*Palliative Medicine* 2006; **20:** 745–754

# Identifying, recruiting, and retaining seriously-ill patients and their caregivers in longitudinal research

**Karen E Steinhauser** Center for Health Services Research in Primary Care and Center for Palliative Care, Durham VA Medical Center and the Department of Medicine and Center for the Study of Aging and Human Development, Duke University, **Elizabeth C Clipp** Geriatric Research Education and Clinical Center, Durham VA Medical Center and Division of Geriatrics and School of Nursing and Center for the Study of Aging and Human Development, Duke University, **Judith C Hays** School of Nursing and Center for the Study of Aging and Human Development, Duke University, Durham, North Carolina, **Maren Olsen** Center for Health Services Research in Primary Care, Durham VA Medical Center, **Robert Arnold** Institute for Doctor-Patient Communication Section of Palliative Care and Medical Ethics, University of Pittsburgh, Pittsburgh, Pennsylvania, **Nicholas A Christakis** Department of Health Care Policy, Harvard Medical School, Cambridge, Massaschusetts, **Jennifer Hoff Lindquist** Center for Health Services Research in Primary Care, Durham VA Medical Center and **James A Tulsky** Center for Health Services Research in Primary Care, Durham VA Medical Center and Center for Palliative Care, Durham VA Medical Center and the Department of Medicine and Center for the Study of Aging and Human Development and Institute on Care at the End of Life, Duke University, Durham, North Carolina

**Background**: In order to improve the state of science in palliative care, we must increase our ability to document the real-time experience of patients and families as they traverse the end of life. Yet, frequently, prospective measurement is impeded by difficulty with patient identification, recruitment, enrollment, and retention. The palliative care literature is replete with descriptions of studies unable to meet enrollment goals, and that as a result, do not have adequate power to test hypotheses or draw conclusions. **Objectives**: To review the literature describing difficulties associated with ascertainment, enrollment, and attrition. To outline the successful recruitment methods of a new longitudinal study of patients and their caregivers. **Design**: A two-year longitudinal study of 240 patients with Stage IV cancer (breast, prostate, colorectal, lung), advanced congestive heart failure (CHF) LVEF $<40$ or advanced chronic obstructive pulmonary disease (COPD) $pCO_2 > 46$, and their caregivers, interviewed monthly for up to two years. Patients were identified using clinical and administrative databases from one geographic region. **Results**: Representative and successful ascertainment was associated with use of clinical criteria and medical record review versus physician or other provider prognostication, use of recruitment letters from personal physician, recruitment letter content, brochure content, small monetary incentives, refined phone scripts, use of matched ethnicity interviewers, in-home and phone interview strategies, measure selection, patient and caregiver rapport, and on-going staff support (including grief and bereavement). **Conclusions**: Recruitment to prospective longitudinal studies at the end of life is difficult, but possible. The lessons learned from this study are applicable to future investigators conducting prospective research. *Palliative Medicine* 2006; **20:** 745–754

**Key words:** longitudinal; methodology; palliative care; recruiting

## Introduction

To improve the care of dying patients and their families, interventions and organisation of care environments must be informed by patient and family preferences. The NIH State of the Science Consensus Conference on End of Life Care stressed the need for research documenting participants' values that would shape patient-centered care.[1,2] However, one of the main impediments to such research is the difficulty in identifying, recruiting, and retaining representative samples of patients with advanced life-limiting illness.

A growing body of literature has outlined the struggle to empanel very sick patients.[3–10] For example, Rinck conducted a literature review of 11 end-of-life studies: two were unable to recruit sufficient numbers of patients to report any results; 10 reported recruiting problems; 10 identified threats to sample heterogeneity;

Address for correspondence: Karen E Steinhauser, PhD, VA and Duke Medical Centers, Center for Palliative Care, Hock Plaza, 2424 Erwin Rd, Suite 1105, Box 2720, Durham, NC 27705, USA. E-mail: karen.steinhauser@duke.edu



10.1177/0269216306073112

four reported significant patient attrition; and four studies were compromised by outcome variable selection problems.[10] The title of another article illustrates the point well: 'It just didn't work, the realities of quality assessment in the English health care context'.[4] Yet, without such work aimed at debriefing and evaluation, an evidence base to guide practice cannot be built.

In this paper, we review common barriers associated with identification, recruitment, and retention of seriously-ill patients, and, when appropriate, their caregivers. For purposes of this study, we use the term 'seriously-ill' to refer to patients with chronic life-limiting illness versus those suffering from acute or traumatic injury. In recruiting patients, we use the term 'seriously-ill' because many potential patients may not, as yet, identify as being at 'end of life'. Though not a formal systematic review, our literature search focused on studies recorded in the Medline database from 1990 to May 2006, using the terms 'palliative care', 'end of life', 'methodology', 'prospective', and 'recruitment', together and in combination; we examined descriptive cross-sectional and longitudinal studies, as well as randomised, control trials. We also offer strategies to overcome these barriers, successfully used in the Pathways study, a five-year longitudinal examination of patients with advanced life-limiting illness and their caregivers. Our strategies for sample identification, recruitment, and retention may be applied throughout all study phases.

## Study overview

The main objective of the Pathways study (an active NIH initiative, grant No. 5R01NR008249-04) is to characterise the progression of multiple dimensions of patients' and caregivers' experiences from serious illness to death. Primary aims are to describe patients' trajectories of physical symptoms, functional status, emotional function, quality of life, preparation for death, spirituality and awareness of dying; describe caregivers' trajectories of anticipatory grief, caregiver burden and awareness of dying; examine the relationships between these trajectories (eg, patient spirituality and functional status; patient and caregiver awareness of dying); and determine the extent to which these trajectories are modified by patient and caregiver characteristics (eg, gender, ethnicity, socioeconomic status, disease type, coping style), and health services utilisation (eg, emergency department visits, hospitalisation, hospice enrollment).

Power analyses indicate enrollment of 240 seriously-ill patients and their caregivers; to date we have enrolled 171 patients and 129 caregivers. We follow these dyads prospectively until death, or the end of the two-year data collection period, whichever occurs first. The primary caregivers are identified by each patient, and followed until six months after the patient's death. In monthly interviews of both patients and caregivers, we measured the multiple domains of interest to the study. These contacts varied between in-home interviews every three months, which included all measures of interest, and short monthly telephone interviews during each of the two intervening months, which focused only on the five primary study outcomes (functional status, emotional functioning, quality of life, caregiver well-being, and caregiver burden). Three months after a patient's death, we interviewed the deceased's caregiver to record a retrospective account of the patient's illness and death, as well as to assess their grief and adjustment to the loss. At six months post-death, we again interviewed the caregiver to capture information on well-being and the bereavement experience.

## Subject identification

### Barriers

While the strength of prospective assessment involves its capacity to capture contemporaneously and repeatedly the subjective experience of patients, a substantial literature outlines the challenges of prospectively identifying who is at the end of life, and therefore, who are potential research subjects. To date, the most common patient ascertainment pathway is health care provider prognostication and referral.[3,5,7–9] Study staff ask the patient's physician, clinic doctor, nurse-practitioner, nurse, or other key personnel to use clinical judgment to identify patients in the practice or clinic who likely are at the end of life and, therefore, candidates for study. Often clinician approval, prior to patient contact, is an institutional review board (IRB) requirement, with the stated goal of protecting patient privacy and/or psychological well-being.[7] Investigators may conclude that using clinicians for patient screening is an expedient step in addressing that requirement. Furthermore, clinician prognostication offers a reasonable solution to the difficult task of prospectively ascertaining a population of 'dying' patients, and many presume the patient's provider to have special knowledge regarding subjects more amenable to research participation.

Unfortunately, this approach has significant disadvantages. First, compared to earlier in the disease trajectory, physicians can prognosticate slightly more accurately the closer a patient is to death, yet clinicians rarely can say with certainty whether an individual likely will live another day, week, or month. Second, in this role, clinicians become study gatekeepers, filtering who may be 'appropriate' through personal interpretation of study inclusion criteria or based on feelings of protectiveness for more vulnerable patients.[3] As gatekeepers, providers

may consciously or unconsciously be less likely to refer 'problem' patients. Conversely, they may refer only those whom they predict may be amenable to or interested in participation, ie, 'good' study candidates and, thus, influence study representativeness. Third, in this role, providers also may be asked to estimate patients' receptiveness to research. However, formal providers' knowledge of any patient's desire to participate in research usually is not known. Fourth, individual interpretation of study appropriateness is highly variable. The literature suggests many such studies suffer from vague eligibility criteria, compounding variation in individual interpretation.[8] Moreover, study criteria which identify patients as 'dying' or 'terminally ill' may present clinicians with a cognitive dissonance when they are offering curative therapies.[9]

Provider referral is also hindered by practical considerations, such as time and incentive.[7,5] No matter how supportive a provider may be of the study goals, additional time dedicated to identifying potential patients must be balanced against the immediate demands of patient care. As a result, patient referrals to the study team often become low priority, or, in some cases, impossible to accomplish. Though many providers pledge support, they have little incentive to persistently and thoroughly review clinic rosters. Finally, samples obtained from one or more clinics are only as representative of a general population as the clinic itself, with additional bias introduced by the practice patterns of a limited number of physicians.[9] In sum, common limitations associated with provider referral studies include: poor prognostic accuracy, gatekeeping, individual variation in interpreting eligibility, lack of time and incentive, and poor generalisability. As a result, studies that rely solely on clinician prognostication to identify patients at the end of life usually face the challenge of significant selection bias and sample homogeneity.

**An alternative strategy**

Overcoming these obstacles begins with study design and continues throughout all phases of implementation. First, the study team must define explicitly the scope of inquiry by answering two questions. What constitutes the period of time considered 'end of life' or the 'dying' phase? What exact time frame is needed to address the primary objectives and study aims? For example, investigators must decide if they are primarily interested in gathering data from patients who have been diagnosed with advanced life-limiting illness or from those within the 'imminent dying' phase of a longer illness process. If interested in capturing a particular transition, such as the transition from curative to palliative care, investigators must ask if the observation interval will include that period of change. If the phenomenon of interest is duration dependent, is the period of observation accommodating? Is the research focus a particular context of care (eg, hospice) or end-of-life care more generally? Is this an investigation of a particular disease process (eg, cancer) or the end-of-life experience across many chronic conditions? As with other studies, investigators must examine whether their recruitment methods will yield the desired mix of age, sex, ethnicity, and functional status. Although every choice involves consideration of selection effects, investigators must be explicit about what each strategy will yield and whether those choices are in concert with study questions.

Our goal was to study the transition from serious illness to death, and, therefore, ascertain patients with on average one-year survival, but who may be followed for up to two years. Furthermore, we wanted to study both cancer and non-cancer trajectories at the end-of-life. We were interested in charting as fully as possible these advanced illness trajectories, as well as the transition to 'imminent dying'. We aimed to study a fundamental human process, rather than a disease-specific process, and, therefore, sought greater breadth in patient selection. Therefore, we defined end-of-life more broadly to include individuals with a 50% one-year mortality. Rather than ask physicians to prognosticate regarding whom in their practice would likely die within one year, we chose clinical criteria associated with an estimated 50% one-year survival for patients with Stage IV cancer (also Stage IIIb lung cancer), NYHA Stage III or IV congestive heart failure (LVEF $<40\%$) and COPD with hypercapnea ($pC0_2 > 46$). To further refine the search for illness severity, among patients with COPD, we added the requirement of one ER visit or hospitalisation within the previous year.

These three categories represent the most common causes of death from chronic disease in Durham County, NC, USA, that do not primarily impair cognitive function and disrupt patients' ability to report on their experiences (as with cerebrovascular disease). Patients with these diseases are usually aware of the serious nature of their illnesses, and their deaths generally are not unexpected. Furthermore, because patients with these diagnoses and disease severity have an approximate 50% one-year survival, the majority of subjects have sufficient time for enrollment and capture of multiple data points along their illness trajectories, yet allowing follow-up through death.[11,12] These diseases represent trajectories with varying levels of certainty regarding illness course and functional decline. In fact, these different trajectories are most often cited and compared to each other with regard to the creation and funding of appropriate health services. Since we expected disease type to influence trajectory patterns, we chose to limit the number of illnesses studied to three categories of advanced chronic disease. We aimed to recruit 80 patients and their caregivers from each of the three groups, for a total of

240 patients and their caregivers (75% of patient sample had caregivers).

Within cancer, we chose four representative malignancies: female breast, prostate, lung and colorectal. These malignancies have the highest mortality rates, which demonstrate relative prognostic accuracy for survival among Stage IIIb and IV patients, allow an equal sampling of male and female overall, and provide a broad age range. With respect to the trajectories we are studying, we did not expect significant differences by disease type in the previous six to 12 months. Clinically, advanced-stage patients with any of these four malignancies tend to experience similar symptoms of fatigue, pain, and discomfort from distant metastases. Thus, for analytic purposes, we chose to treat those with cancer as one group, but with sufficient sub-sample numbers for selective descriptions by primary site.

Second, after choosing whom to study, investigators must identify the most representative source of patient participants, and carefully consider the feasibility of recruiting them. The gold standard population would be geographically based and inclusive of all patients with the targeted illness. Retrospectively, using death certificates, one can identify all within a geographic area that died of particular diseases. Prospectively, there is no similar source or database for identifying all persons with the index diseases. However, a majority of patients can be identified using hospital databases. Therefore, we chose to access all eligible patients with the targeted conditions that live within a 35 mile radius of Durham, NC, USA and who could be identified via databases at the two Durham hospitals – Duke University Hospital and the Durham VA Medical Center. These two hospitals serve different populations. Duke University Hospital is a tertiary referral center for southeastern US, yet has a commitment to serving the health care needs of Durham, and maintains a network of primary care practices, including an indigent care clinic. The Durham VA Medical Center serves the area's veteran population.

**Patient ascertainment (see Figure 1)**

*Cancer.* We identified cancer patients using the Duke Tumor registry (which includes patients from Duke University and Durham Regional Hospitals), the Duke Decision Support Repository, the VA Tumor Registry, as well as the FILEMAN program, to query the hospital VISTA database (computerised medical record). We identified, on a monthly basis, all patients in inpatient or outpatient settings with ICD-9 codes for breast, colorectal, lung and prostate cancer (162.X, 174.X, 153.X, 154.X, and 185.X), and with a home zip code within an approximate 35-mile radius. We then manually scanned the computerised medical records of identified patients to detect which patients had Stage IIIb or IV disease.

*Congestive heart failure.* No common mandated registry exists for CHF as it does for cancer, so ascertainment required a different approach. However, the Duke Heart Failure Program maintains a database that includes all patients referred to the CHF clinic from any location. As Durham Regional Hospital is part of the Duke University Health System, many patients with CHF are referred to the Duke CHF Clinic and are entered into the database. In addition, patients are routinely added by the CHF clinic nurses who review echocardiogram reports at both hospitals and identify all patients with low ejection fractions. The database is up to date, and could be easily queried for patients with NYHA Class III or IV disease and LVEF $<=40\%$, who live within the targeted zip codes.

To ascertain VA patients with CHF, we used a similar method as described above, querying the VISTA database for the appropriate ICD-9 (425.0, 425.4, 428.X, 429.X) and zip codes. This was followed by manual scan of computerised medical records to identify patients meeting the threshold for NYHA Class III and IV disease and LVEF $<=40\%$ at their most recent visit.

*Chronic obstructive pulmonary disease.* As with CHF, there are no mandated registries for COPD. However, because hypercapnea (ie, elevated arterial blood $pCO_2$) is an excellent predictor of mortality in COPD, we used $pCO_2$ to identify eligible patients. At Duke University and Durham Regional Hospitals, the medical records system and/or pathology informatics provided a list of patients that live in the designated zip code areas, had a $pCO_2 >=46$ mEq/l within the last three years, and a COPD ICD-9 code (490.X–496.X). To further increase the probability of identifying patients that met our prognostic requirements, we included those with at least one emergency department visit or hospital admission in the past year. Patients selected in this manner did not require manual record review. At the VA, we used the FILEMAN program to identify an identical set of patients. For all patients, we followed patient health status by periodically checking medical records.

**Caregiver ascertainment**

For every patient enrolled in the study, we sought to enroll his or her primary caregiver. We asked the patient to identify the person who spends most time with them, who provides most of their day-to-day care, assistance, and support. We had used this identification procedure in past caregiver research to identify the person most aware of their needs and concerns.[13–18] In those cases where caregivers could not be identified, or refused to participate, we still enrolled and followed the patients. If a caregiver was identified at a later point during the study period, we enrolled them. As noted, the majority (75%) of patients had caregivers enrolled in the study.

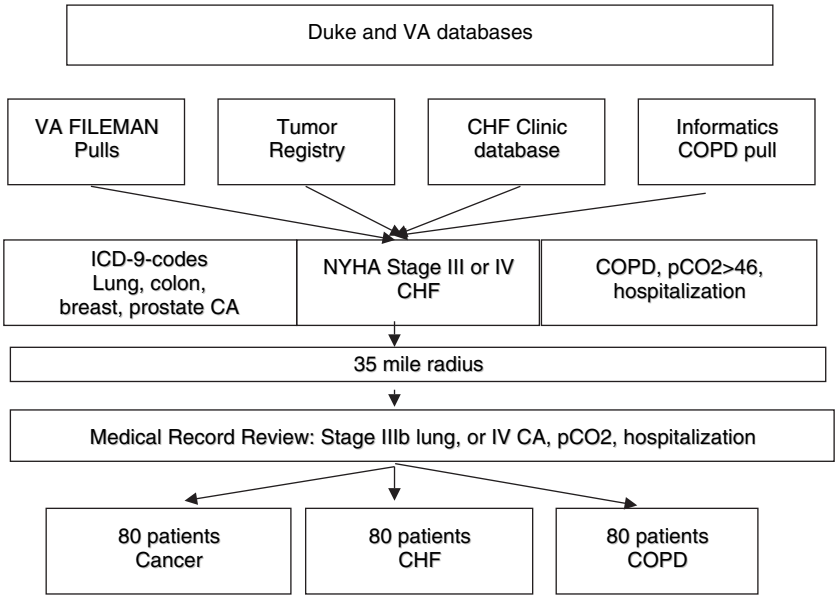


**Figure 1** Patient ascertainment

### Special considerations

Investigators using these methods will note five practical considerations for study planning and execution. First, the team needs to establish relationships with appropriate information technology (IT) personnel, who have the time and technical expertise to conduct the necessary database queries. Second, the study team must budget the IT time, preferably in the proposal development phase. In addition, time also must be allocated above that specified in grant full-time equivalent (FTE) requirements for a research assistant to manually review hospital records and conduct database queries. For example, these queries involve an iterative process of refinement because initial pulls may be too broad, yielding more cases than could practically be scanned. Fourth, time is also needed for double-checking the logic of programming to ensure data retrieval corresponds with eligibility criteria. Fifth, funds will also be needed to hire a nurse for assistance in gaining entrée to and reviewing clinic rosters and, over the course of the study, for co-ordinator time to balance ascertainment with recruitment duties among personnel.

## Recruiting

### Barriers

The most frequently cited problem in recruiting patients is that patients are often referred too late in the disease course, and are or rapidly become too ill for full study participation.[8] In addition, patients are often reported to be too anxious to understand complex study descriptions; additionally, lengthy or confusing screening

**Table 1** Participant ascertainment and characteristics

| Characteristic | Chart review | Clinically qualified | MD approved | Patient contacted | Refused | Excluded | Enrolled |
|---|---|---|---|---|---|---|---|
| Cancer | 3148 | 347 | 270 | 201 | 78 | 48 | 65 |
| Breast | 784 | 59 | 43 | 35 | 6 | 7 | 20 |
| Prostate | 989 | 64 | 54 | 48 | 20 | 9 | 18 |
| Lung | 1062 | 163 | 111 | 80 | 38 | 23 | 17 |
| Colon | 300 | 61 | 48 | 38 | 14 | 9 | 10 |
| CHF | 1404 | 194 | 184 | 158 | 66 | 35 | 51 |
| COPD | 1159 | 192 | 174 | 162 | 48 | 47 | 55 |
| Male | | | | | | | 101 |
| Female | | | | | | | 70 |
| Caucasian | | | | | | | 105 |
| African-American | | | | | | | 58 |
| Other | | | | | | | 8 |

MD disapproval reasons: patient dead, cognitively impaired, patient too ill, physician refusal. Excluded reasons: patient died, cognitively impaired. Table does not include patients in process between being MD approval and patient contact, or patient contact and refusal, exclusion, or enrollment. For example, of the 201 cancer patients who were sent a letter, 78 refused, 48 were excluded, 65 enrolled and 10 are in process.

mechanisms have been reported to deter enrollment.[7] In addition, in seeking to balance privacy concerns with offering patients the opportunity to participate in studies, researchers and institutional review boards debate the relative merit of *opt-in* versus *opt-out* enrollment strategies. Each has implications for ease of enrollment and sample generalisability. Finally, the literature includes studies involving both patients and caregivers; however, the linked-sample design usually obtains data from patients prior to death and family members in after-death retrospective interviews.[19] Few studies include simultaneous patient and caregiver enrollment and longitudinal follow ups. In general, the previously described literature provided useful guidance regarding challenges and pitfalls commonly experienced in end-of-life research and aided our enrollment process design, outlined below.

## An alternative strategy

*Initial contact – recruitment letter.* After identifying potential participants, through the previously described ascertainment, we began the first steps of approaching patients. Our Institutional Review Board (ethics board) required that recruitment letters be sent to patients from their physicians. Therefore, we hand-delivered recruitment letters to physicians (with a small incentive packet of M&M candy), and if agreeable, they signed the letter. Physicians did not sign letters if patients had died or were deemed severely cognitively impaired; in other instances, the clinicians offered no reason but simply did not sign (see Figure 2). Of note, some physicians had left the practice, or did not know the patient. All letters were on institution letterhead and, with the physician signature, served as markers of institutional support and study legitimacy.

We carefully crafted the content of the letter to include the necessary elements of consent, including study description, purpose, voluntary nature, and confidentiality, but without too much detail, which could overwhelm patients. We also included an opt-out 800-number patients could call if they did not want us to contact them about the study. A few months into the study, we added a study brochure and a $10 incentive with the recruitment letter. The brochure offered a study synopsis patients could read and digest prior to contact with an interviewer; it also featured information about study time commitment and payments. As a result, patients were less overwhelmed and more informed prior to the initial telephone call. They also were able to make a quicker decision regarding participation. In some instances, following the brochure, patients called to sign up. The $10 cash incentive was included as payment for their time in considering the study and a good faith gesture of our investment in their participation.

*Follow-up telephone contact.* If patients did not opt-out, we contacted them, as promised in the letter, between seven and 10 days following receipt of the letter. Through pilot testing and other study experience, we learned several lessons about critical elements of this contact. First, the initial telephone contact was best not relayed in a scripted manner, but rather in a conversational style. Key elements of consent were included, but rather than reading this material verbatim, we paraphrased it. The importance of developing a rapport with patients immediately cannot be overstated. Second, all interviewers administered the Short Portable Mental Status Questionnaire over the telephone. Again, interviewers learned the delicate balance of administering questions that can be perceived as overly simplistic or even insulting to cognitively intact respondents. We framed the scale by stating, 'Some of these may sound very basic or even silly'. Third, interviewers learned to schedule the baseline interview within a week following the initial telephone call. If delayed further, interest in the study waned and enrollment rates decreased. In a more nuanced fashion, interviewers learned that some patients expressed interest in the study but delayed initial scheduling of the baseline interview, did not return telephone calls consistently, or cancelled appointments with little notice. These behaviors cued the team to 'passive refusal' of study participation. Learning to identify such refusal sooner than later, prevents waste of time for all involved. Fourth, when possible, we matched the ethnicity of the interviewer and the patient.[20] Our interviewers observed variation by ethnicity in telephone contact. For many African-American families, there were several layers of 'protectors' via family and friends who screened us as we attempted to make contact with the patient. Our interviewers soon learned that recruitment among a portion of the sample, took multiple rounds of initial telephone calls, and was distinct from the process of 'passive refusal'.

*Recruiting the caregiver.* For every patient enrolled in the study, we sought to enroll their primary caregiver. We asked the patient to identify 'the person who spends the most time with you, who provides most of your day-to-day care, assistance, and support'. In those cases where caregivers could not be identified, or refused to participate, we still enrolled and followed the patients. If a caregiver was identified at a later point during the study period, we enrolled them. A large majority (75%) of patients had caregivers enrolled in the study.

While we anticipated some of the challenges outlined in the literature (eg, burden, time, anxiety, etc.) throughout the process of recruiting caregivers, in piloting and full study, we learned valuable lessons for use in future studies. First, identifying a caregiver was often achieved via an iterative conversation rather than a simple

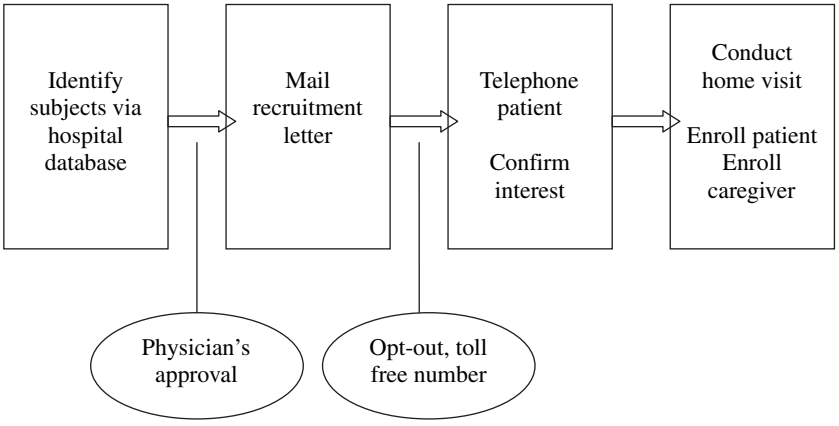


**Figure 2** Recruitment and enrollment process

response to a query. Sometimes, this was clarification on the role of the caregiver in the study, but in other instances, the iterations appeared to relate to patients' reluctance to acknowledge the need for a caregiver, which would imply a level of personal dependency. Second, and related to the dependency issue, we initially used only the definition rather than the word 'caregiver'. Third, approximately 54% of caregivers were spouses or partners, 20% were children, 6% siblings, 3% parents, and 17% non-relatives. Caregivers did not necessarily co-reside with their care-recipients, and many also were dealing with personal chronic health conditions, even life-limiting illness. Others were working, and required special interview times, such as lunch times or evenings. Finally, though adding caregiver interviews may be considered an additional burden to the family unit, our experience suggested that, for many families, enrolling the caregiver decreased burden and improved patient recruitment by moving the caregiver out of the role of gatekeeper and into that of participant.

## Sample retention

### Barriers

Despite the previously reported difficulties with sample ascertainment and enrollment in studies of seriously-ill patients, some researchers report the greatest difficulties with sample retention. For example, Sherman *et al*. reported 73% of AIDS patients and 47% of patients with cancer withdrew from their longitudinal palliative care study (also monthly interview, but for 12 months), for reasons other than death.[21] The study of Bordeleau *et al*. on quality of life among 253 patients with metastatic breast cancer resulted in only 25 patients completing all four data points (baseline, 4, 8, and 12 months). Higher rates of retention have been reported when study designs require fewer data collection points (>monthly) over one year.[22] For example, over 12 months, Bjordal *et al*. realised 61% completion of six data points. Reasons for withdrawal have included comorbid conditions, treatments, and high levels of family and caregiver stress associated with illness.[23,24] Patients and caregivers may offer resistance to standardised questions with Likert scales, desiring rather to tell more of their story.[21,25] In sum, investigators must carefully weigh maintaining low burden against the desire to document the patient and caregiver experience and associated needs at the end of life. Recording that complexity is both the research challenge and the source of multidimensional evidence necessary to improve the formal care rendered to this vulnerable population.

### An alternative strategy (see Table 2)

The literature often treats enrollment and retention as two discrete issues, managed subsequent to one another. However, experience from this study and our previous research suggests sample retention – longer-term study commitment – begins with the first contact. The letter, brochure, cash incentive, signing compensation and a variety of elements of initial contact set the tone for patient and caregiver commitment to the entire study. These elements communicate dedication on behalf of the study staff to the patient and caregiver, thus laying the groundwork for an ongoing reciprocal relationship.

**Table 2** Distribution of patients by monthly interviews completed

| No. of interviews completed | 0–3 | 4–6 | 7–9 | 10–12 | 13–15 | 16–18 | 19–21 | 22–24 |
|---|---|---|---|---|---|---|---|---|
| No. of patients | 20 | 17 | 18 | 16 | 12 | 30 | 5 | 21 |

Of the 171 patient enrolled, 139 are actively enrolled, 32 have died.

Planning for retention and sample care continues from the baseline interview through the last after-death interview, and is relayed in a variety of ways via institutional legitimacy, setting boundaries, defining the relationship, and acknowledging gratitude toward patient and family participants. Finally, staff support and interviewer self-care are crucial to sample retention. If interviewers become burned out and resistant to asking questions or conducting interviews, participants may sense that and respond in kind. We discuss each in more detail below.

*Baseline interview.* All baseline interviews were conducted in the home by interview pairs, one assigned to the patient and one to the caregiver. Establishing a face-to face, in-person relationship at the beginning of the study offered patients and caregivers the most convenient setting for data collection, within their own home. This gesture built initial rapport by demonstrating our willingness to meet them where they lived. Once the interviewer team arrived in the home, introductions and the informed consent process were conducted with patient and caregiver together. This pairing for informed consent appeared to serve several functions: first, it provided safety and comfort for both participants and study staff. Each party was able to evaluate the burgeoning relationship with the support of a familiar partner, and both were privy to the same information. Second, it conveyed the cohesiveness of the interviewer team, which lent both legitimacy and the practical advantage of one interviewer being able to cover for the other in case of an emergency. Following the combined consent, interviews were conducted separately in different rooms of the home. This protected respondents' privacy, reduced contamination threats, and offered a venue for truthful disclosure.

*Setting boundaries.* We made every effort to demonstrate rapport and extend convenience to patients and families. Yet, it was critically important to set boundaries regarding the nature of the interviewer–interviewee relationship. In particular, interviewers were trained to respond and communicate, when necessary, that they functioned in a research role versus and therapeutic or clinical role. They were not able to provide hands-on assistance of any sort, offer clinical advice or referral, or advocate for patients in the health care system. The only exception occurred when a patient's Center for Epidemiologic Studies Depression (CESD) scores exceeded 10 out of 30 and interviewers responded by distributing a sheet of local mental health resources. Additionally, if an interviewer became concerned that a subject may be suicidal, the patient's physician was informed. To date, this situation has not occurred. Finally, patients and families came to feel a personal connection to interviewers and, in some instances, invited them to weddings or funerals. Some studies, not including follow-up bereavement interviews, may choose to permit staff to attend funerals. However, with this study design and goal of capturing caregivers' trajectories of emotional functioning and bereavement experience, it could constitute an intervention and, therefore, was not permitted.

*Sustaining participation.* During the course of serious illness, patients and families experience stressful events in many spheres of life. In addition to often-extensive treatment regimens compounded by feeling ill, many participants in our study were managing ongoing family responsibilities and financial strain due to decreased income and increased health care expenses. For some, scheduling monthly interviews added yet another stressor. For others, the interviews provided a stress relief by providing time to discuss their illness experience. Again, while monthly contact may seem burdensome, it may exert a positive influence on continued participation, by enabling a more continuous relationship and stronger bond between enrollees and staff. In either case, interviewers were frequently impressed by the resilience and commitment of patients and caregivers, and found it useful to share those impressions with participants. Simply noting and routinely thanking participants for their time and commitment to the process served to buoy respondents, particularly those who may have been questioning continued participation. Following the death of any patient, we sent a handwritten condolence card from the interviewers and on behalf of the study; content generally mentioned something small but unique about the patient. Finally, at the end of participation, we distributed certificates of appreciation to patients, if alive, and caregivers. This served as an additional contact and further acknowledged their contribution to the study and the major event of completing data collection. We found it facilitated the after-death interview rapport, because the team had made contact during the most immediate stage of grief. Of the 171 enrolled patients, 32 have died. Time between last interview and death varied from 10 to 156 days (first quartile = 20 days; second quartile = 30; third quartile = 64 days).

*Staff support and self care.* Subject retention may also be related to interviewer support and well-being. A growing literature discusses the importance of self-care for clinical palliative care staff; however, research staff experience similar 'compassion fatigue'. The stress of talking with seriously-ill patients, watching them decline, and eventually die, builds over time and causes strain among the staff.[26] If this is not addressed, staff become fatigued and feel an increasing burden, which may be communicated, unconsciously, to patients and family members, thereby affecting participation. We have taken several measures to address staff self-care. First, we

conduct bi-monthly interviewer team meetings, in which staff members are able to share stories and discuss difficult or even poignant cases and their resulting feelings. This opportunity is repeated at monthly wider palliative care research staff meetings. Second, staff participated in in-service trainings on grief and bereavement as well as self-care sessions. Third, we worked to give staff as much scheduling flexibility as possible to accommodate their evening hours. Fourth, we included intermittent interviewer rewards, such as candy, breakfast foods, lunches, or individualised notes praising particular skills and performance. Finally, we held periodic 'staff play' times, where interviewers across several palliative care projects met for lunch, bowling, park visits, or other mutually agreed upon outings. The focus of these was not to debrief, but simply to relax and have fun. They were carried out during work hours, conducted every few months, and were well-received and restorative.

## Conclusion

In summary, key factors in improving identification, recruitment and retention of seriously-ill patients and their caregivers include the use of clinical criteria and hospital databases for representative ascertainment, and immediate efforts to establish participant-interviewer rapport because longer-term retention may be influenced by relationships built from the first point of contact. In addition, consideration should be given to not only enrolling caregivers, but moving them from their role as gatekeeper to that of study participant. Future research teams should be mindful that members of the research staff experience strain similar to clinical staff and efforts to support them and enhance opportunities for self-care must be extended.

The recommendations of this paper suit, most closely, prospective, longitudinal, studies, similar to the one described. However, the strategies employed are being used in a variety of other studies in our research group, including interventional and RCTs. Still, readers may modify suggestions to apply to their own studies' design and specific aims.

**Acknowledgements**

We wish to thank Robin Gilliam, Annallys Goodwin-Lander, Iris Smith, and Laura Wood, The Pathways Study interview team, for their work identifying, recruiting, interviewing, and following patients and their caregivers every month for the course of the study.

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