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Most Americans will experience a period of illness and disability before they die, and the goal of palliative care is to provide a dignified, comfortable death for these patients. Currently, physicians lack data to guide treatment decisions at the end of life, and empirical research is urgently needed. However, ethical concerns about research among patients at the end of life present barriers to the collection of needed information. David Casarett, MD, MA proposes that these ethical concerns can be addressed through guidelines that promote research but at the same time remain sensitive to the vulnerability of this patient population.

Addressing Ethical Concerns about Patient Decision-Making Capacity in End-of-Life Research

David J. Casarett, MD, MA

CHERP Core Faculty

Staff Physician, Philadelphia VA Medical Center

Assistant Professor of Medicine, University of Pennsylvania

Context: For many people, good end-of-life care means access to quality palliative care, the goal of which is to ease suffering and provide comfort to the dying. Over the last decade, progress in the field of palliative care can be measured by public and private funding initiatives, growth of professional organizations, inclusion of the topic in some medical school curricula, and the appearance of specialty journals such as the *Journal of Palliative Medicine*. Nevertheless, the continued success of palliative care medicine lies in conducting research to understand and meet the needs of patients at the end of life and the needs of their caregivers. Researchers examining end-of-life issues must overcome numerous ethical and methodological challenges, including ensuring informed consent. In a vulnerable patient population such as those at the end of life, the informed consent process requires an assessment of decision-making capacity. This policy brief summarizes Dr. Casarett's recently suggested guidelines for determining the ability of patients near the end of life to make informed decisions about research participation.

Background

As with research among patients suffering from dementia or psychiatric illness, research among patients at the end of life requires that the patients' decision-making capacity be given special consideration, due to the nature of the research population. In general, patients requiring palliative care tend to be old, and old age has been found to be a significant predictor of impaired understanding. In addition, patients at the end of life are often seriously ill, and data suggest that domains of decision-making capacity – understanding, appreciation, reasoning and the ability to express a consistent choice – may be impaired in seriously ill patients. For these reasons, careful consideration of informed consent procedures is warranted in the design and implementation of palliative care research.

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Recommended Guidelines

1. **Formal assessments of decision-making capacity should not be required for all subjects in all studies.** Formal assessments require expertise and time to administer and score; therefore, it is not practical to require that all patients who enroll in palliative care research undergo a formal capacity assessment. Rather, the need for formal capacity assessment should be based on the prevalence of impaired decision making in the population to be studied and the balance of risks and benefits that a study represents.

2. **In determining whether a formal assessment of decision-making capacity is necessary, investigators should consider the characteristics of prospective subjects.** Investigators should consider their research population and identify the patient characteristics most likely to impair decision-making capacity. As mentioned before, among patients at the end of life, increasing age and illness are associated with reduced decision-making capacity, as is lack of formal education.

3. **In determining whether a formal assessment of decision-making capacity is necessary, investigators should consider the study's risks and potential benefits.** In general, the greater the risks involved in a study, the more important it becomes to ensure that prospective subjects have adequate decision-making capacity.

4. **Formal capacity assessments are not needed for studies that pose minimal risks.** Risks to the patient are minimal if they are no greater than those risks a patient would face in daily life. Examples of minimal risk studies include those consisting of surveys or interviews and those that involve education or similar interventions. Such studies require few safeguards of the informed consent process, and assessments of decision-making capacity should not be required.

5. **For studies that pose greater-than-minimal risks and offer potential benefits, the need for a formal capacity assessment should be determined by the characteristics of the prospective subjects.** Studies that pose potential risk, but also may confer benefits, such as drug trials or trials of other therapeutic interventions, require more evidence of decision-making capacity. Additional safeguards for determining such capacity can be designed specifically to meet the needs of the study population. For example, cancer patients in an inpatient hospice who are near the end of life may require more assessments than a population consisting of young, educated outpatients with cancer.

6. **For studies that pose greater-than-minimal risks and do not offer potential benefits, a formal capacity assessment is indicated.** Although rare in palliative care research, studies that present risk and do not offer potential benefits, such as pharmacokinetic studies, require a formal assessment of decision-making capacity.

7. **Decision-making capacity should be assessed using a validated instrument such as the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR).** The MacCAT has been studied in a range of clinical studies and has been modified for clinical research.

8. **Summary judgments of capacity or understanding should be based on *a priori* thresholds.** During the study-design phase investigators need to consider the relative importance of the domains of decision-making capacity – understanding, ability to

Patient characteristics, not research topics, drive the need for extra consideration of decision-making capacity in palliative care research

Strategies to ensure patient decision-making capacity rest in patient characteristics and the risks and benefits of a study

When warranted, formal assessments of decision-making capacity require validated instruments

appreciate, reasoning and the ability to express a choice – and identify the key elements that they believe to be essential for a particular study. These decisions should guide determinations of decision-making capacity.

9. Recruitment protocols should clearly define procedures to be followed if prospective subjects lack decision-making capacity. Procedures for recruitment will vary depending on the nature of the study, the time course of the enrollment process, and the skills and experience of those obtaining consent. Therefore, these procedures should be included in the study protocol.

10. In general, it is appropriate to exclude those patients who lack decision-making capacity. It is however also acceptable to attempt to enhance decision-making capacity and then retest. It is possible that with additional teaching patients can reach acceptable levels of capacity.

Related Research

Casarett and colleagues recently conducted a preliminary study among cancer patients to determine predictors of decision-making capacity. Subjects completed a symptom rating scale and a battery of neuropsychiatric tests. Two raters who were blind to all patient characteristics assessed decision-making capacity using the MacCAT-CR. These scores were summarized in overall capacity judgments using *a priori* criteria established by a panel of experts. No relationship was observed between symptom severity and any domain of decision-making capacity (understanding, appreciation, reasoning, ability to express a choice) or summary judgments. However, several other patient characteristics including age, education and selected neuropsychiatric test results were found to be strongly associated with capacity scores.

Implications

- Casarett addresses concerns about impaired decision-making capacity in patients at the end of life constructively, through ethical reasoning and empirical research. He has found that advanced illness is not a predictor of impaired capacity, but that other characteristics, like age and education, are powerful predictors. Therefore, Institutional Review Boards should tailor their concerns about informed consent to the population being studied.
- The need for formal capacity assessments depends on both the characteristics of the population and the risks of the study, not just on whether a patient population is seriously ill.
- In outlining steps to ensure adequate decision-making among study participants, Casarett reveals several potential research questions. Areas in need of exploration include the determination of predictors of impaired decision-making capacity and the essential components of capacity that should be incorporated into summary judgments. Research is also needed on effective interventions to improve capacity and the ability of clinicians in the field to assess capacity.

Effective strategies for ensuring patient decision-making capacity require planning and should be part of the research design

This issue of the CHERP Policy Brief is based on the following articles: 1) Casarett D. *Assessing decision-making capacity in the setting of palliative care*. Journal of Pain and Symptom Management. April 2003; 25(4): S6- S13. 2) Casarett D, Kirschling J, Levetown M, Merriman M, Ramey M, Silverman P. *NHPCO position statement on the ethics of research that involves patients near the end of life*. Journal of Palliative Medicine. 2001; 4: 441-449. 3) Casarett D, Karlawish J. *Are special ethical guidelines needed for palliative care research?* Journal of Pain and Symptom Management. August 2000; 20: 130-9. 4) Crowley R, Casarett D. *Patients' willingness to participate in symptom-related and disease-modifying research: results of a research screening initiative in a palliative care clinic*. Cancer. May 2003. 97(9):2327-33. 5) Casarett D, Karlawish J, Hirschman K, Sankar P, Asch DA. *Obtaining informed consent for cancer pain research: do patients with advanced cancer and patients with chronic pain have different concerns?* Journal of Pain and Symptom Management. November 2002; 24: 506-516. 6) Casarett D, Karlawish J, Hirschman K. *Identifying ambulatory cancer patients at risk of impaired capacity to consent to research*. Journal of Pain and Symptom Management. July 2003; 26: 615-26.

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