12-11-2009

Ethical and Logistical Challenges of Conducting Research with Hospice and Palliative Care Populations

Ashley M. Wohleber

Pacific University

Recommended Citation

This Thesis is brought to you for free and open access by the College of Health Professions at CommonKnowledge. It has been accepted for inclusion in School of Graduate Psychology by an authorized administrator of CommonKnowledge. For more information, please contact CommonKnowledge@pacificu.edu.
Ethical and Logistical Challenges of Conducting Research with Hospice and Palliative Care Populations

Abstract
Research in palliative care and hospice populations is important for improving quality of care, quality of life, and provider understanding of individuals at the end of life. However, this research involves many potential challenges. This thesis seeks to inform and assist researchers working with hospice and palliative care patients by presenting an exhaustive review of the published literature. Issues discussed include study design, informed consent, recruitment, risks and benefits for participants, ethics, and methodology. Areas of further research are highlighted and synthesized recommendations for researchers in these populations are presented.

Degree Type
Thesis

Rights
Terms of use for work posted in CommonKnowledge.
Copyright and terms of use

If you have downloaded this document directly from the web or from CommonKnowledge, see the “Rights” section on the previous page for the terms of use.

If you have received this document through an interlibrary loan/document delivery service, the following terms of use apply:

Copyright in this work is held by the author(s). You may download or print any portion of this document for personal use only, or for any use that is allowed by fair use (Title 17, §107 U.S.C.). Except for personal or fair use, you or your borrowing library may not reproduce, remix, republish, post, transmit, or distribute this document, or any portion thereof, without the permission of the copyright owner. [Note: If this document is licensed under a Creative Commons license (see “Rights” on the previous page) which allows broader usage rights, your use is governed by the terms of that license.]

Inquiries regarding further use of these materials should be addressed to: CommonKnowledge Rights, Pacific University Library, 2043 College Way, Forest Grove, OR 97116, (503) 352-7209. Email inquiries may be directed to: copyright@pacificu.edu

This thesis is available at CommonKnowledge: http://commons.pacificu.edu/spp/97
ETHICAL AND LOGISTICAL CHALLENGES OF CONDUCTING RESEARCH
WITH HOSPICE AND PALLIATIVE CARE POPULATIONS

A THESIS
SUBMITTED TO THE FACULTY
OF
SCHOOL OF PROFESSIONAL PSYCHOLOGY
PACIFIC UNIVERSITY
HILLSBORO, OREGON
BY
ASHLEY M. WOHLEBER
IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE
OF
MASTER OF SCIENCE IN CLINICAL PSYCHOLOGY
DECEMBER 11, 2009

APPROVED:
Daniel S. McKitrick, Ph.D.

Shawn E. Davis, Ph.D.
Abstract

Research in palliative care and hospice populations is important for improving quality of care, quality of life, and provider understanding of individuals at the end of life. However, this research involves many potential challenges. This thesis seeks to inform and assist researchers working with hospice and palliative care patients by presenting an exhaustive review of the published literature. Issues discussed include study design, informed consent, recruitment, risks and benefits for participants, ethics, and methodology. Areas of further research are highlighted and synthesized recommendations for researchers in these populations are presented.

Keywords: hospice, palliative care, experimental ethics, informed consent, methodology, experimental subjects
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>ii</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Literature Review</td>
<td>4</td>
</tr>
<tr>
<td>Ethicality of Including or Excluding this Population as Participants</td>
<td>4</td>
</tr>
<tr>
<td>Study Design</td>
<td>5</td>
</tr>
<tr>
<td>Preparation Time</td>
<td>6</td>
</tr>
<tr>
<td>Identifying the Target Population</td>
<td>6</td>
</tr>
<tr>
<td>Research Design</td>
<td>6</td>
</tr>
<tr>
<td>Randomized Controlled Trials</td>
<td>6</td>
</tr>
<tr>
<td>Qualitative Research</td>
<td>8</td>
</tr>
<tr>
<td>Mixed Methods</td>
<td>10</td>
</tr>
<tr>
<td>Survey Research</td>
<td>10</td>
</tr>
<tr>
<td>Collaborative Approaches</td>
<td>11</td>
</tr>
<tr>
<td>Sample Size</td>
<td>12</td>
</tr>
<tr>
<td>Diversity</td>
<td>13</td>
</tr>
<tr>
<td>Summary</td>
<td>13</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>14</td>
</tr>
<tr>
<td>Vulnerability and Voluntariness</td>
<td>14</td>
</tr>
<tr>
<td>Competence</td>
<td>16</td>
</tr>
<tr>
<td>Proxy Consent</td>
<td>18</td>
</tr>
<tr>
<td>Process Consent</td>
<td>19</td>
</tr>
</tbody>
</table>
Advance Consent.................................................................................................19
Cluster Consent....................................................................................................20
Wording and Method of Delivery......................................................................21
Exceptions.............................................................................................................22
Summary................................................................................................................22
Recruitment..............................................................................................................23
Inclusion/Exclusion Criteria..............................................................................23
Access.....................................................................................................................26
Preliminary Contact.............................................................................................30
Interest...................................................................................................................31
Summary................................................................................................................33
Risk and Benefit Analysis....................................................................................33
Possible Risks........................................................................................................34
  Fatigue..............................................................................................................34
  Emotional Distress..........................................................................................34
  Burden..........................................................................................................36
Possible Benefits.................................................................................................37
Summary................................................................................................................38
Ethical Issues.........................................................................................................39
Creating Ethical Research Goals.........................................................................39
Dual Roles and Role Conflict.............................................................................40
Confidentiality and Access to Data....................................................................42
Summary................................................................................................................42
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodological Issues</td>
<td>43</td>
</tr>
<tr>
<td>Selection Bias</td>
<td>43</td>
</tr>
<tr>
<td>Attrition/Withdrawal</td>
<td>44</td>
</tr>
<tr>
<td>Assessments</td>
<td>45</td>
</tr>
<tr>
<td>Interview/Questionnaire Construction</td>
<td>45</td>
</tr>
<tr>
<td>Objective Indicators</td>
<td>45</td>
</tr>
<tr>
<td>Assistance</td>
<td>46</td>
</tr>
<tr>
<td>Proxies</td>
<td>46</td>
</tr>
<tr>
<td>Statistics</td>
<td>47</td>
</tr>
<tr>
<td>Missing Data</td>
<td>48</td>
</tr>
<tr>
<td>Reducing Bias in Non-Experimental Research Designs</td>
<td>48</td>
</tr>
<tr>
<td>Summary</td>
<td>49</td>
</tr>
<tr>
<td>Summary of the Literature</td>
<td>50</td>
</tr>
<tr>
<td>Discussion</td>
<td>54</td>
</tr>
<tr>
<td>Additional Areas of Consideration</td>
<td>54</td>
</tr>
<tr>
<td>Abuse Reporting</td>
<td>54</td>
</tr>
<tr>
<td>Statistics and Small Samples</td>
<td>54</td>
</tr>
<tr>
<td>Summary</td>
<td>55</td>
</tr>
<tr>
<td>Controversies</td>
<td>55</td>
</tr>
<tr>
<td>Including or Excluding Hospice and Palliative Care Patients as Research Participants</td>
<td>55</td>
</tr>
<tr>
<td>Minimizing gate-keeping by Excluding Professionals Involved in Direct Patient Care</td>
<td>56</td>
</tr>
</tbody>
</table>
Introduction

Officials in the National Hospice and Palliative Care Organization estimate that in 2007, 1.4 million people received hospice services and 38.8% of all deaths that occurred in the United States were under hospice care (NHPCO facts and figures: Hospice care in America, 2008). The concept of hospice care was first implemented in the United States of America in 1974 with the purpose of providing terminally ill individuals with holistic, palliative care at the end of their lives (Richman, 1995). This care is provided by a team of nurses, home health aides, social service workers, chaplains, physicians, and volunteers (NHPCO facts and figures: Hospice care in America, 2008). An individual must have a terminal diagnosis (usually defined as being expected to live six months or less) and choose not to receive further curative treatments to enroll in hospice (Richman, 1995). Once enrolled, care may take place in a variety of locations such as hospitals, nursing facilities, hospice facilities, or private homes. In 2007, 42% of hospice deaths occurred in private residences, 28.3% in nursing or residential facilities, 19.2% in hospice inpatient facilities, and 10.5% in hospitals not operated by hospice organizations (NHPCO facts and figures: Hospice care in America, 2008).

Hospice services are aimed at increasing the quality of life of patients and include intensive pain management as well as physical, psychological, social, emotional, and spiritual care (Richman, 1995). In particular, the hospice team works to manage the patient's pain, including short-term inpatient care if pain management needs become too extensive to treat at home; to help the patient to cope with the emotional, spiritual, and psychosocial aspects of dying; to assist the family by teaching them how to care for the patient and by providing respite care when needed; to deliver medications, medical equipment and supplies, and special services (e.g., speech or physical therapy); and to provide bereavement care and
counseling to the family after the patient's death (NHPCO facts and figures: Hospice care in America, 2008).

As the number of individuals under hospice care has grown, concerns about research with individuals at the end-of-life have become more prominent. As officials in the National Institutes of Health [NIH] note, “While there is a growing body of research covering a wide range of issues, the research is, in many ways, still in its infancy in terms of rigorous testing and evaluation of models of care, in terms of patients and family outcomes, and in terms of resource utilization” (“Improving end-of-life care,” 2004). However, research with patients at the end-of-life is replete with potential ethical and logistical pitfalls and the literature in this area contains an abundance of discussion on challenges which can be expected to arise when one is researching hospice and palliative care populations (Bruera, 1994; Buss & Arnold, 2004; Casarett, Knebel, & Helmers, 2003; Dobratz, 2003; Fowell, Johnstone, Finlay, D. Russell, & I. T. Russell, 2006; Jordhøy et al., 1999; Kaasa, Hjermstad, & Loge, 2006; Penrod & Morrison, 2004). The implicit question embedded in this discussion is, “How can researchers best proceed in this difficult area?”. Unless and until this question is answered, the pace and quality of this research is likely to suffer. The goal of this thesis is to thoroughly and critically review the literature concerning the ethical and logistical challenges inherent in conducting research with hospice and palliative care patients which has arisen over the last twenty years and synthesize this information into a functional set of guidelines to assist researchers in avoiding the possible pitfalls of conducting research in this area. This literature review will cover the areas of the ethicality of either including or excluding hospice and palliative care populations; issues of study design, informed consent, and recruitment; possible areas of risk and benefit; and ethical and methodological issues.
The following literature review was conducted with the search engines PsycInfo, Medline, and CINAHL. In PsycInfo, the terms “hospice”, “palliative care”, “experimental ethics”, “informed consent”, “methodology”, and “experimental subjects” were used. In Medline, the corresponding terms “hospices”, “palliative care”, “ethics, research”, “informed consent”, “research design”, and “research subjects” were included. To limit the amount of irrelevant information returned from the Medline search, “ethics, research” was used as a mandatory search term. In CINAHL, the corresponding terms “hospices”, “palliative care”, “ethics”, “consent”, “research methodology”, and “research subjects” were included. To limit the amount of information returned from all searches and to provide relatively recent information, results were limited to sources published between the years 1990 through 2009. Although it was not included as a search limit, articles focusing on pediatric hospice were not included. The final main section includes the author’s discussion of the research question.
Literature Review

*Ethicality of Including or Excluding this Population as Participants*

There has been recent debate over whether it is ethical to include or exclude hospice and palliative care patients as research participants. Some researchers have argued that hospice and palliative care patients are too ill and too vulnerable to allow for valid and generalizable research, that there is not enough more to learn about this population to justify its use as research participants, and that this population is too heterogeneous to provide meaningful results (Kaasa & De Conno, 2001). Researchers have also expressed concern that it is unethical to ask hospice and palliative care patients to participate in research because participation may limit the already restricted time and energy these individuals have and because these participants will not have the opportunity to benefit from the results of the research (Addington-Hall, 2002).

While these concerns are valid, the literature generated by this review was overwhelmingly in favor of the ethicality of including this population. Researchers have pointed out several reasons why it may be unethical to exclude this population. Researchers frequently mentioned respect for patients' autonomy as an opposing concern (Addington-Hall, 2002; Bruera, 1994; Gysels, Shipman, & Higginson, 2008; Hudson, Aranda, Kristjanson, & Quinn, 2005; Kaasa & De Conno, 2001). By not offering hospice and palliative care patients the opportunity to participate in research, their right to make their own decisions about research participation and to have their voices heard is violated. Also, while this population will not likely benefit from the knowledge generated by the research, they may experience subjective benefits from their participation which would be unethical to deny (Gysels et al., 2008). These potential benefits will be discussed in greater detail in
subsequent sections.

Terry et al. (2006) argue that reservations about including hospice and palliative care patients as research participants are more a reflection of the societal taboo against speaking about death and dying than they are valid ethical concerns. In regard to a National Institutes of Health consensus conference report which expressed concerns about the 'decency or propriety' of asking these patients to participate in research, they rebutted:

These feelings of shame are, we suggest, those of the researchers. This is the language of taboo and we do not know of any other area of medical research that has, in recent years at least, provoked it. This is unfortunate because one reason to value the opportunity to participate in research commonly expressed by our patients was that it would confirm that they were still, and were regarded as, real people: not taboo (p. 412).

Thus, while it is important to be aware of the possible vulnerability of this population, it is equally important to respect their rights of autonomy and their humanity.

Study Design

The complexities of conducting research with hospice and palliative care populations are apparent from the first steps of the research process. In order for the research to proceed smoothly, researchers must invest a great deal of time creating an appropriate, thoughtful design. Areas of study design that are particularly relevant to hospice and palliative care research are allowing adequate preparation time, identifying the target population, choosing an appropriate research design, determining the sample size, and including diversity for a representative sample.
Preparation Time

Because of the complexities involved, research with hospice patients can be expected to be time consuming well before data collection begins (Seymour et al., 2005). Barnes et al. (2005) reported that almost one year was required to plan and obtain approval for a study on heart failure in older adults. Seymour et al. (2005) suggest that researchers take into account the time required to identify and carry out specific training or educational needs and plan site visits to clarify access, researcher role, and ethical conduct when planning a timeline for research projects involving hospice or palliative care patients.

Identifying the Target Population

Hospice and palliative care patients are a heterogeneous group, and an important, and sometimes problematic, part of designing a study with this population is identifying a specific target population (Bakitas, Lyons, Dixon, & Ahles, 2006). While hospice services exclude patients who plan to continue with curative treatments and have more concrete guidelines regarding life expectancy, patients in palliative care services may span a wide range of life expectancies and concurrent treatments. One third of patients receiving palliative care services are not under the care of palliative care specialists, meaning that using this as an inclusion criteria could exclude a large percentage of palliative care patients who may differ in some way from those under the care of specialists (Addington-Hall, 2002). As Jordhoy et al. (1999) point out, it may be impossible to identify every member of a palliative care population in order to select an unbiased sample, especially as lengthy screening procedures are contraindicated for this population and are often not economically feasible.

Research Design

Randomized controlled trials. While randomized controlled trials (RCTs) are needed in
palliative care and hospice research, they present several challenges which may make them difficult to implement (Penrod & Morrison, 2004; Storey, 2004). For instance, researchers may find that because many palliative care interventions are well established and believed to be efficacious despite the lack of supporting empirical research, it may be considered unethical to withhold a standard treatment from the control group (Penrod & Morrison, 2004). As Grande and Todd explain, “For a trial to be ethically justifiable there must be real uncertainty as to whether the new treatment is superior to no treatment, or existing treatments” (2000, p. 70). This concept is known as 'equipoise' (Grande & Todd, 2000). However, even when equipoise exists, a new treatment may be perceived as more desirable by professionals, patients, and/or families (Grande & Todd, 2000). In this situation, wait list controls are a possible solution; however, the limited life expectancy of palliative care and hospice patients limits the usefulness of this strategy (Grande & Todd, 2000). Alternatively, researchers and care staff may establish participation in the RCT as an entry point to the intervention, thus framings trial randomization as the offer of an opportunity to access a currently unavailable treatment rather than as a means of limiting the availability of the treatment (Grande & Todd, 2000). Cluster randomization, in which potential participants are grouped by a common characteristic (e.g., region, hospice program, etc.) and are assigned to various experimental conditions, may be a more acceptable alternative because which groups will receive which treatments is established before the participants are identified (Fowell et al., 2006; Grande & Todd, 2000; Jordhøy et al., 1999). However, this may result in selection bias through the resentful demoralization of patients selected for the control group and may reduce the statistical power of the trial (Fowell et al., 2006).

A great deal of discussion in recent literature has focused on placebo-controlled trials
in this population. The general consensus is that all research participants in clinical trials should have access to the best available standard of care (Casarett, 2005; Ferrell, 2004). Casarett explains that placebo use can be justified if the participants who receive the placebo also receive the current standard of care, if the symptom being studied has no effective treatment, or if the participants who receive the placebo have access to breakthrough treatment should it becomes necessary (2005). Placebo-controlled trials require careful consideration of the study design to ensure the placebo group does not receive substandard care, as well as additional time and effort in educating medical staff and potential participants on this research methodology (Buss & Arnold, 2004). Terry et al. (2006) found that most palliative care patients were reluctant to participate in placebo-controlled trials. However, their reluctance was related to the assumption that researchers knew that the patients receiving the placebo would have worse outcomes than the patients receiving the treatment. It appears that trials comparing a new treatment to an established, active treatment are more likely to be acceptable to potential participants.

Qualitative research. Because of the difficulties inherent in randomized controlled trials, qualitative approaches are popular among hospice and palliative care populations. Qualitative research frequently utilizes interviews, participant observation, questionnaires, focus groups, case studies, and documentary analysis (Wilkie, 1997), and qualitative methods are often preferred by end-of-life researchers because of their ability to allow participants to discuss issues that are currently important to them (Kendall et al., 2007). Interview methods offer a particularly adaptive, flexible methodology for gaining information about hospice and palliative care patients and their experiences while also supporting the needs and well-being of the participants (Plant, 1996). However, researchers must still be sensitive to possible
ethical concerns in qualitative, as well as quantitative research; In particular, coercion and perceived benefit to participants are areas of potential risk (Larkin, Casterle, & Schotsmans, 2008).

A phenomenological paradigm (i.e., a qualitative approach which searches to understand how people make sense of the everyday world) may be particularly applicable to palliative care research (Seymour & Clark, 1998). In phenomenological research, the researcher attempts to gather data in ways which are minimally intrusive to the participant and which maximize the participant's contribution to the research. Data collection is considered complete when no new material is generated by data collection, and cases which are atypical are emphasized rather than ignored. Seymour and Clark explain, “Phenomenology is not a method ... Rather it should be seen as a philosophical paradigm within which methods are chosen and questions framed” (1998, p. 128).

Case studies are also a qualitative approach which is frequently used in hospice and palliative care settings. Case studies can be an especially diverse approach. As Walshe, Caress, Chew-Graham, and Todd explain, “Case studies can use either qualitative or quantitative methods, can be prospective or retrospective, can have an inductive or deductive approach to theory, can focus on one case or many, can describe, explain or evaluate” (2004, p. 677) and are useful for studying “complex social situations or interventions, where multiple variables exist” (2004, p. 678). However, only qualitative case studies were discussed in the literature on hospice and palliative care research. Walshe et al. (2004) list several situations in which case studies are appropriate in palliative care research, including when complex situations need to be addressed, context is central to the study, multiple perspectives need to be recognized, the study design needs to be flexible, researchers want the research to be directly
congruent with a clinical practice approach, there is no strong theory to which to appeal, and other research methodologies could be difficult to conduct. However, they note that case studies must be used rigorously and only with appropriate reasoning for their use.

Focus groups allow for a group of individuals to provide information collaboratively and may also be applicable to research with hospice and palliative care patients. However, some additional factors must be taken into consideration when using this approach. Seymour et al. (2005) describe how, in a focus group of palliative care patients regarding end-of-life issues, researchers had to be careful to allow individual expression of thoughts and opinions while still maintaining a clear structure around the topics they intended to discuss. Additionally, researchers had to be prepared to allow and create opportunities for participants to take a break from the discussion or to share their personal stories if desired.

Mixed methods. Researchers can use mixed methods, which combine qualitative and quantitative methodologies, to collect and synthesize both types of data (Wallen & Berger, 2004). While little mixed methods research has been done in hospice and palliative care settings, it offers the potential to combine the benefits of both procedures and offer an in-depth set of data for analysis.

Survey research. Surveys are frequently used in palliative care and hospice research (e.g., Takesaka, Crowley, & Casarett, 2004; C. J. Williams, Shuster, Clay, & Burgio, 2006). While surveys are most commonly completed by the patient, in some studies a proxy is used to obtain information regarding patients who may not be able to complete the surveys themselves. While this may be useful in some cases, it may also complicate the data collection process by raising the questions of whether to approach the patient or the proxy first, when to approach the proxy (e.g., it would be inappropriate to contact the proxy when the patient
is rapidly declining), how to schedule data collection in a way that fits a caregiver's schedule, and how to determine who the proxy should be (Kapo & Casarett, 2004). However, it does offer an opportunity for retrospective survey research (i.e., research regarding the patient that occurs after the patient's death) as well as for collecting data on care at the time of death and data from patients who were too ill to participate in direct data collection (Addington-Hall, 2002; Kapo & Casarett, 2004). When conducting retrospective survey research using proxies, it is essential to consider the timing of data collection, as collecting data too soon, when the proxy is not yet ready to discuss the deceased patient, or too late, when the proxy has forgotten important details, may both end with unsatisfactory results (Kapo & Casarett, 2004).

**Collaborative approaches.** Collaborative approaches, which involve patients working as co-researchers with the investigators, have been suggested, and utilized, for research with hospice and palliative care populations (A. Williams et al., 2005; Wright, Hopkinson, Corner, & Foster, 2006). Collaborative approaches may be especially useful with this population as these methods are very sensitive to the needs of the population and allow participants to influence the research in ways that result in study outcomes that are important to them (Wright et al., 2006). In one collaborative study, patients and caregivers volunteered as co-researchers by leading focus groups of hospice and palliative care patients (Wright et al., 2006). Wright et al. (2006) suggested several recommendations for conducting research with co-researchers as a result of this study, including being careful to apply the same ethical guidelines that apply to participations to co-researchers, offering emotional support for all co-researchers if needed, and working to develop a collaborative dynamic in which the experienced researchers and co-researchers work together to ensure the quality of the
Williams et al. (2005) used a collaborative approach known as community-based participatory research (CBPR) to conduct research in a nursing facility for people with end-stage AIDS. In CBPR, community members with strong ties to the research population, rather than members of the research population itself, are included as co-researchers. In this study, staff at the facility were included throughout the research process in order to create a participation opportunity that was feasible and relevant to the community. This method can be particularly useful in populations which are vulnerable and marginalized as it invites the opportunity for those close to the population to advocate for both the researchers and the participants in a manner that creates a beneficial research experience for all parties (A. Williams et al., 2005).

Sample Size

Due to the high rates of attrition that occur in hospice and palliative care research (a topic which will be discussed further in the 'Methodological Issues' section), researchers must take care to begin research with an adequate sample size to allow for attrition (Casarett, 2005). Additionally, researchers should consider the proportion of hospice and palliative care patients that will be excluded from the study due to inclusion/exclusion criteria. In a study by Williams et al. (2006), 64% of hospice patients were ruled out by the criteria that stated participants must be over the age of 19, English speaking, judged able to give informed consent by either the investigator or a hospice nurse, enrolled in hospice services for over a week, and not considered too sick (e.g., actively dying or in a crisis situation) to participate by the hospice nurse or physician. Researchers should be aware that many potential participants may decline to participate for a number of reasons. For example, Williams et al. (2006) had a
return rate of 36% of surveys which were distributed to hospice patients eligible to participate in their study.

*Diversity*

Palliative care and hospice research often includes a paucity of minority participants. For example, only 1 of 14 participants in a focus group study in South Africa was of a minority ethnic background (Wright et al., 2006). Many researchers in a focus group study expressed concern that more efforts needed to be made to include diversity in hospice and palliative care research (Kendall et al., 2007). There are many potential reasons for the lack of diversity in this field of research. As Kendall et al. (2007) state, “Given the recruitment difficulties within the majority population, it is not surprising that many studies fail to engage with people from these small populations” (p. 3). Language barriers and the fact that a lower proportion of minority individuals than majority individuals seek palliative care services likely also play a role in this issue. However, there may be solutions to these problems. As the focus group of researchers suggested, offering something (i.e., information sessions, art based activities, or social events) in return for participation, gaining approval from community leaders, and ensuring that the study design, research materials, and dissemination methods are culturally appropriate may serve to increase the amount of minority patients who participate in hospice and palliative care research (Kendall et al., 2007).

*Summary*

Researchers must be prepared to invest a great deal of time in study design and data collection. The hospice and palliative care population is heterogeneous and complex, and researchers must consider carefully how to define their target population. Once this is decided, there are numerous research designs which are appropriate for use is this
population, including quantitative designs, randomized controlled designs, qualitative designs, phenomenological approaches, case studies, focus groups, mixed methods, survey designs, and collaborative approaches. For researchers to decide which method is best, they must carefully consider the research question as well as the benefits and disadvantages of each methodology. Researchers must also work to obtain an adequate sample size and a good representation of diversity in their sample.

_informed consent_

As hospice and palliative care patients are considered members of a vulnerable population, it is essential that potential participants are given adequate informed consent. Researchers must ensure that participation is voluntary and that potential participants are competent to give consent. Careful consideration should be given to the wording and method of delivery of consent.

_Vulnerability and Voluntariness_

Many researchers consider hospice and palliative care populations to be vulnerable research participants (Casarett et al., 2003; Morreim, 2006). One reason for this is that patients at the end of life may choose to participate out of desperation (Casarett & Karlawish, 2000; Morreim, 2006) or loneliness (Seymour et al., 2005) rather than an informed choice (Casarett & Karlawish, 2000; Morreim, 2006).

Because of this population's vulnerable status, it is extremely important to ensure that research participation is voluntary. It is necessary to understand how the patients' relationships with the investigators and the involved institution influence the decision to participate in order to ensure that patients are not, and do not feel, coerced into participating (Casarett et al., 2003; Silverman, 1996). Researchers must be aware that patients may feel
pressure to participate in research projects in order to please their doctor and must actively help patients realize both that it is alright for them to decline participation and that refusal will not affect their relationship with their doctor or other staff (Casarett & Karlawish, 2000; Speck, 1996). Longer-term research carries additional challenges. Patients who are competent to consent at the time of informed consent may deteriorate to the point where they are no longer competent to consent or understand changes in their condition that warrant their withdrawal (Casarett, 2005). Speck (1996) suggests that a friend or family member of the patient be present at the time of consent to ensure that there is no coercion. Similarly, Silverman (1996) suggests a neutral third party be present to advocate for the patient or proxy consenter, minimize coercion, and promote the participant and/or proxy consenter's understanding.

While it is important that researchers be aware of issues of coercion and voluntariness in informed consent, several researchers have presented evidence that patients are willing to refuse research participation. For instance, Rees and Hardy (2003) reported a refusal rate of 32% in their trial of antimuscarinic drugs for treating the noisy breathing that occurs when dying patients are unable to clear secretions form their airways, often known as “death rattle”; 34 out of 107 palliative care patients approached declined to participate. Terry et al. (2006) reported that the palliative care patients who participated in their focus groups argued that “there is a 'freedom' in being close to death so that they felt they could say precisely what they wished and had nothing at all to lose by voicing their own opinion” (p. 410). As one patient explained, “When you go to the emergency they ask you things, they don't think you have stopped thinking. Why would you not know what to say just because you are dying in the hospice?” (p. 410). In light of concerns that patients may participate
out of desperation to extend their lives, Terry et al. (2006) reported that the majority of participants stated they would only participate in research if it did not have the possibility of extending their life.

As several researchers have pointed out, the potential for coercion in research with hospice and palliative care patients is not unique to this population and many strategies, such as emphasizing the voluntary nature of participation and ensuring that researchers are sensitive to subtle forms of pressure, may be used to overcome these challenges (Casarett & Karlawish, 2000; Fine, 2004). Fine argues that researchers should “not equate vulnerability with involuntariness” (p. 75) and that “dying should not be equated with coercion” (p. 75). Instead, both patients and research should be evaluated in light of their context.

**Competence**

Once vulnerability and voluntariness are addressed, researchers must establish that patients are competent to consent to participate in research. In terms of informed consent, competence concerns “the ability to make a decision” (Silverman, 1996, p. 583). While it has no universally agreed upon definition, it is commonly noted to consist of the capacity to understand information, to appreciate one's situation and its consequences, to consider information pragmatically in light of one's values, and to make a decision (Silverman, 1996). Because this population is diverse with regard to the ability to make competent and informed decisions, patients must be individually evaluated for competence to give informed consent (Casarett, 2005; Casarett & Karlawish, 2000; Casarett et al., 2003; Dobratz, 2003; Fine, 2004). However, researchers should not assume palliative care and hospice patients are incapable of informed consent or that this is a rare phenomena. Gysels, Shipman, and Higginson (2008) noted that most of the palliative care patients they interviewed were capable of making the
decision to participate in an interview, as well as advocating for the conditions under which they wished to participate. Also, competence can fluctuate vastly over time, making it an ambiguous area to assess (Dobratz, 2003; Speck, 1996). Researchers must be aware that known cognitive impairment does not rule out decision making capacity. However, the presence of cognitive impairment may make the process of informed consent more difficult or impossible (Bakitas et al., 2006; Casarett & Karlawish, 2000).

When evaluating competence to consent, consideration must be given to the potential risks and benefits offered by the study (Addington-Hall, 2002; Casarett et al., 2003; Fine, 2004). Fine suggests that when minimal risks are posed by the study, a formal capacity assessment should not be required. When the study poses greater than minimal risks, Fine suggests, formal capacity assessment should be considered when potential benefits are offered and should be required when there are no potential benefits. Additionally, Fine recommends investigators use the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR) for assessing competence to consent, and that investigators determine what the cut-off point for competence will be before administering this assessment to potential participants. The Mini Mental Status Exam (MMSE) has also been commonly used in this field of research (Bakitas et al., 2006; A. Williams et al., 2005) as well as the Mini Mental Status Questionnaire (MMSQ, Bruera, 1994). Bruera (1994) has noted that patients should not be excluded from research due to incompletion of the MMSQ. Nonetheless, researchers should be concerned that such participants may not be capable of completely understanding the study. One downfall of the MMSQ is that it lacks specificity and may result in Type I error (Grealish, 2000). Many researchers have chosen to use informal assessment of competence by a researcher or medical professional rather than a
formal assessment such as the MacCAT-CR, MMSE, or MMSQ (e.g., Dobratz, 2003; C. J.
Williams et al., 2006). Despite the prevalence of this option, it should be noted that one
researcher who used these methods commented that use of a formal assessment of cognitive
function would have been helpful in her study and recommended it for future use (Dobratz,
2003).

Mental status is valuable as an inclusion/exclusion criteria for ensuring that
competent consent is obtained, but it may result in issues with generalizability. Studies which
only include patients who possess a normal mental status may not be generalizable to the
palliative care and hospice population as a whole, in which patients are often sedated,
delirious, or experiencing other declines in mental functioning (Bakitas et al., 2006). In light
of this possible complication, Bakitas et al. (2006) recommend that researchers consider
whether a normal mental status is necessary for the patient to participate in and possibly
benefit from the intervention or if it is solely necessary for the research procedures (e.g.,
informed consent).

*Proxy Consent*

If patients are not competent to give consent, a legally authorized proxy may be able
to consent on their behalf (Bakitas et al., 2006; Casarett, 2005; Hardy, 2000). However, 'dual
consent', in which both the participant and the proxy provide consent, is recommended to
ensure that the participants receive as much information as possible even if they cannot
provide consent themselves (Casarett, 2005). Before using proxy consent in a study,
researchers must first understand their state laws regarding proxy consent for research, as
some states may restrict or prohibit proxy consent (Casarett, 2005). Also, researchers should
be aware the process of surrogate decision-making still needs further exploration and the
families of palliative care and hospice patients may still comprise a vulnerable population as they may feel pressured to do everything they can to increase their loved ones' well-being or to extend their lives (Silverman, 1996).

**Process Consent**

Process consent is one alternative to the traditional, one-time method of obtaining informed consent. In process consent, the researcher regularly asks the participants if they still wish to participate (Addington-Hall, 2002). Process consent is recommended when a study involves several interviews or observations over a period of time (Kendall et al., 2007). It is designed to “acknowledge the dynamic and emerging nature of the research design, include the initial input and suggestions of the participants in the study, and negotiate further input regarding changes over time” (Raudonis, 1992, p. 247). Hudson, Aranda, Kristjanson, and Quinn (2005) caution against gathering informed consent at every data collection point due to the danger of overloading the participant. Rather, they recommend that research staff remain constantly prepared to initiate discussion regarding consent, especially when they sense hesitance in the participant.

**Advance Consent**

In situations where the potential participants will be unable to provide consent at the time they become eligible to participate, advance consent allows researchers to obtain consent to collect data if they should develop target symptoms (Casarett, 2005; Casarett et al., 2003; Rees & Hardy, 2003). For example, in a trial of antimuscarinic medications intended to treat the noisy breathing, or death rattle, that occurs at the end of life, researchers asked patients if they would be willing to participate should they develop noisy breathing at the end of life, at which time they would not be expected to be able to provide
informed consent (Rees & Hardy, 2003). On each subsequent hospital admission, the participant was asked to re-sign the informed consent. If they were no longer competent to consent, the patient's relative or caregiver was asked if there was any reason the patient might have changed his or her mind about the decision to participate. If no indication was stated, the previously signed consent was considered to remain valid. While advance consent is necessary for studies in which the participant is expected to lose capacity to consent or in which the capacity to consent is intermittent, it should be used only when necessary and should be obtained as close to the time of expected study enrollment as is possible (Casarett, 2005). Advance consent may be especially practical when the study poses greater than minimal risk and/or no potential benefits (Casarett, 2005).

**Cluster Consent**

Another alternative method for obtaining informed consent is cluster consent, which involves obtaining consent from an entire group of patients with a 'cluster guardian' responsible for providing consent as a proxy for the group and a 'cluster gatekeeper' responsible for advocating and taking responsibility for individual participants (Fowell et al., 2006). Researchers comparing cluster consent with randomized consent methods found that cluster consent resulted in a larger number of participants recruited and less burden for medical staff, as consent was given at a unit, rather than individual, level (Fowell et al., 2006). However, this method is not without disadvantages. Fowell et al. warn that cluster consent may be more likely to result in selection bias via the resentful demoralization of control participants. Also, the randomization of groups as opposed to individuals reduces statistical power.
Wording and Method of Delivery

The wording and delivery of informed consent can affect patient understanding and ability to provide consent. In order to lessen the risk of physical fatigue, mental fatigue, or emotional distress in the patient or family, the consent form should be concise and simply worded and the patient or proxy should be given ample time to read the consent form fully and discuss it with other family members or medical staff if desired (Bruera, 1994; Silverman, 1996).

Researchers should also be aware that terms such as “palliative care”, “terminally ill”, and “end-of-life” may be detrimental to recruitment as not all patients have been given a clear, terminal prognosis by their doctors and may not identify as terminally ill or dying (Plant, 1996). While some researchers have expressed concern that avoiding such terminology may prevent potential participants from having all the information needed to provide informed consent (Barnes et al., 2005), others argue that this information is unnecessary and should not be considered deceptive (Casarett et al., 2003). Plant (1996) suggests researchers devote time to establishing understanding of the potential participants’ view of their condition before attempting to obtain consent. Additionally, wording that suggests a doctor-patient relationship, such as “doctor”, “patient”, and “drug” as opposed to “investigator”, “subject”, and “study agent”, may suggest that patients are consenting to treatment rather than research (Silverman, 1996). Researchers should similarly avoid the use of ambiguous expressions of probability such as “likely”, “probable”, “expected”, or “moderate” (Silverman, 1996).

Terry et al. (2006) reported the palliative care patients in their sample strongly preferred oral information to written information. As one participant pointed out, “Do you
see anyone writing here? Reading things is so hard” (p. 411). However, Speck (1996) argues that potential participants should be given some form of back-up information regarding consent, such as leaflets, videos, or information sheets, because adjustment to a terminal diagnosis may result in poor information retention. Additionally, while explaining consent orally provides the option for participants to engage in a dialogue about the research process, and thus gain better understanding, the researcher's nonverbal cues, such as tone of voice and behavior, may bias the information being provided (Silverman, 1996). More research is needed to better understand how patients wish to be approached regarding research participation and informed consent (Kaasa & De Conno, 2001).

**Exceptions**

In some situations, it may be impossible to obtain consent in the population or to conduct the research in a population that is capable of providing consent. In these cases, researchers may seek approval from their ethics board to forgo the informed consent process. Although there is precedence for this, there is controversy concerning whether or not this method is ethically sound (Hardy, 2000). Hardy (2000) argues that this approach may be acceptable if patients are unable to provide their own consent, seeking proxy consent would result in delay that would be detrimental to the treatment's efficacy, participation involves minimal risks that are comparable to the risks present in standard treatment, and the research can not be done with a population that can be expected to give consent, such as healthy volunteers.

**Summary**

In order to ensure voluntary consent, researchers must understand how their relationship with potential participants may influence the decision to participate. They must
also be prepared to assess competence to consent, either formally or informally. In cases in
which potential participants are not competent to provide consent, consent may be obtained
through proxy or in advance. Process consent, in which consent is obtained at every data
collection point, is recommended for longitudinal studies.

Recruitment

Once the study design is solidified and the informed consent procedures are
determined, study recruitment can begin. Because hospice and palliative care populations are
so heterogeneous, inclusion and exclusion criteria must be developed to recruit patients who
are applicable for the study and who are likely to complete participation. Additionally,
researchers must decide how they will access this population while minimizing inappropriate
gate-keeping and how they will introduce their study to potential participants. Lastly,
researchers should be aware of the factors affecting the interest of potential participants in
research participation.

Inclusion/Exclusion Criteria

The development of inclusion and exclusion criteria is a necessary part of research
design and recruitment. Appropriate inclusion and exclusion criteria increase the likelihood
that recruitment will target individuals who are relevant for, and likely to complete, study
participation. Additionally, appropriate inclusion and exclusion criteria can lower the
probability that participants from this sensitive population may be harmed by their
participation. In a longitudinal study of the palliative care needs of older adults with heart
failure, Barnes et al. (2005) assumed that individuals who were cognitively impaired,
psychotic, or severely mentally ill were more likely than others to be unable to successfully
complete study materials and to be alarmed by the issues raised in a palliative care study.
Along similar lines, Williams, Shuster, Clay, and Burgio (2006) excluded potential participants who had been enrolled in hospice services for less than a week or who were considered by the hospice nurse of physician as too sick to participate in their study exploring hospice patients' hypothetical interest in research participation.

However, using inclusion/exclusion criteria that are too stringent can limit study recruitment. Mitchell and Abernethy (2005) compared the methodologies of two studies of palliative care patients. The researchers of one study approached only patients who had been approved by the patients' palliative care staff, general physician, and caregiver and who had a life expectancy of over a month. Of the 1137 potential participants screened, 52% were eligible for inclusion, and 51% of their sample died or withdrew before one month. In contrast, the researchers conducting the contrasting study used maximal inclusion criteria and minimal exclusion criteria to facilitate eligibility. Of the 1949 potential participants screened, 79% were eligible for inclusion. There is a fine balance to be reached in order to protect potential participants while simultaneously facilitating a large enough sample size to account for the high attrition and withdrawal rate that is likely in this population.

Life expectancy is an important factor to take into account with research with hospice and palliative care populations, especially in longitudinal studies. As Jordhoy et al. (1999) point out, “The main challenge, however, is to define eligibility criteria that can ensure patients' entry at a time when survival will be long enough for the supposed effect both to occur and to be assessed” (1999, p. 307). Unfortunately, life expectancy is commonly overestimated (Jordhoy et al., 1999; Mitchell & Abernethy, 2005). In determining inclusion and exclusion criteria, it is important to allow for a reasonable length of time before follow-up data is collected (Jordhoy et al., 1999; Kaasa & De Conno, 2001), and to consider using
prognostic factors (e.g., performance status) and providing an allowance for overestimation of life expectancy (Jordhøy et al., 1999). In shorter-term studies, including patients who have a short life expectancy may increase the likelihood of gate-keeping by ethics boards, medical professionals, and/or families. Hudson et al. (2005) recommend excluding patients that are very unwell or very close to death in studies which do not require patients with these characteristics in order to lessen the likelihood of gate-keeping problems.

Additionally, mental status has been identified as an important eligibility consideration for studies and clinical trials with palliative care patients due to its implications in informed consent and the ability for patients to participate in the tested interventions (Bakitas et al., 2006; Dobratz, 2003). Dobratz (2003) suggested using a baseline cognitive assessment tool to assess for cognitive impairments in all potential participants, regardless of diagnosis. However, excluding potential participants on the basis of mental status may exclude a large portion of the palliative care and hospice population and result in a sampling bias. Thus, it is important to consider how the use of mental status as an inclusion/exclusion criterion will effect the generalizability of the results (Bakitas et al., 2006).

Because hospice and palliative care patients constitute a diverse range of age, functional ability, cognitive status, and life expectancy, different exclusion criteria may be needed for different segments of this population. In order to increase flexibility and sensitivity to unforeseen problems in study recruitment, Hopkinson, Wright, and Corner (2005) left their inclusion and exclusion criteria open to adjustment during data collection as well as protocol development.

However, the benefits of this method can be detrimental in studies which use recruiters outside the research team. Bakitas, Lyons, Dixon, and Ahles (2006) recommend
that eligibility criteria be “clear, objective, and easily understood by recruiters and referring clinicians” (2006, p. 278). Additional thought must be put in to the wording of eligibility criteria due to the sensitive nature of end-of-life research. In regards to posters or flyers used to recruit participants, Bakitas et al. (2006) warn:

[Translating eligibility criteria into lay language] calls for creativity in recruiting seriously ill patients, some of whom will be unaware of their 'eligibility' as their condition may not have been presented to them by their physician as 'serious' or 'life-limiting'. Even when clinicians inform patients of their advanced illness status, patients may be in denial regarding the seriousness of their illness and unlikely to identify with an advertisement that is looking for 'seriously ill, dying, or terminally ill' patients. (p. 278)

Thus, it is important to consider who is being targeted by recruitment materials when considering how inclusion and exclusion criteria should be conveyed.

Access

Conducting research with hospice and palliative care patients may involve passing several levels of gatekeepers, including ethics boards, medical staff, hospice staff, family, and caregivers. In order for research to be successful, it is essential that researchers be able to obtain the support and understanding of all levels involved in gaining access to this population. Inappropriate gate-keeping has two main consequences: restricting patients' autonomy and reducing research quality (Hudson et al., 2005). Gatekeepers can reduce the representativeness of the sample and the generalizability of the data by introducing sampling bias. Additionally, gatekeepers can misemploy the time and efforts of both researchers and participants. As Hudson et al. (2005) explain, “When patients or families participate in a
study weakened by gate-keeping that prevents sound conclusions, their time and energies are
misused. Given the limited life expectancy, it is imperative their contributions are
worthwhile” (p. 166). Thus, it is important to understand how and why gate-keeping can
occur in hospice and palliative care research, as well as what can be done to prevent it.

Because hospice and palliative care patients are a vulnerable population, there is
contention about their appropriateness to participate in research (Hudson et al., 2005; Larkin
et al., 2008). As discussed previously, there is debate about whether hospice patients should
be excluded as research participants due to their end-of-life status and vulnerability or
included to protect their rights to autonomy. The paternalism of ethics boards was a
common complaint in a focus group of end-of-life researchers. While the researchers agreed
that potential studies should be scrutinized and their ethicality ensured, there was shared
concern that ethics boards “[acted] as gatekeepers for perceived 'vulnerable' participants,
rather than seeing them as individuals capable of making their own decisions” (Kendall et al.,
2007, p. 3).

Medical and hospice staff are often used as referral sources in hospice and palliative
care research in order to recruit individuals who are most likely to be able to participate
successfully and without harm (Barnes et al., 2005; Buss & Arnold, 2004; Dobratz, 2003;
Hopkinson et al., 2005; Kaasa & De Conno, 2001; Kendall et al., 2007; Phipps et al., 2005;
Storey, 2004; Terry et al., 2006; A. Williams et al., 2005; C. J. Williams et al., 2006; Wright et
al., 2006). While medical and hospice staff are invaluable for this purpose, problems can arise
when these professionals block patients from participation for reasons other than the stated
inclusion/exclusion criteria. As Barnes et al. (2005) point out, “Although clearly well
intentioned, this responsibility for patient protection may cause sample bias, as only those
deemed 'well enough' may be put forward as potential participants” (p. 322). Other researches have described encountering this problem when working with hospice and palliative care populations (Addington-Hall, 2002; Kendall et al., 2007). Barnes et al. (2005) recorded that seven of the primary care practices from which patients were recruited removed 31 potential participants (2% of the participants produced by preliminary search) for reasons other than the exclusion criteria, evidencing the problem that gate-keeping can cause in unbiased study recruitment. This may become even more problematic in studies which involve a control or placebo group. As one researcher acknowledged, “Even the primary investigators were slow to recommend the study to their own patients because of the placebo control design” (Storey, 2004, p. 393).

Buss and Arnold (2004) reported the reservations of the nurses involved in recruiting hospice patients for a study measuring the safety and effectiveness of an anti-nausea drug. They found concern about the value of the study, the risk and burden to dying patients, and the ethics of a placebo trial were common worries. Because medical staff often play a key role in participant selection and recruitment, educating involved professionals on research-related issues, especially the ethical challenges of conducting research with hospice and palliative care patients, is an important way to decrease inappropriate exclusion of potential participants (Bakitas et al., 2006; Kaasa & De Conno, 2001). Assuring that recruitment does not unduly increase the responsibilities of medical and hospice staff can increase participant recruitment (Barnes et al., 2005). For example, Bakitas et al. (2006) provided referring clinicians with flyers and pocket cards explaining the relevant inclusion/exclusion criteria, as well as scheduling meetings with each group to provide professionals with an opportunity to ask questions and raise concerns about the study. They found very few instances of gate-
keeping when the clinicians had a clear understanding of the eligibility criteria.

While researchers do not necessarily need family or caregiver permission to invite palliative care or hospice patients to participate in research, they often act as gatekeepers in providing access to these patients (Hopkinson et al., 2005). For example, Phipps et al. (2005) described how in some cases, the caregiver would answer the researcher's call at the time of recruitment and thus become the researcher's initial contact. In this study, thirteen potential participants were excluded because the caregiver declined on the patient's behalf. While caregivers may act in what they feel is the best interest of the patient, caregivers often have a different perspective on the patients' level of illness and ability to participate than the patients themselves. It has been found that caregivers of hospice patients perceived level of illness as a barrier to research participation more frequently than the patients themselves (49% versus 39%, respectively; C. J. Williams et al., 2006). Also, caregivers were more concerned about emotional distress or pain as consequences of research participation (24% versus 13%; C. J. Williams et al., 2006). Thus, while caregivers may feel appropriately protective of the family members under their care, they may not make the same choices that the family members would make for themselves regarding research participation.

Hudson et al. (2005) suggest several methods to decrease the likelihood of gate-keeping in hospice and palliative care research. For example, offering information sessions and brief face-to-face updates to recruiting medical professionals may increase their understanding of the study and of recruitment, as well as offering professionals the chance to bring up concerns about the study and to problem-solve with the researchers. Also, excluding patients who are very ill or have a very limited life expectancy may increase study recruitment, as gate-keeping is more likely to occur with patients who are perceived as very
vulnerable. Lastly, excluding medical professionals who are involved in the direct care of the patient may decrease the possibility of medical professionals inappropriately protecting patients by not offering the opportunity for study participation or by discouraging patients from participating. The controversial nature of this final suggestion will be further discussed in the Discussion section.

**Preliminary Contact**

Medical professionals and researchers are often the first point of contact for potential participants in this population. Researchers investigating patients' preference for being approached about end-of-life research have found that patients desire to be approached by the medical professionals most involved with their care rather than the researchers conducting the study (Terry et al., 2006; A. Williams et al., 2005; C. J. Williams et al., 2006). This may be especially important when working with minority or stigmatized populations who may be more mistrustful of the researchers and able to communicate more openly with the medical professionals they already have a connection with (A. Williams et al., 2005). While having medical professionals explain and introduce the study to potential participants increases the burden of participation on the professionals, it may also decrease gate-keeping and sampling bias by giving medical professionals more control over the timing of study introduction. In a study in which medical clinicians were responsible for referring patients to participate, researchers found that the referring clinicians rarely neglected to mention the study to eligible patients and would often adjust the timing of recruitment to account for factors such as distress about a terminal diagnosis (Bakitas et al., 2006). However, there is concern that including medical professionals directly in the recruitment process may introduce more opportunity for gate-keeping and inconsistent recruitment approaches
Interest

Researchers have found indications that patients at the end-of-life are indeed interested in participating in research through both formal research and their experiences conducting research with other aims in this population (Hopkinson et al., 2005; Kaasa & De Conno, 2001; Kendall et al., 2007). Williams et al. (2006) found that 46% of a sample of hospice patients reported being interested in research involving surveys or interviews and 45% reported being interested in research involving therapeutic interventions.

There are many reasons why hospice and palliative care patients are interested in participating in research. Many participants express willingness to participate in research in order to help future patients or the care providers (Casarett, Kassner, & Kutner, 2004; Dobratz, 2003; Gysels et al., 2008; Jordhøy et al., 1999; Kendall et al., 2007; Terry et al., 2006; Wilkie, 1997). As one study participant explained, “It would be a way to give something back now before I die, I would have done something good for the future” (Terry et al., 2006, p. 408). One study found a wide variety of motivations for participating in research reported by hospice patients, including helping the doctor or nurse (37%), feeling good about helping others (33%), maybe feeling better (28%), improving symptoms (24%), contributing to science (22%), having a sense of purpose (20%), adding meaning to life (19%), the possibility of being followed more closely by the patient’s doctor or nurse (19%), getting better care (14%), or having the opportunity to be social (11%, C. J. Williams et al., 2006). Having the opportunity to be social may be especially important for patients who have suffered disability arising from their illness and who may feel isolated (Gysels et al., 2008). Having the opportunity to provide feedback regarding services received may also be an important
motivator in patients receiving hospice or palliative care services (Gysels et al., 2008). Interestingly, Phipps et al. found that patients who are in more pain may be more likely to participate in research (2005). They hypothesized this may be because patients hope that participation will mean their pain issues are better addressed. This finding has an important implication for recruitment within these population, as researchers need to be prepared to refer patients with treatable pain problems that are not the focus of research to appropriate clinicians. (Phipps et al., 2005).

There are also many barriers to research participation in this population. Hospice patients were more likely than ambulatory senior citizens to see being too sick, having too little energy, and concern for creating caregiver burden as being barriers to research participation (C. J. Williams et al., 2006). Phipps et al. (2005) recorded the reasons made by end-of-life patients for refusing to participate in research. They found other priorities, such as spending time with family, were cited by 42% of refusing patients. Research-related concerns, such as having had a bad experience with research participation in the past, were cited by 36% of refusing patients and health-related concerns, such as physical weakness or emotional distress, were cited by 28%. General disinterest was cited by 61%, making it the most commonly used reason for participation refusal. When consenting and refusing patients were compared, they found that consenters thought they had more to gain from participation than refusers. Additionally, consenters reported that aches and pains were more problematic for them as compared to refusing patients. Thus, while many hospice and palliative care patients demonstrate interest in participating in research, there are many motivations and barriers which come in to play when making the decision to participate.
Summary

In order for researchers to recruit effectively for their studies, inclusion/exclusion criteria, access to the hospice and/or palliative care population, preliminary contact procedures, and potential participant interest must all be considered. When developing inclusion/exclusion criteria, researchers must seek to avoid criteria that are too liberal, which may result in the inclusion of participants who are not members of the target population, who are unlikely to successfully complete data collection, or who are likely to be harmed by data collection, and to avoid criteria that are too strict, which may result in a low sample size. In particular, life expectancy is an important factor to consider when making these considerations. Researchers must also review what gatekeepers lie between them and the target population and how best to negotiate preliminary contact so that the greatest possible number of potential participants are offered the opportunity to participate while those who are inappropriate to participate in research are avoided. Lastly, researchers should be aware that there is real interest in participating in research in the palliative care population and be knowledgeable about the many factors which involve patients' decisions whether or not to participate.

Risk and Benefit Analysis

It is the researchers' responsibility to ensure that the potential risks and benefits of participation are known, minimized when possible, and made clear to the potential participants. Such risks may include fatigue, emotional distress, and participation burden. Additionally, the possibility of physical and/or emotional benefits should be considered, maximized, and disclosed.
Possible Risks

It can be particularly difficult to distinguish what qualifies as a risk or burden in research with hospice and palliative care research as the priorities of patients often change at the end of life (Casarett & Karlawish, 2000). Given the unique experiences and concerns of these individuals, it may be inappropriate to use the standards of daily life as a means for assessing risk (Casarett & Karlawish, 2000). Research risks are generally defined as “the probability of an adverse medical event or undesirable outcome” (Casarett, 2005, pp. S-153). Alternately, research burden is defined as “unpleasant features of participation in a study that are more certain, and which are better thought of as inconveniences” (Casarett, 2005, pp. S-153-S-154).

Fatigue. It is important for researchers to be aware of the potential for study participants to become fatigued during the process of participation. As Dobratz (2003) noted in her study of home hospice patients, 3 out of 113 potential participants were deemed too fatigued to participate in the study during the consenting phase and an additional 2 participants discontinued participation after only a few minutes due to fatigue. Of the 97 participants who completed data collection, 7 became fatigued to the point where they required multiple sessions to complete the process. While these numbers are small compared to the number of potential participants, there is nonetheless a need for researchers to monitor for fatigue and to modify the data collection process as needed in order to prevent harm to participants.

Emotional distress. There are many possibilities for emotional distress in psychological research participation. This seems to be especially true in research with hospice and palliative care populations. In order to protect the well-being of research participants, researchers must
understand what may trigger emotional distress in participants.

The wording of research materials may be very distressing for participants who are unaware of the terminal nature of their diagnosis or the meaning of the term “palliative care” (Addington-Hall, 2002; Barnes et al., 2005; Seymour et al., 2005). It is common for researchers to reword study materials in a more neutral way to prevent this distress. For instance, Barnes et al. used the term “heart condition”, as opposed to “heart failure” in the materials used in their community-based study of heart failure. However, this technique has its disadvantages. As one researcher queried, “How do you identify people who actually are dying and how do you write it up so that you don't upset some people because they still think they're going to get better?” (Kendall et al., 2007, p. 4). There is also concern that rewording study materials may restrict the amount of information that potential participants have on which to base their decision to participate (Addington-Hall, 2002). The fine line between minimizing distress and limiting informed consent is not clear in this area (Addington-Hall, 2002).

Similarly, there is concern that recalling the experience of being terminally ill or dying may provoke distress or remind participants about the seriousness of their situation (Plant, 1996). A focus group of hospice and palliative care researchers pointed out that the ability of the researcher to monitor the level of distress in the participant, bring the research to an emotionally safe close when the participant became too distressed, and ensure the participant had continued support if necessary was an important aspect of preventing harm to participants (Kendall et al., 2007). As Wilkie (1997) expresses, “The investigator should be sufficiently skilled to know when to stop asking questions” (p. 323).

Wilkie (1997) also points out that the potential benefit of participants being
encouraged to express feelings and discuss experiences with researchers may carry the possibility of harm. As she states, “If participating in the research has become 'therapy' for the patient, what happens when the study finishes?” (1997, p. 324). Participants may also be at risk of feeling guilt after discussing their relationships with care providers, partners, or family members with researchers (2002).

While there is good reason to be concerned about the risk of emotional distress in participants, researchers have noted a low incidence of distress among participants (Wright et al., 2006). Wright et al. (2006) noted that none of the cancer patients who served as co-researchers in their study of palliative care services reported being distressed as a result of mediating focus groups on this subject. Although, it should be noted that the authors did not operationalize how this information was collected, and it appears co-researchers were expected to voluntarily report distress if they experienced it. In a post-focus-group evaluation questionnaire, none of the participants reported distress as a result of participating in a group mediated by a fellow cancer patient.

**Burden.** Research participation often entails burden for participating hospice and palliative care patients. Furthermore, burden that may be minimal for other populations may unduly burden participants who are at the end of life, have limited time with which to participate in research, and may have other priorities (Casarett & Karlawish, 2000). Several strategies exist for reducing or eliminating potential burden. Researchers can use retrospective data or assessment tools that are already routinely administered by medical staff (Head & Ritchie, 2004). They may also pilot the materials to be used in a study in order to ensure that the burden placed on participants is feasible and necessary (Barnes et al., 2005). Once the data collection process begins, researchers can minimize the burden on participants
by being flexible in where, when, and how data is collected (Casarett, 2005). For example, phone interviews may create less burden for some participants than an in-home interview, or several short data collection sessions may be less burdensome than one longer one.

Possible Benefits

While research participation often entails burden and risk, there is also the possibility for participants to reap benefit from the experience. Studies which involve new pharmacological treatments or treatment methodologies may offer participants the opportunity for an increased quality of life (Casarett, 2005). Casarett points out that in these cases, researchers must consider how the findings of these studies can be applied to the research participants in a timely manner as their limited life expectancy may mean that they do not live enough to experience the implementation of new standards of treatment.

Although a large portion of psychological research does not offer direct benefit to participants (Wilkie, 1997), participation may be of value in other ways. Participants may feel empowered by having their voices heard and expressing their feelings (Plant, 1996; Wilkie, 1997). As one focus group participant commented, “When I spoke to [researcher’s name] it really helped me. Because I felt that it was somebody listening, and I know it helped me” (Kendall et al., 2007, p. 3). Other participants may find pleasure and an increased sense of worth in knowing that they have done something to help others (Dobratz, 2003; Plant, 1996). Fine explains, “... instead of additive burdens, there is oftentimes perceived benefit, through 'helping', 'companionship', 'attention', and similar positively viewed attributions of being involved in a social enterprise” (2003, p. S58). One group of palliative care patients stated that the questionnaire they had completed regarding the symptoms they were experiencing had facilitated discussions that were therapeutic and beneficial to both themselves and their
families (Hopkinson et al., 2005).

Williams et al. (2006) explored hospice patients' interest in participating in research as well as the perceived benefits of participation. They found that hospice patients were more likely than ambulatory senior citizens to experience the opportunity to help their doctor or nurse (37% versus 24%), the potential to improve their symptoms (25% versus 10%), the opportunity to have a sense of purpose in their life (20% versus 11%), and the opportunity to be followed more closely by their doctor or nurse (19% versus 9%) as benefits of participation.

Summary

The most prevalent potential risks of participating in research for hospice and palliative care patients appear to be fatigue, emotional distress, and burden. It is important for researchers to understand that fatigue may cause undue harm to participants and limit their ability to participate. In these cases, researchers must be willing to discontinue participation or break participation up into smaller segments if desired. Emotional distress can be caused by many facets of the research experience which may include insensitive wording of materials (especially if the participant is unaware of the nature of their prognosis), recollection of the experience of being very ill, or guilt at discussing their relationships with caregivers, partners, or family. While low distress has been reported, it is vital that researchers be competent to monitor distress throughout participation and end participation in an emotionally safe way if participants do become distressed. Because people at the end of life often have different priorities from the general population, minimizing participation burden is essential. Where there are emotional or physical benefits, such as the feeling of being heard, enjoyment of being altruistic, or the experience of improved quality
of life as a result of receiving a new treatment, researchers should seek to maximize these effects.

**Ethical Issues**

In working with hospice and palliative care patients, researchers must consider the ethical issues of creating ethical research goals, managing dual roles and role conflict, and protecting confidentiality and data access. While these are vital to consider in research with hospice and palliative care patients, it is important to note that these issues are not unique to this population (Casarett et al., 2003). As Fine asserts, “these are the same types of considerations that attend research in other high-risk populations, such as premature infants, burns victims, HIV or bone marrow transplant patients, to name a few examples where there is considerable research precedent” (2003, p. S56). Fine points out that “insufficient funding, pragmatic challenges, and sociological/cultural barriers limit research in this area, not ethical constraints per se” (2003, p. S53). While the following issues may be problematic and necessitate consideration on the part of researchers, they are not inevitable barriers to conducting research with this population.

**Creating Ethical Research Goals**

Because participants are willing to accept the risk of harm and burden in research participation, researchers must in turn seek to maximize possible benefit and minimize potential risk (Casarett, 2005). Seymour and Skilbeck (2002) suggest using the ideas of goal-based morality, duty-based morality, and rights-based morality to conceptualize the balance between the research outcome and risk/benefit to participants. In goal-based morality, researchers aim to produce research that will be maximally beneficial to the population, if not to the participants themselves. In this view, producing research that is generalizable to
the greatest number of individuals is the priority. Comparatively, in duty-based morality the benefit of the participant is weighted over the research goals. Value is placed on making the research experience something that is beneficial to participants rather than ultimately generalizable. Researchers using a rights-based morality approach place emphasis on the participant's rights to choose to participate in the research process and evaluate the potential risks and benefits of the experience. According to Seymour and Skilbeck, it is important for researchers working with hospice and palliative care patients to balance these three perspectives in order to create research that is ethically sound.

*Dual Roles and Role Conflict*

The process of research often places individuals in the role of both investigator and caregiver (e.g., Raudonis, 1992). In this situation, participants may feel coerced into research participation because they are afraid of receiving a lower level of care if they refuse to participate in proposed research or provide negative feedback (Addington-Hall, 2002; Kaasa & De Conno, 2001; Plant, 1996; Wilkie, 1997). Confusion about the role of the researcher may cause distress once data collection is completed. Situations in which a participant mistakes a researcher as a member of their clinical care team may result in confused communication between the patient and medical staff as well as disappointment when research is completed and contact with the researcher ends (Seymour & Skilbeck, 2002).

Researchers themselves may have difficulty balancing these two divergent roles even if the researcher is not directly involved in the medical care of the particular patient (Casarett & Karlawish, 2000; Raudonis, 1992). While the clinician uses their available skills to alleviate the pain and suffering their patients are experiencing, the researcher's duty is to record data from participants as objectively as possible. Clinicians in the role of researchers may feel
pulled to use their clinical skills and knowledge in reaction to information gained in the data collection process (Plant, 1996). Raudonis (1992) describes two situations in which she felt such role conflict. In the first, she describes how a very articulate, informative interviewee declined to continue her participation after her condition deteriorated. Raudonis discusses how, as a researcher, she was disappointed in the loss of a valuable participant, but as a nurse she approved of the patient's decision to discontinue participation. In the second, she describes how she stayed with a participant after data was collected to serve him lunch and help him back to bed at his request. She states:

Although some readers may question the presence of conflict, the author experienced some distress after the incident and questioned if, as a researcher, she should engage in such activities. Reflecting on the experience, she decided it was the nurse responding to the individual's needs and that she would respond accordingly if the situation were repeated. In some small way, as a nurse, the author was able to help this person who had chosen to share his experience with her. (Raudonis, 1992, p. 245)

Role conflict issues may also involve issues such as confidentiality. For example, there may be a dilemma if a research participant discloses about inadequately treated symptoms in the process of data collection (Casarett & Karlawish, 2000). While the issue of reporting will be discussed more thoroughly in the section titled “Confidentiality and access to data”, clinicians who are conducting research must be aware of this facet when they are clarifying their role as researcher. In order to reduce the risk of harm to both patient and researcher, researchers must clearly outline their role before the process begins.
Confidentiality and Access to Data

Researchers must determine how the confidentiality of the participants and data will be protected before the study begins. This is especially important when the research targets information which may be important for the care of the patient. For instance, participants may report symptoms which are being inadequately managed. Casarett and Karlawish (2000) outline three possible solutions to this kind of disclosure: Investigators may decide to never disclose such information to the care provider, always disclose such information to the care provider, or encourage the patient, if they are considered competent, to report the information to their care provider themselves. Casarett and Karlawish point out that the first option places the highest value on confidentiality, where the second option places the highest value on maximizing benefit and minimizing harm. The third option strikes the best balance between these two important ethical areas. They also point out that the researcher may offer to contact the care provider with the permission of the participant, but should never contact the care provider without participant permission. In the case that the participant is unable to report the information to their care provider, Casarett and Karlawish state that “a presumption should exist in favor of disclosing to a patient's provider any information that might assist in the alleviation of that patient's symptoms” (p. 135). Researchers must determine the answers to these questions prior to the beginning of the study and inform patients of what, when, and to whom information will be shared in the informed consent process (Wilkie, 1997).

Summary

Before a project begins, researchers must consider how to create ethical study goals, determine how they will manage and minimize potential harm from dual roles, decide how
they will best protect the confidentiality of participants and data, and determine what information will be shared with care providers. In particular, researchers must seek to strike a balance between maximizing potential benefit to participants and creating a study that is generalizable and able to be applied to help other patients, determine if they have a dual relationship with participants and how this can best be managed, and determine when and how information relevant to the care of patients will be disclosed to their care provider.

Methodological Issues

Researchers must use the soundest methodology possible in order to produce optimally valid and generalizable results. In order to do this, they must have awareness of the effects of selection bias, attrition, and withdrawal on their findings. When interviews or questionnaires are used, researchers should seek to maximize ease of use and minimize participant burden. Assistance (e.g., help reading or completing study materials) may be necessary to minimize the amount of missing data and in some cases, the use of a proxy to participate on behalf of the patient may be optimal, although not without its own challenges. Lastly, researchers must plan statistical analyses to reduce bias and best process data sets with missing values.

Selection Bias

Self-selection bias, in which participants with a certain trait may be more or less likely to choose to participate in the research study, is one possible limitation of research studies with hospice and palliative care patients as participants (C. J. Williams et al., 2006). As a result, researchers should take care to analyze what effect selection bias may have on their results. For example, Williams et al. pointed out that their finding that 45% of hospice patients expressed willingness to participate in research was likely over-inflated due to the
fact the patients had chosen to participate in a research survey to begin with. Researchers should seek to reduce the effects of selection bias whenever possible and, like Williams et al., disclose the likely effects of selection bias on their findings when it cannot be eliminated.

Attrition/Withdrawal

Attrition due to participant death or withdrawal is a major obstacle to conducting research with this population (Jordhøy et al., 1999; Kaasa & De Conno, 2001). Death, discharge, or decline in cognitive function may be involved in attrition rates (A. Williams et al., 2005). In a longitudinal study researching health-related quality of life in palliative care patients, Kaasa and De Conno reported a median survival rate of 81 days after study enrollment and a withdrawal rate, defined as patients who dropped out of the study before their death by not returning questionnaires, of 45%. Of two longitudinal studies of palliative care patients, Mitchell and Abernethy (2005) reported a 51% attrition rate due to death or withdrawal at the goal 3-week analysis in one study and a 54% attrition rate due to death or withdrawal at the goal 8-week analysis in the other. In the latter study, 15% of participants withdrew from the study prior to death. Dobratz (2003) reported a withdrawal-and-attrition rate of 14% in her study of home hospice patients. Because this study was not longitudinal, the percentage was calculated from the number of patients who agreed to participate at the preliminary contact but either died or changed their minds before informed consent or data were collected. Bruera (1994) estimates that approximately 30% of patients in studies longer than 14 days drop out due to noncompliance or complications. While the high attrition rates are problematic in this research, Williams et al. (2006) point out that conducting research with hospice patients is still feasible if allowances for attrition are made when recruiting participants.
Assessments

Researchers must determine how assessments will be used to optimally collect research data. If too many assessments are used, or if the assessments are too long and tiring, researchers risk inducing fatigue in their participants and decreasing the amount of valid data collected. For these reasons, researchers in this population should only use assessments which are necessary and can be clearly justified (Bruera, 1994). Beyond the number of assessments, researchers must consider how the interviews or questionnaires are to be constructed, if objective indicators can be utilized, how assistance will be provided to participants, and if proxies will be used for data collection.

Interview/questionnaire construction. Appropriate interview and questionnaire construction is vital for collecting interpretable data. For example, researchers should be aware that long interviews or questionnaires are not only unlikely to be completed by participants, who may fatigue easily, but they may also increase gate keeping (Addington-Hall, 2002). Fliss, Addington-Hall, and Higginson (2007) conducted research with palliative care patients using questionnaires and subsequently asked for feedback on several topics, including the structure of the questionnaire. They then reformatted the questionnaire based on the feedback provided. The changes included increased font size, removal of gray shading on alternate questions, increased size and boldness of text describing the time period to which symptoms related, and development of a large-print version for participants with vision problems. Additionally, they found that “In general, the questions on psychological rather than physical symptoms required more time and consideration, but no patient was unable to answer them or displayed distress” (p. 90).

Objective indicators. Although not applicable to all studies, Kaasa and De Conno (2001)
suggest that researchers collect objective data, such as tumor burden or biochemical markers, from hospice and palliative care patients whenever appropriate in order to increase the validity, reliability, and scope of the data collected. As they explain, biological indicators may help to explain the method of action of palliative care treatments.

**Assistance.** While some participants may be able to complete the surveys and other materials necessary for study participation, others may need assistance. In one study, researchers asked palliative care patients to complete a series of questionnaires over a period of time and to report the level of assistance they had received with each questionnaire (Jordhøy et al., 1999). Participants reported that they had received assistance with 31% of the total questionnaires and that 23% of those questionnaires had been completed for them by another person. Of the questionnaires completed less than two months before the participant's death, the rate of assistance rose to 50%. Dobratz (2003) reported that 28.8% of the 97 hospice patients who completed study participation needed assistance in reading questions and recording answers due to physical impairment such as poor vision, physical weakness, or other physical handicaps.

**Proxies.** In some cases, it may be necessary for another individual to act as a proxy and provide information on behalf of the hospice or palliative care patient due to the patient's physical or cognitive decline or death (Bakitas et al., 2006). While proxies may be necessary to collect information in some cases, there has been some concern about the reliability of proxy reports (McPherson & Addington-Hall, 2003). McPherson and Addington-Hall conducted a review of the relevant literature in order to clarify these issues. They reported that proxy reports of service provision and evaluation and observable symptoms, such as immobility, activities of daily living, fatigue, difficulty breathing, and vomiting, were reliable.
in comparison to the patients' own reports. In contrast, proxy reports of the patient's subjective experience, such as pain, mood disturbance, symptom distress, and thoughts, were less reliable. Better agreement between patients and proxies was found when simple questions and limited response options were used.

Bakitas et al. (2006) discussed the possibility of requiring participants to have a family member or caregiver who is willing to act as a proxy in order to ensure that data is collected continuously until the participants' deaths. However, complications with this method arise early. The selection of a proxy for research may affect the dynamics of the family in situations when more than one caregiver or family member is heavily involved with the patient by putting more responsibility on one member (Kapo & Casarett, 2004). Other disadvantages may include increased cost and methodological issues (Bakitas et al., 2006). As Kapo and Casarett point out, using a proxy reporter may call for researchers to be available late in the evenings or at other times when caregivers may be most able to spend time away from caring for the patient in order to participate in the study. Researchers using proxy reporters must take care to be tactful with the timing of data collection and avoid contacting the proxy for research purposes if the patient is rapidly declining or struggling with uncontrolled symptoms (Kapo & Casarett, 2004). The use of proxies may beneficially result in increased homogeneity, maximized internal validity, and reduced data attrition (Bakitas et al., 2006). Researchers using proxies also have the opportunity to continue collecting data after the participants' death (Kapo & Casarett, 2004).

**Statistics**

In order for study results to be valid, appropriate statistical procedures must be used. Research with hospice and palliative care populations entails certain challenges which may
make statistical analyses of the data more difficult, such as high rates of missing data and low sample size. Researchers must choose statistical methods which will best overcome these challenges and produce useful results.

*Missing data.* Missing data is problematic because it reduces power to detect differences and introduces bias (Palmer, 2004). While a large number of studies result in randomly missing data, missing data in hospice and palliative care samples tends to be non-random and is usually related to changes in the participant’s health state and level of functionality. Thus, is not appropriately replaced by typical methods such as estimation or the sole inclusion of participants with complete data (Grande & Todd, 2000; Palmer, 2004).

Palmer used three methods for working with missing data, including the exclusion of patients with missing data, the substitution of the baseline value for missing values, and the use of the last known value for subsequent missing values, to analyze one set of data collected from palliative care patients in order to examine if using different methods would significantly alter the results. She concluded that different methods of estimating missing data did result in different conclusions being drawn from the data. Based on these findings, Palmer suggests:

> If missing observations have occurred, publications should report analyses with more than one method of estimating missing data as a form of sensitivity analysis to determine if the conclusions of their study are 'robust' to the potential problems of missing data. (p. 618)

At the least, researchers should be sure to clearly state the method they used to deal with missing data (Palmer, 2004).

Reducing bias in non-experimental research designs. Penrod and Morrison (2004) reviewed
two statistical methods for reducing the potential for bias in non-experimental, or observational, studies: propensity score matching and instrumental variables estimation. Propensity score matching is used to minimize selection effects on the estimation of treatment effects. In this method, each participant's likelihood of being placed in the treatment group is estimated and used to stratify the sample. The treatment effect is then calculated for each stratum. Instrumental variables estimation involves identifying a variable or variables that impact the participant's treatment but not impact the outcome variable. Once the identification is made, the researcher can determine what portion of variation in the outcome variable is determined by the variable as opposed to the treatment. By utilizing these methods, researchers can enhance the statistical rigor of observational research.

**Summary**

Researchers must confront many methodological issues in conducting research with hospice and palliative care patients, including dealing with selection bias, attrition and withdrawal, effective use of assessments, and suitable statistical methods. Researchers must take care to limit the use of assessments to only those that are relevant and justifiable, and to construct interviews or questionnaires in a manner that optimizes ease of use and minimizes participant burden. For example, questionnaires should use large, clear print, not contain shaded areas, and be available in a large-print version for those with vision difficulties. If objective indicators can be appropriately used in a study, it is suggested that they be included. Researchers should be aware that a high proportion of participants may need assistance in reading or completing questionnaires, and in some cases, a proxy may be used to respond on behalf of patients. Lastly, researchers are obligated to use appropriate statistical analyses in order to produce results that are optimally valid and generalizable.
Summary of the Literature

While there are many obstacles in conducting research with hospice and palliative care patients, they are not insurmountable. With careful preparation, researchers can plan for these areas of difficulty and continue to produce research which can be used to better understand the needs, desires, and experiences of this population and be applied to increase the quality of life of people at the end of life. Although there has been some debate over the ethicality of conducting research with this population, writers in the literature are overwhelmingly in favor of supporting patients' rights to make an informed decision regarding research participation (Addington-Hall, 2002; Bruera, 1994; Gysels et al., 2008; Hudson et al., 2005; Kaasa & De Conno, 2001; Terry et al., 2006).

Adequate preparation time is essential to solid study design in this population (Seymour et al., 2005). This preparation may include obtaining IRB approval; identifying and carrying out training and/or education for involved individuals and organizations; clarifying access, researcher roles, and ethical conduct; and identifying the target population (Bakitas et al., 2006; Barnes et al., 2005; Seymour et al., 2005). Depending on the research goals, researchers may need to evaluate the advantages and disadvantages of several applicable research designs such as randomized controlled trials, qualitative methods, phenomenological paradigms, case studies, focus groups, mixed methods, survey research, and collaborative approaches (Addington-Hall, 2002; Kapo & Casarett, 2004; Penrod & Morrison, 2004; Seymour & Clark, 1998; Seymour et al., 2005; Storey, 2004; Wallen & Berger, 2004; Walshe et al., 2004; Wilkie, 1997; A. Williams et al., 2005; Wright et al., 2006). Researchers should anticipate how attrition and withdrawal may affect the target sample size (Casarett, 2005) and consider how to maximize the diversity included in the sample (Kendall et al., 2007; Wright...
Because hospice and palliative care patients are considered a vulnerable population, special considerations must be taken to ensure that their consent is informed and their participation is voluntary (Casarett et al., 2003; Morreim, 2006). One such consideration is the assessment of competence to consent, which may be determined through formal or informal means (Bruera, 1994; Fine, 2004; C. J. Williams et al., 2006). In cases where patients cannot provide competent consent, researchers may collect dual or proxy consent (Casarett, 2005), and advance consent is recommended when potential participants will be unable to provide consent at the time they become eligible to participate (Casarett, 2005; Casarett et al., 2003). Regardless of the type of consent used, researchers must be aware of the effects of wording and delivery on patient understanding and seek to make the informed consent process maximally effective. This may include wording the informed consent form to avoid potentially disturbing terms such as “terminally ill” and “end of life”, emphasizing that potential participants are consenting to research rather than treatment, providing information orally, and providing an appropriate form of back-up information (Plant, 1996; Silverman, 1996; Speck, 1996; Terry et al., 2006).

In order to recruit patients who are eligible for the study and most likely to complete participation, researchers must design appropriate inclusion and exclusion criteria. While overly lenient inclusion and exclusion criteria may result in the inclusion of participants who are inappropriate or unlikely to complete participation, overly strict criteria may result in low study recruitment. Some frequently mentioned inclusion and exclusion criteria in this population include life expectancy and mental status (Bakitas et al., 2006; Jordhøy et al., 1999). In order to access potential participants, researchers may have to pass several levels of
gatekeepers including ethics boards, medical staff, hospice staff, family, and caregivers. Certain strategies, such as offering informational sessions and excluding patients who are very ill or have a very limited life expectancy, may be beneficial to study recruitment (Hudson et al., 2005). While the recruitment process may be difficult, it appears that many hospice and palliative care patients are interested in research participation (Hopkinson et al., 2005; Kaasa & De Conno, 2001; Kendall et al., 2007; C. J. Williams et al., 2006). Participants have cited many reasons for participating in studies, including to help current or future patients and care providers, to feel good about helping others, to improve symptoms, to contribute to science, to have a sense of purpose, and to increase social interaction (Terry et al., 2006; C. J. Williams et al., 2006). Conversely, there are also many barriers to research participation, such as illness, low energy, and the potential for caregiver burden (Phipps et al., 2005; C. J. Williams et al., 2006).

Research participation carries many possible risks and benefits. Such risks may include fatigue, emotional distress, and burden (Casarett & Karlawish, 2000; Dobratz, 2003; Kendall et al., 2007). Additionally, participants may reap direct and indirect benefits, such as new treatments, the feeling of empowerment through helping others and having their voices heard, and opportunities for social interaction (Casarett, 2005; Fine, 2003; Plant, 1996).

Researchers must confront many ethical issues when designing and conducting research in hospice and palliative care populations. Because participants accept the risk of burden and harm when participating in research, researchers must seek to maximize possible benefit and minimize harm while still producing research that is methodologically sound and generalizable (Casarett, 2005; Seymour & Skilbeck, 2002). The roles of researcher and clinician may overlap in many settings, and researchers must clarify exactly what their role
will be (Casarett & Karlawish, 2000; Raudonis, 1992). The area of confidentiality and inadequately treated symptoms may be especially problematic. Researchers must clarify if, how, and when they will break confidentiality in order to inform the primary care provider of problematic symptoms (Casarett & Karlawish, 2000).

There are also many methodological problems inherent in conducting research with this population. As in all research using volunteer participants, researchers must anticipate the effects of selection bias and take this into account when attempting to generalize the results of the study (C. J. Williams et al., 2006). Research with this population is especially vulnerable to participant attrition and withdrawal (Jordhøy et al., 1999; Kaasa & De Conno, 2001), and the statistical analyses should take these problems into account. When interviews or questionnaires are used, they should be justified, constructed for the ease of participant use, and require as little burden as possible (Addington-Hall, 2002; Bruera, 1994). The fact that many participants will require assistance in completing study materials should also be taken into consideration (Jordhøy et al., 1999).

The road to valid and generalizable research using hospice and palliative care patients is replete with possible hazards for researchers, participants, and research projects. But this does not minimize the need for continued research in this area or signify that such research is impossible or not worth the effort of conducting. Rather, it highlights the need for synthesized guidelines to inform researchers and guide them through these potential problems. In the remainder of this thesis, the focus will be on providing information on additional areas of concern, summarizing the controversies in the literature, providing guidelines for researchers in this area, and identifying areas of further research and clarification.
Discussion

As evidenced by the sheer number of articles on the topic of hospice and palliative care patients, such research is certainly possible. However, as noted regarding the many pieces of literature reviewed in this thesis, it is also very challenging. Researchers must have the time and understanding to carefully review, evaluate, and implement the most effective solutions to possible problems. In order to assist researchers in this area, the goal of this discussion section will be to highlight additional areas of consideration not reviewed previously, discuss the current controversies, offer synthesized recommendations for researchers, and call attention to topics in this area necessitating further research.

Additional Areas of Consideration

Although care was taken to make the review exhaustive, some potentially challenging areas of conducting research with hospice and palliative care patients did not emerge in the literature. Such areas include abuse reporting and statistics with small sample sizes.

Abuse Reporting

Depending on the laws of their state, psychologists who are conducting research may be required to report suspected elder abuse (Bergeron & Gray, 2003). However, there is some debate in the child abuse reporting literature concerning whether research activities are included in the official capacity of a psychologist, and thus covered by the mandated reporting statutes in most states (Allen, 2009). Due to the high proportion of elderly individuals in this population, researchers should consult their state laws regarding abuse reporting and include such limits to confidentiality in the informed consent.

Statistics and Small Samples

As previously discussed, the challenges involved in conducting research with hospice
and palliative care patients may result in a sample size that is smaller than desired. The minimum sample size needed may vary with the normality of the distribution of the variable. For example, a variable which is normally distributed may require a smaller sample size than one which is not normally distributed (Pett, 1997). In cases where the distribution of the variable is not known and the sample size is small, nonparametric methods should be used in data analysis (Pett, 1997).

Summary

The literature does not contain discussion of every area that researchers in hospice and palliative care populations must take into consideration. Researchers must also consider how they will handle any disclosures of abuse or neglect by elderly research participants and how they can utilize appropriate statistical methods despite the likelihood for small sample sizes.

Controversies

Not all discussion of the ethical and logistical issues of conducting research with hospice and palliative care patients has been straightforward. Of the topics reviewed, the issue of whether it is ethical to include hospice and palliative care patients as research participants has received the most discussion. While it did not result in discussion in the literature, the suggestion of excluding professionals involved in direct patient care from the recruitment process as a means of minimizing gate-keeping will also be discussed.

Including or Excluding Hospice and Palliative Care Patients as Research Participants

While there has been debate in the literature regarding whether it is ethical to include hospice and palliative care patients as research participants, the consensus is that it would be unethical to disrespect patients' autonomy by excluding them as potential research
participants (e.g., Addington-Hall, 2002; Gysels et al., 2008; Terry et al., 2006). After my
review of the literature, I agree with this consensus. While there are undeniably many issues
which much be taken into consideration when designing research with hospice and palliative
care populations, the challenges to designing appropriate, ethical research are not
insurmountable, and research in this area is important to increase the quality of care and to
understand the needs and desires of individuals at the end of life. Additionally, participants
may experience many indirect and intangible benefits from research participation. As long as
participants are adequately informed of the potential risks of research and are not unduly
burdened by participation, I think it is important to respect patient autonomy by extending
the invitation to participate in appropriate research.

Minimizing Gate-Keeping by Excluding Professionals Involved in Direct Patient Care

Researchers have suggested many ways of reducing gate-keeping, such as excluding
the professionals directly involved in the care of the potential participant from recruitment
(Hudson et al., 2005). While this could indeed reduce instances of inappropriate gate-
keeping in study recruitment, it also goes against the suggestions and experience of other
researchers, as well as the reported wishes of potential participants. Many researchers have
used hospice and palliative care professionals to recruit patients who are most likely to be
able to complete participation with the least likelihood of harm (Barnes et al., 2005; Buss &
Arnold, 2004; Dobratz, 2003; Hopkinson et al., 2005; Kaasa & De Conno, 2001; Kendall et
al., 2007; Phipps et al., 2005; Storey, 2004; Terry et al., 2006; A. Williams et al., 2005; C. J.
Williams et al., 2006; Wright et al., 2006). The most persuasive argument against this
suggestion, however, may be the research documenting patients’ desire to be approached
about research by the professionals most involved in their care (Terry et al., 2006; A.
Williams et al., 2005; C. J. Williams et al., 2006). In light of these findings and the many alternative possibilities for reducing gate-keeping suggested by Hudson et al. (2005), such as offering information sessions and brief face-to-face updates to recruiting medical professionals and excluding patients who are very ill or have a very limited life expectancy, excluding involved medical professionals from recruitment may be ill-advised.

**Recommendations**

In conducting research with hospice and palliative care patients, researchers face many challenges in the areas of study design, informed consent, recruitment, risks and benefits, ethical issues, and methodological issues. The following recommendations include many previously suggested in the literature and others based on the information previously reviewed. In order to minimize these challenges and increase the quality of future research, researchers should:

1. Allow plentiful time for planning and study design (Seymour et al., 2005).
2. Plan for high attrition rates (Jordhøy et al., 1999; Kaasa & De Conno, 2001). Attrition rates of 30-50% have been found in longitudinal studies (Bruera, 1994; Mitchell & Abernathy, 2005) and 15% in one-time studies (Dobratz, 2003), with rate increasing over the length of the study (Kaasa & De Conno, 2001), have been reported in the literature.
3. Seek to increase diversity in samples by using culturally appropriate materials and involving the cultural community in recruitment (Kendall et al., 2007).
4. Consider implementing a “silent opt-out”, in which patients can decline to participate through inaction, to minimize coercion.
5. Use formal competence assessment when possible (Dobratz, 2003; Fine, 2004).
6. Use dual consent when proxy consent is required (Casarett, 2005).

7. Use process consent in longitudinal studies (Addington-Hall, 2002; Head & Ritchie, 2004; Kendall et al., 2007; Raudonis, 1992).

8. Deliver informed consent orally, with simple, straight-forward written materials for participants to keep for reference (Speck, 1996). Researchers have reported that participants from these populations prefer oral, versus written, information (Terry et al., 2006).

9. Understand the specific target population's understanding of their life expectancy or terminal status and word recruitment materials accordingly to minimize distress and increase participant recruitment (Plant, 1996).

10. Include life expectancy as an inclusion/exclusion criteria (Hudson et al., 2005; Jordhøy et al., 1999; Kaasa & De Conno, 2001). This will help ensure that participants will be able to complete study participation and decrease gate-keeping (Mitchell & Abernethy, 2005).

11. Educate other involved professionals on research related issues, Researchers have reported this helpful in minimizing gate-keeping and maximizing study recruitment (Bakitas et al. 2006).

12. Understand participants' preference to be approached by the medical professionals most involved in their care (Terry et al., 2006; A. Williams et al, 2005; C. J. Williams et al., 2006).

13. Train data collectors to be alert to signs of adverse effects (Dobratz, 2003; Wilkie, 1997). Researchers involved in a focus group warned of the potential harm that can be caused by data collectors who do not pay attention to the emotional state of the
participant or who do not end data collection with hospice and palliative care patients if a participant becomes distressed (Kendall et al., 2007).

14. Use retrospective or routine assessment data whenever possible to minimize the burden to patients (Head & Ritchie, 2004).

15. Conduct pilot tests if there is concern about the burden or feasibility of the planned study. Researchers have indicated that pilot tests are helpful to reduce participant burden and increase the likelihood that all needed data is collected (Barnes et al., 2005).

16. Be flexible with where, when, and how data is collected in order to reduce burden (i.e., collect data at the participant's residence, schedule data collection for times when they are usually most alert, collect data in several shorter sessions rather than one longer one). Researchers have reported that such steps can reduce the burden of research participation (Casarett, 2005).

17. Seek benefit for participants in creative ways.

18. Understand the potential for role conflicts or dual roles and clearly define roles as researchers and/or clinicians. Many researchers have discussed their experiences with role conflicts and dual roles in doing research with this population (Addington-Hall, 2002; Kaasa & De Conno, 2001; Plant, 1996; Raudonis, 1992; Wilkie, 1997).

19. Plan for how to deal with participant disclosure that is relevant to the patient's treatment and include this in the informed consent (Casarett & Karlawish, 2000; Wilkie, 1997). Follow Casarett and Karlawish's recommendation that the participant contact their medical provider, or offering to contact the medical provider on behalf of the patient, as it respects the confidentiality and autonomy of the patient while
addressing the problem of unreported symptoms.

20. Use only assessments which are necessary and can be clearly justified (Bruera, 1994).

21. Use objective indicators when possible (Kaasa & De Conno, 2001).

22. Be prepared to assist or have others assist participants with completion of study materials. Researchers have noted that a large proportion of hospice and palliative care patients will need assistance to complete study materials (Dobratz, 2003; Jordhøy et al., 1999).

23. Consider how assistance may affect participant disclosure.

24. Use proxies for service evaluation projects or when data is needed up to the time of death. Researchers have reported the reliability of proxy reported for service evaluation projects and the utility of proxy reporters for providing information after the patient can no longer be expected to participate (Kapo & Casarett, 2004; McPherson & Addington-Hall, 2003).

25. Conduct and report the results of multiple analyses of variables with missing data (Palmer, 2004).

26. Use appropriate statistical methods if the sample size is small.

27. Disclose the possible effects of selection bias when the study is published (see C.J. Williams et al., 2006).

Areas of Further Research

While a great deal of literature exists concerning the ethical and logistical challenges of conducting research with hospice patients, several areas could still benefit from further exploration. These areas include increasing the inclusion of diverse populations in research, coercion in the consent process, proxy consent and the reliability of proxy-provided
information, and the role of assistance on disclosure in research. For the purposes of this discussion section, unless specified, the term 'research' is used to refer to published accounts of researchers' experiences working with this population as well as empirical research studies, as both offer perspectives which can be useful to researchers working with hospice and palliative care populations.

*Increasing the Inclusion of Diverse Populations*

Many researchers have expressed concern regarding the small proportions of ethnic minority individuals who participate in hospice and palliative care research (Kendall et al., 2007). However, little of the research covered in this review included discussion of this issue. It would be beneficial for future literature to be made available which includes discussion of the challenge of increasing the recruitment of diverse individuals for research in this population and suggestions for overcoming this challenge. Additionally, researchers should seek to include diverse participants, such as racial and ethnic minorities, sexual orientation minorities, and people with disabilities, whenever possible.

*Coercion in the Consent Process.*

While a great deal of speculation regarding the role of coercion in the consent process is present in the literature, this area of research could benefit from more empirical investigation. For example, research on whether refusal rates vary by the relationship of the researcher to the potential participant could be beneficial in determining how much the existing patient-researcher relationship affects the recruitment and consent process. Replication of Terry and colleagues' (2006) focus groups of hospice and palliative care patients may be especially helpful in determining which factors may be unintentionally coercive in research recruitment. Overall, increasing the understanding of potentially
coercive aspects of recruitment will be of benefit to future researchers seeking to reduce coercion in their studies.

Proxy Consent and the Reliability of Proxy-Provided Information

The process of proxy decision-making is not yet well understood and researchers could benefit from further research on the subject (Silverman, 1996). Areas of potential exploration include levels of agreement between proxy and patient, issues of vulnerability and coercion in the families of hospice and palliative care patients, and factors influencing the proxy's decision for the patient's participation. Because proxy information can be so useful in research involving hospice and palliative care patients, more research is needed to ensure when proxy-provided information is reliable and when it should not be depended on. While McPherson and Addington-Hall (2003) discussed this topic in their article, more research is needed to ensure when proxy-provided information is valid and can be used appropriately in research.

The Effects of Assistance on Disclosure

As many patients can be expected to need assistance completing research measures (Jordhoy et al., 1999), more empirical research is needed to clarify if and when assistance influences participant disclosure in research. While it may not be feasible to deny assistance to participants, research in this area will allow for researchers to better understand how assistance may affect the information gathered and to hypothesize how assistance may have influenced the research findings.

Summary

Aside from the many areas discussed in the literature review of this thesis, researchers should also consider how they will deal with the possibility of abuse reporting.
and using statistics appropriate for small sample sizes. Researchers should also be aware of
the current areas of controversy, including whether it is ethical to include or exclude hospice
and palliative care patients as research participants and how best to minimizing inappropriate
gate-keeping. Several challenging areas of research in this population still need further
clarification, both empirically and by published accounts of researchers’ experiences. Such
areas include how to increase the inclusion of diverse populations, the role of coercion in
the consent process, issues involving proxy consent and proxy-provided information, and the
effects of assistance on participant disclosure.

While conducting research with hospice and palliative care patients is often difficult, it is not impossible. Taking time early in the research process to anticipate potential challenges and choose the best possible methods of working around them will result in more fruitful, valid research in this population. However, researchers new to this area can benefit greatly from the experience of others in the field. The literature is rich in accounts of successes and shortfalls, and much is to be gained from the experiences and suggestions of researchers experienced with this population. Similarly, researchers should be aware that their accounts of problems and successes when working in this population can be invaluable in informing others and increasing the quality of later work. Lastly, although research in this population can be challenging, it is important to increase the quality of life, quality of care, and understanding of individuals at the end of life. Much remains to be gained in this area, despite the challenges.


Raudonis, B. M. (1992). Ethical considerations in qualitative research with hospice patients. *Qualitative Health Research, 2*(2), 238-249.


participation among hospice patients, caregivers, and ambulatory senior citizens: Practical barriers or ethical constraints? *Journal of Palliative Medicine, 9*(4), 968-974.