is my level that low?”

“You probably don’t need blood within the next few hours, but you may need it in the next couple of days. However, it’s best that we discuss the transfusion now, in case you continue to bleed and your symptoms worsen. I certainly would want to avoid that.”

“I understand, doctor. But, is it risky to get a blood transfusion?”

“Blood transfusions are considered extremely safe in the United States. Although blood is extensively screened to ensure such safety, there are still some uncommon risks involved, including a small chance of getting an infection from the blood or having a bad reaction to the blood, similar to an allergic reaction.”

“Infection? That doesn’t sound good.”

“Most infections transmitted through blood transfusions are viral in nature. Hepatitis C and HIV are examples of the worrisome infections that can be passed through transfusions. Again, these are very rare occurrences. On the other hand, receiving the blood would be beneficial in that it would improve your symptoms of lightheadedness and fatigue. In fact, if you continue to bleed, a transfusion could be life-saving.”

“Can I call my family to talk this over with them first?”

“Of course. Take some time to discuss things and I’ll be back to answer any other questions that you or your family may have.”

“Thanks, Dr. Gerard.”

The resident and medical student leave to check on other patients and return 20 minutes later. Dr. Gerard then briefly discusses alternatives to transfusion, including no intervention.

“Do you have any other questions, Mr. Baros?”

“No, I think I’m all set.”

“Do you understand why you may need a blood transfusion?”

“Yes. If the transfusion would help me from feeling tired, and if it could save my life, I’d be willing to do it.”

“You understand the major risks?”

“Yes. You said infection and allergic reactions are possible. But it seems the benefits of receiving the transfusion are probably more important to me than these risks.”

“We need to admit you to the hospital for tests to help us find the source of your bleeding. The doctors will continue to check your blood and may need to give you the transfusion if your hemoglobin level falls any lower. I’ll order the transfusion now, so it’s ready in case you need it.”

“That sounds good, doctor. I appreciate that.”

“I hope you don’t feel that we are pressuring you into this decision.”

“Not at all, doc.”

“If you have other questions, Mr. Baros, don’t hesitate to ask. I’ll be back to see you shortly.”

Dr. Gerard leaves the room and asks the medical student to provide Mr. Baros with a copy of the consent form that he signed, so he can look it over more thoroughly. He writes a brief progress note documenting the consent process and moves on to his next patient.

Summary

Informed consent was not obtained during the interaction between Mr. Baros and the medical student. Dr. Gerard properly initiated a new discussion of the proposed intervention with the patient, reviewing the facts of the case and discussing the indications for a blood transfusion. He created opportunities for the patient to ask questions regarding risks and benefits and provided time for the patient to contemplate the decision and discuss it with his family by phone. After confirming that the patient understood the pertinent information and was comfortable with his decision, Dr. Gerard documented the consent process in the medical record. Thus, he performed all the necessary steps to obtaining informed consent (Table 1).

This case example and related discussion are intended to provide residents with an introduction to the theory and process of informed consent in the acute care setting. Although several practical challenges have been identified, informed consent can be complicated by a variety of other factors. These include the use of surrogate decision-makers, issues of consent for research participation, obtaining consent...
for autopsy and organ donation, refusal of care by a competent adult, and a surrogate’s refusal of care for a minor [10,18–20]. Each of these important topics, although outside the scope of this article, deserves further reading by residents in all specialties.

In summary, informed consent reflects the process by which a patient makes an autonomous decision to participate in a proposed medical intervention. This decision-making process can be particularly complex for patients in an acute care setting, who may feel pressured by the urgency and severity of their condition. Physicians who care for patients in this environment must be familiar with the steps required to ensure that consent is obtained from a truly informed patient. Although patient illness and setting can complicate the informed consent process, physicians should make every attempt to respect the autonomy and decision-making capacity of their most severely ill patients.

References

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