NHPCO Task Force Statement on the Ethics of Hospice Participation in Research

DAVID CASARETT, M.D., M.B.A., BETTY FERRELL, Ph.D., FAAN, JANE KIRSCHLING, R.N., D.N.S., M.B.A., MARCIA LEVETOWN, M.D., FAAP, MELANIE P. MERRIMAN, Ph.D., M.B.A., MELANIE RAMEY, M.S.W., J.D., and PHYLLIS SILVERMAN, Ph.D.

ABSTRACT

There is an urgent need for robust empirical data to guide the assessment and treatment of patients near the end of life. Because they are important providers of end-of-life care in this country, hospices have an important role to play in facilitating this research. However, hospices may also face considerable ethical challenges in doing so. This task force statement begins by discussing the importance of hospices’ potential contributions to research. Next, we describe ways in which characteristics of hospice patients, and hospices’ structure, create ethical challenges that may limit these contributions. We conclude by proposing ways in which hospices and national professional organizations can begin to overcome some of these challenges.

INTRODUCTION

The goal of good end-of-life care is to relieve suffering and to improve quality of life. However, access to palliative care is often poor, and standards to guide care have not been established clearly. At least in part, these deficiencies exist because of a lack of solid evidence on which to base clinical and policy decisions. Therefore, there is an urgent need for research that can define the standard of care and to increase access to quality care.

Recent years have seen a dramatic increase in research that involves patients near the end of life. In the category of research, we include all activities that are designed to contribute to generalizable knowledge. This succinct definition hides a heterogeneous mix of qualitative and quantitative studies, and descriptive and interventional designs. Although these studies encompass a wide spectrum of goals, designs, and methods, they share a focus on patients near the end of life.

These studies have begun to recruit subjects from increasingly diverse sites, including clinics, hospital wards and, more recently, palliative care units. A small but growing number of studies are focusing on hospice populations, and collaborations with hospices have produced descriptive data, as well as evaluations of therapeutic interventions in these patients, as well as evaluations of the effectiveness of the hospice program itself. In general, however, it appears that most end-of-life research, and particularly clinical trials, have been conducted in nonhospice populations. This is unfortunate because hospices can make a unique and important contribution to our understanding of end-of-life care.

However, hospices, clinicians, and investigators may have concerns about the ethics of such...
research. It is essential that concerns about the ethics of research are addressed first, because there is some uncertainty in the research community about whether patients near the end of life should ever be asked to participate in any form of research. Others have objected to this extreme position, but many providers, Institutional Review Boards (IRBs), and even investigators remain unsure about the ethical limits of research involving dying patients. Of course, there are other obstacles to hospice participation in research, including a lack of training, a lack of staffing resources, and short lengths of stay. Nevertheless, it is essential that hospices first establish a foundation for ethical conduct before addressing other barriers.

To address these ethical concerns, the National Hospice and Palliative Care Organization (NHPCO) convened a Task Force on the Ethics of Hospice Participation in Research drawn from members of that organization’s Research and Ethics Committees. This task force identified salient issues, developed recommendations, and produced this paper through a consensus process. The task force was chaired by the first author (D.C.) and all other contributing members are credited as authors in alphabetical order.

This paper begins by summarizing arguments

| Table 1. Recommendations for Hospices |

Recommendations related to patients’ vulnerability

**Decision-making capacity**
- Hospices that frequently conduct research that poses greater than minimal risks (e.g., clinical trials) should provide training to the hospice personnel who recruit in assessing decision-making capacity.
- Studies that pose greater than minimal risks should use questionnaires ("quizzes") to assess understanding prior to enrollment.

**Voluntariness**
- The informed consent process for all research should emphasize the distinction between research and clinical care.
- Where resources permit, hospices should consider obtaining consent through a third party, such as the researcher or designee, who is not involved in patients’ care.
- For prospective studies that take place over several weeks or months, hospices should consider ongoing informed consent that periodically reminds patients that their participation is voluntary.

Recommendations related to structural sources of ethical challenges

**Assessing the risks and benefits of research**
- Hospices that participate in research should establish policies for research review, including a mechanism of review.
- Hospices that frequently participate in research should either:
  - Constitute their own IRBs, with adequate training and support for members, or
  - Seek cooperative relationships with a medical center or university’s IRB.
- Hospices that conduct research infrequently should, at minimum, identify a staff member who is familiar with requirements of review and informed consent, and who can ensure that projects receive adequate oversight from an investigator’s home institution.

**Education**
- Hospices that participate in research should provide basic education in research ethics to their clinicians who will be involved in recruiting patients. Education might be provided at the hospice or at state or national meetings, and should include an overview of:
  - informed consent
  - decision-making capacity
  - voluntariness
  - research review
  - privacy and confidentiality

**Short lengths of stay**
- Hospices should assess the burdens of research on staff and patients, and the prevalence of impaired decision-making capacity, in light of lengths of stay

**Capitated payments**
- Hospices should assess the demands of a research project on resources and personnel needs to ensure that research participation does not adversely affect care.
- Hospices should define needs for support in advance and incorporate into funding proposals.

IRBs, Institutional Review Boards.
in favor of hospice participation in research, and goes on to review some of the ethical challenges that hospices will face in doing so. The task force’s recommendations for meeting these challenges are described briefly throughout the text, and are summarized in two tables. Table 1 offers specific recommendations that are intended for hospices. Table 2 offers more general recommendations for national organizations and funding agencies. These recommendations were developed for these audiences, and are intended to complement the recommendations of the American Academy of Hospice and Palliative Medicine (AAHPM), which is issuing a position statement that is directed to investigators.

THE IMPORTANCE OF HOSPICE PARTICIPATION IN RESEARCH

Hospice participation in research is vital for at least four reasons. First, by participating in research, hospices can provide innovative interventions that may improve their current patients’
quality of life. By participating in these studies, hospices can benefit their patients directly by offering them interventions that may become the future standard of care.

However, not all interventions prove to be beneficial. For instance, a new analgesic therapy may not be more effective than usual care. Nor do all studies offer the possibility of benefit. Indeed, descriptive studies will not generally benefit patients directly, even though they may generate important knowledge that will benefit future patients. Therefore, in deciding whether to participate in research, hospices should consider other reasons other than potential benefits to their patients.

Second, hospices should also consider participating in research in order to allow their patients to make a contribution to science and to help others. In general, altruism is an important motivation for people who participate in research. Altruism may be particularly important for patients near the end of life, for whom the opportunity to make a lasting contribution can be a central component of a good death. Therefore, hospices may consider participating in research in order to give their patients a chance to fulfill these goals.

Third, hospices should also consider participating in research in order to ensure that the results of end-of-life research are generalizable to their patients. The generalizability, or external validity, of any study’s results depends on their applicability to clinical practice. That is, if a study’s results are to benefit future patients, the study must enroll subjects who resemble, in clinically significant ways, the future patients to whom results will be applied.

A generalizability gap is a common problem for hospice care, which involves patients at the far end of the spectrum of curative and palliative care. In 1999, the average length of stay in hospice care programs was 48 days, and the median was 25 days. These patients are unique in terms of their physiology, psychology, and quality of life, making it difficult to generalize study results from other less seriously ill populations. Generalizability may be limited, too, if research subjects receive care in a different setting than do home hospice patients. For instance, if research is concentrated in inpatient settings and in academic medical centers, the results may not be easily generalized to home care settings, where available resources are different and family caregivers’ contributions to care contribute further variability. By participating in research, hospices can ensure that the results of that research are applicable to their patients, in the settings in which their patients receive care.

Fourth, by participating in research, hospices can provide indirect, or collateral, benefits to their patients. Even if a study offers no direct benefits, patients may find indirect benefits, such as additional attention from providers or more intensive care and monitoring, very appealing, particularly for symptom-related research. It is also possible that patients who participate in research may enjoy better outcomes than those who do not. Although these better outcomes may simply be because of selection bias, they may also result from added attention and monitoring in a study, or to the often cited but poorly understood Hawthorne effect, which refers to the impact of observation on behavior. If even some of these benefits can be attributed to research participation, rather than to selection bias, they offer important reasons for hospices to consider participating in research.

ETHICAL OBSTACLES TO HOSPICE PARTICIPATION IN RESEARCH

The arguments outlined above suggest that hospices should seriously consider participating in research. Indeed, some might argue that hospices have an ethical obligation to participate in research. However, any obligation to participate in research should be tempered by a frank acknowledgement of some of the ethical challenges that this research creates for hospices.

Hospices that participate in research must be able to ensure that a study’s design respects their patients’ vulnerability, and that the study itself offers a reasonable balance of risks and benefits. Hospices that participate in research will also need to consider the demands of research in light of other demands that are imposed by short lengths of stay and by capitated payments. Below we discuss each of these problems, and outline specific recommendations in the text and in Tables 1 and 2.

VULNERABILITY

The principal source of ethical uncertainty about hospice research comes from concerns that patients near the end of life are vulnerable. That is, they may be relatively (or absolutely) inca-
pable of protecting their own interests. Patients near the end of life may be vulnerable because of inadequate decision-making capacity, and because research participation may not be entirely voluntary. Each of these concerns about vulnerability is discussed below.

**Vulnerability because of inadequate decision-making capacity**

Concern about vulnerability comes in part from uncertainty about subjects’ capacity to consent to research. “Capacity” refers to subjects’ ability to understand relevant information, to appreciate the significance of that information for them, and to reason through to a conclusion that is consistent with their goals. Concern about capacity is reasonable given the prevalence of cognitive impairment at the end of life. These concerns parallel concerns in research involving patients with dementia, psychiatric illness, and patients in the intensive care setting among others. Perhaps the most concrete aspect of decision-making capacity is understanding. Even if a research study is explained adequately in nontechnical terms, subjects may fail to understand the risks and potential benefits of end-of-life research if they are cognitively impaired. Cognitive impairment in terminally ill patients occurs in 10% to 40% of patients in the final months and in up to 85% of patients in the last days of life. Cognitive impairment may be difficult to identify in palliative care research because cognitive function may vary over time, and because impairment may result from the experimental or therapeutic medications themselves, such as opioids, benzodiazepines, or corticosteroids. Investigators who conduct trials of medications will encounter these challenges even more frequently if trials are designed to evaluate treatments for delirium, for which some degree of impairment is an inclusion criterion.

These challenges may be compounded in prospective studies that require participation over days or weeks. In these studies, even if patients have the capacity to consent at the time of enrollment, they may not retain that capacity throughout the study. Thus, days or weeks after patients give consent to participate, they may be unable to understand changes in their condition clearly enough to withdraw. The result can be a “Ulysses contract” of sorts, in which research subjects find it easier to enroll than they do to withdraw.

**Special problems of decision-making capacity in hospice research**

Challenges of impaired decision-making capacity and inadequate understanding exist in research in a variety of settings. However, these deficits may be particularly challenging in hospice research because hospices frequently lack the training and resources to detect deficits in capacity. The skills of capacity assessment are straightforward and easily summarized. Nevertheless, capacity assessment is likely to be difficult for hospice clinicians who lack formal training in these skills.

Although there are no simple tests of capacity to consent to research, it is possible to assess understanding by administering a quiz prior to enrollment in research. This strategy is being used increasingly by IRBs and, most recently, in a nationwide effort sponsored by the Department of Veterans Affairs. For instance, a 5–10 item quiz covering principal elements of a study (e.g., risks, benefits, alternatives) can be included easily in the informed consent process.

Such assessments should not be required for all research, but they are appropriate for studies that pose greater than minimal risks. A risk is defined as being greater than minimal in federal regulations if it is greater than the risks ordinarily encountered in daily life or those associated with routine physical or psychological examinations or tests. For example, an assessment of understanding is not necessary for most survey research, but should be performed for most clinical trials.

**Vulnerability because of coercion or inducement**

Even if subjects near the end of life have decision-making capacity and adequately understand the risks and potential benefits of participation in hospice research, they may still be vulnerable to coercion or inducements. For instance, there is reason for concern that patients with intractable pain may be desperate for relief, and may readily confuse research with therapy. In addition, as in other forms of research, subjects may be vulnerable if their illness makes them dependent on relationships with health care providers or if they depend upon an institution, such as a hospice, for care. These patients may be reluctant to jeopardize their care by refusing to participate in research conducted by the hospice in which they are enrolled.
Special problems of inducement and coercion in hospice research

These concerns are common in research in a variety of settings. However, they are particularly acute in the hospice setting, where the structure of care creates close relationships between the hospice team and patient, and the patient’s family. Whereas other patients with less far-advanced disease may maintain relationships with several clinicians, hospice patients nearing the end of life are often homebound and largely dependent on the hospice team for care. These concerns are magnified when patients are admitted to a dedicated hospice care unit. These patients may be influenced by an environment that is a “total institution,” which in other settings has been suggested to make patients vulnerable to influence. These threats to voluntariness have at least three implications for hospice clinicians who participate in research. First, when hospice staff recruit patients to participate in a study, even subtle suggestions may have a powerful effect on patients’ willingness to enroll. Second, once patients have agreed to participate, they may be reluctant to withdraw from a study for fear of jeopardizing the relationship they have developed with a hospice clinician. Third, because of the close relationships that many patients develop with hospice clinicians, they may be unable to distinguish between the clinician’s responsibilities as a study representative and those of clinical care. Specifically, patients may believe that procedures, medications, or questionnaires are a part of clinical care, and therefore intended to benefit them, when in fact they are conducted as a part of research and offer no certain clinical benefit. This “therapeutic misconception” threatens the validity of patients’ informed consent and may be particularly problematic in the hospice setting, in which one nurse may be the patient’s sole contact with both research and clinical care.

These concerns may be ameliorated if someone who is not part of the hospice team obtains consent and gathers data throughout a study. As with assessments of understanding described above, this approach to consent is not necessary for all research. Nevertheless, it might be appropriate for those studies that pose greater than minimal risks, such as clinical trials.

STRUCTURAL SOURCES OF ETHICAL CHALLENGES

The challenges of hospice research described above are related to the ethics of research that involves human subjects. These challenges are compounded by at least four administrative and structural features of hospice care. These features include the lack of mechanisms for research review, a lack of familiarity with research in hospices, increasingly short lengths of stay, and the capitated payment system through which hospices are reimbursed. Each of these is discussed briefly below.

Mechanisms of research review

One additional ethical challenge of hospice research has to do with the balance of risks and benefits that such research offers to patients. The federal regulations governing research require that a study’s risks be proportionate to its benefits and to the importance of the knowledge to be gained. Although this balancing is a core requirement of ethical research, it may be difficult for hospices to assess a study’s risks and potential benefits accurately if they participate in research only infrequently. Specifically, most hospices lack adequate mechanisms for research review, such as IRBs that are established for this purpose, with salary support for an IRB chair and funds for administrative support. This structure provides a mechanism for review and oversight, and ensures that IRB members can develop experience in review, a growing knowledge base, and an institutional memory that allows them to offer consistent assessments over time. Without similar structures that support an IRB, hospices may find it very difficult to adequately and consistently balance the risks and benefits of proposed research.

Therefore, hospices that conduct research should identify a strategy for research review that is commensurate with their research volume (Table 1). Hospices that participate in research frequently might establish their own IRB, if they have the resources to provide staffing, support, and training that is consistent with existing standards. For most hospices, however, it will be more appropriate to establish a cooperative relationship with a university’s IRB. Hospices that rarely participate in research should, at a minimum, identify a staff member with an interest in research who would help to identify mechanisms of review as the need arises.
**Education about research ethics**

When hospices participate in research only infrequently, their staff may lack an understanding of fundamental aspects of ethical research, such as techniques of obtaining informed consent and assessing decision-making capacity. Without training, hospice professionals are likely to be ill equipped to ensure that their research, and particularly their informed consent procedures, are ethically sound. Therefore, efforts to enhance hospice participation in research should be accompanied by intensive educational initiatives through in-house education, in newsletters, on the Internet, and at national meetings. These initiatives should enhance hospice clinicians’ awareness of key aspects of research and research ethics as outlined in Table 2.

**Capitated payments and research ethics**

The current system of reimbursement creates other ethical challenges for hospices that would like to participate in research. The pressures of a capitated payment system mean that hospices interested in research will face a series of difficult resource allocation choices. Because hospices rely on fixed per diem rates for care, any resources they devote to research, such as personnel time, must be volunteered, reimbursed from external sources, or reallocated from other administrative or clinical activities. This challenge is analogous to the challenge that hospices face in developing other non-reimbursed programs, such as those related to education, in the setting of scarce resources.

A simple solution is not likely. However, several steps may be useful (Table 2). First, educational programs should be developed to familiarize hospices with external sources of funding for research that would allow them more flexibility in allocating resources. Second, national organizations such as the NHPCO and the AAHPCM can investigate and define the legality of billing Medicare for research-related expenses for hospice patients. Third, educational initiatives can be directed at investigators and funders in order to enhance awareness of the financial challenges that hospices face, and to encourage them to consider hospices’ personnel time in budgeting.

**Short lengths of stay and research ethics**

A related challenge arises because patients are referred to hospice quite late in their illness. This means that hospice patients are very near the end of life, with the attendant decreases in mental status and decision-making capacity. Similar to the challenges created by capitated payments, a simple solution is not readily apparent.

In general, hospices with extremely short lengths of stay should be more alert to the possibility that their patients lack the capacity to give consent for research participation. In addition, hospices with very short lengths of stay (e.g., <14 days) should consider a routine assessment of understanding prior to research enrollment. These hospices might also wish to explore research in other similar populations with longer lengths of stay. These populations may share enough characteristics with hospice patients to allow generalization, but without some of the challenges of short lengths of stay and impaired decision-making capacity.

**CONCLUSION**

Many opportunities exist for hospice involvement in research. The potential benefits to patients may be significant, and patients may also value the opportunity to contribute to improved end-of-life care. Finally, and perhaps most important, by contributing to end-of-life research, hospices have an opportunity to ensure that research results will be relevant to their unique patient population. For all of these reasons, it will be important to build hospices’ capacity for research.

However, as noted above, numerous ethical challenges limit opportunities for hospice research. These challenges are created by a combination of patient vulnerability, a lack of resources such as IRBs, and systemic factors such as a capitated payment system and decreasing lengths of stay. Therefore, the success of any effort to advance hospice research will depend on a multi-faceted approach that addresses all of these challenges at a local and national level. Although these challenges are substantial, they deserve a concerted effort because the alternative—inadequate data to guide care at the end of life—poses substantial dangers as well.
ACKNOWLEDGMENTS

The authors would like to thank Drs. Neil MacDonald, Perry Fine, Inge Corless, Bruce Jenning, and Stephen Connor and the other members of the NHPCO Research and Ethics Committees for their invaluable comments and suggestions. Dr. Casarett is a recipient of a Health Services Research Career Development Award from the Department of Veterans Affairs.

REFERENCES

33. Steinhausen K, Cipp EC, McNeilly M, Christakis NA, McIntyre LM, Tulsy JA: In search of a good death:
Observations of patients, families, and providers. Ann Intern Med 2000;132:825-832.


46. Elliott C: Caring about risks: Are severely depressed patients competent to consent to research? Arch Gen Psych 1997;54:113-116.


Address reprint requests to:
David Casarett, M.D., M.A.
Institute on Aging
University of Pennsylvania
3615 Chestnut Street
Philadelphia, PA 19104

E-mail: Casarett@mail.med.upenn.edu