

ED Legal Letter™

The Essential Monthly Guide to Emergency Medicine Malpractice Prevention and Risk Management
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Informed consent: Are you up on the basics?

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Editor's note: *Informed consent is an important and challenging aspect of emergency medical care. Emergency physicians should use the informed consent process to ensure the protection of the rights of patients to be informed about proposed medical treatment and procedures. For many emergency department (ED) patients, there may be barriers to the informed consent process, including impaired decisional capacity, impaired cognition, language barriers, illiteracy, insufficient time, problems with communication, among others. Because many ED patients may be medically ill in unfamiliar surroundings, and in a vulnerable state, particular attention should be given to ensure adequate delivery of material information, understanding of the proposed intervention and its risks and benefits, and voluntariness of the informed consent.* —**Richard J. Pawl, MD, JD, FACEP**

The Doctrine of Informed Consent

Informed consent is recognized as a fundamental principle of American law. The concept from which the informed consent doctrine evolved is based upon the common law tenet in American jurisprudence that every person has the right to be free from undesirable personal contact from another person. The United States Supreme Court articulated this common law concept in *Union Pacific Railroad Company v. Botsford* in 1891... "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from

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all restraint or interference of others.”¹ The importance of consent for treatment was initially recognized in 1914, in the case *Schloendorff v Society of New York Hospital*,² in which a patient underwent surgery without her consent. The court determined in this landmark case that patients have the right to consent to or refuse treatment, and many subsequent cases have quoted Judge Cardozo’s statement that “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages.” The term *informed consent* was first introduced in 1957, in the case *Salgo v Stanford*.³ Informed consent is an important aspect of the fundamental right of patient autonomy in medical decision making.⁴⁻¹⁰ Informed consent is a process, and includes three essential elements: determination of the patient’s *decisional capacity*, delivery of *information*, and voluntary *consent* from the patient.

The American Medical Association has stated, “Health care professionals should inform patients or their surrogates of their clinical impression or diag-

nosis; alternative treatments and consequences of treatments, including the consequence of no treatment; and recommendations for treatment.”¹¹ The American College of Emergency Physicians has affirmed in its Code of Ethics: “Emergency physicians shall communicate truthfully with patients and secure their informed consent for treatment, unless the urgency of the patient’s conditions demands an immediate response.”¹²

Appropriate informed consent has several essential elements:

- the nature of the patient's condition;
- the disclosure of information regarding the proposed treatment including the material risks and benefits;
- the treatment alternatives and their risks and benefits;
- voluntariness on the part of the patient to consent.

Informed refusal of care requires a similar disclosure of information and voluntary decision making. The informed consent doctrine is based upon the perspective that although physicians have the training and experience to diagnose and treat medical conditions, the patient is best prepared to make decisions, based upon his/her value system and goals.

Informed consent may be granted by patients in one of three basic forms. *Express consent* is granted when a patient agrees to a specific intervention. *Implied consent* refers to consent implied by the patient's conduct (for example, a patient willingly holds his arm out to have blood drawn).¹³ *Consent implied in law* occurs when emergency treatment is necessary to save life or preserve health and the patient is unable to give consent in life-threatening situations.

Informed consent may occur by one of several mechanisms. Some routine ED procedures, such as intravenous lines and blood drawing, may be performed appropriately after general consent to treatment, either verbal or written. Other more invasive procedures require additional disclosure of information regarding the procedure, its purpose, risks, benefits, and alternatives to the proposed procedure or intervention.¹⁴⁻¹⁶ Nevertheless, current practices regarding informed consent vary widely, including patient discussions and documentation.¹⁷

Informed consent should be obtained by the physician who will be performing the procedure.^{13,18} The physician has the ultimate responsibility for the

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TABLE 1: Stepwise Approach to Determination of Capacity

1. Ensure the patient's ability to communicate.
2. Correct any reversible environmental, metabolic, mental and physical challenges to capacity.
3. Utilize standardized tests of capacity, if indicated.
4. Assess patient goals and values using open-ended questions about the choices (including risks and benefits), alternatives (including the option not to treat), and consequences.
5. Communicate with the patient and his/her health care advocates, if appropriate, about the decision and its ramifications.
6. Document essential elements of capacity or its impairment in the medical record.

delivery of information, including risks, benefits, and alternatives. The process of informed consent should not be delegated to others who may not be present or who may be unfamiliar with the intervention and its risks, benefits, and alternatives.

In general, providing emergency medical care requires consent for treatment from the patient. Importantly, there are several significant exceptions to the physician's duty to obtain informed consent. In emergency situations, if a patient is unable to give informed consent, no legally authorized decision maker is available, and immediate treatment is indicated, appropriate medical treatment should be rendered, under the presumption that a reasonable person would consent. Other exceptions to the duty to obtain informed consent include public health or legal requirements, patients who may waive their right to consent, and the rarely used therapeutic privilege, when the physician judges that the information would be unduly traumatic to the patient so as to impair the patient's ability to consent.

The Assessment of Decisional Capacity

Decisional capacity refers to the ability to make an authentic choice; the concept of decisional capacity incorporates cognitive and affective functions, including attention, intellect, memory, judgment, insight, language, emotion, and calculation. Appropriate decisional capacity requires the following elements:

1. the ability to receive information;
2. the ability to process and understand

information;

3. the ability to deliberate;
4. the ability to make and articulate a choice.

Decisional capacity should be assessed for all patients, although a formal process may not be necessary for patients judged by the physician to be alert and of sound mind. Decisional capacity is the first essential element of the process of informed consent or informed refusal of treatment.¹⁹⁻²¹ Frequently, decisional capacity can be assessed during routine interactions with the patient who is alert and demonstrates appropriate speech and judgment. In many cases, however, the determination of adequate decisional capacity requires additional steps.

Decisional capacity is not necessarily consistent over time; a patient's mental status, his/her psychological status, or environmental factors may vary. Decisional capacity is a dynamic attribute and is also task-specific. Decisional capacity may be recognized as a spectrum of ability, depending upon the particular health care decision. Decisional capacity can be determined using a stepwise approach.²² A suggested approach is summarized in *Table 1*. Standardized tests may be valuable in the determination of capacity, when capacity is unclear.²³⁻³⁰ The Mini-Mental Status Examination (*Table 2*) is an example of a test easily administered in the ED.³¹ A score of 25-30 is considered acceptable mental status, 20-25 is borderline, and below 20 indicates significant impairment of mental status. Another available evaluation is the formulation by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.³²

Impaired decisional capacity may result from impairment of any of the essential elements: ability to receive, process, and understand information, deliberate, or to communicate a decision. An individualized assessment of capacity must be done for each patient. Numerous conditions and circumstances may present a threat to decisional capacity, some of which are reversible.^{33,34,44-43} Some examples of clinical conditions that may result in impaired capacity include dementia,^{35,36} intoxication, psychiatric conditions, language impairment, cultural issues, physical communication impairments, severe pain, organic disease states,^{37,38} and numerous other conditions. Reversible etiologies of impaired capacity should be addressed, if possible. Even in cases of some impaired capacity, some

patients may demonstrate sufficient understanding of the decision at hand to make an appropriate informed choice.

Patients Unable to Consent

Often, patients present to the ED in conditions in which they are unable to provide informed consent (e.g., unconscious patients, intoxicated patients, or patients with any condition rendering them unable to participate in medical decision making). In such circumstances, physicians should act in accordance with the *reasonable person* standard, that is, what a reasonable person would want in similar circumstances. If an advance directive is available, it may be helpful in providing guidance. If time allows, consent may be obtained from a surrogate decision maker. Some states determine the hierarchy of surrogate decision makers, but it typically includes the patient's spouse, adult children, parents, and siblings.

An interesting case illustrates this principle. In *Barnett v. Bacharach*, a surgeon operated on a patient for a presumed ectopic pregnancy, following obtaining consent for such surgery. During the surgery, the surgeon noted acute appendicitis, and removed the appendix, based upon the assumption that a reasonable person would agree to this course of action, although the patient was unable to provide consent at the time she was under general anesthesia. Despite the patient's claim that she had not consented to this procedure, the court found that the surgeon had acted properly, in accordance with his professional judgment.³⁹

The courts have indicated that alcohol intoxication may render a patient incapable of granting informed consent, and that the standard of medical competency should be used when making such a determination. In *Miller v Rhode Island Hospital*, an intoxicated patient (with a blood alcohol level of 0.233) was brought to the hospital after he was injured in a motor vehicle collision. In the course of evaluating the patient for a traumatic injury, the physicians advised the patient that a diagnostic peritoneal lavage was going to be performed. The patient stated that he did not want that procedure, but the physicians thought that the patient was sufficiently impaired by his alcohol intoxication such that the patient lacked the capacity to understand the purpose of the procedure. After resisting the efforts of the physicians, the patient was restrained, and a

TABLE 2: Mini-Mental Status Examination

	Score	Max
Score		
ORIENTATION		
What is the (year) (season) (date) (day) (month)?	___	5
Where are we? (state) (county) (town) (hospital) (floor)	___	5
REGISTRATION		
Name three objects and ask patient to repeat.	___	3
ATTENTION AND CALCULATION		
Serial 7's (one point for each correct up to 5)		
Option: Spell "world" backwards.	___	5
RECALL		
Ask for the three objects repeated above.	___	3
LANGUAGE		
Name a pencil and watch. (2 points)	___	9
Repeat "no ifs, ands, or buts." (1 point)		
Follow a three-stage command. (3 points)		
Read and follow the command: "Close your eyes." (1 point)		
Write a sentence. (1 point)		
Copy a design. (1 point)		

diagnostic peritoneal lavage was performed. The patient later sued for battery. Finding that intoxication did not affect the plaintiff's legal competency, the trial court found in favor of the plaintiff, but the defendants appealed the decision. The Rhode Island court found that intoxication could very well affect the plaintiff's mental capacity to make decisions and that the issue was one that should be decided by a jury. The Supreme Court of Rhode Island found in favor of the defendants and remanded the case back to the district court for a new trial, wherein the issue of the plaintiff's capacity to make medical decisions in light of his intoxication would be decided by a jury.⁴⁰

Procedures That Require Informed Consent

Prior to significant interventions, the risks, benefits, and alternative treatment options should be discussed with patients. Currently, there is tremendous variability among emergency physicians regarding the type of consent (verbal, written, or none) obtained for emergency procedures, such as lumbar puncture, endotracheal intubation, arthrocentesis, venipuncture, and others.⁴⁴ There is no existing

national standard that dictates specific procedures that require written consent. Interventions with high risk of complications may indicate that written documentation of the discussion of the procedure, risks, benefits, and alternatives is appropriate. Some authors have suggested that written consent be obtained for certain interventions, including invasive procedures.^{45,46}

Disclosure of Information

In *Canterbury v Spence*, an 18-year-old man underwent back surgery. A day after the operation, he fell from his hospital bed after having been left without assistance while voiding. A few hours after his fall, the patient became paraplegic and was taken back to surgery. Unfortunately, the patient remained partially paralyzed and suffered from urinary and bowel incontinence. Among other claims, the plaintiff claimed that he had not been informed of the risks of surgery. The majority of the jurisdictions at that time applied a “reasonable physician” standard when evaluating the kind of information required of the physician when obtaining an informed consent from a patient. The reasonable physician standard required the court to inquire about what a reasonable physician in a similar circumstance would have disclosed to a patient. Such an inquiry usually required expert witnesses to establish the standard of care. The *Canterbury* appellate court rejected the reasonable physician standard, stating that what was material to the informed consent inquiry was rather what a reasonable person would have wanted to know prior to granting an informed consent.⁴⁷

The necessary amount and detail of information to be delivered as part of the informed consent process varies by circumstances. Sufficient information to allow the patient to weigh the risks and benefits should be presented. However, in some cases, an overwhelming amount of information may have negative ramifications, if confusing or intimidating to patients.

A large proportion of jurisdictions in the United States use the reasonable person standard of disclosure, requiring that information should be disclosed that would be considered material to a reasonable person making a decision in that particular case. Typically, important information would include the patient’s diagnosis, proposed intervention, alternatives, and expected outcomes or consequences of

TABLE 3. Disclosure of Information in the Informed Consent Process

1. Diagnosis
2. Proposed intervention
3. Alternatives to the proposed intervention
4. Expected outcomes of consent or refusal

consent or refusal of the proposed intervention. (See *Table 3*.) Some jurisdictions use an objective approach to evaluating the reasonable person standard for informed consent by asking whether a reasonable person would regard certain information as important in granting an informed consent. A few jurisdictions use a subjective approach to the reasonable person standard, taking into account the patient’s particular idiosyncrasies and preferences.

Material risks generally are interpreted as risks that are considered significant for decision making by a reasonable person. Nevertheless, every conceivable risk need not be disclosed routinely. Risks that are considered very remote, or those that are commonly known, need not be disclosed.

When patients refuse care, disclosure of the risks of the refusal should be performed. This principle was demonstrated in the case *Truman v Thomas*.⁴⁸ In *Thomas*, the children of a deceased mother filed suit against their mother’s physician for failing to inform their mother of the consequences of refusing Pap smears. The mother later died from cervical cancer. Having refused the Pap smears because of the costs involved, the children’s mother was never informed that her refusal could result in failing to identify cervical cancer at a stage that would be early enough to treat effectively.

In this 1980 case, the Supreme Court of California stated that the central issue of the case was whether Dr. Thomas breached his duty of care to Mrs. Truman when he failed to “inform her of the potentially fatal consequences of allowing cervical cancer to develop undetected by a Pap smear.”⁴⁹ The defendant physician claimed that the informed consent doctrine only applies to when a patient consents to the recommended procedure. In rejecting the defendants’ notion, the California Supreme Court said that the right of a patient to make decisions about their own bodies should not be diminished by the manner in which that right is exercised. The California Supreme Court then held that physicians

have a duty to inform patients when refusing care of the risks of refusing such care.

Disclosure of Training Status

General consent to treatment is provided by patients prior to medical interventions, in most cases, unless emergency intervention is necessary. In teaching institutions, this general consent also may include general information about treatment by trainees, including residents, interns, and students under appropriate supervision. Despite this general disclosure, however, many patients are unaware of the training status of health care professionals.^{50,51} Many authors believe that patients should be informed about the specific training level of health care providers participating in their care. There is considerable debate regarding the disclosure of details about previous training and experience. For example, should an intern tell his/her patient, “This is my first lumbar puncture”? Some argue that such information is relevant and should be disclosed, while others argue that fewer patients would consent to treatment by less experienced learners.

Many patients indicate that they are willing to be treated by students and residents, if this information is disclosed appropriately.⁵² However, many patients indicate a reluctance to have students perform a procedure for the first time on them, and many indicate that they should be informed if the resident or student is performing a procedure for the first time.^{53,54}

Refusal of Medical Care

All competent patients have the right to participate in the informed consent process prior to medical interventions. Similarly, competent patients also have the right to refuse medical care. Patients may elect to refuse all treatment, or specific tests or therapies, as well as hospital admission. As is true of informed consent, informed refusal is a *process*, not merely a signature on a form. Some practitioners erroneously conclude that documenting that the patient is leaving against medical advice, or an Against Medical Advice (AMA) form, is sufficient to end the physician’s involvement in the patient’s care. However, the process should include determination of decisional capacity, delivery of relevant information (including risks of refusing treatment, alternative treatments), and documentation of these

elements. As was seen from the results of the *Canterbury* case, when a patient refuses medical treatment, care should specifically be taken to ensure that the patient understands the consequences, and that the physician expresses a willingness to treat the patient, including providing reasonable alternative treatments, should the patient refuse the recommended course of action.

The right to refuse medical care has been recognized by the justice system, both in state courts, based in the law of battery.⁵⁵ More importantly, the Supreme Court of the United States recognized that a patient has the right to refuse treatment in *Cruzan v Director of Missouri Department of Health*.⁵⁶ In *Cruzan*, the Supreme Court clearly stated that individuals have a liberty interest in refusing unwanted medical care based upon the 14th Amendment’s due process clause that no State shall “deprive any person of life, liberty, or property, without due process of law.”

In certain circumstances, patients should be treated even if they specifically refuse care. Examples of appropriate treatment without consent include patients who present significant public health risks and patients who pose an immediate threat to themselves or others. Medical interventions necessary to prevent potential loss of life, limb, or significant impairment may appropriately be undertaken in patients who lack decisional capacity.

The safety of staff and patients is an important concern when treating patients who may refuse medical care.^{57,58} Some patients may require physical restraints, without their consent, to ensure safety of the environment. Physical restraints should be limited to use in cases where the safety of the patient, other patients, or staff is threatened (e.g., violent or suicidal patients). Restraints should be used in the least restrictive manner and for the least duration of time necessary to ensure patient and staff safety, and their necessity must be documented in each case. The American College of Emergency Physicians has stated, “restraints should be individualized and afford as much dignity to the patient as the situation allows” and “any restraints should be humanely and professionally administered.” The policy also states that protocols should ensure appropriate observation, treatment, assessments, and documentation of medical care.⁵⁹ Restraints should never be used to impose medical care on competent patients who refuse care (except in certain circum-

stances noted above).⁶⁰

When a patient refuses medical interventions, an informed refusal discussion should take place between physician and patient. Many institutions use an AMA form, but this does not ensure adequacy of the process of refusal of medical care. The AMA form can be an important documentation of the refusal to the physician and the information that the patient understood before refusing treatment, but is not a substitute for the discussion and delivery of information.

Minors and Informed Consent

Adults deemed capable of making their own health care decisions are able to consent to or refuse medical care. In contrast, for minors this right is generally not legally recognized. In most circumstances, parents have the right to consent to medical care, or refuse it for their minor children. State laws vary widely, and emergency physicians should be aware of the state laws regarding minors and autonomy. Many states allow adolescent minors some autonomy in specific areas without parental permission (e.g., contraception or treatment for sexually transmitted disease or substance abuse). In many states, *emancipated minors* are recognized as minors who are considered competent to make their own health care decisions. Emancipated minors often are defined as minors who meet certain measures of independence (e.g., married, living independently and supporting themselves, serving in the military, or, in some cases, those who are pregnant or have children).

In some states, the *mature minor* may be recognized as an adolescent who is mature enough to have a progressively greater part in the decision making process for medical decisions. A recent case illustrated the importance of the opinions of the mature minor. The case *In re Swan*, a 17-year-old male suffered severe brain injuries following a motor vehicle collision. The parents and physicians wished to discontinue artificial nutrition and hydration and allow the patient to die, while the district attorney opposed this. A statement made previously by the patient proved helpful in this case; he had previously visited a disabled friend, and apparently stated at that time "If I can't be myself...no way...let me go to sleep." Regarding this case, Maine's Supreme Court ruled that "capacity exists when the minor has the ability

of the average person to understand the weight the risks and benefits." The Court allowed the parents to withdraw life support in accordance with the mature minor's previously stated wishes.⁶¹

Frequently, pediatric and adolescent patients present to the ED without a parent or guardian available to consent for treatment (approximately 2-3% of pediatric ED patients).⁶² Several national organizations (The American College of Emergency Physicians, American College of Surgeons, Emergency Nurses Association, and the National Association of EMS Physicians) have endorsed the following statement addressing such circumstances, "Appropriate medical care for the pediatric patient with an urgent or emergent conditions should never be withheld or delayed because of problems with obtaining consent."⁶³ The Emergency Medical Treatment and Active Labor Act (EMTALA) requires that a screening examination for an emergency medical condition be performed for all patients (including minors) presenting to EDs, even if a parent is not available to consent.

Several recent cases illustrate the importance of providing emergency treatment, even if parental consent is unavailable. In *Jackovach v Yokom*, a 17-year-old boy was injured and sustained a severe scalp wound and elbow fracture. He was taken to surgery for the scalp wound, and during the surgery, the surgeons decided that it was necessary to amputate the arm. The patient and his parents later sued because the procedure was done without their consent. However, the courts upheld that the physicians acted with appropriate judgment when performing the life-saving intervention.⁶⁴ In *Younts v St. Francis Hospital*, a 17-year-old girl sustained a severe finger injury, which was surgically repaired after the patient consented (the mother was ill and unable to consent). The patient's mother later sued, and stated that she would not have consented to the procedure without first seeking advice from the primary care physician. The court concluded that the patient's consent was sufficient for the procedure, using the mature minor exception.⁶⁵

Occasionally, parents may refuse treatment for their minor children. In some circumstances, the state allows medical personnel to deliver emergency medical care to children, even if parents refuse care, particularly if the child's well-being is at stake. In such circumstances, physicians should treat emergency medical conditions of minors, even if the par-

ents object.^{66,67} In general, a court order should be obtained, although emergent treatment should not be delayed awaiting a court order.

The courts have upheld the duty of physicians to treat minor children, even if parents refuse life-saving interventions. In *State v Perricone*, the Jehovah Witness parents of a child with congenital heart disease were found guilty of neglect because of refusal to consent for blood transfusions for their infant.⁶⁸ In general, courts will exert the *parens patriae* interest of the state when considering medical care for children against the will of the parents. Minor children are considered by states to be a protected class of constituents, where the state will take great care in protecting the well-being of the children.

Mandatory Reporting

In some clinical situations, the disclosure of protected health information (PHI) may be indicated, even without specific consent from patients. For example, disclosure of PHI is permissible when required by law (e.g., court order, statute, or regulation, in some states to include suspected neglect, abuse, or violence), for FDA reporting, and in reporting certain communicable diseases and certain work-related illnesses or injuries.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) addresses disclosure of PHI. According to HIPAA, disclosure to law enforcement officials may be permissible in some circumstances without patient consent (e.g., in response to court orders, warrants, or subpoenas; to assist in the identification or location of a suspect, fugitive, witness, or missing person; or when responding to a law enforcement official's request for information about a crime victim; when a person's death may be the result of criminal activity; or when PHI may be evidence of a crime that occurred on hospital property).⁶⁹

Another circumstance that warrants disclosure without consent is when physicians have a duty to warn individuals or groups that there is a significant risk posed by a patient or by information divulged by a patient. This duty to warn has been recognized by courts in multiple cases.⁷⁰ HIPAA and statements and policies of national organizations also recognize the appropriate disclosure of PHI in cases in which there is a potential threat to an individual or to the public, including those written by the American

Medical Association and the American College of Emergency Physicians.⁷¹⁻⁷⁵

Individual states regulate mandatory reporting of certain conditions to public health officials. Examples of common statewide reportable conditions include motor vehicle crashes, penetrating trauma, residential fires, occupational injuries, suicide prevention, falls, poisoning, violence, and drowning. The Centers for Disease Control and Prevention maintains the Public Health Information Network, which contains data regarding national reportable conditions.

Informed Consent for Research

In most research trials, informed consent should be obtained from research subjects prior to participation in medical research. In some cases, verbal consent is sufficient, but in most cases, written informed consent is warranted. Federal guidelines for written informed consent for research state that the forms should be appropriately worded, understandable, and should include an explanation of the purposes of research, duration of participation, description of the study, risks, benefits, alternates, confidentiality, compensation, and information about voluntary participation.⁷⁶⁻⁸¹ Informed consent documents should be written at an appropriate reading level, and may, in some cases, require individual adaptation.

The ideal informed consent process for research has not yet been reached. Many questions exist regarding the best communication methods and the appropriate amount of material to disclose to potential subjects. Several studies have demonstrated that research subjects' understanding of detailed informed consent is poor.⁸²⁻⁸⁴ The appropriate amount of detail to include in informed consent documents has not been clearly delineated. Several recent studies indicated that most patients prefer detailed information rather than abbreviated information,⁸⁵⁻⁸⁷ while another study demonstrated improved information retention with a short form, compared with a more detailed form.⁸⁸ Unfortunately, many informed consent documents are written at an inappropriately high reading level.⁸⁹ However, attention to the written informed consent document and its language can improve the readability.⁹⁰

As is true in clinical settings, in research settings informed consent is a process, not merely a signa-

ture. Decisional capacity should be assessed prior to obtaining informed consent, appropriate and relevant information should be delivered, and the potential subject should voluntarily agree to participate. A discussion with the potential subject should include feedback from the subject regarding his/her understanding of risks and benefits.

Coercion of potential research subjects is unethical and should be avoided. Coercion may occur either overtly or may be disguised or masked. Although most researchers agree with this ethical principle of research, many may unintentionally coerce subjects in subtle ways. Examples of coercion may include excessive monetary incentives, failure to inform the subject of voluntariness of participation, pressuring the subject to participate, repeated questioning despite subject refusal to participate, inappropriate representation of the study benefits, withholding of treatment prior to consent, and numerous others. All forms of coercion must be avoided.

Documentation of Informed Consent

As discussed previously, informed consent is a process, with necessary elements, including the discussion between the physician and patient, delivery of material information, including a description of the intervention, risks, benefits, and alternatives, and the patient's agreement to the proposed intervention. The documentation does not constitute informed consent and is not a substitute for the discussion. However, such documentation may serve to provide evidence of the patient's agreement that the informed consent process did take place and that the patient voluntarily agrees to the intervention. Appropriate documentation should include confirmation of the informed discussion, information disclosed, patient's decisional capacity, and the patient's consent to the intervention.

Conclusions

Informed consent is an essential element of the protection of patients' rights, and it remains a complex and challenging process. In all cases, decisional capacity should be evaluated, and if the patient is deemed to have decisional capacity, the physician should communicate with the patient regarding the proposed intervention, risks, benefits, and alterna-

tives, and the patient's goals and values of therapy. Voluntary agreement of the patient and important aspects of the discussion should be documented in the medical record.

Endnotes

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CE/CME Objectives

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Participants who complete this activity will be able to:

- identify high-risk patients and practices within the ED;
- discuss a standard of care in the ED for treatment of conditions that may be considered as high-risk;
- explain conditions and practices in which informed consent is required in the ED;
- cite methods of minimizing risk in the ED setting.

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

At the conclusion of this semester, you must complete the evaluation form that will be provided at that time, and return it in the reply envelope that will be provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

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24. Informed consent may be granted by patients in only one form.
A. True
B. False
25. Appropriate decisional capacity requires which of the following elements?
A. The ability to receive information
B. The ability to process and understand information
C. The ability to deliberate
D. The ability to make and articulate a choice
E. All of the above
26. An Against Medical Advice (AMA) form is sufficient to end the physician's involvement in the patients's care.
A. True
B. False

CE/CME Questions

20. Who should obtain informed consent from a patient?
A. Nurse
B. Primary care physician
C. Physician performing the procedure
D. Secretary
E. Resident
21. In the majority of states, what information should be disclosed when obtaining informed consent?
A. All information available in the medical literature
B. Only information requested by the patient
C. Information routinely disclosed by other similar professionals
D. Information that would be considered to be material to the decision by a reasonable person
22. If a patient has decisional capacity and refuses life-saving medical intervention, which of the following courses of action is the best?
A. Confirm that the patient has decisional capacity, inform the patient of the consequences of refusal, ensure that the patient understands the consequences, and allow the patient to refuse treatment.
B. Restrain the patient to administer life-saving medical care.
C. Obtain consent from the next of kin.
D. Obtain consent from two physicians for emergency care.
23. Which of the following is an example of implied consent?
A. A patient signs the general consent for treatment.
B. A patient signs a specific informed consent document.
C. A patient indicates by actions agreement with the intervention.
D. A physician renders emergency care for a patient unable to consent.

Answers:

20. C
21. D
22. A
23. C
24. B
25. E
26. B