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Conducting Research with End-of-Life Populations: Overcoming Recruitment Challenges when Working with Clinical Agencies

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Abstract

Conducting end-of-life (EOL) research can present numerous challenges associated with recruitment and retention of research subjects. Such issues may result from working with a variety of clinical settings or the uniqueness of the patient population. The purpose of this article is to describe recruitment challenges in EOL research when collaborating with different types of clinical agencies and to discuss strategies that are being used to overcome these recruitment issues.

Keywords

hospice care; nursing methodology research; research subject recruitment; clinical nursing research; research-subject relations

Introduction

Numerous challenges may be encountered when working with clinical agencies to recruit and retain study participants for end-of-life research. Some challenges include staff protection of patients and bereaved relatives (Addington-Hall, 2002; Kendall et al., 2007;

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McMillan & Weitzner, 2003; Wiegand, Norton, & Baggs, 2008), lack of clear inclusion criteria because of a lack of definition of dying or end of life (Kendall, et al., 2007; Steinhauer, 2005), prognostic uncertainty for ill children and adults (Hinds, Schum, Baker, & Wolfe, 2005; Lee & Kristjanson, 2003; Wiegand, et al., 2008) and the often short and rapidly changing condition of the patient (Addington-Hall, 2002). Further, utilizing family members as proxy respondents for EOL research may prevent patients from ‘telling their story’ and sharing their own perspectives while causing family members to project their own experiences and emotion upon research protocols (Addington-Hall, 2002; Burr, 1996; Casarett, 2005; Dean & McClement, 2002). Some researchers have discussed these issues and have provided insights for developing and implementing EOL research (Addington-Hall, 2002; Field, Cassel, & editors, 1997; Kendall, et al., 2007; Lee & Kristjanson, 2003; McMillan & Weitzner, 2003; Wiegand, et al., 2008), including employing subject recruitment processes that are done in a caring manner and conveying respect for patients and the sensitive nature of their diagnoses (Gorman et al., 2008; Kavanaugh, Moro, Savage, & Mehendale, 2006; Kendall, et al., 2007). However, challenges to subject recruitment specific to the type of clinical agency have not been addressed previously in the literature, despite the growing variety and structure of agencies caring for persons at end of life.

Subjects for EOL and other sensitive research are recruited from a variety of clinical agencies and settings. These settings range from home to outpatient clinics to intensive care inpatient units (Wiegand, et al., 2008), each of which provides different levels and types of care. The knowledge and valuing of research within these diverse settings and conditions can vary greatly and lead to formidable challenges for the researcher when garnering support for a study. Understanding the dynamics and variances across settings is of key importance in developing positive collaborative relationships for the conduct of research.

Research conducted within a Center for End-of-Life Transition Research (CEoLTR) [P30 NR010680] has encountered recruitment challenges in the varying clinical agencies where the studies are in progress. The purpose of this article is to describe these recruitment challenges discovered when collaborating with different types of clinical agencies and to discuss strategies to overcome the challenges in a variety of clinical settings.

Description of Studies within the Center for End-of-Life Transition Research (CEoLTR)

The CEoLTR is designed to advance nursing science as it relates to respectful death across the life span including infants, children, young adults, adults, and older adults (Keenan et al., 2011). In this paper, we are focusing on our experiences with recruitment challenges in two of the ongoing studies funded by the CEoLTR. The first study involves examination of the presence and clusters of symptoms as well as the potential for symptoms to predict mortality in adults with advanced heart failure (EOL heart failure study) who are being recruited from two hospital outpatient clinics. The second study examines the presence, severity and functional impact of oral health conditions in terminally-ill cancer patients receiving home-level hospice care (EOL oral conditions study). Potential subjects for this second study are being recruited from two community hospice facilities. Faculty mentorship has been provided throughout these studies; the CEoLTR director and co-directors meet regularly with the investigators from the funded studies to offer guidance regarding all aspects of the studies’ conduct, including working with a variety of clinical agencies to facilitate the conduct of the studies.

Commonly Encountered Setting-Specific Challenges

Challenge #1: Ensuring Subject Recruiters Understand Inclusion Criteria for Defining End-of-Life

One issue that has presented a challenge within the two outpatient hospital clinics in the EOL heart failure study has been the application of definitions for appropriate subject inclusion criteria for approaching end-of-life. Subject identification can vary among care providers depending on how the criteria are perceived. An important inclusion criterion in the heart failure study is the care provider's response to the question, "Would you be surprised if this patient died within the next two years?" This question has been used successfully in a number of heart failure studies (Ciemins, Stuart, Gerber, Newman, & Bauman, 2006; Stuart, 2007) and has been found to be a reasonable approach to identifying persons with severe heart failure who are approaching the EOL.

In our experience, we have found that attending physicians are able to easily answer the question. However, residents and fellows at one data collection site (all from the same medical school) have referred very few of their patients to the study. These residents and fellows are more hesitant to answer the question and interpret it to be a prediction about the remaining length of a patient's life stating that their patients "are not going to die" or "I am not going to predict that my patients will die". Even after the meaning of the inclusion criterion question was reviewed, the residents from this site seemed unable to interpret "not being surprised about a patient's death" as different from a prediction of the patient's death. Interestingly, residents and fellows at our other data collection site, who attend a different medical school, are generally reluctant to make statements related to EOL issues, but have had little trouble determining whether or not they would be surprised if their patient were to die in the next two years. This discrepancy may be due to the differences in teaching styles, philosophies of care and experiences at the medical schools attended by the residents and fellows at these two outpatient hospital sites.

Strategies to overcome challenge #1—Garnering support in identifying subjects for the study continues to be a challenge at this one data collection site. We have worked individually with each resident and fellow to describe the research study and review the inclusion criteria, emphasizing that the inclusion criterion question is not a prediction of death but rather a statement indicating that the subject's death would not be unexpected. We have also involved the attending physician in this review of the study criteria and have requested that the attending physician encourage the residents and fellows to refer patients to our research team.

The strategy that has proved to be the most beneficial to manage this challenge has involved individual direct contact with each referring physician and resident/fellow and a discussion about his/her concerns about referring subjects to the research study. Further, inviting the referring physicians to observe portions of the research process has helped to clarify the inclusion criteria and build trust with referring clinicians.

Challenge # 2: Reducing Subject Burden at the End-of-Life

Subject burden is a concern when conducting end-of-life research. Computers can support research endeavors by reducing the burden of data collection and by serving as an incentive for subjects to participate. However, we have encountered several issues associated with subjects' acceptance of the computer and willingness to be recruited. In the EOL heart failure study, data are being collected utilizing touch screen computers and web-based data collection instruments. The two hospital outpatient clinics utilized for subject recruitment are in close proximity to one another, and although they serve different populations of

patients (VAMC vs. University-affiliated site), the patients they serve share surprisingly similar demographic characteristics. The majority of the subjects being recruited for this study are older, from minority groups, and of lower socioeconomic status. Many are not computer literate and some have refused study participation because they “do not use a computer”. In addition, we had originally planned to enroll the subjects in the study and then allow them to complete follow-up surveys from their homes via the internet. We found that very few subjects had computers or internet access, which made this plan difficult to implement. We also speculate that a number of the subjects who met the inclusion criteria may not be able to read, which would further complicate data collection via the touch screen computer and internet platform.

Another burden for participants at the end of life is having patients in multiple studies. We have faced a unique challenge involving “competing” research studies recruiting within hospice facilities and studying the same vulnerable patient population. One hospice facility declined participation in the oral conditions study because it was participating in another research study and did not want to commit to another study, expressing concerns that participation in multiple research studies could burden their EOL patients. Another hospice organization that was part of a larger research-intensive medical facility expressed interest in participation; however, it did not have the time or manpower to participate in an “external” research project beyond its internal research obligations.

One other issue with competing research studies at hospice facilities has involved priority for research participation being given to drug companies with substantially more monetary support than federally-funded studies. Finally, with multiple research studies involving the same patient population, some potential subjects may be ineligible to participate in multiple studies, depending upon the nature of the research. For example, a patient participating in an outcome-based intervention study to alleviate pain may be ineligible to participate in an observational study that is evaluating pain characteristics in this population.

Strategies to overcome challenge #2—To address the issue of computer literacy, data collectors have offered to help patients who were willing to participate in the study but were not able to use the computer. Data collectors have made every effort to use non-judgmental encouragement to help patients participate. For example, data collectors have stated, “A lot of patients are not familiar with the computer. I will be happy to help you if you are still willing to participate.” In this circumstance, if the patient has agreed to participate, the data collectors have read the survey tool to the subject and have used the touch screen computer to record the verbal responses while also showing the subject how to enter data via the computer.

Because a number of subjects did not have internet access and were unable to complete follow-up surveys independently, we developed a plan whereby we have been monitoring clinic visit appointments so that a data collector has been present when patients have come to the outpatient clinic for their appointments. While time consuming, this strategy has been beneficial for study retention. However, it has made the timing of follow-up data collection (scheduled for 3, 6, 9 and 12 months) less precise.

Overcoming the other challenge of competing research studies has required patience and persistence. If the hospice facility has declined participation due to competing studies, we have asked if we may contact the facility in the future since our study is ongoing for a few years. When a facility has agreed to be contacted, our strategy has been to maintain communication with the organization and to suggest a face-to-face meeting when the facility is ready to discuss our study. In one case, after about a year of time and much patience, a hospice recently agreed to participate in our study since another competing study had ended.

It is important to note that drug company studies, while well-funded, often are of short duration, usually no more than one year of study recruitment and enrollment.

Another helpful strategy to remind hospices about our study has involved working with an individual who has a relationship with the hospice organization. For example, a hospice nurse who provides care at a hospice facility and who has a research interest and/or background may be an ideal individual to advocate for our research study with the hospice administrators. This approach helped us to get involved with one of our hospice facilities. One other strategy has been to offer educational training to the hospice personnel. These interactions have helped to develop a rapport with the hospice personnel so that they may consider our research study when competing studies have ended.

Challenge #3: Assuring Staff Support for Providing Referrals to End-of-Life Research

An ongoing difficulty with subject identification and recruitment has been the limited time and resources of clinic staff and is complicated by the varying approaches towards recruitment within each clinical agency. In the heart failure study, although residents and fellows are present in both clinics from which study subjects are recruited, the learning demands of their rotation and fast pace of clinical settings often leaves them with little time to focus on activities other than their learning needs.

For the EOL oral conditions study, subject recruitment is dependent upon direct referrals from the hospice personnel and therefore requires active collaboration with hospice facilities. We have found recruitment to be most effective when hospice personnel initially approach the potential subjects to ask them if they are interested in learning about our research study. Due to structural differences in the hospices, this initial approach for subject recruitment varies between the two facilities.

Strategies to overcome challenge #3—To manage this challenge, we have utilized a variety of approaches unique to each of the clinical agencies. At the two sites for the heart failure study, we found it necessary to have a member of the research team present at all clinic sessions to recruit potential research subjects. Clinics are held over a period of 32 hours per week; consequently, having a research team member present at all of the clinic times has been a challenge both logistically and financially. Over the course of the study, our creative strategies have involved utilizing student volunteers to assist with subject identification and consent and developing collaborations with advanced practice nurses at one of the clinics. These nurses know the patients and are willing to identify potential subjects prior to the clinic sessions or contact the research team member to meet with potential subjects if the research team member is not present. Additionally, multiple research teams recruiting subjects from the same outpatient facilities have worked together to help identify potential subjects for the ongoing research studies. This strategy has proven to be not only time-efficient but also has decreased the number of research team members who have to wait in the clinic's staff area for subject recruitment.

For the EOL oral conditions study, we have developed strategies individual to each hospice facility. At one hospice, the admissions nurse who screens all patients upon admission to hospice also screens patients for our study and provides referrals to us when patients agree to being contacted. At this facility, it has been extremely important to maintain open and positive communication with the admissions nurse and to thank her for her efforts whenever possible. This scenario allows for all patients who meet the inclusion criteria to be contacted. However, patients are approached about the study soon after admission to hospice, and since this may be an overwhelming time for patients, they often decline participation.

At our other hospice facility, we depend on referrals from the nurses who are providing home hospice services. These nurses have established rapport with their patients and often not only introduce, but also recommend, study participation to their patients. Since patients often comply with the nurse's recommendations, the rate of participation is very high. However, the nurses are busy providing exemplary care to their patients, and our research study is not their top priority. To facilitate the direct referrals, we have attended their team meetings on a routine basis to speak briefly and remind the hospice personnel about the study inclusion criteria. While attending hospice team meetings is time-consuming, it is imperative for successful subject recruitment when we are depending on referrals from hospice personnel.

Commonly Encountered EOL Population-Specific Challenges

Challenge #4: Preparing for the Rapidly Changing Condition of Subjects

As expected, dramatic changes in the patient's condition are always possible. Depending upon the study design and population, this may involve rapid progression through the EOL transition or, contrarily, improvement of the condition being studied. The oral conditions study is limited to patients in the advanced stages of cancer. Nationally, cancer patients in hospice care have an average lifespan of 24 days in hospice care (NHPCO Facts and Figures: Hospice Care in America, October, 2009). For our collaborating hospice facilities, cancer patients comprise less than 50% of their patient population, and their longevity is approximately 7 to 21 days. This short timeframe does not allow much time for patients to participate in our research study. More importantly, patients at this stage of the EOL transition may not have the strength or may be too ill to participate in a research study. Some patients who have expressed an interest in participating in our study have cancelled the data collection session due to medical concerns including having medication side effects, being in significant pain, or just having a "bad day".

In the study of outpatients with severe heart failure, the trajectory of heart failure symptoms has been variable. At the baseline visit, patients are generally very symptomatic. After optimization of medical therapy, a number of patients have had improvement of their symptoms such that their NYHA classification has changed, and they no longer meet the inclusion criteria at subsequent visits. Further, two patients in this study have received heart transplants, which means that they no longer have a diagnosis of heart failure.

Strategies to overcome challenge #4—EOL researchers should be prepared to address changes in the condition of research participants. It is important to be flexible and expedient with scheduling data collection sessions and to be understanding of unexpected circumstances which may prevent patients from participating in the study. It may be advantageous to call patients an hour or two prior to the data collection appointment to ensure that they are still able and willing and eligible to participate on the scheduled day. In the case of condition improvement, research participants may need to be removed from the subject pool if they no longer meet the study criteria. Initial recruitment numbers should take into consideration this potential challenge. It may also be advantageous to consider attempting to identify why the subjects have common condition changes, as this could identify a new criterion for subject exclusion or inclusion for future studies.

Challenge #5: Involvement of Caregivers in End-of-Life Research Protocols

The oral conditions study requires dyads, consisting of the EOL patient and the primary caregiver, to participate in study procedures. While the involvement of dyads can significantly contribute to our understanding of issues facing EOL patients, inclusion of the primary caregiver adds an additional element of complexity to study recruitment. If one

member of the dyad is not interested in study participation, then neither potential subject is eligible.

Strategies to overcome challenge #5—It is important to be sensitive to the level of interest of each member of the dyad without either participant feeling coerced to participate. Consequently, during our initial contact when we explain study procedures, our strategy has been to first identify and speak to the primary caregiver. Only after receiving affirmation from the primary caregiver regarding interest in the study do we then speak to the EOL patient. Similarly, at the study visit, we first review informed consent procedures with the primary caregiver, followed by the patient. This protocol allows for decreasing the burden to the patient if the primary caregiver declines study participation. Further, by separately speaking to each member of the dyad, we may reduce any passive coercion by either member of the dyad.

Discussion

Subject recruitment and retention for research in EOL studies has been consistently identified as a significant challenge for researchers who are not part of the care system (Wiegand, et al., 2008). While some of these challenges are similar across clinical settings, other challenges vary by the type of clinical agency, study design and population being studied. From our experiences with two EOL studies of different patient populations, we identified the following recruitment challenges that varied by clinical setting: ensuring subject recruiters understand inclusion criteria for defining end-of-life, reducing subject burden at the end-of-life, and assuring staff support for providing referrals to end-of-life research. Solutions to these challenges were discussed and represent a need to develop unique and effective methodologies to overcome recruitment challenges in EOL care settings. Further, two recruitment challenges were related to the unique patient population rather than the recruitment setting: preparing for the rapidly changing condition of the subjects and involvement of caregivers in EOL research protocols. Creative and potentially generalizable solutions to all of these challenges were presented and have been utilized in the CEoLTR research studies highlighted in this paper. Whereas some solutions present the researchers with additional demands on time and resources (i.e., discussing inclusion criteria individually with clinicians and residents), other solutions do not increase the resources required for the study's conduct, such as use of student volunteers for subject identification and recruitment.

Some newly-identified challenges are reflective of the evolving climate of community-based clinical care, including the use of informatics and the growing issue of competing research studies vying for the same clinical resources and patient populations. As community clinical agencies increasingly depend on informatics for patient records and communications, researchers will need to become versatile with these advances in technology and flexible with the technological abilities of research subjects. Further, community-based clinical sites are becoming more involved with multi-site intervention studies supported by pharmaceutical companies, providing these sites with significant financial support for research and clinician effort. With significant funding from pharmaceutical studies, community-based facilities may not be as interested in participating in smaller, grant-funded studies. Importantly, researchers may be required to exercise increased patience and involvement in the clinical site to successfully compete with studies supported by significant funding.

Conclusion

Due to the diversity of settings in which EOL care can occur, researchers must consider the varying characteristics and challenges inherent in these clinical care settings. Further, research subject recruitment and retention may present with another set of challenges resulting from the uniqueness and diversity of the patient population. EOL research provides numerous potential benefits for subjects and family members, such as sharing their stories, reflecting upon experiences and contributing to research, thereby creating a need to successfully meet these challenges. The examples described in this article provide researchers with some guidelines for addressing new challenges to subject recruitment and retention in a variety of clinical care settings in EOL research.

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