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Informed Consent *for* Medical Research: Case Studies

Catherine A. Marco, M.D., FACEP

ABSTRACT

Informed consent for medical research is an essential, but challenging, process to assure the protection of the rights of potential research subjects. Numerous barriers to the informed consent process exist among patients, including impaired decisional capacity, impaired cognition, language barriers, illiteracy, insufficient time and communication, and numerous others. Because of the inherent vulnerability of patients, particular attention should be paid to addressing barriers to adequate informed consent, and steps should be taken to ensure adequate delivery of information, understanding of the study and its risks and benefits, and voluntariness of the informed consent.

CASE ONE

A 56-year-old female presents to the emergency department with chest pain, and is found to have an acute myocardial infarction. She meets all inclusion criteria for a research study to evaluate a novel therapeutic modality for treatment of acute myocardial infarction. The research assistant approaches the patient, who is suffering from ongoing pain and anxiety. The research assistant presents a six-page informed consent document for signature to the patient, who willingly signs the document in triplicate.

CASE TWO

A 24-year-old male presents with a laceration to the forearm. He meets inclusion criteria for a research study to evaluate the efficacy of a newly developed suture material. His primary language is Spanish, although he speaks some limited English. He cannot read in any language. The research assistant approaches the patient and requests his signature on an informed consent document to participate in the research protocol. Due to the brevity of the discussion, the research assistant was unaware of the patient's illiteracy and the patient willingly signed the document.

INTRODUCTION

The doctrine of Informed Consent is a fundamental principle of the U.S. legal system, introduced by case law in 1957. Informed consent and refusal of treatment are recognized as important legal and ethical rights of patients.¹ Although physicians, by virtue of education and training, typically make diagnoses and recommend treatment, individual patients have the rights and abilities to decide whether the proposed interventions are acceptable. Informed consent represents one of the most fundamental rights of patient autonomy in medical decision making.^{2,3,4,5,6,7} As with informed consent for procedures, informed consent for research is a process, not merely a document. The process should include the delivery of information regarding the study, its risks and benefits, demonstration of adequate understanding of the potential research subject, voluntary agreement to participate, and documentation of the agreement.

ESSENTIAL ELEMENTS OF INFORMED CONSENT FOR RESEARCH

Informed consent for research should be appropriately worded, understandable, and should address multiple

issues of importance to the potential research subject, including an explanation of the purposes of research, duration of participation, description of the study, risks, benefits, alternates, confidentiality, compensation, and information about voluntariness.^{8,9,10,11,12,13}

The language of informed consent is essential to ensuring the adequate information delivery to potential research subjects. Informed consent documents and discussion should be written and delivered at a reading level appropriate to the potential subject. This may require some individual adaptation, particularly of the informed consent discussion.

ENSURING SUBJECTS' UNDERSTANDING

There exist many unanswered questions about the ideal informed consent process, the ideal ways to appropriately inform patients of risks and benefits in ways that improve understanding and retention of information presented. Several recent reports indicated that a majority of patients prefer detailed information compared to abbreviated information, when asked directly.^{14,15,16} Several recent studies demonstrated that research subjects' understanding of detailed informed consent is poor.^{17,18,19} Another study demonstrated improved information retention with a short form, compared to a more detailed form.²⁰ Another recent study demonstrated that subjects may be less willing to participate in a hypothetical study when explicit statistical information is presented, compared to abbreviated information.²¹ Although many informed consent documents are written at an inappropriately high reading level,^{22,23,24} careful attention to the written informed consent document and its linguistics can improve its readability.²⁵

While obvious cognitive impairments are usually recognized, minimal cognitive impairments may be overlooked. A detailed discussion with the potential subject, including feedback from the subject regarding their understanding of risks and benefits, may elucidate the level of understanding, and provide opportunity for additional education. Safeguards for the cognitively impaired may include involvement of surrogates, subject assent, and appropriately balancing the risks and benefits of participation.^{26,27}

BARRIERS TO THE INFORMED CONSENT PROCESS IN EMERGENCY MEDICINE

The emergency department environment hosts numerous barriers that can impair aspects of the informed consent process. Several studies have demonstrated that acute conditions can impair the ability to appropriately give consent.^{28,29} Emergency department patients are inherently vulnerably, by virtue of their situation. They typically seek help for emergent or urgent conditions that

TABLE 1: BARRIERS TO ADEQUATE INFORMED CONSENT

Acute medical or traumatic conditions
Impaired decisional capacity
Impaired cognition
Psychiatric illness
Intoxication with illicit or pharmaceutical agents
Language barriers
Pain
Anxiety
Speech or hearing deficits
Illiteracy
Time constraints
Inadequate communication skills
Lack of understanding of voluntariness

may impair decisional capacity, attention span, ability to focus, and ability to form and articulate rational questions. Specific examples of barriers in emergency medicine may include impaired decisional capacity, distractors (such as pain or anxiety), time constraints, inadequate communication or delivery of information, illiteracy, language barriers, limited education, and perceived coercion (*see Table 1*). Because of these numerous potential barriers to the informed consent process, it is essential that emergency medicine researchers address and attempt to overcome any existing barriers. The rights of individual patients must always be protected, above that of specific research interests.

AVOIDING COERCION

Coercion of potential research subjects, either overt or masked, is unethical. Although most researchers accept this principle, many continue to coerce subjects in subtle ways. Examples of inappropriate coercion include excessive monetary incentives, failure to inform the subject of voluntariness of participation, repeated questioning, inappropriate representation of the study benefits, withholding of care prior to consent, and numerous others. Any form of coercion must be avoided.

SUPERVISION OF RESEARCH ASSISTANTS

The principle investigator assumes responsibility for the design of the informed consent document and for the informed consent process, although these duties may be delegated to co-investigators or research assistants. The investigator has a duty to ensure that all research assistants have been adequately trained in human subjects' rights, in privacy and confidentiality, and in the individual research protocol. Additionally, training and ongoing supervision of the informed consent process specific to the protocol are the responsibility of the investigator.

CASE DISCUSSION

Case One

This case depicts some of the inherent difficulties with emergency medicine research. The patient was in obvious distress and may not have possessed her usual ability to focus and discuss complex issues. Much emergency research endeavors to study patient populations who may be in distress related to their presenting conditions. When studying such patient populations, the recognition of inherent vulnerability must be recognized and specific steps taken to avoid the inappropriate coercion of such patients. Specifically, patients should be informed of the voluntary nature of participation, and should be assured that prompt and appropriate medical care will be given, regardless of research participation.

Case Two

This case depicts language and literacy barriers to the informed consent process. Such barriers may be unrecognized, particularly if the informed consent discussion is very brief. When enrolling research subjects with potential language or literacy deficiencies, particular attention should be paid to ensuring their full understanding of the study and potential risks and benefits of participation. For some patients, this may require additional time with verbal discussions, utilizing the services of an interpreter, or involving a family member who may assist with interpreting or understanding. Because of the inherent vulnerability of such patients, special attention should be paid to avoiding coercion of any type, and ensuring understanding of the voluntariness of participation.

CONCLUSIONS

Informed consent for research in emergency medicine is an essential element of the protection of human subjects' rights, yet it remains a complex and challenging process. Investigators must strive to not only meet the letter of the law found in federal guidelines, but to also address the individual needs of individual potential research subjects to protect their rights and welfare.

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