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Research Participation by Older Adults at the End-of-Life: Barriers and Solutions

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Abstract

The purpose of this paper is to elaborate upon barriers to research participation by older adults at end-of-life. We focus on the hospice setting and classify barriers to research participation into six domains:1) societal attitudes towards death; 2) research procedures; 3) health care organizations; 4) agency staff; 5) patients' families and caregivers; and 6) patient characteristics. We characterize particular participation issues, uncertainties in participation for individuals with advanced illness, infringements upon patient self-determination, as well as, potential solutions to these research challenges. Our observation of the complex palliative context included the realization that a singular change would not have large enough impact. We concluded that simultaneous with the need to expand the research base addressing the needs of dying persons is a need to understand the challenges of implementing research projects with older persons at end-of-life.

Introduction

Research aimed at improving end-of-life care and understanding physical, emotional and spiritual aspects of dying is of great importance. Death is a universal experience and current evidence confirms there is unnecessary suffering and unmet needs associated with dying. Funding agencies such as the National Institute of Health (NIH), the National Institute of

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Nursing Research (NINR), and the National Cancer Institute (NCI) have acknowledged the relevance of this area (Grady, 2005). Specifically, the NINR has issued a number of research solicitations in response to the 1997 Institute of Medicine report, "Approaching Death: Improving Care at the End-of-life", and presents an important opportunity for nursing science to contribute to evidence-based practice (EBP) that has the potential to address critical practice questions associated with older persons at the end-of-life.

Despite the prospects of funded research projects exploring issues at the end-of-life, serious difficulties in recruitment and participation are becoming evident (Agarwal, 2003; Casarett et al., 2001a; Casarett & Karlawish, 2000; Kirchhoff & Kehl, 2008; McMillan & Weitzner, 2003; Ransom et al., 2006; A. Williams, 2007). Investigations into end-of-life processes are confronted by a multitude of obstacles imposed by societal biases, values within health care organizations, absence of palliative care expertise on Institutional Review Boards, care provider reluctance, and the daunting and oftentimes rapidly changing clinical issues of patients with far advanced disease (Head & Faul, 2007; Kirchhoff & Kehl, 2008; McMillan & Weitzner, 2003). Often older patients at the end of life may be seen as vulnerable or easily coerced, or desperate (Agrawal, 2003). All of these views and processes culminate and create additional difficulties in conducting research with this population.

During the initial data collection phase of a large multi-site study testing a translational research intervention to enhance EBP for managing pain in older adults in hospices, we experienced these challenges to research recruitment and participation. In our attempt to examine pain in older adults receiving hospice care, it became necessary to integrate research processes and the complex palliative care context.

The purpose of this paper is to elaborate upon barriers to recruitment of older adults at the end-of-life in the hospice setting based upon our randomized controlled trial involving 16 hospices of diverse size in the Midwestern United States. Recruitment efforts were aimed at older patients with cancer newly admitted to hospice in the home setting. Our research plan involved participation in brief telephone interviews to gather data about their pain experience. Taking a broad view of the literature and using this to frame our own experiences, we classify barriers to research participation into six domains: 1) societal attitudes towards death; 2) research procedures; 3) health care organizations; 4) agency staff; 5) patients' families and caregivers; and 6) patient characteristics. From this framework, we characterize particular recruitment or participation issues, uncertainties in research participation for individuals with far advanced illness, infringements upon patient self-determination, a key outcome of end-of-life care, as well as, potential solutions to this myriad of research challenges.

Background

Patients' social and clinical contexts have important implications for research participation and these weigh heavily for patients with far-advanced illness. More than 81% of all patients entering hospice are older adults (age>65) with diagnoses of cancer, heart disease, dementia, debility, and lung disease (NHPCO, 2006). These patients are often viewed as too ill, clinically unstable, or otherwise unable to complete requirements for study participation (Fine, 2003; McMillan & Moody, 2003; McMillan & Weitzner, 2003).

Compromised cognitive capability is an added challenge, insofar as 40% to 60% of older adults at the end-of-life experience compromised cognition (Bruera et al., 1992; Covinsky et al., 2003; Pereira et al., 1997; Radbruch et al., 2000; Stiefel & Holland, 1991) and this proportion increases to 70–83% when patients enter the final days of life (Bruera et al., 1992; Conill et al., 1997). This contributes to the issue of classifying patients at the end-of-life as vulnerable, a position that contributes to the ethical debate regarding research

participation with this population. This concern has been analyzed by Agrawal (2003) who concludes vulnerability must be determined on a case-by-case basis and vulnerability in and of itself does not equate with involuntariness (the inability to make an independent, informed decision to participate or not in research). Similarly, those who are dying are no more or less susceptible to coercion (Agrawal, 2003).

An important difference in this population, though, is the decision-making (gatekeeper) role played by caregivers, who may see their ill and aged loved ones as particularly vulnerable. Gatekeepers often exhibit the appropriate desire to protect dying persons, but this may translate into the belief that dying persons should not be asked to spend their limited time participating in research (Kirchhoff & Kehl, 2008). A fundamental question we attempt to address is whether older persons at the end-of-life are capable of protecting their own interests and giving informed consent.

Barriers to End-of-life Research

Societal Barriers to End-of-Life Research

American society approaches death with the unconscious, and very powerful, defense mechanism of denial (Last Acts Committee, 2002; Zimmermann, 2007). This results in a passive resistance to advance planning and an unwillingness to engage in frank discussion regarding one's own or a loved one's mortality, perpetuating an ideological "way to die" (Steinhauser et al., 2000; Zimmermann, 2007). However, when pressed for directed choices, most people surveyed state they would prefer to die with a focus on comfort measures, in the familiar setting of their own home (Last Acts Committee, 2002). The failure to prepare for the means to actualize these preferences creates a barrier to palliative care (Zimmermann, 2007) often resulting in crisis-based hospital admissions and late stage referrals to hospice care (Casarett et al., 2001a), making impossible the most basic life closure events, such as mending important relationships (Byock, 1997) or saying farewell to friends and family (Steinhauser et al., 2000).

Commitment to end-of-life care education for all health care professionals is lagging despite the Institute of Medicine (IOM), American Medical Association (AMA), American Academy of Hospice and Palliative Medicine (AAHPM), and End-of-Life Nursing Education Consortium (ELNEC) call for training in end-of-life care in undergraduate and graduate curricula and as ongoing topical CME programs (AAHPM, 2007; AMA, 2007; ELNEC, 2008; Field & Cassel, 1997). The result is providers often lack sufficient training in end-of-life care, disclosed by focus groups involving physicians, nurses and social workers (Steinhauser et al., 2000). These providers noted that acquisition of knowledge regarding dying care occurred informally and only one physician out of six had formal training in palliative care. Similarly, Fox (2007) surveyed 608 health professionals included 321 nurses and 38 medical providers. Fox found only 30% of professionals had received some education in palliative care and only 11% had completed formal palliative care clinical training. In both studies providers reported they are often uncomfortable with care at the end-of-life and lacked sufficient training and experience. The potential result of this lack of attention to palliative care training is a biomedical approach focusing on disease with less priority given to burden of disease, including physical symptoms, spiritual and emotional concerns at the end-of-life (Steinhauser et al., 2000). Similarly, and not surprisingly, it is in these domains where research is lacking.

Compounding the complexities of societal and medical perspectives of death is the uncertainty in which health providers are able to predict life expectancy. Variance in chronic progressive disease prognosis is as much a sociological as a medical phenomenon (Christakis & Lamont, 2000). This incongruity in prognosis is an important confounding

variable in recruitment to end-of-life research protocols. It is the sum of ambivalent societal attitudes, lack of professional training in end-of-life care, and prognostic uncertainty, superimposed upon the diverse health systems environments within the United States, that creates the daunting milieu in which end-of-life research must be conducted.

To overcome these many barriers so that advances can be made through methodologically sound research. Our experience leads us to recommend immediately actionable approaches at the community level which can lead to positive change. Awareness among the public can be greatly enhanced through professional-to-public and peer-to-peer educational encounters and forums that dispel myths, encourage discussion and inspire positive approaches to improve end-of-life care and ignite interest in end-of-life research. When coupled with national organizational advocacy programs (e.g., the past RWJ Partnership to Improve Care at the End-of-life; the current Caring Connections [see www.caringinfo.org]) substantial changes have occurred within communities that have embraced this approach to social change. For example, Hammes & Rooney (1998) found that following a community-wide effort to facilitate advance care planning that included major patient education efforts and provider training, completion of advance directives increased from 15% before the intervention to 85% after.

Barriers of Research Process

In addition to obstacles presented by society and the context surrounding dying patients, elements of the research process and associated stakeholders may play a role in presenting barriers to research recruitment and participation. Two specific procedures that may obstruct the research process include the institutional review process and demands of data collection.

Institutional review—Critical activities of the research process itself can present barriers to patient recruitment and retention. All studies must obtain Institutional Review Board (IRB) approval prior to the initiation of contact with study participants. In the course of the review, the IRB must decide whether a particular study raises any unique ethical issues (Casarett & Karlawish, 2000). Researchers have the responsibility to demonstrate and describe how patients might perceive risks and benefits (Casarett & Karlawish, 2000). Additionally, IRBs consider how and if these risks are beyond the risks of usual care. This is particularly salient when addressing research involving the care of frail older adults and in the provision of hospice care since a priority of care in these populations is comfort, along with minimization of harms from aggressive, or futile, interventions.

To assist members of IRBs to balance the risks and potential benefits of research involving older adults at end-of-life, these boards should include at least one professional with expertise in palliative care within their membership (Casarett et al., 2001a; Casarett & Karlawish, 2000). A second suggestion is for IRBs to help tailor consent forms to the specific needs of patients at end-of-life (and their proximate family members) to minimize burden without compromising the integrity of the consent process (Casarett & Karlawish, 2000). In our experience we had frequent conversations with IRB officials and were able to reduce the page length and expansive language of the consent documents and interview scripts. We encourage other research teams and IRB officials to be adaptive, flexible, and collaborate to determine needs on a case by case basis (Casarett & Karlawish, 2000). Hospices that are new to research should consider having at least one staff member or retained consultant who is experienced and knowledgeable about research ethics, consent and IRB processes, can provide administrative oversight, and act as a key collaborator with the sponsoring research team and institution (Casarett et al., 2001a). This individual should also be able to help other staff understand both the importance of research and the impact on and protections for patients in research recruitment and participation. Another option, and

one offered to our recruitment sites, is a partnership with the larger institutional IRB that may serve as a resource for ethical and general concerns regarding research process with older adults at the end of life.

Another important health systems issue that impacts clinical research is the Health Insurance Portability and Accountability Act (HIPAA). HIPAA requirements have been shown to impede patient recruitment and research project development. Beebe et al. (2007) found that inclusion of even a "minimally burdensome" HIPAA authorization form reduced participation by 15%. Similarly, Dunlop et al. (2007) found that refusal rates were 12% higher in comparison groups where prospective participants were given a HIPAA authorization form in addition to informed consent documents. Persons refusing participation were more apt then the informed consent only group to cite privacy issues, mistrust of research, and misunderstanding of the HIPAA form as reasons for non-participation. Patient privacy laws prevent researchers from directly re-contacting participants, placing the burden of recruitment on the agency employed staff (Kirchhoff & Kehl, 2008). To ameliorate this issue, we obtained IRB permission for a partial HIPAA waiver, allowing specific contact information for patients who met inclusion criteria to be released to grant staff. Frontline hospice staff responsibilities were then reduced to leaving a pre-made packet of information describing the goals of the project and expectation of participation with the patient upon their first contact. A cover letter clearly indicated that the patient would receive a call from a member of the research staff in approximately 72 hours. Negotiating direct access to patient contact information allowed the research assistants to make the inital contact and present project details, ultimately the most effective method in patient recruitment.

Demands of data collection—Research participation involving older, frail, or seriously ill adults should consider the patient's contribution of energy and time required to complete required tasks in relation to data collection. Often, older adults at the end-of-life and their caregivers, report feelings of being too sick, fatigued, or overwhelmed to participate in research. Researchers must determine the most effective method to gather desired data while maintaining minimum burden for this population. One way to decrease the burden on patients is to avoid the use of lengthy questionnaires. In the experience of our project, we found that reassuring patients and caregivers of the minimal (approximately 20 minutes) time commitment, was a critical aspect in their commitment to participate.

Organizational Culture

Organizations that provide care for persons at the end-of-life can create barriers to recruitment of subjects through direct policies or indirect gatekeeping activities. Depending on the philosophy of the organization (e.g. hospice) and its cultural value for research and advancing science, access to patients may be positively or negatively impacted. Agencies have been shown to play a protective role, often demonstrated through hesitancy to supply patient or family information (Kirchhoff & Kehl, 2008). The organizational leadership clearly establishes the tone for the value of research, importance of patient self-determination and procedures that facilitate or impede conduct of research and access to patients. These issues may be further compounded by lack of staff training, lack of staffing, and short lengths of stay.

Organizational impediments in subject recruitment can be observed in the excessively burdensome policies/processes for contacting/identifying eligible subjects or otherwise interfere with patients' abilities to make their own independent decisions about participation in research. Permission for researchers to contact patients and/or family members may be

difficult to obtain due to over-interpretation of privacy laws and an absence of commitment by organizational leadership to facilitate research.

Investigators can positively impact organizational commitment to recruit research subjects through several approaches. First, early engagement with the organization is necessary to garner commitment to the project, create an understanding of the value of the research and its goals, and provide an understanding of subject requirements. Involvement of agency representatives in grant development, as well as on-going research process activities can be helpful (Kirchhoff & Kehl, 2008). It may also be beneficial to invite early buy-in even at the initial stages of grant writing (Cook et al., 2002). This may allow all potential agency representatives to invest at an earlier stage and increase participation of organizations by regularly including them in the on-going research planning (Kirchhoff & Kehl, 2008) in the spirit of shared goals and outcomes. The optimal outcome of attempts at early buy-in affords organizations and staff a voice in the process facilitating likely long-term investments in partnering research projects.

Sharing information with administrative and clinical leadership regarding studies documenting the positive outcomes of patient self-determination in decision-making related to research participation may help minimize gatekeeping activities. As noted in the literature, it was also our observation that educational programs on research, EBP and how these impact quality of care and provider practices for older adults at the end of life are needed in the hospice setting (A. Williams, 2007). Staff may not be familiar with the current emphasis on EBP and relevance of research in palliative care. Offering to provide informative programs of this nature may be an early strategy to build interest and understanding so staff members become more invested in recruitment activities. Concomitantly, the research team should demonstrate that the study design respects the potential vulnerability of its patients and has a reasonable balance of risks and benefits.

The respective healthcare organization (e.g., hospice) has responsibilities to the research process that can diminish or eliminate specific barriers. Program leadership needs to communicate with the research team the potential for a research project to strain resources and adversely affect care. Areas of need for support should be declared in advance and researchers need to include these in any funding proposals (Casarett et al., 2001a). Hospices that participate in research should have the opportunity to provide feedback such that results of the studies might benefit their future patients (Casarett et al., 2001a).

Frontline staff-hospice staff

Direct contact staff that provide personal care to patients may play a critical role in facilitating or preventing patients from participating in research. Staff may interfere with research participation for many reasons. They may feel the research process may uncover something wrong with the care they are providing which adversely impacts their willingness to promote research (Kirchhoff & Kehl, 2008). Others may have concerns about confidentiality (Williams et al., 2006). Staff invested in the daily care of patients may feel their patients or family caregivers are too busy and will refuse on their behalf or would not follow through with a participation request for fear of placing additional burden on these patients, families, or themselves (Kirchhoff & Kehl, 2008; C. J. Williams et al., 2006).

Increasing the knowledge of hospice staff regarding the importance and understanding of the research process may serve to reduce barriers to both research participation and self-determination of individuals in their care. Frontline hospice staff should receive basic education in research ethics including an overview of informed consent, decision-making capacity, voluntariness, research review, and issues of privacy and confidentiality (Casarett et al., 2001a). Hospice staff can assist in determining the burden of research on staff and

patients, as well as potential issues of compromised decision making ability (Casarett et al., 2001a) often associated with ill older adults at the end of life.

Education may be a key component in the ability to use direct care staff as an asset to research projects. Without this, there exists a high likelihood they may present a major barrier to patient recruitment. Kirchhoff and Kehl (2008) reported staff avoided offering research participation to families if there was an impending death or patients were “having a hard time” or whose family appeared “overly distraught”. Our experiences with older adults in the hospice setting were consistent with these observations as we noted staff members acted as gatekeepers when they felt some patients would not make good research participants. Rejected referral forms from some of the hospice agencies would have notes written to the research staff requesting they not call a particular patient and family. For example, one staff member wrote, “Please don’t call, family situation chaotic” and another, “Family not handling end-of-life issues very well”. Due to the inherent protectiveness of hospice staff, patient recruitment may best be managed outside the scope of organization staff responsibility (Kirchhoff & Kehl, 2008; McMillan & Moody, 2003). Even subtle signals by hospice staff can have a powerful influence on patient participation (Casarett et al., 2001a).

A potential intervention to reduce the threat of staff protectiveness is to designate a clinical change champion who has a broad understanding of the project, has an awareness of both short and long-term research goals, and is able to keep everyone informed throughout the research process (Kirchhoff & Kehl, 2008). Others recommend recruiting patients through a proxy associated with the research project who does not provide direct patient care (Casarett & Karlawish, 2000, p.132). It was our experience changing patient recruitment responsibilities from front-line hospice staff to members of the research team greatly increased patient recruitment. As mentioned previously, the role of front-line hospice staff changed from directly referring patients to providing all patients who met inclusion criteria with a packet of information about the project. Using the procedure allowed by the partial HIPAA waiver, research assistants then called the patients for potential participation in the project. Recruitment rates doubled after making this specific procedural change.

Research teams should assess and anticipate concerns about research participation and identify ways organization staff can participate without compromising direct care or increasing their own workloads unduly. Educating staff about the research process and their role can be critical. An understanding of basic research principles and a discussion of the challenges and benefits of conducting research in the hospice setting should assist buy-in (Casarett et al., 2001a). In the meetings with sites that participated in our clinical trial, we dovetailed the highly valued end-outcome of comfort at end-of-life with our research goal, to improve processes that ensure good pain control. This helped create an alliance between researchers and the care team. Another goal of these meetings was to provide a forum in which any questions or concerns about the project could be addressed. As stated previously, education of staff without research experience at all levels, as well as validating any concerns, assists in building a research partnership and likely reduces threats of gatekeeping and makes circumvention unnecessary.

Caregivers and Family

In addition to healthcare organizations and agency staff serving in protective roles that can interfere with research participation at the end-of-life, family and other nonprofessional caregivers also serve as gatekeepers. McMillan (2005) reported the most common reasons for refusal to participate in research could be attributed to the caregivers. Caregivers often disallowed research assistants to communicate directly with patients. Our experience was consistent with other studies that reported caregivers perceived research participation as an

additional burden on themselves since they were already overwhelmed with care responsibilities and were experiencing emotional distress under the circumstances (McMillan & Weitzner, 2003; Ransom et al., 2006). Caregivers often believed the patients were too ill to be capable of participation. Other studies have also noted it is not unusual to find situations where the patient wishes to participate but the family member or caregiver, serving in a protective role, refuses (Davies et al., 1995; Hudson et al., 2001; McMillan & Weitzner, 2003). Our experience reinforces findings reported by others, whereby we found caregivers often gave the impression they 'already had enough on their plate' (McMillan, 2005; Ransom et al., 2006).

Our experience with older adults at the end of life suggests participation could be improved by the use of local coordinators and finding creative, gentle, and effective ways of reducing the effect of caregiver and family gatekeeping. Due to the intensity of emotions and task completion within the first days of hospice admission, we attempted to decrease patient and caregiver burden by changing the initial contact from 24 hours to 72 hours post-admission. We found flexibility in call times (including evenings and weekends) best accommodated the schedules of patients and caregivers.

Patient

Cognitive impairment—Aged patients with far-advanced illness may have disease-related cognitive impairments that present challenges to research participation. Although these confounding factors are not unique to palliative care research, they require insight and ability to determine decision-making capacity as part and parcel of the palliative care skill set (Casarett & Karlawish, 2001). Nevertheless, in determining which patients may lack adequate decision-making capacity to give consent is not always clear cut, but this is critically important since obtaining informed consent is an ethical imperative (Casarett & Karlawish, 2000). In the absence of capacity, a proxy for medical decision-making needs to assume this role. These and other complex considerations involving both routine clinical and research-related issues pursuant to older chronically ill patients means consent processes need to be tailored to meet individual needs. For research protocols, all methods will have to be negotiated with local review boards to determine research responsibilities and goodness of fit for the particular situation (Casarett & Karlawish, 2001). Consistent with our experience and methods suggested by other researchers, consent can be obtained from the patient or her/his designated surrogate through an appreciation of the unique clinical and social circumstances of each patient, clear communication and careful planning.

Investigators in other fields have developed strategies to address issues such as those encountered in emergency and dementia care. Casarett & Karlawish (2000) suggest patients should be formally assessed if risk is considered to exceed that encountered in everyday life or standard medical care (Casarett & Karlawish, 2000). As examples, assessments such as the Cognitive Test for Delirium (both long and abbreviated forms), Confusion Assessment Method–ICU, Intensive Care Delirium Screening Checklist, NEECHAM scale, and the Delirium Detection Score have been documented in the literature for use in settings such as the intensive care unit (Devlin et al., 2007). However, research studies such as ours that only involve survey interviews do not constitute extraordinary risk and this type of formal assessment is not necessary and may not be valid in the hospice/home setting. Our procedure involved that if we determined consent from the patient was questionable, consent from the caregiver and assent from the patient were obtained. This "dual consent" (Casarett & Karlawish, 2000, p.133) ensures caregivers understand the goals of the research process and what is being asked of the patient. (Casarett et al., 2001a) described a short series of questions (a "quiz') given to patients after consent information was presented. This allowed them to repeat back important points of the study demonstrated their understanding of study

participation. We found this strategy helpful in determining cognitive capacity of our participants.

Patients approaching death—As patients approach death, goals usually shift to an exclusive focus on comfort (Casarett & Karlawish, 2000). Due to the inevitable and often rapidly changing clinical circumstances during the terminal phase of a life-limiting condition, the risk-benefit calculus involved in research may change, and there must be flexibility in anticipation of these changing conditions built in to research processes (Casarett & Karlawish, 2000). In addition to potential cognitive and communication limitations, older patients near death may not want to spend their remaining time answering questions. Also, if they are requiring increasing levels of care they may be hesitant to place additional burden on family or caregivers (Casarett & Karlawish, 2000). These variables require understanding and flexibility in protocols, not special restrictions for the conduct of end-of life-research (Casarett & Karlawish, 2001).

Involuntary consent is an important ethical concern when conducting research. In the absence of overt coercion, this may come about due to a sense of misplaced duty, dependency, appreciation, or feelings of desperation on the part of the patient or proxy. The risk of involuntary consent seems increased when care providers and research investigators are institutionally connected (Casarett & Karlawish, 2001). To counter this, recruitment can occur through a third party, and emphasized that, although this research is approved by their healthcare providers, participation is purely voluntary. This gives patient an “out” so they don’t feel they are jeopardizing their care if they choose not to participate (Casarett & Karlawish, 2001).

Avoiding coercion—There is concern that recruiting older adults facing death into research projects may be coercive. These patients may feel desperate for a rescue from the realities of their condition, (Casarett et al., 2001a; Casarett & Karlawish, 2000) which may be potentially compounded if a particular treatment has the potential to be (or is implied to be) life extending. Additionally, patients may perceive research participation and clinical care as one and the same (Casarett et al., 2001a). To avoid the threat of coercion, research participation must emphasize voluntary participation that can be revoked at any time without any consequences. Secondly, it must be demonstrated that research participation and clinical care have clear demarcations.

In an attempt to reduce risk of coercion, we reminded patients participation was voluntary. This “reality check” was reiterated within the consent discussion and during each call prior to completing interviews and survey tools. Episodic and recurrent cognitive assessments included a question of what the patient would do if they no longer wanted to participate. If patients were unable to answer, they were reminded repeatedly they need only tell the research assistant and participation would end without negative consequence.

To differentiate research and clinical care processes, we utilized hospice office staff to screen admissions and provide contact information to the research team coordinator. This way, direct care staff had no knowledge of who was or was not participating, unless disclosed by the patients themselves. Another intervention suggested by Casarett and Karlawish (2000) is an allowable period of time for symptom management prior to research recruitment. We deferred our initial contact to 72 hours post admission to provide sufficient time for the hospice staff to address symptom concerns and allow tasks in the hospice admission phase to be completed.

Physical capability and logistical barriers—The difficulties involved in contacting and “consenting” critically ill patients have been described (Kirchhoff & Kehl, 2008). Our

experience was similar. Of 94 older adults that agreed to participate in the initial phase of our project, 24% of these were lost to follow-up due to death or were actively in the dying process. Important to identifying and remedying these recruitment challenges was the collection of data that explained these drop-outs. Kirchhoff & Kehl (2008) note this important aspect should be included as part of study data collection. These authors suggest utilizing multiple methods of patient contact such as in-person, telephone, and invitations via colorful brochures may increase participation. Our methods also accommodated the wishes of the primary participant when they wanted family or caregivers to be involved (Kirchhoff & Kehl, 2008) and we extended the consent and study explanation processes to these individuals, as well.

Threat to Patient Self-Determination

Self-determination, as defined by Nicholson and Matross (1989) is “the basic right of all individuals to act in accordance with their own values, goals, and personal choices” (p.234). Gatekeeping activities can create barriers to access patients and paradoxically may negatively impact patient rights to self-determination (Ewing et al., 2004; Hudson et al., 2001; Kirchhoff & Kehl, 2008). This can also create inadvertent selection bias that confounds generalizability of results (Ewing et al., 2004; Hudson et al., 2001). Self-determination is a core value of hospice and palliative care, and presumably support this in multiple ways, including patient education, providing informed choices regarding treatment options, actively involving family in decision-making to the extent desired by the patient, respecting ethnic and cultural traditions, and honoring the concept of holistic care (Sahlberg-Blom et al., 2000; Waldrop, 2006). For individuals at the end-of-life, promoting patient self-determination requires a climate in which decision-making is both facilitated and adaptive (i.e., accommodating to changes in attitudes based upon real-time experiences) at a time when control over various aspects of life is in decline. Vigilance is required to assure patients maintain their rights of self-determination for as long as possible, only relinquishing control to a proxy who has a deep appreciation of the individual’s values and desires. This is best accomplished far in advance of serious declines in personal health, and, practically speaking, prior to discussions concerning participation in a specific research protocol. Since advance directives remain the exception in our society, it is overly optimistic to anticipate systematic discussions, no less documentation, of predilection for research participation prior to the time a patient may be contacted for a specific protocol.

Notwithstanding certain burdens associated with research participation, surveys of research subjects have found these patients experience emotional benefits from research participation; especially the sense of making a lasting contribution despite the imminence of death (Casarett, 2005; Hudson, 2003). Steinhauser et al. (2000) noted a prominent theme along these lines; participants wished to contribute in some way to the well-being of others. Patients participating in research may have the opportunity to feel satisfaction in the potential to help future patients and through telling interested listeners their own stories and finding personal meaning in their illness, living, and death (Casarett et al., 2001a; Ling et al., 2000; Phipps, 2002; Steinhauser et al., 2000). It is even possible patients may benefit from the attention of the research team to their circumstances and condition (Casarett et al., 2001b) and with the potential for improvement in patient outcomes. Ling et al. (2000) found patients who participated in research studies did not feel too much was being asked of them and were glad they participated. Research participation offers patients a chance to make their own decisions and exert their own self-determination at a time when many decision are made for them by caregivers.

Conclusion

Conducting research with older adults at the end-of-life can present significant challenges to recruitment and participation. Our observation of the complex palliative context included the realization that a singular change would not have large enough participation impact. Simultaneous with the need to expand the research base addressing the needs of dying persons is a need to understand the challenges of implementing research projects with this population. The potential for high rates of refusals must be anticipated (Kirchhoff & Kehl, 2008) and careful planning undertaken to overcome barriers. The validity of a study's findings depends on the design chosen by the investigator. Therefore, evaluation of patient recruitment and data collection methods was an important aspect of our implementation of a larger translational research study testing an intervention to promote the use of EBPs for assessing and treating cancer pain in older adults receiving care by hospices.

Older adults, their families, and hospice staff face many challenges associated with a terminal diagnosis and care at the end-of-life. Often the situations in which we insert our recruitment strategies and research processes are complex. Our experience with older adults at the end of life reflects the difficulty of participating in a research study during this often overwhelming and emotional time period. Knowledge of the barriers, as well as potential solutions to overcome them, can assist in recruitment of participants so knowledge of ways to improve care of older persons during this challenging time can be gained. In addition, barriers should be examined for the potential threat of restricting patient self-determination and efforts made to assure patients the opportunity to make their own decisions when possible.

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