

# Recruiting for Research in Hospice: Feasibility of a Research Screening Protocol

DAVID CASARETT, M.D., M.A.,<sup>1</sup> CORDT T. KASSNER, Ph.D.,<sup>2</sup>  
and JEAN S. KUTNER, M.D., M.S.P.H.<sup>3</sup>

## ABSTRACT

**Background:** The growth of palliative care research has been limited by challenges of slow recruitment and underenrollment. One potential solution to this problem is the use of screening questions embedded in clinical data collection, which identify patients who are interested in participating in research and who can then be approached directly. The goal of this study was to evaluate the feasibility of this strategy for identifying hospice patients who are interested in research participation.

**Design:** Cross-sectional survey.

**Setting/ Subjects:** Patients and their families who had enrolled in one of two community-based hospice programs.

**Measurements:** Three screening questions (for survey-based research, clinical trials and family-focused research) were integrated into the intake process of two community-based hospice organizations.

**Results:** Of the 214 patients who were able to respond, 54% indicated willingness to be approached about survey-based research, 40% were willing to be approached for clinical trials and 65% were willing to be approached for family-focused research.

**Conclusions:** These results suggest that screening questions may be useful in identifying hospice patients who are willing to be recruited for research. Further study is needed to define the likelihood that these patients will consent and whether these screening questions introduce selection bias in the recruitment process.

## INTRODUCTION

**I**N RECENT YEARS, research studies have increasingly recruited hospice patients. These studies have included both descriptive and interventional studies that promise to improve the evidence base that guides clinical treatment choices for patients near the end of life.<sup>1-6</sup> This area of research is critically important to continued devel-

opment of palliative care as an evidence-based specialty.<sup>7,8</sup> It is particularly important in ensuring that the expanding palliative care evidence base is applicable to hospice patients.

However, researchers and hospices face considerable challenges in recruiting subjects from this population. Patients are typically referred to hospice very near the end of life, often within days of death.<sup>9,10</sup> They may have multiple severe

<sup>1</sup>Center for Health Equity Research and Promotion, Philadelphia VAMC, University of Pennsylvania, Philadelphia, Pennsylvania.

<sup>2</sup>Colorado Hospice Organization, Colorado Springs, Colorado.

<sup>3</sup>University of Colorado Health Sciences Center, Denver, Colorado.

symptoms<sup>11-13</sup> and their families may face substantial caregiving burdens.<sup>14</sup> It is not surprising, therefore, that hospices have substantial concerns about research participation, and particularly about the appropriateness of recruiting patients and families under these difficult circumstances.<sup>15</sup> Many of these challenges—particularly those related to informed consent and decision-making capacity—were the subject of a recent conference sponsored by the National Institutes of Health.<sup>16</sup>

In addition, when recruiting patients for research, hospices face two additional interrelated challenges. First, hospice staff need to identify those patients who would like to be told about the opportunity to participate in research. Some patients may be very willing to participate, and may even see participating as a way to enhance the meaning they find in their last weeks. It is important for hospices to identify these patients, in order to give them the opportunity to participate in research that they value.

Second, hospices need to identify those patients who do not want to participate in research and who do not want to be approached about studies for which they may be eligible. These patients may feel that attempts at recruitment are invasive and intrusive. Indeed, there are ethical concerns, which Institutional Review Boards (IRBs) appear to share, that patients who are very sick may feel that attempts to recruit for research are intrusive, or intimidating.<sup>7,17,18</sup> Therefore, it is important for hospices to avoid recruiting these patients.

If hospices do not address these challenges and balance them appropriately, recruitment for hospice-related research will be limited. Inefficient recruitment can lead to slow accrual and under-enrollment, and studies that do not meet planned enrollment numbers may be delayed, or may be underpowered if they end early. Inefficient recruitment also introduces the possibility of selection bias, if patients who refuse or who are not approached differ in clinically significant ways from those who enroll.<sup>19</sup>

Investigators and hospices would be better able to balance the need to recruit efficiently without being overly intrusive if they are able to distinguish those patients who are interested in participating in research from those who are not. This would ensure that investigators are able to approach as many patients as possible, and that patients who are not interested in research partici-

pation could be avoided in recruitment efforts. One potential solution to this problem is a screening program that identifies those patients and families who are willing to be approached to participate in research. This strategy has been evaluated in an ambulatory cancer population, with promising results.<sup>20</sup> However, this strategy has not been employed in a hospice population. In this paper, we describe the feasibility of administering, at the time of hospice enrollment, three screening questions that were previously used to identify ambulatory patients with cancer who are willing to be approached for research recruitment. We describe the screening questions used, patients' responses, and patient characteristics associated with willingness to be recruited.

## METHODS

The goal of this anonymous chart review-based study was to assess the feasibility of a routine intake/enrollment assessment of hospice patients' potential interest in participating in hospice-based research.

### *Study setting*

Two community-based hospices in Colorado. Both hospices provide home hospice care and have freestanding hospice facilities. Neither is affiliated with an academic medical center nor has an independent research program or agenda. Both are active members of the Population-based Palliative Care Research Network (PoPCRN).

### *Study procedures*

The participating hospices incorporated three screening questions about potential research participation into their routine intake process (see Appendix for details of study questions). Over a 4-month period, responses to these questions were recorded in the medical record, along with basic demographic data that are routinely collected by hospice staff at the time of hospice enrollment. Because the research screening questions were incorporated into the hospice intake process, as with other intake questions, they were answered by the patient, if able, and the family, if available. The study was approved as an exempt study by the Colorado Multiple Institutional Review Board (COMIRB) and by the Institutional Review Board of the University of Pennsylvania.

For the purposes of this study, records were stripped of all identifiers by hospice staff before the study data were sent to the investigators. Selected patient clinical data and the responses to the research screening questions were sent to the study investigators. Data (anonymous) included patient age (for patients younger than 89 years of age; for patients 89 years of age or older, age was recorded as "89 years or older" per Health Insurance Portability & Accountability Act (HIPAA) requirements for anonymous data), gender, primary admitting diagnosis, ethnicity, site of care (i.e., home, nursing home, hospice facility). Each patient and/or family member was also asked whether they would be willing to be approached to participate in survey-based studies, clinical trials, and family-focused research (Appendix A). For each type of study, patients and/or families were asked to describe why they would or would not want to be recruited.

### Statistical analyses

Data were entered into a computerized database. To permit calculation of mean age, patient age was recoded as 90 years for those for whom "89 years" or older was noted. Descriptive statistics describe the study population and frequency of responses to the study questions. *t* Tests and  $\chi^2$  were used to explore associations between participant characteristics and research screening question responses.

## RESULTS

Data are available for 214 patients who were asked the research screening questions during the study period. Patient characteristics are depicted in Table 1. Responses to the three study questions are depicted in Figure 1. A large portion of the study population was not able to answer the research screening questions: 44% for the question regarding surveys, and 37% for the question regarding clinical trials. For 23% of respondents, the family was not asked the question about family-focused research.

There were four commonly cited reasons for willingness to be approached about each of the three study types: to help others, to help oneself, to help the hospice and out of interest or curiosity (Table 2). There were also four commonly cited reasons for a desire not to be approached

TABLE 1. PATIENT CHARACTERISTICS ( $n = 214$ )

Patient characteristics	n (%) <sup>a</sup>
Age, years	
$\leq 18$	2 (1)
19–64	35 (17)
65–79	65 (32)
80–89	54 (26)
$> 89$	49 (24)
Gender, Female	114 (53)
Primary admitting diagnosis	
Cancer	69 (32)
Frailty, global decline	40 (19)
Pulmonary disease	12 (6)
Neurologic disease	12 (6)
Dementia	6 (3)
Cardiac disease	5 (2)
Other	7 (3)
Race, White	201 (94)
Ethnicity, Hispanic or Latino	15 (7)
Site of care	
Home	83 (39)
Nursing home	40 (19)
Hospice facility	68 (32)
Other (assisted living, hospital)	14 (7)

<sup>a</sup>Where total is less than 100%, data are missing.

about research, across all three study types: burdens or hassles involved, fatigue or other symptoms, the perception that it would take too much time, and lack of benefit (Table 3).

Responses to the three research screening questions were generally independent of patient characteristics. Although male patients were more likely to refuse approach for survey studies (47%

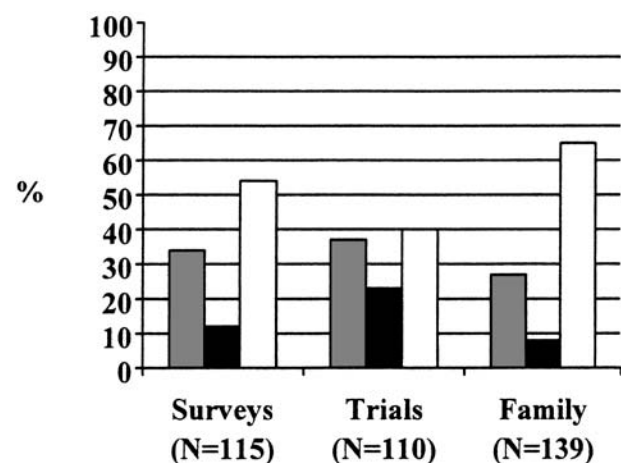


FIG. 1. Responses to three screening questions. Excludes "Unable to answer" responses. "Surveys" = research that does not involve medications, tests, or changes in usual care; "Trials" = clinical trials, "Family" = family-focused research.

TABLE 2. REASONS FOR EXPRESSED WILLINGNESS TO BE APPROACHED ABOUT RESEARCH

<i>Reason</i>	<i>Surveys (n = 62)</i> n (%) <sup>a</sup>	<i>Trials (n = 44)</i> n (%) <sup>a</sup>	<i>Family (n = 90)</i> n (%) <sup>a</sup>
Help others	48 (77)	29 (66)	75 (83)
Help self	21 (34)	24 (55)	32 (36)
Help hospice	27 (44)	17 (39)	48 (53)
Interest/curiosity	10 (16)	10 (23)	14 (16)

<sup>a</sup>Total > 100% as response categories not mutually exclusive. Represents responses only from those who answered "Yes" to the screening question.

versus 17%,  $p = 0.001$ ), there were no gender differences in responses to the other two research types (clinical trials, family studies). On average (imputing age 90 for all those age 89 years or older), those who were willing to be approached about clinical trials were younger than those who were not interested (70 versus 78 years,  $p = 0.025$ ). There were no age differences in responses to questions about the other two research types (surveys, family studies). There were no differences in responses based on diagnosis (cancer vs. non-cancer) or site of care. While no significant differences were found based on race or ethnicity, the lack of racial and ethnic diversity of the study population precludes definitive conclusions based on race or ethnicity.

## DISCUSSION

Researchers and hospices face considerable challenges in recruiting subjects from hospice populations. These challenges have produced substantial concerns about hospices' participation in research, and particularly about the appropriateness of recruiting patients and families.<sup>15</sup> This study's results have three implications for the conduct of hospice-based research.

First, this study found that questions to screen for interest in research can easily be incorporated

into routine data collection procedures at the time of hospice admission. That is, these questions can be administered quickly, and can be designed to fit logically within a series of other clinical questions. This strategy appears to pose an insignificant administrative burden and, more importantly, is acceptable to seriously ill patients and their families.

Second, this study found different responses based on the type of research described. This finding suggests that patients and families are able to distinguish among the types of research study that were described in screening questions. This finding is particularly important, because as hospice research increases in scope, it is likely that hospices will be involved in a variety of types of studies, ranging from descriptive interview studies to clinical trials. If patients and families have clear preferences about participation in these types of studies, it will be important to use screening questions that correspond to these preferences, so that patients' and families answers will be most useful to hospices and investigators.

Third, this study found few associations between patients' responses to these screening questions and patient characteristics. Where there are differential responses based on patient characteristics, this screening strategy may produce selective enrollment in research. If these patient characteristics are related to outcome variables,

TABLE 3. REASONS FOR EXPRESSED DESIRE NOT TO BE APPROACHED ABOUT RESEARCH

<i>Reason</i>	<i>Surveys (n = 39)</i> n (%) <sup>a</sup>	<i>Trials (n = 41)</i> n (%) <sup>a</sup>	<i>Family (n = 38)</i> n (%) <sup>a</sup>
Burdens/hassles	15 (38)	19 (46)	21 (55)
Fatigue/other symptoms	13 (33)	10 (24)	8 (21)
Will take too much time	9 (23)	6 (15)	7 (18)
No benefit	3 (8)	6 (15)	3 (8)

<sup>a</sup>Total > 100% as response categories not mutually exclusive. Represents responses only from those who answered "No" to the screening question.

selective enrollment may result in selection bias.<sup>19</sup> Future research is needed to determine whether screening questions used in conjunction with usual recruitment increase or decrease selective enrollment compared to usual recruitment alone. Further research is also needed to determine whether, and how, reasons for patients' and families' reluctance to participate may be related to clinical and demographic characteristics.

In general, these results are encouraging and suggest that hospices may wish to consider using a similar strategy to identify hospice patients and families who are willing to be approached for research. However, further research is needed to determine how well responses to screening questions predict actual enrollment decisions. Previous work in outpatient settings suggest that willingness to participate in research predicts future responses to actual recruitment.<sup>21</sup> However, it is not known whether expressed preferences have the same predictive value under the challenging circumstances of hospice. Specifically, it will be important to determine whether responses to screening questions predict research enrollment accurately, and whether screening questions produce overestimates or underestimates of the proportion of patients and families who are willing to enroll in research studies.

Furthermore, there are several reasons why caution is needed before applying this strategy more widely. First, this study found that approximately one third of patients were unable to respond to the screening questions related to patient-focused research. Moreover, one quarter of family members were not asked about family-focused research. Hospice enrollment often takes place under difficult circumstances. For instance, patients are typically referred to hospice very near the end of life, often within days of death.<sup>9,10</sup> They may have multiple severe symptoms<sup>11-13</sup> and their families may face substantial caregiving burdens.<sup>14</sup> It is likely, therefore, that these circumstances were in large part responsible for high patient non-response rates, and for many of the instances in which intake personnel did not ask these questions of family.

This finding is not necessarily a limitation of this research screening strategy, because it is likely that those patients who could not respond would also be unable to provide informed consent for a study. Therefore, a high non-response rate to these screening questions is unlikely to alter the characteristics of a recruited study sam-

ple. Nevertheless, it is possible that some patients were unable to respond because of reversible symptoms such as pain, dyspnea, or confusion. If a hospice team is able to initiate effective treatment, the same patient who was unable to respond at the time of hospice enrollment might be able to respond soon afterward. If this is the case, screening questions that are administered at the time of hospice enrollment may underestimate the proportion of patients who are able to express a willingness to be approached for research. Therefore, further research is needed to define the optimal time at which these screening questions should be administered.

Second, caution is required in generalizing these findings to other hospice populations. This screening strategy was evaluated in a relatively small patient population at two hospices in a single geographic region. This population was also ethnically homogeneous. Indeed, this lack of diversity may explain the lack of a relationship between ethnicity and interest in research that has been reported in a previous study of a similar screening technique.<sup>20</sup> Furthermore, because the current study was not able to draw on a rich source of clinical data (e.g., symptom burden, functional status) it is possible that some sources of selective response were not detected.

Although this study is preliminary, its results are promising and suggest that a screening strategy may prove to be useful in promoting hospice research. As the field of palliative medicine grows, clinicians will increasingly look to empirical research to provide solid evidence base for their practice. As this happens, it will be important to ensure that hospice patients are included in the studies that comprise that evidence base, so that study results will be applicable to that population. The screening strategy described here offers one way in which hospices and investigators can include patients from this vulnerable population in a way that balances privacy, dignity, and the need for research that will ensure continued improvements in care in the future.

#### ACKNOWLEDGMENTS

We are grateful to the staff, patients and families at the Hospice of St. John, Lakewood, Colorado, and Pikes Peak Hospice and Palliative Care, Colorado Springs, Colorado, for their time and effort in making this study possible.

## REFERENCES

1. Ashby M, Fleming B, Wood M, Somogyi A: Plasma morphine and glucuronide (M3G and M6G) concentrations in hospice inpatients. *J Pain Symptom Manage* 1997;14:157-167.
2. Kimball LR, McCormick WC: The pharmacologic management of pain and discomfort in persons with AIDS near the end of life: Use of opioid analgesia in the hospice setting. *J Pain Symptom Manage* 1996; 11:88-94.
3. Hunt R, Fazekas B, Thorne D, Brooksbank M: A comparison of subcutaneous morphine and fentanyl in hospice cancer patients. *J Pain Symptom Manage* 1999;18:111-119.
4. Zeppetella G, O'Doherty CA, Collins S: Prevalence and characteristics of breakthrough pain in cancer patients admitted to a hospice. *J Pain Symptom Manage* 2000;20:87-92.
5. McMillan SC, Mahon M: The impact of hospice services on the quality of life of primary caregivers. *Oncol Nurs Forum* 1994;21:1189-1195.
6. Herbst LH, Strause LG: Transdermal fentanyl use in hospice home-care patients with chronic cancer pain. *J Pain Symptom Manage* 1992;7(3 Suppl):S54-57.
7. Casarett D, Kirschling J, Levetown M, Merriman M, Ramey M, Silverman P: NHPCO Task Force Statement on Hospice Participation in Research. *J Palliat Med.* 2001;4:441-449.
8. Raudonis B, Kirschling JM: Hospice research: The importance of program participation. *Am J Hosp Palliat Care* 1992;9:21-25.
9. Christakis NA, Escarce J: Survival of Medicare patients after enrollment in hospice programs. *N Engl J Med.* 1996;335:172-178.
10. *National Trend Summary 2002*. 2003 National Hospice and Palliative Care Organization, Washington DC.
11. Vainio A, Auvinen A. Prevalence of symptoms among patients with advanced cancer: An international collaborative study. Symptom Prevalence Group. *J Pain Symptom Manage* 1996;12:3-10.
12. Somogyi-Zalud E, Zhong Z, Lynn J, Hamel M: Elderly persons' last six months of life: Findings from the Hospitalized Elderly Longitudinal Project. *J Am Geriatr Soc* 2000;48:S131-139.
13. Kutner JS, Kassner CT, Nowels DE: Symptom burden at the end of life: hospice providers' perceptions. *J Pain Symptom Manage* 2001;21:473-480.
14. Emanuel EJ, Fairclough DL, Slutsman J, Alpert H, Baldwin D, Emanuel LL: Assistance from family members, friends, paid care givers, and volunteers in the care of terminally ill patients. *N Engl J Med* 1999; 341:956-963.
15. Casarett D, Karlawish J, Hirschman K: Are hospices ready to participate in palliative care research? Results of a nationwide survey. *J Palliat Med.* 2001;5: 397-406.
16. Casarett D, Knebel A, Helmers K: Ethical challenges of palliative care research. *J Pain Symptom Manage* 2003;25:S3-S5.
17. Casarett DJ: Research ethics. In: Berger A, Portenoy RDW, (eds): *Principles and Practice of Palliative Care and Supportive Oncology*, 2nd ed. Philadelphia: Lippincott, Williams, and Wilkins; 2002, pp. 1131-1140.
18. Casarett D, Karlawish J: Are special ethical guidelines needed for palliative care research? *J Pain Symptom Manage* 2000;20:130-139.
19. Meinert CL: *Clinical Trials. Design, Conduct, and Analysis*. Oxford: Oxford University Press; 1986.
20. Crowley R, Casarett D: Patients' willingness to participate in symptom-related and disease-modifying research: Results of a screening initiative in a palliative care clinic. *Cancer* 2003;97:2327-2333.
21. Halpern SD, Metzger DS, Berlin JA, Ubel PA: Who will enroll? Predicting participation in a phase II AIDS vaccine trial. *J Acquir Immune Defic Syndr Hum Retrovirol.* 2001;27:281-288.

Address reprint requests to:

*David Casarett, M.D.*

*Center for Health Equity Research and Promotion*

*Division of Geriatrics*

*University of Pennsylvania*

*3615 Chestnut Street*

*Philadelphia, PA 19104*

*E-mail: casarett@mail.med.upenn.edu*

## Appendix

### Screening Questions

#### **Willingness to participate in research that does *not* involve medications, tests, or changes in usual care**

We sometimes do research studies that involve things like surveys, questionnaires, interviews or observations. These studies are designed to find ways of taking better care of our patients. If we begin any such studies that you could participate in, would you like us to tell you about them?

#### **Willingness to participate in clinical trials**

We sometimes do studies to test new medications for pain or other symptoms. These studies are designed to find better ways to help make people comfortable. If we begin any such studies that you could participate in, would you like us to tell you about them?

#### **Willingness to participate in family-focused research**

We sometimes do studies that involve things like interviews, surveys, questionnaires or observations that involve our patients' families. These studies are designed to find better ways help the families of patients in hospice. If we begin any studies like this, would you like us to tell you about them?

Copyright of Journal of Palliative Medicine is the property of Mary Ann Liebert, Inc. and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.