**Grant Number:** 5R01NR008252-02
**PI Name:** MCMILLAN, SUSAN C.
**PI Email:** smcmilla@hsc.usf.edu
**PI Title:** PROFESSOR
**Project Title:** Systematic Assessment to Improve Hospice Outcomes

**Abstract:** DESCRIPTION (provided by applicant): Complete, accurate, and systematic assessment is known to be essential for providing effective care in any setting. However, research reveals that this assessment is frequently missing from patient records, leading to care that are less than ideal. This need for careful assessment is no less necessary in hospice homecare. Growing numbers of patients are receiving hospice care each year; thus, improving assessment in this setting has the potential for improving care to thousands of patients each day. The primary aims of this study are to determine the efficacy of providing systematic feedback from standardized assessment tools for hospice patients and caregivers in improving hospice outcomes compared to usual practice, and in addition, using those standardized assessments, to identify symptom clusters in hospice patients and how they impact on patient and caregiver well-being. Patient outcomes to be measured include symptom intensity and distress, quality of life, depression, and spiritual well-being. Caregiver outcomes being measured include depression, spiritual well-being during active care, and depression 3 and 12 months after the death. The sample of 306 patient/caregiver dyads will be drawn from three large hospices that are partners in the Center for Hospice, Palliative Care and End of Life Studies at the University of South Florida. Patients must have cancer, and will be screened using the Short Portable Mental Status Questionnaire and the Palliative Performance Scale. In each hospice, two interdisciplinary care teams will be identified that provide homecare to equivalent groups of patients; one will be randomized as the control team and one the experimental team. Patients and caregivers on all teams will be admitted to the study 24-72 hours after admission to hospice and will complete all assessments. For the experimental teams, the RN's and social workers who are collecting the data will attend the weekly interdisciplinary team meetings and report the data they have collected during the previous week. Data collection and reporting will occur at baseline and then weekly for two weeks at which time the patients will be finished with the study. In order to monitor care changes that result from the enhanced assessments, charts will be audited to compare the numbers of home visits and medication and other careplan changes between the experimental and control groups. Caregivers will be visited again at 3 and 12 months after the death to evaluate whether the improved care provided to patients on the experimental teams resulted in significantly less depressive symptoms. Patient/caregiver dyads will be accrued for 30 months with an additional 12 months of follow-up data collection for depression data. Quantitative data will be analyzed using mixed models analysis, repeated measures multivariate analysis of variance, discriminant function analysis and cluster analysis.

**Institution:** UNIVERSITY OF SOUTH FLORIDA
3650 Spectrum Blvd., Suite 160
TAMPA, FL 33612
**Fiscal Year:** 2005
**Department:** NONE
**Project Start:** 01-SEP-2004
**Project End:** 31-MAY-2008
**ICD:** NATIONAL INSTITUTE OF NURSING RESEARCH
**IRG:** ZRG1

## Introduction

It is well established that in order for symptoms to be well-managed, complete, accurate, and systematic assessment must first occur. In a series of studies, it has been found that while nurses support the need for complete assessment, chart documentation confirming that assessment in oncology and hospice settings continues to be sketchy and often absent (Hermann, 2001a; McMillan & Tittle, 1995; McMillan, Tittle, Hagan, & Laughlin, 2000a; McMillan, Tittle & Hagan, 2000b; Tittle & McMillan, 1994). It has been widely demonstrated that health care providers under-diagnose depression in medical patients, and that providing feedback to the professionals from standardized depression scales improves such detection. It also has been found that, without the use of standardized depression scales, fewer than 25% of social work notes included information on the completion of screening for hospice caregiver depression. Earlier studies with cancer patients also have demonstrated that improving assessment improves pain outcomes (Faries, et al. 1991; McMillan, Williams, et al. 1987). However, these latter studies have not been conducted in hospices or with persons near the end of life, and they have focused on improvement in a single symptom.

George (2001) and Tennstedt (2001), in their papers presented at the NIH-sponsored End of Life Conference, called for greater focus on symptoms rather than disease categories. Because of the likelihood of comorbidities, if only the index diagnosis is the focus of a symptom study, then the full range of symptoms and their impact on the functional ability and quality of life of the individual may be missed. Further, Tennstedt recommended investigating the relative contribution of each symptom or class of symptoms to explain variability in the patient's experience at the end of life.

In her paper presented at the same October NIH Conference, Tilden (2001) called for a focus on symptom clusters. Much still is not understood about how various symptoms interact and the extent to which these interactions enhance patient and caregiver well-being or increase distress. For example, when pain is treated with opioids, constipation is very likely to occur in the majority of patients (McMillan & Williams, 1989), and nausea may occur in a smaller subgroup (Weitzner, et al., 1997b), thereby increasing distress. However, treating pain may alleviate depression (Jenson et al., 2001; Syrjala & Chapko, 1995), thereby enhancing the patient's sense of well-being. Pain's interaction with other symptoms such as fatigue has been studied (Dodd, et al 2001), but still is not fully understood. Nor do we fully understand the complex interactions among the various other problems that patients face near the end of life such as dyspnea, nausea, anxiety, and sleep disturbances. Further, when patients experience symptoms, caregivers are impacted; for example, if pain is adequately managed but the patient is sedated, the caregiver may feel distressed. And it has been shown that depression in the patient is correlated with caregiver depression (Thielemann, 2001).

While all organizations caring for patients at the end of life use some type of assessment tools, the validity and reliability of the resulting data are usually unknown. Tilden (2001) recommended that studies be conducted that evaluate the psychometric properties of instruments used at the end of life, thus contributing to the body of knowledge about such instruments. Use of valid and reliable measures can only enhance the understanding of the interdisciplinary team (IDT) about the needs of the patient and caregiver, thus enhancing care and improving hospice outcomes.

**STUDY AIMS:** The primary aims of this study are to determine the efficacy of providing systematic feedback from standardized assessment tools for hospice patients and caregivers in improving hospice outcomes compared to the usual clinical practice and, using those standardized assessments, to identify symptom clusters in hospice patients and how they impact on caregiver and patient well-being.

**Primary Aims:**

**AIM 1**. To determine the effect on patient and caregiver outcomes of providing systematic data from valid and reliable measures to members of the interdisciplinary hospice team at three private not-for-profit hospices.

Hypothesis 1: It is hypothesized that patients and caregivers who are cared for by members of the interdisciplinary teams that receive the intervention will have significantly better scores for target outcomes for patients (symptom distress, depression, spiritual well-being and quality of life) and for caregivers (depression, spiritual well-being) compared to the teams that receive no intervention.

**AIM 2:** To evaluate the effect of the intervention on caregiver's bereavement outcomes at 3 months and 12 months.

Hypothesis 2: It is hypothesized that caregivers of patients cared for by the interdisciplinary teams that receive the intervention during hospice care will have significantly less complicated grief at 3 months and one year after the death.

**Secondary Aim:**

**AIM 3.** To determine how symptoms and symptom clusters reported by hospice patients vary among patients with advanced cancer, and how variations impact the well-being of family caregivers.

Hypothesis 3: It is hypothesized that there will be similarities in symptoms among the patients in the *cancer* diagnostic groups and that unique symptom clusters will emerge for groups of patients with *different types of cancer* but that the impact on well-being of patients and caregivers will be similar among these *cancer types*.

## BACKGROUND

### Conceptual Framework

In her paper presented at the NIH-sponsored End of Life Integrative Conference, Tilden (2001) called for end of life studies based on conceptual frameworks. The model developed by Emanuel and Emanuel (1998) is an example of a conceptual model that can appropriately be used in end of life research. Although untested, the model is recommended as a framework for "understanding and evaluating a good death" (p.22).

The framework includes four critical components including: **A**). the fixed characteristics of the patient; **B**). the modifiable dimensions of the patient's experience (these are elements that may respond to events or interventions); **C**). the potential interventions provided to patients, families, friends, healthcare providers, and others, and **D**). the outcomes. In the second component, the modifiable dimensions of the patient, Emanuel and Emanuel (1998) take pains to point out the interrelatedness of many of the aspects listed in the component. For example, depression is affected by pain, and pain is affected by hopelessness. The strength of the interventions component is that it includes more than medical care. A weakness of the model as presented by the developers is that caregiver needs seem to be only a peripheral concern.

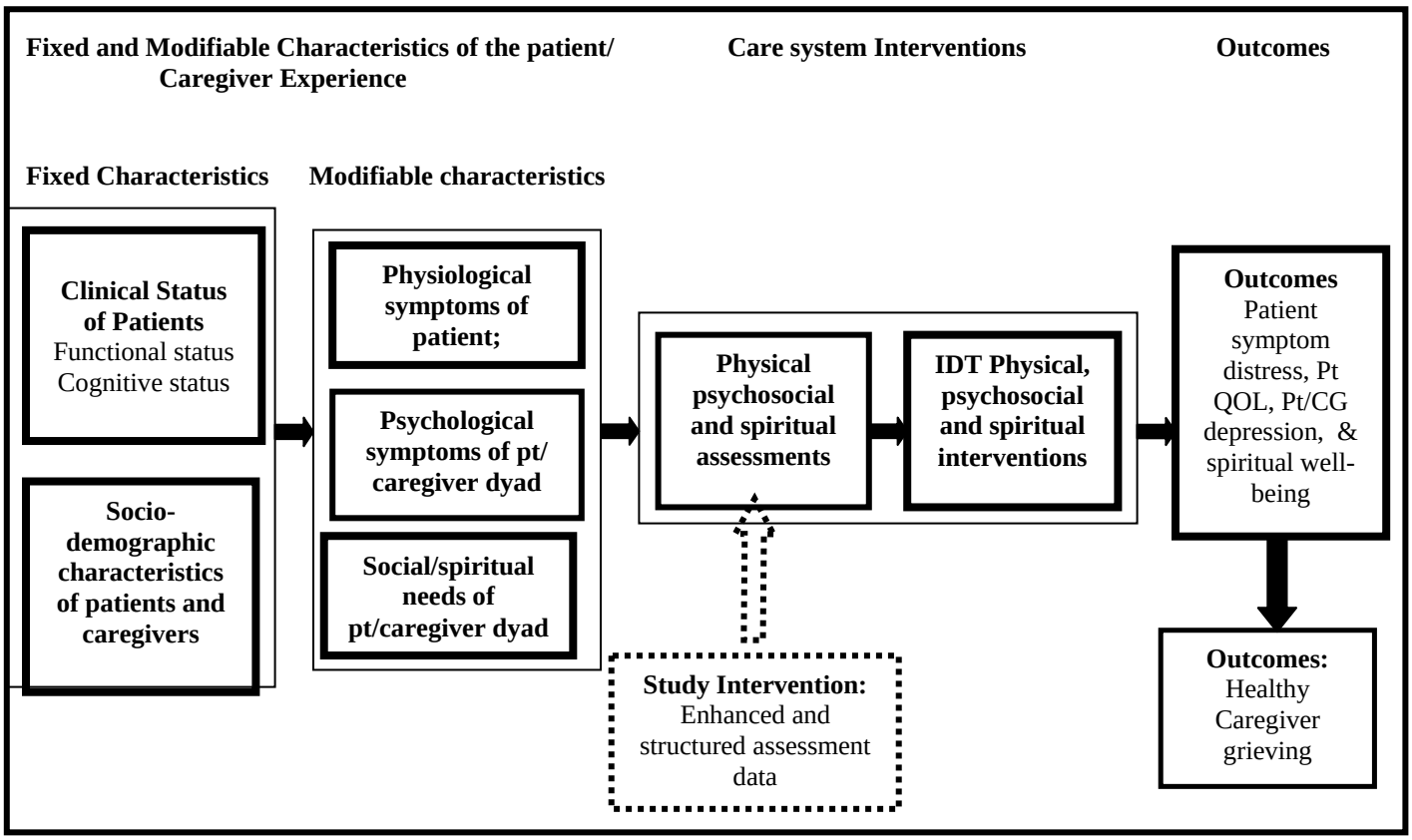


Figure 1. Modified Emanual & Emanuel (1998) model for a peaceful death

This project is based on a revision of the model by Emanuel and Emanuel (1998) that is made to reflect the importance of the patient/caregiver dyad as the unit of care and to clarify the flow from left to right. While the fixed characteristics of the patient and caregiver may serve as co-variates in a study of this type, it is the modifiable characteristics that may be affected by the study; that is, these modifiable characteristics may be changed by interventions that are guided by careful assessments. As will be reviewed in detail below, while hospice care is generally well received by patients and provides important benefits, there is considerable evidence that usual hospice care is hampered by inadequate assessment. We propose to provide an add-on to usual hospice care system assessment (shown with dotted lines below) to enhance the usual process of care while not disrupting this care. The improved interventions that will result from more systematic assessment should bring about desirable outcomes for patients including improved symptom distress, quality of life, depression, and spiritual well-being and for caregivers including depression, spiritual well-being, and healthier grieving following the death.

**Review of Literature**

Assessment

Sorenson (2000) points out the need for systematic assessment of patients by reminding researchers that among patients near the end of life, the subjectively reported levels of dyspnea do not seem to match the degree of disease. This discrepancy varies patient to patient making careful assessment of the individual essential. However, this assessment in many cases seems to be lacking; at least documentation that the assessment has been done is lacking. Documentation about pain and pain-related side effects has been found to be less than ideal in persons with cancer who were receiving care in hospitals and a hospice (McMillan & Tittle, 1995). Sloan et al. (1999) reported that hospice nurses did fairly well in assessing pain intensity (85%) and location (75%), but did not do as well with reporting other aspects of pain assessment, and only 44% of nurses assessed other symptoms the patients might be experiencing. Cadd (2000) found very little documentation about constipation on two palliative inpatient units where constipation was known to be a problem. Hermann (2001) found limited documentation relating to symptoms in general for hospice patients in the last seven days of life. Ellershaw et al. (2001) found that assessments were not recorded in many cases in patients in the last 48 hours of life. This lack of documentation is puzzling given that it is a basic tenet of care that careful assessment is necessary for effective management. The literature confirms that depression is often missed in older medical patients (Callahan, et al., 1994; Bartels et al., 1997). Although there is little relevant research about assessing depression in hospice patients, we have found in our local hospice that psychosocial assessments were missing the check-offs for depression about 75% of the time. We also have found that depressed bereaved hospice caregivers receive no more hospice bereavement services than non-depressed spouses (Haley, LaMonde et al., 2002), suggesting that care is not being provided according to need.

Although pain and symptom management are a focus of hospice care, optimal outcomes are not automatic. Two studies of pain outcomes demonstrated this. First, a prospective study of pain and pain-related side effects was conducted using 25 hospice patients with cancer (McMillan & Tittle,1995). Results indicated that during a 24 hour period, patients continued to have pain in spite of their pain management regimens with some patients reporting average daily pain to range as high as 96.7 on a 0 to 100 scale A follow-up study was conducted via secondary analysis of pain data from a quality of life study conducted at two large hospices (McMillan, 1996a). The cancer patients (n=118) were asked how bad their pain was at its worst (1 to 10) and asked how much pain relief they were getting (1 to 10). Pain relief, even after three weeks of hospice care, was not optimal with 43% of patients reporting pain relief at a level of 5 or less, rather than 10, which was the goal.

Results of these two studies led hospice staff to implement a comprehensive hospice-wide, nurse-focused pain assessment and management plan. After a year, data showed a significant improvement in pain relief (from a mean of 6.4 to 8.3 on a 0-10 scale) and a decrease in the number of patients reporting pain relief at a level of five or less; this statistic decreased from 43% to a more acceptable 10% (Holzheimer & McMillan, 1998). This series of studies documents how important valid and reliable data can be in making patient decisions. Had the staff not had the systematic assessment data from the first two studies, their pain assessment and management behaviors would not have changed. The improved pain assessment and management stimulated by these studies resulted in greatly improved pain outcomes for patients.

A study by Rhodes, McDaniel and Matthews (1998) showed that symptoms improved in 53 hospice patients from admission to week 2 and again in week 4. This result might be attributable to the fact that the hospice nurses had been given a standardized tool, the Adapted Symptom Distress Scale to use in assessments at admission and weeks 2 and 4. This consistent improvement over time has not been seen in earlier studies where this type of valid and reliable assessment data was not available to the nurses providing care (McMillan & Mahon, 1994a,b; McMillan, 1996). Other researchers have found that when valid and reliable assessment tools were integrated into the usual patient assessments conducted in palliative care settings, significant improvements were seen in symptom outcomes (Ellershaw, et al., 1995; Jarvis, Burge & Scott, 1996; Peruselli, et al., 1997). However, it should be noted that these studies were not controlled clinical trials, but were evaluations of palliative care services. Further study of this issue is needed.

Attempts have been made to change care provider behaviors with mixed results. The most effective educational interventions have actively involved the learner (Oxman, 1998; Weingarten, 1997). Traditional methods such as providing practice guidelines for physicians, grand rounds presentations and physician conferences to clinicians are generally ineffective in changing provider behavior without additional incentives or practice change interventions (Lin et al., 1997; Oxman, 1998; Seigel, et al., 1997). One important component of effective clinical change models is improved communication and coordination between members of the health care delivery team (Hunkler et al., 2000; Katzelnick et al., 2000; Rost et al., 2001; Simon et al., 2000a,b; Wells et al., 2000). Providing a one-on one contact between experts and primary care practitioners Detrich et al., 1992) and practical provider-specific information has increased detection rates for

depression (Pond et al., 1994) and decreased prescriptions for contraindicated medications (Avorn et al., 1992; Oxman et al., 1995; Soumerai. 1998).

*A recent paper (Soon &Levine, 2002) provides evidence that providing standardized screening information to clinicians can have a considerable impact on improving clinical practice. This study was conducted in a nursing home setting. This study screened 701 nursing home residents without a charted diagnosis of depression and found that 25% of them had elevated scores on the Geriatric Depression Scale. This confirms numerous studies showing that depression is underdetected in a variety of healthcare settings, including hospice and palliative care (Block, 2000). For half of the residents with high scores, their physicians were sent a letter notifying them of the score; for the other half of residents, the letter was sent on a delayed basis (4 weeks later). Chart review at 4 weeks showed that 25% of patients of physicians who got the immediate notification letters had taken some concrete step to address depression (e.g. mental health referral, prescription for a psychotropic medication), while only 2% of patients of physicians randomized to receive delayed letters had taken such action. The study also replicated this finding by showing that 25% of patients of physicians in the delayed group took steps to address depression at the 8-week followup (4 weeks after they had received their letter). This study replicates previous research (Callahan et al., 1994) that showed that informing physicians about patients' depression in a primary care setting led to about a 300% increase in chart diagnosis of depression and prescription of antidepressant medications.*

Symptoms, Symptom Distress, and Quality of Life

Hospice patients are known to experience multiple symptoms. Studies of patients near the end of life have shown the most common of these symptoms to be: fatigue (68-81%), pain (54-80%), shortness of breath/dyspnea (59-95%), constipation (30-82%), anorexia (73%), sleep disturbance (40-55%), depression (40-43%), cough (39%) and nausea (25-47%) (Chang, Huang & Feuerman, 2000; Conill, Verger, Henriquez et al., 1997; Grassi, Indelli, Marzola et al. 1996; Edmonds et al. 1998; Ellershaw, Peat & Boys, 1995; Kurtz, Kurtz, Given & Given, 1996; Ng, & vonGunten, 1998; Skilbeck, Mott, Page, et al. 1998; Tishelman, Degner & Mueller, 2000; Weitzner et al.,1997b. Tishelman et al. (2000) asked about the importance of these symptoms in contributing to overall symptom distress and found that patients identified breathing, pain and sleep disturbance as most important.

Studies also have demonstrated the relationships between symptoms and quality of life. Pain relief, for example, has been shown to be positively correlated ($r=.41$; $p<.001$) with overall quality of life (Holzheimer, McMillan & Weitzner, 1999; McMillan, 1996a). Dyspnea also is known to detract from overall quality of life (Sorenson, 2000). Spiritual well-being has been shown to be a factor in increasing hospice patients' overall quality of life (Thomson, 2000). Morrison, Siu, Leipzig, Cassel and Meier (2000) called for researchers to identify those aspects of quality of life that are amenable to change and to find appropriate measures of them. In addition, they called for serial measures to track those outcomes.

Symptom Clusters

Earlier work on symptoms seems to focus on single symptoms, their etiology and their effect on patient quality of life. Symptom clusters are defined as three or more symptoms that are related but that may have the same or different etiologies. Dodd et al. (2001) found that pain, sleep disturbance and fatigue were all significantly related to each other and predicted functional status in patients being treated for cancer with 48.4% of the variance in functional status accounted for by these three symptoms. Lee (2001) proposed that sleep disturbances can negatively impact the patient's level of fatigue and pain. Berger and Walker (2001) found that symptom distress from nausea and mood disturbance were strongly related to fatigue. And in apparently healthy adults, sleep disturbances have been shown to be related to increased clinical depression (Ford & Kamerow, 1989). In a study of homecare patients with cancer, clinical depression was significantly correlated with overall quality of life, fatigue, sleep disturbance, and anorexia, as well as physical, emotional, and cognitive functioning (Grassi et al., 1996).

In our population of patients, (see preliminary data section) pain, sleep disturbance, and depression all have been shown to be related to each other (McMillan & Small, 2002). Pain, dyspnea and constipation are known to occur commonly in hospice patients with cancer and to be interrelated, but the prevalence is not known in *patients with different cancers*, and it is not known if there are relationships among these symptoms in *different* cancer populations.

One approach to the study of symptom clusters is to select, a priori, three or more symptoms of interest and test their interrelatedness. This is what Dodd et al. (2001) has done. Another approach would be to use a measure of multiple symptoms such as the Memorial Symptom Assessment Scale and use cluster analysis to allow the symptom clusters to emerge from the data. In this way, it would be possible to identify symptom clusters in subgroups of patients, for example patients with different primary cancers. In the study reported in the Preliminary Work section of this proposal, just such a study was conducted with data from a group of hospice patients with cancer (McMillan & Small, in review 2002). Significant differences were found among groups of patients with three different types of cancer (see also Preliminary Work section). *Further work is needed to confirm* what symptom clusters predominate in persons with *a variety of*

*different cancers* who are near the end of life. Armed with this information, intervention studies could be designed that would evaluate the effect on several symptoms of successful management of one of them.

Caregiving for Cancer Patients

Although limited work has been done with caregivers of hospice patients, some descriptive studies exist that indicate that caregiving for cancer patients, although usually shorter in duration than caregiving for other diagnostic groups such as Alzheimer's patients, takes a toll. One study of hospice caregivers (McMillan & Mahon, 1994c) compared their QOL scores to a group of non-caregiving adults and found, as expected, that the caregivers had significantly lower QOL scores than did the non-caregivers. In addition, mean QOL scores of caregivers decreased slightly over the three weeks of the study, with the caregivers of more debilitated patients showing the greatest decrease, particularly in the financial and physical domains. A follow-up study (McMillan, 1996b) of hospice caregivers found that QOL did not change significantly from admission to week four, with the lowest scores occurring in the physical domain. Stetz (1987) interviewed 65 spouses of adults with cancer who were terminally ill and showed that caregivers were confined to the home an average of 23.2 hours per day. Caregiving demands fell into one of four dimensions-physical care, psychosocial concerns, role alterations, or financial alterations. Physical demands of care were ranked as most demanding. A qualitative study of 26 family caregivers of persons with cancer and AIDS shed some light on what caregivers themselves believed they needed (Stetz & Brown, 1997). As a result of the experience of caregiving, caregivers identified an important consequence as coming to know their own strengths. Sub-themes included learning to become a patient advocate and feeling an increased competency. Caregivers indicated that they needed information and resources and wanted to be treated as a legitimate part of the health care team.

Until recently, most research in psychosocial oncology focused largely on the patient (Cassileth & Chou, 1992). However, facing the end of life, regardless of the specific disease process, is a major stressor for both the patient and the family caregiver, causing a new set of challenges for both (Sabo, 1990; Lewis, 1986). At the very least, the routine of daily life is altered and both patients and family members must struggle to adjust and respond to new demands (Northouse & Peters-Golden, 1993). The impact of caregiving on family members' QOL appears to be considerable (Hinds, 1985). Research suggests that family caregivers experience depression and anxiety, psychosomatic symptoms, restrictions of roles and activities, strain in marital relationships, and diminished physical health (Ell et al., 1988; Given et al, 1993; Johnson, 1988; Lewis, 1986; Northouse, 1988; Sales, 1991; Toseland et al., 1995). Indeed, research suggests that spouses experience as much, if not more, distress than patients (Baider & Kaplan-DeNour, 1988; Baider et al, 1989). This emotional distress may affect role functioning, both within the family as well as in society including the ability to care for the patient (Given & Given, 1994; Hinds, 1992). Caregiver distress is an important concern because family caregivers are assuming more responsibility for care as treatment moves increasingly to the outpatient arena (Carey et al., 1991; Hileman et al., 1992; Given et al., 1993; Laizner et al., 1993; McCorkle et al., 1989).

It is increasingly important to evaluate family caregiver outcomes because of their increased responsibility and contribution to the care of patients. Schumacher, et al. (1993) evaluated the emotional well-being of family caregivers of patients receiving chemotherapy. Results suggested that ineffective coping and decreased social support were associated with increased caregiver depression. Given et al. (1993), explored factors that may impact caregiver depression. They found that patients' levels of immobility, symptom distress, and dependencies in activities of daily living were positively associated with caregivers' levels of depression. One study seemed to indicate that caregiver functioning affects patient outcomes. Blanchard et al. (1997) conducted a study of spouses of persons with cancer who were not hospice-eligible. Although the problem solving intervention had no measurable effect on caregiver distress, at six months follow-up, the patients showed a significant decrease in depression. Social support has been defined as the perceived support and may include support that is emotional, instrumental, or informational (Hutchison, 1999). Several studies have demonstrated that a lack of perceived social support contributes to caregiver distress and depression (Chang et al., 2001; Miller et al., 2001; Nijboer et al., 2001).

Haley et al. (2001) conducted a study of hospice caregivers including both cancer and non-cancer patients. These results indicated that hospice family caregivers showed elevated psychological distress and poorer physical health than non-caregiving controls, regardless of the patient's diagnosis (either lung cancer or dementia).

Factors Affecting Bereavement

*Family members are central to all end of life care, including hospice (Haley et al., 2002). A recent study from our group found that spouses providing end-of-life care for patients with lung cancer in hospice reported an average of 120 hours per week of caregiving activities (Haley et al., 2001). Family members are involved in many aspects of care, including providing emotional support, administration of medications, help with activities of daily living, and often assist with very personal activities such as toileting. They are also often asked to make reports of patients' symptoms, such as*

*pain (Weitzner et al, 1997b) serving as a surrogate when the patient is either incapacitated or being sheltered by family and/or staff.*

Caregivers often are caring for loved ones that they know, sooner or later, will die from their diseases. It seems important to know what impact caregiving has on subsequent grieving. In a descriptive study conducted in Australia, Grbich et al. (2001) reported that caregivers felt strong positive emotions about caregiving and found caregiving to be a way to express their love. Never-the-less, these caregivers experienced intense grief following the death.

Most hospice caregivers are elderly, and research has confirmed that bereavement within the past two years is a risk factor for depression in the elderly (Turvey, et al, 1999). Results of a comparison of widows (n=92) and widowers (n=58) seemed to suggest that women had higher levels of traumatic grief and symptoms of anxiety and depression than the men did. Further, results showed that the level of traumatic grief was significantly associated with later negative health events such as heart attacks or cancer (Chen et al., 1999). A study of 318 Finnish widows and widowers revealed that respondents perceived support from family and friends to be important to healthy grieving (Kaunonen et al., 1999).

No studies were found of interventions before the death that were designed to support healthy grieving after the death. However, some intervention studies have been conducted that shed light on this issue. A clinical trial comparing palliative care (n=113) versus standard care (n=70) included the use of a grief scale for family members who were followed for a year after the death. No part of the intervention was aimed at the families, however, there was a trend toward lower grief scores in the intervention group where patients had received comprehensive palliative care (Ringdal et al., 2001). This supported the work of Cameron and Parkes (1983) who found that relatives of patients who received palliative care during the terminal phase of cancer care reported significantly fewer psychological symptoms and less lasting grief and anger than relatives who had received standard care. These researchers attributed the differences to successful relief of pain, and support given to the family after the bereavement. An earlier study (Vachon et al., 1980) found intervening with caregivers to be effective but this intervention was offered after the death. In a clinical trial to test the effects of an oncology home care (OHC) intervention, McCorkle and colleagues (1998) found that intervening with caregivers during the patient care period, reduced the overall level of psychological distress during the bereavement period. At 6 weeks, 6 months, and 13 months following the death, the differences between the OHC treated and untreated groups were both clinically and statistically significant. Although limited in number and scope, reports in the literature seems to support the idea that more effective palliative care results in better bereavement outcomes for family members.

*There have been few longitudinal studies addressing how end of life care might affect caregiver bereavement. One recent study looked at how one particular aspect of care, use of advance directives, influenced family members' stress during bereavement. Tilden et al. (2001) found that family stress associated with the decision to withdraw treatment was high immediately following the death of the decedent and, while it decreased over time, remained high half a year later. Several factors affected stress; most notably, family stress was highest in the absence of advance directives, was lower when verbal advance directives(Ads) guided the family, and was lowest when written ADs guided the family.*

*There are a number of reasons to believe that successful efforts to improve end of life care can transfer into benefits for the family member during bereavement. It is increasingly recognized that experiences during family caregiving affect the subsequent bereavement reaction (Schulz et al., 1997). Family caregivers who experience high levels of depression while caregiving, or who witness traumatic episodes while caregiving (such as patients in uncontrolled pain) are at risk for problems including chronic depression or traumatic grief during bereavement (Prigerson et al., 1997; 2001; Schulz et al., 1997). Bereaved family members interviewed as informants about ways in which end-of-life care might be improved (Hanson, Danis, & Garrett, 1997) found that in reviewing their experiences in end-of-life care, families report that the most troubling experience they had was dealing with inadequate pain control of their relatives. In addition, numerous caregiving studies have documented the phenomenon of "emotional contagion", e.g. high levels of patient depression are associated with high levels of depression in the caregiver (Schulz et al., 1997). Thus, our interventions, targeting improvement in depression and pain, appear likely to improve caregiver well-being both while caregiving and during bereavement.*

Summary

In summary, the literature clearly shows that patients near the end of life experience a variety of symptoms that cause distress. Further it is clear that symptom intensity and distress are negatively associated with overall patient quality of life. Previous research also indicates that symptoms are under-assessed and that inadequate assessment leads to less than ideal outcomes for patients. The limited work done in the area of improving assessment showed that more systematic assessments resulted in improved outcomes. Caregivers of patients near the end of life also have been found to experience significant distress that has a negative impact on their quality of life. Several factors have been shown to be associated with caregiver distress including social support, patient condition, religious well-being, and living in a rural area. Bereavement in caregivers following the death of the patient needs further investigation, however, some work has been

done that suggests that grief is less severe and depression is less likely when patients received better care and when caregivers received support along with the patient. Thus, improving patient assessment is likely to result in improved patient care, and that may result in better bereavement outcomes for caregivers.

Preliminary Work

An interdisciplinary group of university faculty, including those involved in this project, met with hospice staff periodically over an 18 month period under the leadership of Dr. Ronald Schonwetter to identify valid and reliable instruments that would be useful in a hospice setting. The resulting tools, including measures of physical, functional, psychological, social, and spiritual issues were incorporated into the clinical database for Lifepath Hospice and Palliative Care, replacing assessments that were in use but had unknown validity and reliability. In 2000, this group from Lifepath Hospice joined an interdisciplinary research interest group from the USF College of Nursing to form the **Center for Hospice, Palliative Care and End of Life Studies at the University of South Florida**. This **Center**, which reports to the Vice President for Health Sciences, is composed of interdisciplinary University faculty and representatives from five large hospices. The **Center** is unique in that it allows a true partnership between university and hospices in the community, allowing multisite research to be conducted that would not be possible elsewhere. Faculty members come from a variety of colleges including medicine, nursing, arts and sciences, and public health. Hospices involved in the **Center** include the Hospice of the Florida Suncoast with 1600 patients per day, Lifepath Hospice with 1,400 patients per day, Hernando-Pasco Hospice with 500 patients per day, Hospice of Southwest Florida with 500 patients per day and Good Shepherd Hospice with 280 patients per day. Each hospice is within an hour's drive from the University. This partnership between university and hospices provides a combined patient population of more than 4,000 patients per day making multisite research projects in these hospices very feasible.

The investigators have worked together on other projects including an NIH-funded R01 entitled **"A Caregiver Intervention to Improve Hospice Outcomes"** (McMillan, R01 CA 77307, 1999-2003). The successful implementation of this on-going project and others demonstrates that these investigators are able to work collaboratively to complete this proposed one. In addition, the participation in the *Center* by the three target hospices and their relatively large sizes provides compelling evidence that the environment is conducive. Preliminary work is described in the following pages.

**a. Background of the Investigators**

**Susan C. McMillan, PhD, ARNP, FAAN** is Professor and Chair of Oncology Nursing at the University of South Florida College of Nursing. She is a member of the Board of Directors of Lifepath Hospice and Palliative Care and has served on its Patient Care Committee since 1987. She has conducted research there and at the Hospice of the Florida Suncoast and she has consulted on projects with staff at Hernando-Pasco Hospice. Her major areas of research have been symptom management and assessment (McMillan, 1996a; McMillan & Tittle, 1995; McMillan & Williams, 1989; Tittle & McMillan, 1994) and quality of life of patients (McMillan 1996b; McMillan and Mahon, 1994 a,b; McMillan & Weitzner, 1998) and caregivers (McMillan, 1996b, McMillan, 1994c; Weitzner & McMillan, 1999; Weitzner, McMillan & Jacobsen, 1999). The representative studies cited below highlight relevant aspects of Dr. McMillan's work and provide information about the development and refinement of the Hospice Quality of Life Index that is included in this project.

1. Development of the Hospice Quality of Life Index

Through a series of studies, the Hospice Quality of Life Index was developed and refined. Each successive version of the HQLI had its validity and reliability studied and published (McMillan & Mahon, 1996b; McMillan, 1996; McMillan & Weitzner, 1998). A study of the validity and reliability of the final version of the HQLI was published in 1998 (McMillan & Weitzner, 1998). Factor analysis confirmed three subscales: Psychophysiologic ; Functional; and Social/Spiritual Well-being. Reliability using Cronbach's alpha was high for the total scale (r=.88) and the subscales (r=.837 to .840). The validity and reliability of the revised HQLI was reconfirmed. This version of the HQLI was subsequently translated into Japanese.

Finally, to make the HQLI more acceptable in a clinical situation, the original 28-item HQLI was pared down to the HQLI-14. Reliability and validity of the revised HQLI are presented in the Instruments section.

2. Pain in Cancer Patients

Three studies were conducted that shed light on pain management in hospice patients. First, a prospective study of pain and pain-related side effects was conducted at LifePath Hospice using cancer patients (McMillan & Tittle,1995). Results indicated that during a 24 hour period, patients continued to have pain in spite of their pain management regimens with some patients reporting average daily pain to range as high as 96.7 on a 0 to 100 scale. A follow-up study found pain relief, even after three weeks of hospice care, was not optimal with 43% of patients reporting pain relief at a level of 5 or less (10 was the goal). Results of these two studies led hospice staff to implement a comprehensive hospice-wide, nurse-focused pain management plan. After a year, a third study revealed that pain relief significantly improved (from 6.4 to 8.3) (Holzheimer & McMillan, 1998). A large intervention study funded by the Veterans Administration included

assessment of pain intensity in veterans with cancer. One of the instruments used to assess pain was the Brief Pain Inventory (BPI) which also is being used in the current study (McMillan et al. 2000b). The study confirmed that patients continue to have moderate to severe pain in spite of their pain management regimens.

3. Symptom Clusters and Symptom Distress in Three Types of Advanced Cancer

As an outcome of the presently funded "Caregiver Intervention" grant, a study of the relationships between symptom clusters and symptom distress was conducted (McMillan &mall, 2002 in progress). Clear evidence of symptom clusters was found with significant differences in these clusters between three groups of cancer patients: 1) those with lung cancer (n = 62); 2) those with colorectal cancer (n = 25); and 3) those with pancreatic cancer (n = 11). The results of a MANOVA on the symptom distress items revealed an overall effect of cancer diagnosis (Wilks $\lambda = .42$, ($F(48, 144) = 1.63$, $p < .05$).

**Michael Weitzner, MD**: Dr. Weitzner is the Chief of Palliative Care at the H. Lee Moffitt Cancer Center and Associate Professor in the Department of Interdisciplinary Oncology. He is also an Associate Professor in the Departments of Neurology and Psychiatry and Behavioral Medicine at the USF College of Medicine (COM). His research focuses on quality of life issues in primary brain tumor patients (Weitzner et al, 1995a; Weitzner et al, 1996a) and in family caregivers of cancer patients (Weitzner et al, 1995b; Weitzner et al, 1996b). Dr. Weitzner has conducted research in two of the hospices involved in the *Center*. The representative studies cited below highlight relevant aspects of his work.

1. A Quality of Life Instrument for the Family Caregiver: A series of papers has been published describing the development, revision, and implementation of the COQL-C. (Weitzner et al. 1997a ; Weitzner et al, 1998; Weitzner et al, 1999). A fourth paper (Weitzner & McMillan, 1999) compared the QOL of family caregivers of patients with cancer in active treatment (n=267) with those in a hospice setting (n=134). As expected, the hospice caregiver group had significantly lower CQOL-C scores (p.<0001). In a fifth paper, Dr. Weitzner has further refined the CQOL-C using factor analysis. Complete references are in Dr. Weitzner's biosketch.

2. Symptom Management Issues in Hospice Care This manuscript (Weitzner, Moody, & McMillan, 1997) presents the results of a study examining the prevalence of symptoms/problems faced by hospice patients and caregivers, and the incidence of physical problems in caregivers that may impact the burden experienced by the family caregiver.

3.Dr. Weitzner also has an ongoing NCI-funded study of family caregiving in lung cancer. In addition to comparing spousal caregivers to non-caregivers, he has also gained additional experience with several of the proposed measures.

4. Clinical Depression, Hopelessness and Desire for Death in Outpatient Hospice Patients (under editorial review)
This study sought to examine the prevalence of depressive disorders using DSM-IV criteria as well as hopelessness and desire for death in 52 cancer patients receiving outpatient hospice services. Of note, 15% of the patients had mild to serious thoughts of suicide, 50% had feelings of hopelessness, and 35% of patients had mild to severe desire for a hastened death. These data suggest that a substantial number of patients receiving outpatient hospice services are suffering from a depressive disorder that could benefit from psychosocial intervention.

**William Haley, PhD**: Dr. Haley is the Chairman of the Gerontology Department at USF and has adjunct appointments in the Departments of Psychology and Geriatric Medicine at USF. Dr. Haley has had extensive experience in the study of family caregivers of patients with Alzheimer's disease (AD). Dr. Haley's research has focused not only on the study of factors predicting family caregiver quality of life, but also on interventions to improve caregiver quality of life; these experiences will be vital to the conduct of this study.

1.Psychological, social and health impact of caregiving: A comparison of black and white dementia family caregivers and noncaregivers (Haley et al., 1995). Results suggested that caregiver appraisals and coping responses predicted better quality of life in white and African-American families. While depression remained stable in caregivers and noncaregivers over a two-year period, both White and African-American caregivers showed declining physical health over time.

2.Current projects with AD Caregivers Dr. Haley has remained active in research aimed at evaluating the impact of caregiver interventions. He has recently completed a 5-year study based at the University of Alabama at Birmingham, and funded by the NINR, that includes a multisite evaluation of caregiver interventions.

3. Current projects with hospice and cancer caregivers Dr. Haley has studied family caregiving in the contexts of cancer and hospice care, with a project based at LifePath Hospice that includes a comparison of stress, appraisal, coping, social support, and caregiver depression between families caring for a relative with AD versus those caring for a relative with lung cancer (Haley, LaMonde et al., 2002). In addition, Dr. Haley has collaborated with Dr. Weitzner on a project applying the stress process model of family caregiving to families of patients with lung cancer at Moffitt Cancer Center, a project recently funded by the National Cancer Institute for five years.

**Ronald Schonwetter, MD**: Dr. Schonwetter is the Chief Medical Officer of LifePath Hospice and Palliative Care, Inc. He is a Professor and Director of the Division of Geriatric Medicine as well as the Director for the Geriatric Medicine Residency Program at USF. Dr. Schonwetter is Director of the *Center for Hospice, Palliative Care, and End of Life Studies at USF*. He put together the multidisciplinary group that identified and integrated valid and reliable assessment tools into the standard assessment documentation forms at Lifepath He has been very involved in palliative medical education (Schonwetter and Robinson, 1994; von Gunten, et al, 2000) and was also instrumental in developing an ongoing required hospice rotation for all medical students at USF. In addition to editing an issue of Clinics in Geriatric Medicine on Care of the Terminally Ill Patient (Schonwetter, 1996b), Dr. Schonwetter has also edited a national curriculum for hospice and palliative medicine for the American Academy of Hospice and Palliative Medicine (Schonwetter, Hawke, and Knight, 1999). He has also served as a co-investigator for a Physician Hospice/Palliative Care Training Grant funded by the National Cancer Institute and focused his efforts of the development of a pocket guide for physicians in hospice or palliative care. He has participated in multiple areas of research regarding hospice and end of life care. His knowledge and experience in the care of patients in hospice and near the end of life (Schapira, et al 1996; Schonwetter, 1996a; Schonwetter, 1996c; Schonwetter, et al, 2000b) are crucial to the success of this study.

1. Decision Making Near the End of Life Dr. Schonwetter conducted some of the early studies regarding decision making near the end of life (Schonwetter, et al, 1991; Schonwetter, et al, 1993; Schonwetter, et al, 1994b; Schonwetter, et al, 1996). Dr. Schonwetter was awarded a grant from the Soros Foundation's Project on Death in America to identify the factors that impact the decision of whether to enter a hospice program or continue with a traditional curative approach to care in cancer patients with limited life expectancies
2. Prognosis Near the End of Life Believing that a clinician's generally poor estimation of prognosis was a barrier to hospice referrals, Dr. Schonwetter has attempted to identify factors that would assist clinicians in estimating prognosis of patients near the end of life (Schonwetter, et al, 1989; Schonwetter, et al, 1990; Schonwetter, et al, 1994a; Schonwetter, et al, 1998).
3. Dr. Schonwetter has collaborated with all of the co-investigators on several projects and grants as previously described. He has also been instrumental in coordinating the implementation of the assessment instruments into routine clinical care at LifePath Hospice which has resulted in some of the pilot data for the current proposal.

**Brent Small, PhD**: Dr. Small is Assistant Professor of Gerontology at USF, and holds a joint appointment in the Department of Psychology. During his training, Dr. Small has had experience on two large-scale longitudinal studies on aging, the Victoria Longitudinal Study (Victoria, BC, Canada) and the Kungsholmen Project (Stockholm, Sweden). Dr. Small has developed considerable statistical expertise as a result of analyzing data from these two projects. This includes the application of repeated measures multivariate analysis of variance, the use of residualized change regression to predict individual differences in longitudinal performance, as well as more sophisticated methodologies such as longitudinal confirmatory factor analysis and structural equation modeling. In addition, Dr. Small serves as statistical consultant on 5 funded grants from the National Institute on Aging, National Cancer Institute, National Institute for Nursing Research, and the American Cancer Society. Finally, Dr. Small is the methodologist for the Caregiver Intervention project on which all of the co-investigators are currently working.

**b. Feasibility Studies**

In 2000, Lifepath Hospice and Palliative Care implemented a new set of valid and reliable assessment tools for use by the interdisciplinary team. These are the tools being used in the proposed project. As a preliminary to this proposed project we analyzed some of the data that has already been collected at Lifepath using some of their new clinical tools (see 1,2 and 3 below).

1. A chart review of 35 Lifepath hospice charts of patients admitted the year before the new charting system was put in place was conducted to determine the number of patients assessed for symptoms of depression and the number of cases diagnosed. No evidence was found in any of the 35 charts that the patients were assessed for symptoms of depression by the psychosocial staff. However, in six charts it was noted that a family member had commented to the psychosocial staff that the patient seemed depressed. Using charts that included the new assessment instruments, a chart review was conducted to evaluate data from the CES-D. In this assessment, 23% of patients who were assessed were found to meet the cut-off for clinical depression and all but two of the others had depressive symptoms. Clearly, the use of standardized assessment tools resulted in an improvement in the rate of diagnosing depressive symptoms in hospice patients.
2. To support validity of the proposed tools for use with hospice patients, we accessed data from the Lifepath computers and conducted correlations between selected tools.

- Between the Palliative Performance Scale and Katz ADL scale (predicting a moderate positive relationship), we found r=.50 (p=.000). This predicted correlation further supports the validity of the new PPS for use with these patients.

- Between the Pain Severity Item on the MSAS and the BPI items (predicting moderate to strong relationships), we found the expected relationships between the MSAS pain item and the BPI *pain now* (r=.67, p=.000) and the *worst pain* (r=.61,p=.000) items. These predicted relationships support the use of the BPI with hospice patients.

3.As an assessment of reliability, we looked at internal consistency of the MSAS intensity and distress scores. Results indicate acceptable reliability for both the Intensity subscale (alpha=.73) and Distress subscale (alpha=.74).

4.Some preliminary work has been done that sheds light on symptom clusters in hospice patients. Because of work that Dr. McMillan and Dr. Small have done on the current Caregiver Intervention project (McMillan & Small, 2002), we already know that pain, constipation, and dyspnea are significantly related to each other and all three are significantly related to quality of life (Table 1). However, this study *included only selected symptoms rather than including* all possible symptoms. The manuscript is appended (Appendix B).

*5. An additional outcome of the presently funded "Caregiver Intervention" grant, was a study of the relationships between symptom clusters and symptom distress (McMillan & Small, 2002 in preparation). First, we examined the endorsement rates of specific disease symptoms from the Memorial Symptom Assessment Scale among three groups of cancer patients: 1) those with lung cancer (n = 69); 2) those with colorectal cancer (n = 29); and 3) those with pancreatic cancer (n = 16).*

**Table 1.** Intercorrelations Among Pain, Constipation, Dyspnea, and HQLI Scores

| Variables | Pain | Constipation | Dyspnea |
|---|---|---|---|
| Constipation | r=.38<br>p<.001 | | |
| Dyspnea | r=..20<br>p<.05 | r=.21<br>p<.05 | |
| HQLI | r= -.24<br>p<..01 | r=-.38<br>p<.001 | r= -.32<br>p<.001 |

*For the lung cancer group, the top five endorsed symptoms were lack of energy, shortness of breath, pain, feeling drowsy, and lack of appetite. For the colorectal group, the top symptoms were lack of energy, dry mouth, dizziness, pain, and feeling drowsy. Finally, the top five symptoms for the pancreatic cancer group were lack of energy, pain, dry mouth, lack of appetite, and feeling nervous. Spearman rank correlations were computed on the ranking of the 24 symptoms pairwise across the three cancer groups. The results indicated that the rankings for each pair of diagnostic groups was approximately .28. Thus, although there was some similarity across the groups, they were certainly not overlapping. Next we examined differences in reported level of distress for the three patient groups. A MANOVA was conducted on all 24 items across the three cancer groups. The results revealed an overall effect of cancer diagnosis (Wilks $\lambda$ = .41, (F (48, 176) = 2.03, p < .001). The preliminary mean-level comparisons suggest that while the 3 cancer groups show comparable levels of distress on many of the items, there are clusters of items that are able to discriminate among the three groups.*

6. The Palliative Performance Scale (PPS), although designed for palliative care, is relatively new and untried. As part of our present Caregiver Intervention project, we evaluated the validity and reliability of that new tool. To evaluate validity, we correlated scores on the PPS with scores on the more seasoned Karnofsky Performance Status (PFS) scale using 23 hospice patients. The predicted strong positive relationship was found (r=.88-.95, p<.001) thus supporting validity of the PPS. Reliability was assessed using two raters. Resulting inter-rater reliability was high (r=.95; n=23).

7. Also as part of our current project, preliminary assessment of the validity of the MSAS for use with cancer patients receiving hospice home care was conducted and included correlation with quality of life (HQLI) scores. As predicted, the correlation between MSAS distress scores and HQLI scores were moderately strong (r= -.72; p<.001). This provided support for construct validity of the MSAS for use with cancer patients near the end of life (McMillan & Small, 2002).

8.The instruments being implemented in this proposal were adopted by Lifepath Hospice in 2000. In order to determine how long it takes to administer the packet of instruments *six hospice patients who met study criteria were asked to complete the packet of instruments. After signing an informed consent, all were able to complete the instruments with no interruptions for rest, taking an average of 24 minutes (range= 20-28).* Time to complete caregiver instruments is estimated to be 16 minutes.

## METHODS

### Settings

George (2001) recommended that end of life studies include patients from multiple sites and use carefully developed inclusion and exclusion criteria. This multisite study will be conducted at three large hospices in the area surrounding the University of South Florida. The communities in which these hospices are set are all different with varying numbers of patients from rural, small community, suburban, and urban settings. All are private, not-for-profit hospices that serve more than one county and do not compete with one another. All of these hospices offer comprehensive services provided by interdisciplinary teams including nurses, physicians, social workers/counselors, clergy, and hospice

care aides. A unique feature of this study is the research coalition formed by a group of five hospices and the university. The hospices involved in this project are three of the five hospices that are involved in the Center for Hospice, Palliative Care and End of Life Studies at the University of South Florida. One hospice that is not involved in the project but that is involved in the Center is Lifepath Hospice and Palliative Care in Tampa, Florida. While it is not a study site, it did provide much of the pilot and preliminary data for this proposed project. Hospice of the Florida Suncoast is not involved because it is already beginning plans to implement some of the same instruments that will be included in the study; it is expected that some of these may already be in use when this project is funded.

*The three involved hospices structure their interdisciplinary team (IDT) meetings in the same way. Each team meets weekly and includes RN's, social workers, bereavement counselors, Home Health Aides, MD, volunteer coordinator and clergy. The meetings include a review of patient deaths and how the family is doing, and sympathy cards are prepared by hospice staff who cared for the patient. The new patients usually are presented by the team leader or primary nurse. The average time spent on each new patient is seven minutes with a range of 4-9 minutes. The patients who take only four minutes have not yet had their psychosocial visits. During this part of the meeting, the nurse gives a brief history of the current illness, a list of symptoms, clarifies the level of consciousness and the performance status, and lists any allergies, and services needed by the patient. If the patient has pain, a pain intensity rating is given, but no intensity or distress ratings are given for any other symptoms. The medications related to the present illness that are covered by the hospice are listed. The psychosocial staff member reports on the family, spiritual needs, and whether the patient has a history of psychiatric problems. However, no depression assessment is reported. After all new patients are introduced, 30-day follow-ups are reviewed, recertifications are discussed, and other patient problems are presented for discussion.*

As partners in this study, all three hospices have agreed to provide, at no cost to the grant, space, desks, and telephones for the research team to use. In addition, all three hospices have agreed to allow recruitment of their staff members to work on the grant for the duration of data collection. Further, these hospices have agreed to give the research team access to their admission records so that potential patient/caregiver dyads can be identified. *Hospice liaisons have been identified in each of the hospices and their role has been described in the budget justification.* Letters of support from the hospice administrators are appended (Appendix C). The existing university/community partnership (via the *Center*) provides resources that are unique in the nation or the world. Having a common database from four large independent not-for-profit hospices (*the three in the study, plus Lifepath Hospice),* and potentially five when Suncoast integrates these instruments, will provide a unique resource. Because of the proliferation of small independent hospices around the nation, a model for multi-site hospice studies would be useful. The unusually large sizes of these hospices make this study very feasible.

**Good Shepherd Hospice**

The Good Shepherd Hospice is a not-for-profit organization that serves three counties to the east of the University. While Highlands and Hardee Counties are largely rural, the larger Polk county is mixed urban, small communities, and rural. These counties are predominantly white. The population in this hospice, like the counties it serves is predominantly Caucasian (90%) with smaller numbers of African-Americans (8%) and Hispanics (2%). Approximately 24% of deaths in these counties are due to cancer.. The average daily census at Good Shepherd is 280; approximately 190 of these patients are cared for by the teams centered in Auburndale, in Polk County. Seventy-five percent of patients receive homecare and have a family caregiver. Homecare in Polk County is provided largely by the Red and Blue teams which serve groups that are equivalent in diagnosis mix, socioeconomic status, and ethnicity. During 2000-2001, 65% of patients had cancer as their primary diagnosis. The mean length of stay is 49 days, and the median is 22 days (Table 2). Patients who are believed to have less than 10 days to live are placed in the Special Touch program in order to accelerate services. Patients in the Special Touch program will be excluded from the study. *The teams chosen for the study are equivalent in several important ways based on data taken in mid-October, 2002 (Table 3)*

**Table 2. Mean and Median Length of Stay and Mean Annual Admissions with Frequency and Percent of Patients with the Target Diagnosis in Each Hospice**

| Hospice | Mean/Median Length of stay | Mean Annual Admissions | | Cancer Frequency/Percent | |
|---|---|---|---|---|---|
| Good Shepherd | 49/22 | 1525 | | 991/65 | |
| Hernando-Pasco | 47/19 | 4250 | | 2125/50 | |
| Southwest Florida | */31 | 4328 | | 2164/50 | |
| **Total Available** | **na** | **10,103** | | **5280** | |

*mean not calculated at this hospice; thus not available.

Hernando-Pasco Hospice

The Hernando-Pasco Hospice is set in the two counties just north of the University and provides services to an average of 450 patients per day. These predominantly white counties are largely rural and contain five small cities. Approximately 25% of the deaths in these counties are due to cancer (Table 2). The largest proportion of the hospice patients have a cancer diagnosis (50%). Patients are cared for by interdisciplinary teams with approximately 60 patients per team. The nurse to patient ratio is 1:8. Other members of the IDT include social workers, bereavement counselors, chaplains, and home health aides. The teams meet weekly to discuss patients. The patients receiving care reflect the ethnic makeup of the community with most patients and caregivers being white. The average length of stay is 47 days and the median is 18 days. Approximately 90% of patients receiving homecare have an identified family caregiver. *The teams chosen for the study are equivalent in several important ways based on data taken in mid-October, 2002 (Table 3).*

Hospice of Southwest Florida

The Hospice of Southwest Florida, set in Sarasota, Florida, also serves a four-county area with a high proportion of retirees. It has an average daily census of 500 patients. The four counties served are predominantly white with urban, suburban, and rural areas. Approximately 25% of deaths in the county are caused by cancer (Table 2). Interdisciplinary teams provide care to approximately 70 patients each. The nurse to patient ratio is approximately 1:12. Each team also has social workers, home health aides, and bereavement counselors. This hospice has *one paid* chaplain, but also relies on close ties with clergypersons in the local community. Each new patient is discussed in the weekly team meeting. The largest number of patients have a cancer diagnosis (50%). A large majority (approximately 80%) of homecare patients have identified family caregivers. The mean length of stay is not calculated and the median is 31 days (Table 2). The ethnic makeup of the patient population closely resembles the community in which the institution is set, with a majority of patients being white. *The teams chosen for the study are equivalent in several important ways based on data taken in mid-October, 2002 (Table 3).*

***Table 3. Percentage of cancer patients, male/female patients, and payment type by team.***

| | ***Good Shepherd*** | | ***Hernando-Pasco*** | | ***Southwest Florida*** | |
|---|---|---|---|---|---|---|
| ***Variable*** | ***Red*** | ***Blue*** | ***North*** | ***South*** | ***West*** | ***North*** |
| *Percent cancer patients* | *62* | *67* | *44* | *44* | *44* | *43* |
| *Gender: Percent male* | *48* | *52* | *54* | *66* | *38* | *35* |
| *Percent female* | *52* | *48* | *46* | *34* | *62* | *65* |
| *Mean age* | * | * | *74* | *72* | * | * |
| *Payment type (percent)* | | | | | | |
| *Medicare* | *71* | *75* | *61* | *57* | *87* | *88* |
| *Private Insurance* | *17* | *18* | *2* | *2* | *5* | *3* |
| *Medicaid* | *13* | *7* | *2* | *2* | *4* | *5* |
| *No pay* | * | * | *35* | *39* | *3* | *3* |

**not available at this hospice*.

Sample

The study sample will consist of patients and caregivers who are receiving hospice home care from one of the three involved hospices. *Inclusion criteria for patients:* Patients will be *identified by admission face sheets as those who have a cancer diagnosis, have an identified family caregiver, are adults (18+ years old), either male or female, able to read and understand English, and able to pass screening with the SPMSQ. Inclusion criteria for caregivers*: *Caregivers will be identified by the hospice as the primary caregiver. In rare cases, there are two or more individuals sharing caregiving responsibilities. In these situations, the research team will be trained to identify the individual who is the decision-maker and also provides at least 4 hours of care each day. If this cannot be determined, the patient/caregiver dyad will be excluded from the study. Caregivers must be adults (18+ years old). Exclusion criteria: Patients will be excluded if they are confused, excessively debilitated, comatose or actively dying. Caregivers will be excluded if they are in active treatment for cancer themselves.*

We will identify two teams in each of the three hospices that are equivalent in make-up and type of patients. Post hoc analysis will be conducted to insure equivalence of teams (see data analysis section). We will randomly assign one team in each hospice to receive the intervention. Patients *and caregivers* from both teams will be recruited for the study. The feasibility of accruing adequate numbers for our sample is presented in Table 4, below. These tabled estimates are for one year, indicating that over the *18* months of data collection, we should anticipate 1899 available patients with cancer. Using power analytic techniques, it was determined that 102 completed patient/caregiver dyads are needed in each

hospice (51 in treatment and 51 in control) *for a total sample of 306*. Even in the smallest hospice (Good Shepherd), there will be sufficient patients to accrue to the study.

**Table 4. Estimates of Available Patients in three Hospices Annually with Cancer Diagnosis Accounting for Availability of Caregiver, Screening Scores, and Rate of Consent**

| Diagnosis | Number of Annual Admissions | 80% with Family Caregiver | 60% with Passing Score on PPS & SPMSQ | 50% Who Consent to Participate |
|---|---|---|---|---|
| Good Shepherd | 991 | 793 | 476 | 237 |
| Hernando-Pasco | 2125 | 1700 | 1020 | 510 |
| Southwest Florida | 2164 | 1731 | 1039 | 519 |
| Totals | 5280 | 4224 | 2535 | 1266 |

All patients and caregivers on both teams who meet study criteria will be approached within 24-72 hours of admission to participate. Patients will be screened for admission to the study using the Short Portable Mental Status Questionnaire (SPMSQ) and the Palliative Performance Scale. The recommended cutoff for the SPMSQ is 8 (MacNeill & Lichtenberg, 1999), and a score of 40 or higher on the performance measure (PPS) will be required; we have found this to be an appropriate cut-off in our previous projects and both of these instruments have proven to be effective in screening patients for our present hospice project.

## Instruments

Instruments are included that will be used: 1) to screen patients for inclusion in the study; 2) to assess study outcomes for both patients and caregivers, and 3) to track the interventions used by the hospice interdisciplinary team to bring about the outcomes. In addition, two instruments will be used to assess grief in the year following the death. The instruments used to measure the study outcomes are those that have been implemented at Lifepath Hospice and Palliative Care over the past two years. The instruments used for patients and caregivers are in Table 5. In her paper presented at the End of Life Conference at NIH, Tilden (2001) recommended conducting studies that adapt existing measures to extend the utility of assessment tools that are already in use. Part of the focus of this project is the utility of the tools for use with hospice patients. All instruments are appended (Appendix D).

## Screening Measures

### Palliative Performance Scale

The purpose of the Palliative Performance Scale (PPS) is to assess the physical condition and functional status of persons receiving palliative care (Anderson et al, 1996 ). It is a relatively new tool based on the Karnofsky Performance Scale (KPS) and is proposed to provide a framework for measuring the progressive decline in palliative care patients. The PPS does not assess functional level by focusing on need for hospitalization as palliative care patients may not be treated in a hospital setting. This instrument measures three broad areas: mobility, intake and level of consciousness in five categories (degree of ambulation; ability to do activities and extent of disease; ability to do self-care; food/fluid intake; and state of consciousness. The PPS is scored from 0-100% at 10% increments, similar to the KPS..

Validity. The initial validity study assessed 119 patients at home and 213 patients admitted to a hospice unit. Validity of this instrument was assessed comparing the PPS score with length of survival. The average period until death for 129 patients who died on the unit was 1.88 at 10% PPS on admission, 2.62 at 20%, 6.7 at 30%, 10.3 at 40%, 13.87 at 50%. Only two patients at 60% or higher died in the unit. As part of an earlier project we assessed validity and reliability of the PPS. The predicted strong positive correlations between PPS and KFS (r=.88-.97, n=23)) support construct validity.

Reliability. Although no reliability data were reported by the tool developers, we evaluated reliability in our preliminary work. Inter-rater reliability between two raters was very strong (r=.95).

### Short Portable Mental Status Questionnaire

The 10-item Short Portable Mental Status Questionnaire (SPMSQ) will be used as a screening instrument for cognitive impairment. While the SPMSQ is a brief instrument that may lack sensitivity to mild cognitive impairment, it has proven validity in detecting moderate to severe cognitive impairment (MacNeill & Lichtenberg, 1999). Numerous studies of physicians and other health care professionals demonstrate that, in the absence of usage of a systematic mental status assessment, most cases of dementia are not detected (Zarit & Zarit, 1999).

### Memorial Symptom Assessment Scale

Several researchers have called for differentiating symptom distress from symptom intensity and frequency (Chiou, 1998; McClement, Woodgate & Degner, 1997; Rhodes et al., 1998; Tishelman et al., 2000). One expert defined symptom distress as “how bothered” the patients were by the symptom (Chiou, 1998). The Memorial Symptom Assessment Scale (MSAS) is designed to differentiate among frequency, intensity, and distress from symptoms.

**Table 5. Instruments for Patients and Caregivers based on Conceptual Model Variables**

| Model Variable Measured | Instrument | Subjects |
|---|---|---|
| **Clinical Status of Patients** | | |
| Functional status | Katz Activities of Daily Living Index<br>Palliative Performance Scale | Patients<br>Patients |
| Cognitive Status | Short Portable Mental Status Questionnaire | Patients and Caregivers |
| **Sociodemographic characteristics** | | |
| Patient Demographics | Demographic data tool | Patients |
| Caregiver Demographics | Demographic data tool | Caregivers |
| **Physiological Symptoms/Health** | | |
| Symptom Intensity/Distress | Memorial Symptom Assessment Scale | Patients |
| Pain | Brief Pain Inventory | Patients |
| Caregiver physiological status | Health Subscales of SF-36 | Caregivers |
| **Psychological Symptoms/Health** | | |
| Presence/intensity of depression | Center for Epidemiological Studies: Depression (CES-D) | Patients and Caregivers |
| Suicidal Ideation | Structured Clinical Interview-Depression (SCID): Suicide | Patients and Caregivers |
| **Social/Spiritual Needs** | | |
| Social Support | *Received Support and Satisfaction Scale* | Caregivers |
| Spiritual Well-being | *Spiritual Needs Inventory* | Patients |
| **Outcomes** | | |
| Symptom intensity/distress | Memorial Symptom Assessment Scale | Patients |
| Pain | Brief Pain Inventory | Patients |
| Quality of Life | Hospice Quality of Life Index | Patients |
| Depression | CES-D | Patients and Caregivers |
| Suicidal ideation | SCID- Suicide Item | Patients and Caregivers |
| Spiritual Well-being | *Spiritual Needs Inventory* | Patients and Caregivers |
| Grieving | Grief Scale | Caregivers |
| Complicated Grief | Inventory of Complicated Grief | Caregivers |
| **Care System Interventions** | | |
| Changes in Care Plan | Chart Audit | Patient Chart |

Patient Assessment Measures

The MSAS was designed to incorporate the following features: (1) ability to record the prevalence of a broad group of physical and psychological symptoms experienced by diverse types of cancer patients; (2) use of an empirically-derived method of scaling according to severity, frequency, and/or distress; (3) capacity for meaningful subscales, including one that measures global symptom distress; and (4) demonstrated reliability, validity, and ease of use. The original MSAS has 33 items reflecting symptoms commonly associated with cancer. Separate 4 or 5 point Likert-type scales were created for each of 3 dimensions: (1) severity of the symptom; (2) frequency with which it occurs; and (3) the distress it produces. The items are scored by summing the items in each subscale (i.e., physical, psychological). The higher the score, the more severe, frequent, or distressing the cluster of symptoms are for the patient. (Porteney, et al, 1994).

Validity and reliability data have been strong when the tool was used with persons receiving active cancer therapy. Factor analysis confirmed two factors that distinguished three major groups of symptoms. The three confirmed groups of symptoms were Psychological, High Prevalence and Low Prevalence Physical Symptoms. Reliability coefficients indicated strong internal consistency for the Psychological and High Prevalence Physical Subscales (alpha=.83-.88) but a somewhat lower reliability estimate in the Low Prevalence Physical subscale (Portenoy et al., 1994).

For this project, a revised MSAS will be used that was developed for use with hospice patients with cancer. A group of hospice experts including researchers reviewed the items and removed those that seemed least likely to be problematic for hospice patients, for example alopecia, a side effect seen with chemotherapy but seldom in palliative care. In addition, a constipation item was added because it had been omitted from earlier versions. A total of *25* items has been included in the revised version of the MSAS. *Items are rated from 0-4 for severity and from 0-4 for distress, resulting in subscale scores for intensity and distress that range from 0-100 for each.*

*Validity and Reliability of the Revised MSAS were studied as part of an earlier project. As can be seen in the Feasibility Section of this proposal, preliminary assessment of the validity of the MSAS for use with cancer patients receiving hospice home care was conducted and included correlation with quality of life (HQLI) scores. As predicted, the*

*correlation between MSAS distress scores and HQLI scores were moderately strong and negative (r= -.72; p<.001). This provided further support for construct validity of the MSAS for use with cancer patients near the end of life. In addition, reliability of the intensity and distress scores were acceptably high (r=.73-.74) using coefficient alpha (McMillan & Small, 2002).*

Hospice Quality of Life Index-14

The Hospice Quality of Life Index-14 (HQLI-14) is a shortened version of the previously used and validated Hospice Quality of Life Index (McMillan & Weitzner, 1998). The original version has 28 items with each item rated on a 0-10 point numeric rating scale. Total scores can range from 0-280. The HQLI includes three aspects of overall quality of life: Psychophysiological Well-being; Functional well-being; and Social/spiritual Well-being (McMillan & Weitzner, 1998). Evidence of validity was provided by the ability of the HQLI to differentiate between hospice patients and apparently healthy controls using both discriminate analysis (p=.00) and comparison of means (p=.00). The finding that HQLI scores correlated at the expected level (r=.26; p=.00) with functional status scores provides further evidence of validity. Finally, factor analysis confirmed the factor structure of the HQLI (See Preliminary Work section). Reliability of the HQLI was provided by generation of coefficient alphas for both total scale scores and subscale scores. Subscale alphas all were .84 and the total scale alpha was high for both cancer (r=.88) and AIDS (r=.93) patients.

The shortened version (HQLI-14) is designed for repeated clinical use with hospice patients. Each item is scored on a 0 to 10 scale with 10 being the most favorable response; item scores are added to obtain a total scale score. Total scores can range from 0 (worst quality of life) to 140 (best quality of life). Subscales measure three aspects of quality of life including Psychophysiological well-being (six items), Functional well-being (four items), and Social/spiritual well-being (four items). Mean scores in a group of 255 hospice patients with cancer were calculated for the total HQLI-14 and its subscales. The mean for the total was 101.2 (SD=19.2). The means for the subscales were as follows: Psychophysiological well-being (mean=42.3); Functional well-being (mean=23.2); and Social/spiritual (mean=35.7).

Validity. Construct validity of the short form was evaluated by correlation with the original HQLI. The correlation between total scale scores was very strong at r=.94 (r=.000). Correlations between the original subscales and the shortened subscales were as follows: Psychophysiological well-being (r=.90, r=.000), Functional well-being (r=.96, p=.000), and Social/ spiritual well-being (r=.89, p=.000). These strong correlations provide excellent evidence of the validity of the shortened HQLI.

Reliability. Reliability of the short form was estimated using Cronbach's alpha. Alpha for the total tool was strong (r=.77). For the subscales, the alphas were as follows: Psychophysiological (r=.68), Functional (r=.72), and Social/spiritual (r=.82). It is to be expected that scales with smaller numbers of items have lower alpha coefficients. Thus, these results are acceptable and to be expected in a shortened scale.

Brief Pain Inventory

The purpose of the Brief Pain Inventory (BPI) is to assess pain in cancer and non-cancer patients by using a self administered questionnaire that measures pain at its worst, its least, average, and current level (Daut, Cleeland & Flaner, 1983; McCormack et al., 1993). The instrument can be self administered if the patient is able to do so or completed by the interviewer with the patient answering the questions. The majority of the instrument is scored on a 0-10 numeric rating scale for level of pain. Pain is shaded on a body diagram in areas where the patient feels pain. One question on percent of pain relief with current regimen is included.

The instrument is completed if there has been any pain from the current time through the last month. Pain has generally been interpreted on a 0-10 scale as follows: 0-3 (mild pain); 4-6 (moderate pain); and 7-10 (severe pain). The single percent score on pain relief in the last 24 hours can be very useful.

Validity. Data was from patients with cancer at 4 primary sites (n=1200) and from patients with rheumatoid arthritis (n=34) as well as an HIV sample suggesting that the BPI is a valid and reliable instrument in cancer and non-cancer patients. The validity of this instrument was noted by determining the relationship between pain medication use and overall pain ratings. The percent of patients taking medications increased significantly with higher pain ratings (opioids p=.002; non-opioids p=.002). The correlation between usual pain ratings and pain interference was also high (r=.624; p=.001). As expected, those with more intense pain had more interference with activities.

Reliability.Test-retest revealed higher reliability when the interval was short (r=.93 for the worst pain, r=.78 for usual pain, r=.59 for pain right now). This was considered logical since real changes in pain would be expected over a longer period of time. The consistency of responding to the pain history items was assessed on a long-term follow-up sample. The percentage agreement for the initial pain was 76%, 81% for pain ever, and 67% for pain in the last month.

Katz Activities of Daily Living Index

The Activities of Daily Living Index (ADLI) assesses six activities of daily living bathing, dressing, toileting, transfer, continence,and feeding (Katz et al, 1963). The assessment of these six areas results in a seven-point grading with "A" being the highest (independent in all six functions) and "G" being the lowest (dependent in all six functions).

Demographic Data – Patient

Standard Demographic data will be collected from patients and patient records. Data will include: age; gender; education level; marital status; religion; occupation; cancer type; length of time since diagnosis and whether the dwelling is urban, suburban, or rural.

Assessment Tools for Both Patients and Caregivers

Social Support: Patients

A single item assesses the extent to which patients are satisfied with the support that they have received from others. Social support is vital in coping with any life stress, especially terminal illness, caregiving, and bereavement. Clinically, this item should be useful in identifying caregivers and patients who state that they have little or no satisfaction with support from others. In terms of program development, monitoring this item will help us understand whether social isolation and lack of perceived support might be a risk factor for poor outcomes in hospice, and poor bereavement outcomes for the caregiver.

We pulled a single item assessing satisfaction with social support from a multidimensional measure from the work of Krause and Borawski-Clark (1995). Satisfaction with social support is the social support dimension most closely related to psychological distress.

*Received Support and Satisfaction: Caregivers*

*Social support, or perceptions of help received from others, will be assessed via an 18-item, multidimensional measure from the work of Krause and Borawski-Clark (1995). This self-report summated rating scale has total scale scores ranging from 18 (lowest support) to 72 (highest support). Items 15-18 are reverse scored. We have used these scales in our other studies of stress and coping in community samples, including hospice caregiving (Haley et al., in press ; Jang et al., in press ; Jang et al. 2002). Received support scales include tangible support, such as help with transportation (3 items, $\alpha$=.72), emotional support, such as having others listen and show interest (4 items, $\alpha$=.83), and informational support, such as sharing suggestions and information (4 items, $\alpha$=.77). Satisfaction with support (3 items, $\alpha$=.69), and negative social interaction, such as criticisms and demands by others (4 items, $\alpha$=.76), will also assessed. In a forthcoming paper (Haley et al., in press) we found that several of these dimensions of social support predicted caregiver depression and life satisfaction in a hospice caregiving sample. In particular, caregivers with more social support and lower negative social interactions had lower depression and higher life satisfaction, even after controlling for patient impairment and caregiver appraisal variables in regression analyses.*

Center for Epidemiological Studies – Depression (CES-D) Short Form

Without use of a systematic screening instrument for depression, the majority of cases of depression are not detected by physicians and other health care providers in a variety of health care settings (Callahan et al., 1994). The CES-D (Radloff, 1977) is a widely used scale that has proven useful both as a screening instrument to detect individuals at risk for depression, and to measure the *symptoms* of depression. The CES-D is widely used in research on depression, has been translated into multiple languages, and has impressive reliability, validity, sensitivity, and specificity (Lewinsohn, Seeley, Roberts & Allen, 1997). The CES-D has also been used to measure depression in research on bereavement (Bodnar & Kiecolt-Glaser, 1994; Edelstein et al., 1999).

The full 20-item CES-D has been widely used, but recently there have been efforts to develop and validate shorter versions of the CES-D for use in clinical settings and large scale survey research projects. The LifePath Hospice psychosocial assessment includes a 10-item version of the CES-D (sometimes referred to as the "Boston short form") that has been developed to balance ease of administration and psychometric concerns. Items are scored as either present or absent, rather than rated for frequency as with the full CES-D. Irwin et al. (1999) assessed psychometric characteristics of this short form CES-D. Results showed that Cronbach alpha was.92 for this short form, and test-retest reliability was .83. These indicate excellent reliability. Correlation of the short form and full CES-D was .88, suggesting that the short form is highly correlated with the lengthier and more widely validated full version. It was also determined that, using a cutoff of greater than or equal to 4 on the scale, sensitivity, specificity, and positive predictive value of the scale were 97%, 84%, and 85% respectively when compared with clinical diagnosis of depression using the SCID. This indicates excellent validity for the scale.

Structured Clinical Interview-Depression Suicidal Ideation

The Structured Clinical Interview for Depression (SCID-I-RV) is administered to assess mood. The SCID-I-RV allows the clinician to determine if the interviewee meets criteria for selected Axis I disorders of the DSM-IV [Diagnostic

and Statistical Manual of Mental Disorders, Fourth Edition]. The SCID-I-RV consists of the following diagnostic modules: Mood Episodes, Psychotic Screening, Alcohol Use Disorders, Anxiety Disorders, Somatoform disorders, Eating disorders, and Adjustment Disorder. The SCID-I-RV modules to be administered in this study will be for the Mood Disorders (i.e., current and lifetime episodes). The administration will follow the standard SCID format in that all symptoms will be rated as present, subthreshold, or absent on a 3-point scale ranging from 1 ("absent") to 3 ("present"). The "subthreshold" category represents the situation in which the threshold for criterion is almost, but not quite, met (e.g., the individual has been depressed for 10 days rather than the required two weeks). The interviewee must have either or both of the screening items present in order to continue with the rest of the interview. The SCID has well-documented validity and reliability. It has no limitations and has been used in a palliative setting (citations). The item inquiring about suicidal ideation will be the only item used in this study.

Spiritual Needs Inventory

*The Spiritual Needs Inventory is being administered to both patients and caregivers. The purpose of the scale is to assess the extent to which patients have spiritual needs and which of these needs remain unmet (Hermann, 2001b). This 17-item questionnaire has two main parts. First the patient and caregiver will be asked to rate the items in response to the stem: "In order to live my life fully, I need to:" This stem is followed by items in column A such as "Sing/listen to inspirational music" and "Talk with someone about spiritual issues". The subject responds on a scale in column B from 1 (never) to 5 (always). Scores in this section may range from 15 to 75 with a higher score representing a greater spiritual need. In column C, the respondents indicate which of these needs remains unmet by marking yes or no. Individual categories and/or questions may also be viewed for areas of strength or areas for intervention by the Chaplain for care-planning issues.*

*Validity and Reliability. Validity was assessed by Hermann (1998) using factor analysis which confirmed the inclusion of all items. Reliability was assessed using Cronbach's alpha. This evaluation indicated a high degree of internal consistency (alpha=.85).*

## Caregiver Assessment Tools

Self-rated Health and Functional Health

We have included two subscales from the Medical Outcomes Study Short Form Health Survey (MOS; Stewart, Hays & Ware, 1994). The MOS health measures have been widely used in health services research, including a study of the effects of HMOs on older adults (Ware et al., 1996), and in a study of hospice caregiving (Haley et al., in press). The physical functioning scale (6 items, $\forall$=.75) includes such items as ability to climb stairs or carry groceries. The health perceptions scale (5 items, $\forall$=.85) includes items assessing overall self rated health and comparison of health to others. Self-rated health perceptions have been found to be valid indicators of physical health and important predictors of mortality in older adults. Haley et al. (2001) found that, in a hospice sample, the health perceptions scale was lower in spousal caregivers of dementia patients and spousal caregivers of lung cancer patients than in noncaregiving controls. The scales have extensive normative information, but no clinical cut points have been identified.

## Scales for Long-term Follow-up of Caregivers

Two scales will be used strictly to follow caregivers after the death to evaluate long-term outcomes and how they may differ in the treated and untreated groups. However, data from these tools will not be part of the assessment data shared with the IDT as part of the intervention.

Grief Scale

The most commonly used instrument to assess grief experiences is the Texas Revised Inventory of Grief (TRIG) Present Feelings Subscale (Faxchingbauer et al., 1977). This scale will be used to collect follow-up data from caregivers 3 and 12 months after the patient has died. The inventory includes 13 self-report items assessing common grief symptoms, and has been used to track grief symptoms over time. Owen, Goode and Haley (2001) found that TRIG items were sensitive to racial differences in the experience of grief. Owen et al. (2001) used the TRIG with a sample of hospice caregivers and found good reliability (alpha=.88). Positive correlation between caregiver depression and negative correlation with caregiver social support and activity provided good evidence of construct validity.

Inventory of Complicated Grief

Complicated grief has been defined as symptoms associated with the loss that are unresolved and are associated with impairment in performance of daily activities. The Inventory of Complicated Grief will be used to collect follow-up data from caregivers 3 and 12 months after the death. This is a 19-item scale developed to assess grief symptoms that have been found in a series of studies to predict later dysfunction (Prigerson et al., 1995a,b). Excellent evidence of validity and reliability of this instrument have been published, and it has been used clinically to identify individuals over a cut-point indicative of syndromal level of complicated grief. Particularly promising have been efforts to conceptualize complications in the grieving process itself that are distinct from major depression, panic disorder, and post-traumatic

stress disorder (Horowitz et al., 1997). Jacobs, and colleagues (2000), for example, have recently garnered empirical support for a set of diagnostic criteria for "traumatic grief" marked by efforts to avoid reminders of the deceased, purposelessness and futility, a shattered world view, and clinically significant disruption in life functioning. Moreover, diagnosis of traumatic grief six months following the loss has been associated with deleterious long-term outcomes, in terms of a range of both psychological and medical outcomes (Prigerson et al., 1997)

Demographic Data - Caregiver

Standard demographic data will be collected from caregivers. The following demographic variables will be assessed via self-report in a semi-structured interview: age; race; gender; education; marital status; occupation; employment status; religion; and income. In assessing socioeconomic status (SES) income can be a poor estimate in older persons (particularly those who are retired), and measures of education or occupational status may be problematic among women who were homemakers while their husbands held relatively high-status occupations. Thus the Nam-Powers Index of Occupational Status (Nam & Terrie, 1988), a measure of family SES, will be used. Subjects will not only report their own, but also their spouse's typical occupation, which will then be scored using standard criteria for quantifying occupational prestige on a scale of 0 (low) to 100 (high). The higher score of the married couple will be used as our index of family SES.

## Process Data Collection

Chart Audit

Tilden (2001) in her paper presented at the NIH Integrative Conference on End of Life Care recommended collection of both process and outcome data. In this project, the intervention will be the addition of standard assessment data provided to the IDT with the goal that they use the information to improve the interventions offered to patient and caregiver. Process data for this project will include number of home visits by nurses, aides, social workers, or chaplains during the two weeks following the first participation of the RA's in the IDT conference, as well as the number of changes in the care plan , number of hospitalizations, and number of medication changes as a result of the team conference. This data will be collected on a Chart Audit Form (Appendix E). *Data collected will allow comparison between the experimental and control groups to determine whether there were more care plan changes and home visits for patients in the experimental group.* Collection of this data will help investigators in understanding the extent to which systematic assessment data might have changed the process of giving care and which care processes might have had an impact on outcomes.

## Procedures

Approvals

This project has been approved by the administrators of the three involved hospices (Appendix C). In addition, the proposal will be submitted to the USF Institutional Review Board for the Protection of Human Subjects.

Screening for Study Admission

Eligible patient/caregiver dyads who are potential study subjects will be identified initially by hospice admission staff and referred to the RA data collectors at the beginning of each day. The RA data collectors will contact the caregiver to arrange a visit. During this visit, the study will be explained, consent of both patient and caregiver obtained, the mental status of the patient and caregiver will be assessed, and the functional status of the patient will be evaluated. Baseline data will be collected from patients and caregivers who meet eligibility criteria. A notice will be placed in the front of the patient's chart stating that the patient is involved in a study that *involves collection of data from the patient and caregiver.* The notice will not identify the treatment condition.

Random Assignment to Groups

Although the sample cannot be randomly selected, the two teams in each of the hospices will be randomly assigned to the two treatment conditions including (1) standard care; and (2) standard care plus additional systematic assessment. Although it would be desirable to randomly assign patient/caregiver dyads to the experimental conditions, this was not deemed to be desirable because of the high probability of contamination during the course of the study. Because the RA-data collector will routinely be attending the team meetings to report the data from the standardized assessments, it is possible that the team members would see the value of this data and change the way they conduct their assessments. If this change occurred on a team that had control patient/caregiver dyads, the study would be fatally flawed. Thus, although not ideal, it was determined that random assignment at the team level would be superior to random assignment by dyads. (See Verification of Randomization Scheme under Data Analysis section).

Experimental Conditions:

**Group I:** Patients and caregivers in Group I, the experimental group, will consist of study patients who are on the team in each of the three hospices that is designated to receive the intervention. These patients and caregivers will

receive the standard assessments conducted by the staff. In addition, within 24-72 hours of admission, they will complete the standardized assessments included in our study. For this group, the RA-data collectors will attend and participate in the interdisciplinary team (IDT) conference to share the results of the assessment conducted as part of the study. The RA's will not offer suggestions for changing the careplans but will simply offer the results of the data collection for patients and caregivers in the experimental group.

*A standardized written report will be given to team members on the three Experimental teams during the IDT conferences and filed with the three team leaders at the end of the conference; team leaders will control the reports and insure confidentiality of this data. This report will follow a standard format that contains the results of all of the patient and caregiver assessments. However, none of the standardized instruments will be named on the report; withholding the name will insure that the staff on the experimental teams cannot share the instrument names with staff members on the control teams. The format of the report is appended (Appendix F). In addition, an oral report will be given during the IDT conference on each patient/caregiver dyad in the study. The oral report will last only 4-5 minutes because of the busy agenda for the regular IDT conferences. Only critical information will be reported orally including:*

- *Up to 11 of the highest priority problems from the MSAS will be reported. Previous researchers have reported that patients with advanced cancer have a median number of 11 symptoms each with a range from 1-27 (Walsh et al., 2000). This is the rationale for reporting up to 11 symptoms. Priority will be determined by which symptoms cause the greatest distress (based on the MSAS distress scores). All symptoms with distress scores of 2 or higher will be orally reported up to 11 symptoms. The symptom intensity scores for these symptoms will be verbally reported along with the distress scores. Previous research with hospice patients has shown that 80% of hospice patients report pain, so if patients have significant unrelieved pain (intensity score of 4 or higher), the Brief Pain Inventory results also will be reviewed. Overall quality of life scores will be reported; up to 5 items on the HQLI with the lowest scores will be identified. Although there may be some overlap with usual hospice assessments in what is reported, the numerical scoring of symptoms other than pain is seldom done in these hospices. Thus, this scaling of symptoms should help to put the symptom severity and priority into greater perspective. Further, overall quality of life is not assessed in these hospices, even though it is the stated outcome of care in each of them. In addition, this reporting will be done twice in two weeks, allowing the IDT members to better understand the extent to which their symptom management efforts have or have not been successful over time.*
- *The depression scores (CES-D) for the patients and caregivers will be reported if they are above the threshold (4 or greater) for clinically meaningful depressive symptomatology. If the suicidal ideation item (from the SCID) for either patient or caregiver is 3 or greater (thinks of suicide often but has no specific plan), this also will be reported. Social support data will be orally presented only if the patient or caregiver perceives a significant lack of such support (a score less than 3 for patients and lower than 45 for caregivers). This early reporting of psychosocial data probably will not be duplicative in the first IDT meeting after admission because no systematic assessment of depressive symptoms is currently being done. Further, it should be noted that Medicare guidelines require only that the first psychosocial contact be made with the patient within the first seven days after admission. This required contact might be a visit or might only be the telephone call to set up an appointment. Thus, the depression and suicidal ideation data will be unique and the psychosocial assessment might occur much earlier than it would have under standard hospice conditions and may even be presented twice for some patients before the usual first psychosocial visit.*
- *The total score from the SpiritualNeeds Inventory will be reported along with the three unmet spiritual needs that were highest priority for the patient and caregiver.*

The RA-data collectors will consist of a team from each hospice that includes an experienced hospice RN and an experienced hospice social worker. It is necessary to have two data collectors in the home so that independent data can be collected from the patient and the caregiver. Previous research has shown that patients allow caregivers to provide information that they themselves could and should provide (McMillan, 1996; Weitzner et al., 1997). Every attempt will be made to have the patient and caregiver provide data in different rooms in the home. In addition, it has been shown through earlier research that caregivers are reluctant to leave patients unattended even for a brief time (Reese, 1996; Robinson, 1988). An RN will collect patient data while the social worker is collecting caregiver data. Having the RN with the patient while the caregiver is participating in data collection should provide reassurance that the patient is in capable hands. We are using two data collectors in our current clinical trial and it has been quite effective (R01CA-77307, McMillan). There are three reasons for using mixed teams of RNs and social workers. First, there is a nursing shortage, and finding two RNs would be even more difficult that finding one. Second, social workers' average salaries are significantly less than RN salaries this will help keep the project costs somewhat lower. Third, using RNs and social workers together reinforces the interdisciplinary team concept and should prove helpful when the data are being reported back to the interdisciplinary team in each hospice.

**Group II:** Patients and caregivers in Group II, the control group will receive the standard assessments that are conducted for all patients in each of these three hospices. In addition, these dyads also will complete all of the standard assessments required by the study within 24-72 hours of admission to hospice. Both the patients and caregivers in the control group will participate in the follow-up data collection process.

*Informing Hospice Staff About the Study: We will approach each team that has been chosen for participation to offer them information about the study. They will be told that the reason for the study is to test some different assessment tools to determine how helpful and clinically meaningful they will be to hospice staff; we are not there to evaluate the care that they are giving. Also, they will be informed that for some teams the research nurse and research social worker will attend and participate in team meetings and for other teams they will not. For the control teams, it will be explained that data will be collected from patients and caregivers, but that there will be no contact with the hospice staff, and staff will receive no reports from researchers. If study RA's and hospice staff should meet in the home, the RA's will give the staff priority and will either wait until the staff members have finished with their care, or will return at another time.*

*Selection of Staff*

*Two RA data collectors and one back-up data collector will be identified at each hospice to serve on the research team. One will be a nurse and the other a social worker; the backup will be a nurse. Criteria for selection will include the following: 1) must have at least a bachelor's degree; 2) must have at least 6 months experience working in the hospice. The human resources departments at each hospice will be asked to post these positions so that any nurses or social workers who are interested might apply by calling the PI. Members of the investigative team will interview the candidates and select those who are best prepared to participate in the study. Because experience tells us that hospice staff sometimes feel that research with hospice patients is inappropriate, the interview questions will inquire about the candidates' attitudes toward doing research with persons who are nearing the end of life. Other questions will involve their previous experiences that they believe prepare them to participate in conducting this research.*

Training of Staff

Two RA data collectors will be hired from each hospice and will work as a team. While the RN data collector is collecting data from the patient, the Social worker (SW) data collector will be administering tools to the caregiver. A two-day training session is planned for the full-time RA-data collectors and one back-up data collector from each site. The back-up will be available to work when one of the full-time data collectors is on vacation or is ill. *The backup will be an RN because a social worker might have difficulty filling in for an RN in collecting symptom data, but an RN should have no difficulty collecting psychosocial data if trained to do so.* The investigators will teach the RA's how to identify and screen subjects, how to explain the study to obtain consent and how and when to collect the data, insuring complete data on each questionnaire. This training will include clarification of how to administer each of the study instruments and will provide opportunities for the RAs to role play several scenarios for practice. The RA's will be taught to focus on collecting data without providing care. They will be taught how to deflect issues related to symptom assessment or management by referral to hospice staff and to focus only on data collection. They will be asked to role play several scenarios that include situations in which the caregiver asks for assistance with patient problems. They will then be rated on how well they handle these situations and taught methods for modifying their responses. In addition, they will be instructed what to do in cases where potential suicide, abuse or neglect are suspected. In addition, they will be told what to do if the patient is dying or has died when they arrive at a home. These policies will be included in the Data Collection Manual that will be developed during the first two months of the grant.

*Integrity of the Intervention*

*Steps will be taken to insure that there are no shifts in the intervention from the beginning to the end of the study and that there are no variations from site to site. To insure consistent compliance by the RAs with the intervention protocols, 10% of all intervention team conferences will be attended by the Project Manager who will use the Project Manager Check Sheet of IDT Conference (Appendix G) to evaluate the presentation of data by the RAs. Following the IDT meeting, the Project Manager will review the check sheet with the two RAs. These will be assembled by the project manager for review each month by investigators to determine that all of the RA's are providing the interventions according to the protocol and to insure that there is no shifting away from the protocol. Follow-up training sessions will be planned as needed.*

*In addition, the Standardized Report of Patient/Caregiver Assessment Forms will be collected and filed. At the end of each month, a 10% sample will be reviewed by one of the investigators to insure that the RA's are adhering to the intervention protocol. If breaks in protocol are identified, the RA's will be counseled about protocol adherence. To minimize possible interference by hospice staff members, hospice staff will be told that if a patient or caregiver asks a question about the study, he or she should be referred to the RAs whose beeper numbers will be provided to the staff.*

*While we believe it unlikely, it is possible that hospice staff will change their behavior toward patients or caregivers because of their knowledge of the study. To monitor drift in the standard care provided, we will ask a single question during the final data collection period about the caregiver's perception of how much time the hospice nurse spent talking to the caregiver about symptom management (Appendix H). If this number remains constant throughout the study, we will have evidence that the hospice staff members did not change their behavior as a result of the project. This data will be monitored monthly and monthly debriefing meetings with hospice staff nurses will be held as needed if a shift in these numbers begins to appears.*

Data Collection

All patients are discussed at every team conference and are included in a team conference within one week of admission to hospice services. Data collection for all subjects will be on admission to the study (24-72 hours after admission to hospice), one week after the first interdisciplinary team conference (between days 8-12 of hospice admission) and one week after the second team conference (between days 15 and 19 of hospice admission) (Figure 2).

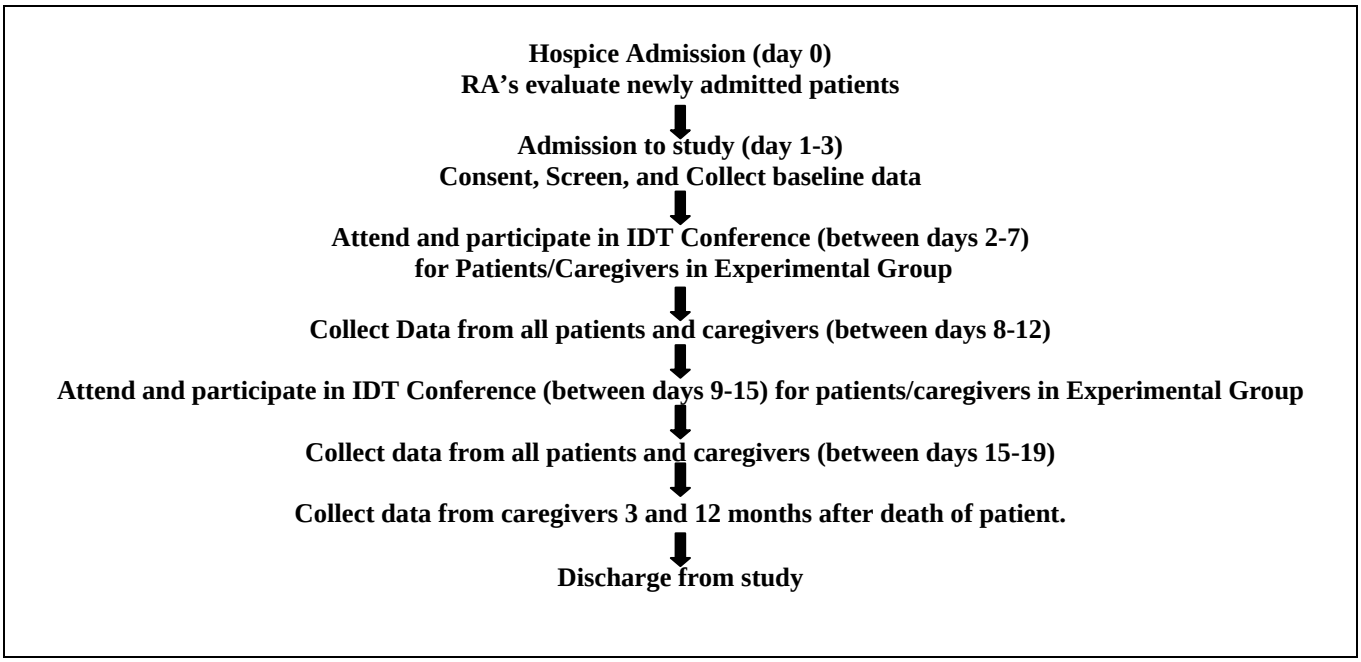


**Figure 2. Data Collection Schedule**

**Baseline data collection** will take place between 24 and 72 hours after admission to hospice. Previous research (McMillan & Mahon, 1994a) revealed that accruing patients to a study on the day of admission is difficult because of the stress caused by the admission process and consents required for admission. However, it is desirable that the baseline data be collected as soon after admission as is feasible. Previous studies (McMillan & Mahon, 1994b) have shown that data may successfully be collected within 24-72 hours of hospice admission.

Patients and caregivers who meet the admission criteria will be asked to fill out their respective questionnaires independently, in separate rooms when possible. The RN-data collector will collect patient data and stay with the patient to assist as needed and to reassure the caregiver that the patient will not be alone while the social worker-data collector is collecting data from the caregiver. Caregiver data collection will be conducted simultaneously with patient data collection, so the caregiver will be able to concentrate on the questionnaires knowing that nurse-RA is with the patient.

The nurse-RA will interview the patient independently, screening the patient using the Short Portable Mental Status Questionnaire and Katz ADL scale. Using data from the Katz, the nurse-RA will complete the Palliative Performance Scale. If the patient meets the minimum criteria, the BPI, MSAS, HQLI-14, Social Support item, the CES-D and Suicide item and *Spiritual Needs Inventory* will be administered and demographic information will be obtained.

Caregivers will be screened using the SPMSQ. If they pass this criterion, they then will be asked to complete a packet of questionnaires including the Received Support and Satisfaction Scale, the CES-D, and the *Spiritual Needs Inventory*, and demographic data will be recorded.

**Post-intervention data collection** will occur at approximately one week after the first IDT conference in which the patient is discussed (between days 8-12), and again approximately one week after the second IDT conference in which the

patient is discussed (between days 15 and 19). The patients and caregivers will be asked to complete the same questionnaires each time (excluding the demographic data forms and the screening questionnaires).

**Follow-up data collection** will occur for caregivers at 3 and 12 months after the death. Because average length of stay in these hospices is approximately 50 days and half of patients are dead within 20 days (median), this will not unnecessarily prolong data collection. The data manager will track the patient records and notify the RA's when it is time for the follow-up data collection.

At this follow-up data collection period, the caregiver will be given a packet of questionnaires to complete including the Health subscales of the SF-36, the CES-D, the Spiritual Needs Inventory, Suicidal Ideation, the Grief Scale and the Pathologic Grief Scale. Collection of the 12 month data will complete the caregiver's participation in the study.

**Process Data:** Both RA's in each hospice will be responsible for auditing charts using the Chart Audit Form (Appendix E) for patients in both the experimental and control groups. The Care Plan for each patient is begun before the first interdisciplinary team conference in which the patient is discussed. This care plan will be audited to ascertain changes that occur following the reporting of the standardized data. This auditing will be done after the post-intervention data collection has been completed. Once the audit data have been placed in the patient/caregiver research record, the record will be turned over to the data manager who will enter the data into the data set.

Project Timeline

A detailed timeline for this *three* year project is appended (Appendix I). Start-up, including advertising, interviewing, hiring and training project staff *(including piloting methods*) is expected to take 4 months. Subject accrual, baseline data collection, providing the intervention, and post-intervention data collection, and collection of process data is expected to take *18* months. One-year follow-up data collection will take 12 months and final data entry, data analysis, writing reports, abstracts, and publications will take *2* months.

Integrity of the Data

The program manager for the study will insure that all patients admitted to the study meet all the study criteria by doing a random survey of 10% of all cases each month. To insure that questionnaires are answered completely, data collectors will be instructed to review each form as the patient or caregiver completes it and point out omissions with gentle encouragement to answer questions that might have been omitted. Previous experience with this population indicates that this is a critical step to avoid missing data. In addition, the two RA's will swap forms before leaving the home and will check each other's forms for completeness. *As the Data Manager enters the data, she will note missing data on assessment forms and bring this to the attention of the investigators and the Program Manager. The Program Manager will bring this to the attention of the RA's, try to determine the cause for the missing data, and coach the RA's in obtaining complete data in every case possible. If the drop-out rate from the study exceeds 40%, the Program Manager and PI will meet with the RA's to determine possible causes.*

Missing Data

Patient/caregiver dyads for whom only baseline data is available will be included in analyses to determine the descriptive analyses, and the analyses to verify the randomization scheme. *Concerns about missing data will be addressed in two ways. First, we anticipate relatively few problems with sporadic missing data points because well-trained research personnel will be administering the study measures to participants during the home visits. If necessary, sporadic missing data points will be imputed using multiple imputation procedures, after considerations with regard to the pattern of missing data, whether missing are random or not missing at random, will be implemented (e.g., Schafer, & Olson, 1998). In terms of data that is missing because of death or nonparticipation, the mixed model data analysis procedures that we use (see below), are more powerful than procedures that require listwise deletion because they take advantage of all the data that is available.*

## Data Analysis

Power Analysis and Consideration of Multiple Significance Tests

Considerations of sample size were based upon statistical power analysis (Cohen, 1988). In general, we adopted the parameters of a medium-sized effect, alpha level of .05, and a power of .80 to derive the necessary sample sizes. For example, to compare the outcome measures using a 2 (intervention group: experimental, control) X 3 (hospice site) between subjects analysis, we would require a total of approximately 240 persons to achieve a .80 power value. However, in order to compare two groups, whether to contrast the intervention groups or pairs of hospice sites, we would require a total of 102 persons. Taken together, in order to achieve a .80 power, we need a minimum of 51 persons per intervention group at each hospice site for the between subjects analysis. Given the number of persons available in the current proposal, we believe that we will have ample power to generate the necessary comparisons. Based on our current ongoing study, we expect a high attrition from the study (approximately 40%); thus, *85* subjects will be sought in each hospice for each intervention group for a total of 510 patient/caregiver dyads accrued and 306 patient/caregiver dyads completed.

In terms of within subjects analysis, because many fewer persons are required to achieve the same level of statistical power in repeated measures analysis, the number of individuals available in the current proposal is also sufficient to detect changes in mean-level performance over time.

Finally, conventions for power analysis of cluster analysis and discrminant function analysis are not well articulated. Instead, we adopt the recommendations of Tabachnick and Fidell (2001) for calculating statistical power of multiple regression. In this case, sample size is 50 + 8*M, where M represents the number of predictor variables that are used. Again, the number of participants examined here is adequate for sufficient statistical power in these analyses.

Adequate analysis of study data will require multiple statistical tests. However, we will take a number of steps to safeguard against spurious findings. We will ensure that that the number of significant findings in each "family" of analyses exceeds chance by introducing a sequential Bonferroni adjustment to maintain a family-wise alpha level of .05 (Ramsey, 1982). Each univariate effect is arranged in descending order based on the F value for each test. The critical alpha level for each test is determined by the formula $1 - (1 - .05)^{1/DV}$ where DV equals the number of dependent variables remaining. This procedure is repeated until a nonsignificant effect is found or until all effects are tested. Further, multivariate F-tests will be employed to examine group differences and group changes in functioning. The use of omnibus tests of significance does offer some control over inflated Type I error produced by multiple tests of significance (Stevens, 1986).

Comparability of Group Assignment and Hospice Site

In order to verify that the randomization scheme has resulted in groups that are equivalent at baseline, multivariate analysis of variance (MANOVA) will be performed to test for differences between groups (control vs. experimental) in patient age, patient gender, patient diagnosis, patient functional status, patient depression, caregiver age, caregiver gender, caregiver health status, relationship of patient/caregiver, caregiver education, patient symptoms, caregiver social support, patient quality of life, and depression. If any significant differences between groups at baseline are identified, hypothesis testing will employ multivariate analysis of covariance (MANCOVA) rather than MANOVA and will control for those factors on which differences are found to exist if standard assumptions for covariance analyses are met.

In addition to verifying the comparability across experimental group, baseline analyses will also be computed on information across the 3 hospice data collection sites. Again, MANOVAs will be computed on the baseline data to determine comparability across the different hospice data collection sites. If reliable differences are observed, then covariate analyses will be implemented to statistically control for those differences. *Further, we will also examine the comparabilityof the experimental and control teams within each hospice site to insure equivalence.* However, we should note that the key analyses from this project, those that examine longitudinal changes as a result of group assignment are less affected by any baseline differences that might exist. This, of course, is due to the fact that each person will act as his or her own control for the longitudinal component of the data.

**Hypothesis 1**: It is hypothesized that patients and caregivers who are cared for by members of the interdisciplinary teams that receive the intervention will have significantly better scores for target outcomes for patients (symptom distress, depression, spiritual well-being and quality of life) and for caregivers (depression, spiritual well-being) compared to the teams that receive no intervention.

*For these repeated measures analyses, and those that follow that examine performance across more than 2 time points, we have chosen to examine changes over time with mixed models analysis (Littell, Milliken, Stroup, & Wolfinger, 1996). The mixed models approach has a number of advantages over the more traditional repeated measures MANOVA. First, it allows differential follow-up intervals to be incorporated into the analytic mode, as is the case in Hypothesis 2. However, the most important advantage of mixed models is that they allow the presence of missing data. That is, whereas a requirement of MANOVA is listwise deletion of missing data, the mixed models are able to utilize all of the information that is present and link the effects to the time points they are measured on. Thus, although we anticipate little missing data because of the well-trained interviews and data retention measures that are in place, this analytic procedure allows us to use cases with a small amount of missing information. In all cases, the analyses will be performed using SAS PROC MIXED.*

A mixed models analysis will be computed on the data to examine the main effects of group (control, experimental), time (baseline, 1 week, 2 weeks), and the interaction between group and time on the outcome measures. Separate analyses will be computed on data from the caregivers and patients. The time effect will include both linear and quadratic contrasts in order to examine whether the changes are linear or non-linear in nature. For the patient data, *separate analyses will be computed on* the dependent variables symptom distress, depression, spiritual well-being, and quality of life. The key result from this analysis will be the presence of a significant group X time interaction. Its presence will indicate that the control and experimental groups exhibit different trajectories across the follow-up periods.

The interaction will be decomposed *with within group longitudinal analyses*. This will enable us to determine the point at which the groups begin to diverge, in terms of the dependent variables that are examined.

For the caregiver data, *the mixed models analyses* will be computed on the depression and spiritual well-being scores. The analysis will include the linear and quadratic effects of time, as well as between group comparisons and the interaction. Again, the presence of a significant group X time interaction will indicate that the caregivers in the control and experimental groups experienced different magnitudes of longitudinal change across the follow-up period. Like the patient data, follow-up comparisons for the significant interactions will consist of *within groups analyses on the longitudinal data.*

**Hypothesis 2:** It is hypothesized that caregivers of patients cared for by the interdisciplinary teams that receive the intervention during hospice care will have significantly less complicated grief at 3 months and 1 year after the death.

In order to assess whether caregivers in the experimental and control groups experience complicated grief, two sets of analyses will be compared. The analyses differ in terms of the time points that the data were collected as well as the analytic methods that will be applied to this information. The analyses will either examine the grief scales collected at 3 months and 1 year post bereavement, or the broader battery administered during the intervention phase as well as post bereavement.

In the first set of analyses, a repeated measures MANOVA with time (3 months) as the within subjects factor and group as the between subjects factor (experimental, control) will be computed on the grief scales. In addition, a time X group interaction will be computed and represents the key analytic outcome of these analyses. In this case, the presence of a significant interaction would demonstrate that the control and experimental groups experience different longitudinal trajectories across the 9 month follow-up period. Finally, the significant interaction will be decomposed by computing between subjects MANOVAs on the data from the 3 month and 1 year follow-up point. This will allow us to determine whether the groups are significantly different at each point in time and will also allows us to compute measures of effect size ($eta^2$, $omega^2$) to examine the magnitude of group differences at each point.

The second set of analyses will focus on the measures of depression, suicidal ideation, health, and spiritual well-being from multiple measurement points. Specifically, we will use information from the baseline, 1 week, and 2 week assessment points during the intervention phase, as well as the 3 month and 1 year post bereavement points. As a result of this complex collection of data, a different analytic strategy is required. Because the intervals between measurement points are not constant, MANOVA analyses are not appropriate here (Tabachnick & Fidell, 2001). Rather, we will use a mixed models approach to data analysis (Littell, Milliken, Stroup, & Wolfinger, 1996). The mixed models approach has a number of advantages over the more traditional MANOVA. First, it allows differential follow-up intervals to be incorporated into the analytic model. However, the most important advantage that mixed models is that they allow the presence of missing data. That is, whereas a requirement of MANOVA is listwise deletion of missing data, the mixed models are able to utilize the information that is present and link the effects to the time points they are measured on. Thus, although we anticipate little missing data because of the well-trained interviews and data retention measures that are in place, this analytic procedure allows us to use cases with a small amount of missing information.

The mixed models analyses will be performed to examine the longitudinal trajectories of the outcome measures as a function of the control and experimental groups. The analyses will be performed using SAS PROC MIXED (Little et al., 1996). The specific effects that were modeled on the data include the main effect of group and time, the linear interaction between group and time, as well as a quadratic time effect and a quadratic interaction between time and group. The key term in the analysis is the presence of a significant time by group interaction, indicating a differential changes in performance as a function of intervention group. Further, the quadratic terms were entered to determine whether the time effects were linear in nature (e.g., consistent change in ratings) or non-linear (e.g., plateau or decrements in functioning).

**Hypothesis 3:** *In this hypothesis, we will examine the prevalence and self-rated distress caused by a variety of symptoms from the MSAS for the most common cancer diagnostic groups, depending on observed types.* It is hypothesized that there will be similarities in symptoms among the patients in the *cancer* diagnostic groups and that unique symptom clusters will emerge for groups of patients with *different types of cancer* but that the impact on well-being of patients and caregivers will be similar among these *cancer types*.

Before the analyses are conducted, preliminary MANOVAs and chi-square analyses will be computed on the data to determine whether the diagnostic groups are comparable, in terms of demographic background characteristics (age, gender, years of education. If statistically significant, the measures will be incorporated into the analyses on symptom distress as covariates.

In order to identify whether the disease groups are different or similar, in terms of specific symptoms that exist, *several* analytic approaches will be implemented. *First, we will examine the prevalence rates for all of the MSAS symptoms to determine the communality of the symptoms for the three cancer groups. Specifically, we will rank the*

*symptoms within each group, according to the percent of people endorsing each item, and compare these percentages across the groups. Analytically, Spearman rank correlations will be compute to determine the correspondence between the occurrence rates across each pair of cancer diagnostic groups.*

*We will then use information about the distress rating for each of the MSAS symptoms in order to derive clusters of symptoms.* In this case, three analytic approaches will be used: MANOVA, Discriminant Function Analysis, and Cluster Analysis. Each, described below, has unique properties that when combined should provide information about whether the diseases share common features or represent separate entities, in terms of the specific symptoms associated with each class of disorders. Symptom data will be from the baseline assessment point only. This was done to avoid any potential effects of the intervention on the presence and severity of specific symptoms.

With the MANOVA approach, the *25 MSAS* symptoms will be compared with a between groups MANOVA with disease as the between subjects factor. IF the overall F-test is statistically significant, between groups ANOVAs will be computed on the individual symptoms to determine the source(s) of the effects. For the univariate follow-ups, *we will employ the modified Bonferroni procedures to minimize Type I error.* Finally, post-hoc follow-up comparisons on the significant univariate ANOVAs will be computed to determine which groups are different from one another on the individual symptoms.

The next method of differentiating the disease groups will involve discriminant function analysis. This analytic procedure is conceptually similar to MANOVA with one exception. In the discriminant function analysis, group membership is predicted by the independent variables. That is, rather than comparing group differences on symptoms, we use information about symptoms to differentiate between the groups. Further, the discriminant function analysis adopts a predictive approach and as a result we can determine whether all of a subset of symptoms are able to differentiate between the three disease groups.

The final statistical method that will be used to differentiate the groups will be cluster analysis. Traditionally, this analytic method is used to find similar (homogenous) groups in a dataset when none exist a priori (Hair & Black, 2000). The present situation is a little unique because we know that there are a number of disease groups at the outset. By applying this statistical technique in the current proposal, we are interested in whether the groups are distinct entities, in terms of the symptoms that exist across the disease groups, or whether they can be collapsed into a smaller number of symptom groups. In summary, the three analytic techniques will be employed in hopes that they will converge on a similar solution, in terms of the types and severity of symptoms experienced by the *cancer diagnostic* groups.

In addition to differentiating the different cancer diagnostic groups, another goal of this aim is to determine whether the clusters of MSAS symptoms that the persons experience affect the well-being of patients and caregivers in a similar manner. To do this, a hierarchical regression analysis will be computed separately for each measure of well-being, for each participant group. *Specifically, the dependent variables in the separate regressions for the patients will be depression, spiritual well-being, and quality of life. For caregivers, the outcome measures will consist of depression, suicidal ideation, health, and spiritual well-being. In each analysis, the regression will consist of three blocks of variables.* The first block will include demographic and background characteristics that are related to the measures of well-being. On the second block, the symptom clusters that were generated in the analytic step above will be entered. In addition, dummy coded contrasts that represent pairwise comparisons of the disease groups will be included. On the final step, the interaction terms will be entered that combine the symptom clusters with the pairwise group comparison dummy coded variables. If reliable, the interactions will be interpreted by stratifying the data by disease group and examining the correlation between symptom clusters and well-being.

**Process Data**: Process data will consist of information about the number of visits by select health-care providers, whether the patients have been hospitalized, and the number of medication changes that were instituted during the course of treatment. In terms of health-care provider visits, the frequency will be pooled across visits by nurses, aides, social workers, and chaplains, to account for differential composition of teams across the hospice sites. The control and experimental groups will be compared with t-tests, with number of visits serving as the outcome measure. Further, because the number of visits are stratified according to when they occur (0-7 days, 8-15 days, 16-23 days), a repeated measures MANOVA with time as the within subjects factor and group (experimental, control) as the between subjects factor. In this case, we are interested in the group X time interaction, to determine whether the groups diverge from each other at some point during the intervention. In addition, $\chi 2$ analyses will be computed, between the control and experimental groups, on whether individuals were hospitalized over the course of treatment. Medication changes will be examined with $\chi 2$, in terms of whether changes were instituted, as well as t-tests on the total number of changes between the groups. Finally, the total number of care plan changes will be compared for the two groups with t-tests.

## GENDER AND MINORITY INCLUSION

Both men and women will be included in the study both as patients and as caregivers. Our previous research in this community indicates that, on average, caregivers are slightly more than half female and patients are slightly more than half male. We anticipate that that pattern will continue.

***Children*** *will be excluded from this project for four reasons. First, the percentage of children admitted to hospice care is very low in these hospices, accounting for less than 1% of all patients. Attempting to address this small subset of patients would require additional accrual time and different analyses, negatively impacting our timeline and budget. Second, the very few children who are admitted tend to be admitted very late, so there would be no time to impact their care. Third, developmental issues with children arise requiring different instrumentation that currently is not available. Finally, the few children who are admitted to hospice care have a special set of needs unlike those of adults that deserve study in and of themselves.*

According to the 2000 Census, all of the counties involved in the study are predominantly white with 6 to 12% African-American and approximately 1% Hispanic/other (Table 7). Admissions to the three involved hospices reflect these population numbers resulting in somewhat limited opportunities to accrue minorities to the study. To enhance minority recruitment, we will attempt to hire minority research assistants to work on the project, and put a focus on minority recruitment during the 18 months of data collection.

**Table 7. Ethnic Makeup of Counties Served by Target Hospices**

| Hospice | Counties | Total Population | Percent White | Percent African-American | Percent Other |
|---|---|---|---|---|---|
| Good Shepherd | Polk | 483,624 | 86 | 13 | 1 |
| | Highlands | 83,403 | 91 | 8 | 1 |
| | Hardee | 22,732 | 90 | 9 | 1 |
| **Totals** | | **589,766** | **87** | **12** | **1** |
| Hernando-Pasco | Hernando | 131823 | 96 | 3 | 1 |
| | Pasco | 333,410 | 97 | 2 | 1 |
| **Totals** | | **465,235** | **93** | **6** | **1** |
| Southwest Florida | Sarasota | 327,504 | 95 | 4 | 1 |
| | Manatee | 258,665 | 92 | 7 | 2 |
| | Charlotte | 141,631 | 95 | 4 | 1 |
| | DeSoto | 29,187 | 82 | 17 | 1 |
| **Totals** | | **756,987** | **93** | **6** | **1** |

## HUMAN SUBJECTS

***A. Characteristics of the subject population:*** *The study sample will consist of patients and caregivers who are receiving hospice home care from one of the three involved hospices. Inclusion criteria for patients: Patients will be identified as those who have a cancer diagnosis, have an identified family caregiver, are adults (18+ years old), either male or female, able to read and understand English, and able to pass screening with the Short Portable Mental Status Questionnaire. Inclusion criteria for caregivers: Caregivers will be identified by the hospice as the primary caregiver. Caregivers must be adults (18+ years old). Exclusion criteria: Patients will be excluded if they are confused, excessively debilitated, comatose or actively dying. Caregivers will be excluded if they are in active treatment for cancer themselves.*

***B. Sources of research material:*** *Patients will be identified by admission face sheets, screened for eligibility for the study, and called by telephone to determine their interest in participating in the study. The individuals who do the screening and calling will be hospice staff. No investigator will see the patient/caregiver data until the dyad has*

*signed an informed consent. No lab data or physical specimens of any kind will be collected. No drugs, devices, or medical procedures are involved in this study. Patients and caregivers will respond to standardized assessment forms.*

***C. Plans for recruitment:*** *Trained research assistants who are hospice employees will call the eligible patient/caregiver dyads and ask for permission to visit the home to explain the study.*

***D. Consent procedures*** *The research assistants will call the patient/caregiver dyad and ask permission to visit the home to explain the study. In the home, the research assistants will explain the study, allow the subjects to read the informed consent, and offer to answer any questions. If the subjects agree, they will sign the consent and will be given a copy to keep. The consent will assure them that their participation is voluntary and that they may withdraw at any time. Subjects in the control group will be told that there may be no direct benefits to them as a result of the study, and both groups will be told that the knowledge gained may improve the quality of care for hospice patients in the future. Subjects in the experimental group will be told that they may benefit because of the standardized data that will be reported to the hospice team. All patients and caregivers will be told that there are no known risks to participating in the study, and that they will not be paid for participating, nor will the study cost them anything.*

***E. Potential risks:*** *There are no anticipated physical risks. Patients and caregivers may see lack of privacy as a potential risk; therefore, they will be assured of the confidentiality of the data and that no one outside of the research team will see the raw data. The subjects in the intervention group will be told that only their hospice care providers will be given summarized reports of their study results. The completed data will be kept in a locked file cabinet in a locked office, first at the hospices and then at the University. A second risk is that the patients or caregivers may become upset as a result of answering some of the questions. They will be told that if the questionnaires become too upsetting, they may withdraw from the study at any time. If severe or lasting emotional distress should occur, the study subject would be referred to a member of the hospice team with psychosocial expertise. If referral to a psychologist or psychiatrist is deemed necessary or desirable, both are available on the team of investigators.*

***F. Procedures for minimizing risks:*** *If the patients or caregivers become overly upset by any of the questions in the surveys, they will be referred to a healthcare worker who specializes in psychosocial care. No reports of any kind will be given to the staff members on the control teams unless there is immediate threat of suicide or homicide or if the research team suspects abuse or neglect. In the event that any of these risks is uncovered for subjects on either experimental or control teams during a home visit, the research assistants will revert to the suicide/homicide or abuse and neglect protocols and inform their hospice liaison*

***G. Why is risk reasonable:*** *Risk of lack of privacy has been managed by keeping the data confidential. Risk of emotional upset is very minimal. We offer this judgment based on interviews with approximately 350 hospice patient/caregiver dyads who have been entered into our current study. Tearfulness is not uncommon, but our staff are trained to be supportive and empathetic. We have never had a case of severe emotional distress, and relatively few subjects have chosen to withdraw from the study because of feeling upset.*

## VERTEBRATE ANIMALS

Not applicable. No vertebrate animals will be included in the study.

## DATA SAFETY MONITORING PLAN

**Monitoring the Progress of Trials and Safety of Participants**

This clinical trial involves little or no risk to the participants. However, there are protocols that spell out what the data collectors and intervention team members are to do in the event of untoward circumstances (for example, if *patient or caregiver experiences emotional distress during data collection* or they suspect abuse or neglect). These are spelled out in the appendix of this proposal and will be included in the Data Collection Manual with specific examples and procedures to follow (Appendix J). These procedures parallel the procedures used by the agencies in which the data is

being collected. The procedures that are spelled out include the reporting of adverse events to the appropriate people at the agency and to the investigative team.

**Plans for Assuring Compliance with Requirements Regarding Reporting of Adverse Events.**

This is a low risk project with an intervention provided only to the hospice staff and not to the patient or caregiver directly. The Division of Research Compliance at this university requires reporting of all adverse events (USF form in Appendix K). An annual progress report also is required by that Division (Appendix L).

**Plans for Assuring That any Action Resulting in Suspension of an NCI-funded Clinical Trial is Reported to the Grant Program Director Responsible for the Grant.**

The principal investigator, Dr. Susan McMillan, will remain in contact with Dr. *Claudette Varricchio at NINR*, and will keep her advised of any problems that might result in suspension of the clinical trial. Because this trial does not involve drugs, devices or medical procedures, it is unlikely to be an issue.

**Plans for Assuring Data Accuracy and Protocol Compliance**.

Several steps have been taken to insure the accuracy of the data. First, patients are carefully screened according to study protocol to insure that they are eligible for accrual to the study. To help confirm this, the project manager will review demographic data and screening data in 10% of subject records to insure that patients and caregivers meet study criteria before the data is entered into the computerized data base.

Second, the data collectors take steps to insure that they are gathering complete data. There are two data collectors in each home, a social worker for the caregiver and RN for the patient. Each checks behind the study subjects and reminds them to complete unanswered questions. Then, prior to leaving the home after each visit, the RN and the social worker exchange instrument packets and verify each other's forms to make sure that all items have been completed. If there are any missing items at that point, they make every attempt to have the patient or the caregiver complete the items. If the patient or caregiver refuses to answer those missing items, the data collectors would document the reason for the refusal.

At the time of data entry, the data manager will check for missing data and report to the team if any data are missing so that the teams of data collectors can be encouraged to be more vigilant. To insure accuracy of data entry, data will be double entered. This allows the team to catch entry errors before they can affect the data set.

When the project is funded, a Data Collection Manual will be developed for use in training the members of the research team. The Data Collection Manual will specify the exact protocol for approaching patients and caregivers and for collecting the data. It also will specify the approach to use in reporting patient and caregiver data to the interdisciplinary team.

To insure that the treatment intervention is consistently implemented according to protocol, the Project Manager will attend one interdisciplinary team conference at each hospice each week to monitor the activities of the RA-team to insure that they are adhering to the project protocol and are not making suggestions for changes in the care plan, but are only providing the data from their data collection forms that is appropriate to give to the IDT. This process monitors drift in the interventions and assures that the interventions are provided in the same way to all study subjects from the beginning to the end of the project.

**Protocol for Responding to Requests for Assistance or Information or a Death**

At the first contact, the caregiver and patient will be told that the Research Team is there for data collection only and is not able to provide nursing assistance or information. If, during the data collection, the caregiver requests assistance with care or asks for health care information for the patient, the nurse and social worker must refer the caregiver to the hospice interdisciplinary team. Death is not an untoward event in this patient population. If the Research Team arrives at a home and finds that a patient is dying or has died, the study is suspended, the hospice nurse is notified, and the Research Team members remain with the caregiver until someone from the Hospice arrives. Protocols for managing situations such as these have been developed (Appendix J) and will be included in the training manual for the Research Teams.

## REFERENCES


Anderson, F., Downing, G.M., Hill, J., Casorso, L., Lerch, N. (1996). Palliative Performance Scale (PPS): A new tool. *Journal of Palliative Care, 12*(1): 5-11.

Avorn, J., Soumerai, S.B., Everitt, D.E., Ross-Degnan, D., Beers, M.H., Sherman, D., Salem-Schatz, S.R. & Fields, D. (1992). A randomized trial of a program to reduce the use of psychoactive drugs in nursing homes. *New England Journal of Medicine, 327*, 168-173.

Baider L, Kaplan-DeNour, A. (1988). Adjustment to cancer: Who is the patient--the husband or the wife. *Israel Journal of Medical Science, 24*, 631-636.

Baider, L., Perez, T., Kaplan-DeNour, A. (1989). Gender and adjustment to chronic disease: A study of couples with colon cancer. *General Hospital Psychiatry, 11*, 1-8.

Berger, A & Walker, S.W. (2001). An explanatory model of fatigue inwomen receiving adjuvant breast cancer chemotherapy. *Nursing Research 50*(1), 43-52.

Blanchard, CG, Toseland, RW& McCallion, P. (1997). The effects of a problem solving intervention with spouses of cancer patients. *Journal of Psychosocial Oncology, 14*, 1-21.

*Block SD. Assessing and managing depression in the terminally ill patient. Ann Intern Med 2000;132:209-218.*

Bodnar, J. C., & Kiecolt-Glaser, J. K. (1994). Caregiver depression after bereavement: Chronic stress isn't over when it's over. *Psychology and Aging, 9*, 372-380.

Cadd, A, Keatinge, D, Henssen, M, et al. (2000). Assessment and documentation of bowel care management in palliative care. *Journal of Clinical Nursing, 9*, 228-35.

Callahan, CM, Hendrie, HC, Dittus, RS, Brater, DC, Hui, SL & Tierney, WM. (1994). Improving treatment of late-life depression in primary care: A randomized clinical trial. *Journal of the American Geriatrics Society, 42*, 839-846.

Cameron, J, Parkes, CM. (1983). Terminal care: Evaluation of effect on surviving family of care before and after bereavement. *Postgraduate Medicine Journal, 59*, 73-78.

Carey, P.J., Oberst, M.T., McCubbin, M.A., Hughes, S.H. (1991). Appraisal and caregiving burden in family members caring for patients receiving chemotherapy. *Oncology Nursing Forum, 18*, 1341-1348.

Cassileth, B.R., Chou, J.N. (1992). Psychosocial issues in the older patients with cancer. In Balducci, L., Lyman, G.H., & Ershler, W.B. (Eds.), *Geriatric Oncology*. New York: J.B. Lippincott Company, 311-319.

Chang, B, Brecht, M & Carter, P. (2001).Predictors of social support and caregiver outcome. *Women & health, 33*, 39-61.

Chang, V, Hwang,S & Feuerman, M.(2000).Validation of Edmonton Symptom Assessment Scale. *Cancer, 88*, 2164-71.

Chiou, C-P (1998). Development and psychometric assessment of the Physical Symptom Distress Scale. *Journal of Pain and Symptom Management, 16*,(2), 87-95.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). New York: Lawrence Erlbaum Assoc.

Conill, C, Verger, E, Henriquez, I, et al. (1997). Symptom prevalence in the last week of life. *Journal of Pain and Symptom Management, 14*, 328-31.

Daut RL, Cleeland, CS, Flaner, RC. Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. *Pain*. 1983; 17:197-210.

Dodd, M.J., Miaskowski, C, & Paul, S.M. (2001). Symptom clusters and their effect on the functional status of patients with cancer. *Oncology Nursing Forum, 28* (3), 465-470.

Edelstein, B, Kalish, KD, Drozdick, LW & McKee, DR (1999). Assessment of depression and bereavement in older adults. In Lichtenberg (Ed.).*Handbook of assessment in clinical gerontology*. (11-58). New York: John Wiley.

Edmonds, PM, Stuttaford, JM, Penny, J. Lynch, AM & Chamberlain, J. (1998). Do palliative care teams improve symptom control? Use of a Modified STAS as an evaluation tool. *Palliative Medicine, 12*, 345-51.

Ell, K., Nishimoto, R., Mantell, J., Hamovitch, M. (1988). Longitudinal analysis of psychosocial adaptation among family members of patients with cancer. *Journal of psychosomatic Research, 32*, 429-438.

Ellershaw,J, Peat,S, Boys, L.(1995)Assessing effectiveness of hospital palliative care team.*Palliative Medicine, 9*, 145-52.

Ellershaw, J, Smith, J, Overill, S, Walker, SE & Aldridge, BA. (2001). Care of the dying: Setting standards for symptom control in the last 48 hours of life. *Journal of Pain and Symptom Management, 21*(1), 12-17.

Emanuel, EJ & Emanual, LL. (1998). The promise of a good death. *The Lancet, 351*, 21-29.

Faries, JE, Stephens, D, goldsmith, DW, Phillips, KD, Orr, J. Systematic pain records and their impact on pain control. *Cancer Nursing, 14*, 306-313.

Fauschinbauer, TR, Devaul, RA & Zisook. (1977). Development of the Texas Inventory of Grief. *American Journal of Psychiatry, 134*, 696-98.

Ford, DE & Kamerow, DB. (1989). Epidemiologic study of sleep disturbances and psychiatric disorders. *Journal of American Medical Association, 262*, 1479-84.

George, L.K. Research design in end of Life Research: State of the Science. Presented at NIH Integrative Conference on End of Life research: focus on Aging, October 22, Bethesda, MD.

Given, C, Stommel, M, Given, B, Osuch, J, Kurtz, M. (1993). The influence of cancer patients' symptoms and functional states on patients' depression and family caregivers' reaction and depression. *Health Psychology, 12*, 277-285.

Grassi, L, Indelli, M, Marzola, M et al. (1996). Depressive symptoms and quality of life in home care assisted cancer patients. *Journal of Pain and Symptom Management, 12*(5), 300-307.

Grbich, C, Parker, D & Maddocks, I. (2001). The emotions and coping strategies of caregivers of family members with a terminal cancer. *Journal of Palliative Care, 17*(1), 30-36.

Hair, J. F. Jr. & Black, W. C. (2000). Cluster analysis. In L. G. Grimm & P. R. Yarnold (Eds.), Reading and understanding more multivariate statistics (pp. 147-205). Washington, DC: American Psychological Association.

Haley, W.E. (1997). The family caregiver's role in Alzheimer's disease. *Neurology, 48, S6*, S25-29.

Haley, W.E., Burton, A.M., LaMonde, L.A. & Schonwetter, R.S. (in press). Family caregiving for older cancer patients. In L. Balducci, G.H. Lyman, W.B. Ershler, & M. Extermann (Eds.), *Comprehensive Geriatric Oncology* (Second Edition). London: Harwood Academic Publishers.

*Haley, W.E., Allen, R., Reynolds, S., Chen, H., Burton, A., & Gallagher-Thompson, D. (2002). Family issues in end-of-life decision making and end-of-life care. American Behavioral Scientist, 46, 284-297.*

*Haley, W.E., LaMonde, L.A., Han, B., Burton, A.M., & Schonwetter, R. (in press). Predictors of depression and life satisfaction among spousal caregivers in hospice: Application of a stress process model. Journal of Palliative Medicine.*

Haley, W.E., LaMonde, L.A., Han, B., Narramore, S., & Schonwetter, R. (2001). Family caregiving in hospice: Effects on psychological and health functioning in spousal caregivers for patients with lung cancer or dementia. *The Hospice Journal, 15*, 1-18.

Haley, W.E., West, C.A.C., Wadley, V.G., Ford, G.R., White, F.A., Barrett, J.J., Harrell, L.E. & Roth, D.L. (1995). Psychogical, social and health impact of caregiving: A comparison of black and white dementia family caregivers and noncaregivers. *Psychology and Aging, 10*, 540-552.

*Hanson, L. C., Danis, M., & Garrett, J. (1997). What is wrong with end-of-life care? Opinions of bereaved family members. Journal of the American Geriatrics Society, 45, 1339-1344.*

Hermann, C. (2001a). The effectiveness of symptom management in hospice patients during the last seven days of life. *Journal of Hospice and Palliative Care Nursing, 3*(3), 88-96.

Hermann, C. (2001b). Spiritual needs of dying patients: A qualitative study. *Oncology Nursing Forum, 28*, 67-72.

Hileman, J.W., Lackey, N.R., Hassanein, R.S. (1992). Identifying the needs of home caregivers of patients with cancer. *Oncology Nursing Forum, 19*, 771-777.

Hinds, C. (1985). The needs of families who care for patients with cancer at home: Are we meeting them? *Journal of Advanced Nursing, 10*,575-581.

Holzheimer, A, McMillan, SC & Weitzner, M. (1999). Improving pain outcomes of hospice patients with cancer. *Oncology Nursing Forum, 26*(9), 1499-04.

Horowitz, MJ, Seigel, B., Holen, A, Bonnano, GA, Milbrath, C. & Stinson, C. (1997). Diagnostic criteria for complicated grief disorder. *American Journal of Psychiatry, 154*, 904-910.

Hunkeler, E.M., Meresman, J., Huargreaves, W., Fireman, B.H., Berman, W., Kirsch, A., Groebe, J., Braden, P., Getzell, M., Geigenbaum, P., Hurt, W., Peng, T. & Salzer, M. (2000). Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care. Archives of Family Medicine.

Hutchison, C. (1999). Social support: Factors to consider when designing studies that measure social support. *Journal of Advanced Nursing, 29*(6), 1520-26.

Irwin, M., Artin, K.H., & Oxmnan, M.N. (1999). Screening for depression in the older adult: Criterion validity of the 10-item Center for Epidemiological Studies Depression Scale. Archives of Internal Medicine, 159, 1701-1704.

Jacobs, D, Mazure, C & Prigerson, H. (2000). Diagnostic criteria for traumatic grief. *Death Studies, 24*, 185-99.

*Jang, Y., Haley, W.E., Small, B.J., & Mortimer, J.A. (in press). The role of health appraisal, mastery, and social resources in the associations between functional disability and depression in later life. The Gerontologist.*

*Jang, Y., Mortimer, J. A., Haley, W. E., Hnath-Chisolm, T. E., & Graves, A. B. (2002). Non-auditory determinants of self-perceived hearing problems among older adults: The role of stressful life conditions, neuroticism, and social resources. Journal of Gerontology: Medical Sciences, 57a, M466-M469.*

Jarvis, H, Burge, FI & Scott, CA (1996). Evaluation a palliative care program: Methodology and limitations. *Journal of Palliative Care, 12*(2), 23-33.

Johnson, J. (1988). Cancer: A family disruption. *Recent Results in Cancer Research, 108*, 306-310.

Kane, RA, Penrod, J. (1995). *Aging and family Caregiving Policy*. Newbury Park: Sage.

Katz, S., Ford, A., Maskowitch, R., et al. (1963). Studies of illness in the aged: The Index of ADL-A standardized measure of biological and psychological function. *Journal of the American Medical Association, 185*, 914-919.

Katzelnick, D.J., Simon, G.E., Pearson, S.D., Manning, W.G., Helstad, C.P., Henk, H.J., Cole, S.M., Lin, E.H., Taylor, L.H. & Kobak, K.A. (2000). Randomized trial of a depression management program in high utilizers of medical care. *Archives of Family Medicine, 9*, 345-351.

Kaunonen, M, Tarkka, M-T, Paunnonen, M & Laippala, P. (1999). Grief and social support after the death of a spouse. *Journal of Advanced Nursing, 30*(6), 1304-11.

Krause, N & Borawski, E. (1995). Social class differences:social support in older adults. *The Gerontologist, 35*, 498-508.

Kurtz, ME, Kurtz, JC, Given, CC & Given, B. (1996). Concordance of patient and caregiver symptom reports. *Cancer Practice, 4*(4), 185-190.

Laizner, A.M., Shegda, B., Yost, L.M., Barg, f.K., McCorkle, R. (1993). Needs of family caregivers of persons with cancer: A review. *Seminars in Oncology Nursing, 9*, 114-120.

Lee, K. (2001). Sleep and Fatigue. In Fitzpatrick, et al., (Eds.) *Annual Review of Nsg Research, 19*, 249-73.

Lewis, F.M. (1986). The impact of cancer on the family: A critical analysis of the research literature. *Patient Education and Counseling, 8*, 269-298.

Lewis, F.M. (1990). Strengthening family supports. *Cancer, 65*, 752-759.

Lewinsohn, P.M., Seeley, J.R., Roberts, R.E., & Allen, N.B. (1997). Center for Epidemiological Studies-Depression Scale (CES-D) as a screening instrument for depression among community-residing older adults. *Psychology and Aging, 12*, 277-287.

Lin, E, Katon, W, Simon, G, VonKorff, M, Bush, T, Rutter, C, Sanders, K & Walker, E (1997). Achieving guidelines for of treatment of depression in primary care: is physician education enough. Medical Care, 35, 831-842.

Littell, R. C., Milliken, G. A., Stroup, W. W., & Wolfinger, R. D. (1996). SAS system for mixed models. Cary, NC: SAS Institute

MacNeil, S.E. & Lichtenberg, P.A. (1999). Screening instruments and brief batteries for assessment of dementia. In P.A. Lichtenberg (Ed.)., *Handbook of assessment in clinical gerontology*. (pp. 417-441). New York: John Wiley.

McClement, S, Woodgate, R & Degner, L. (1997). Symptom distress in adult patients with cancer. *Cancer Nursing, 20*(4), 236-43.

McCorkle, R, Robinson, L, Nuamah, I, et al. (1998). The effects of home nursing care for patients during terminal illness on the bereaved's psychological distress. *Nursing Research, 47*, 2-10.

McCormack, JP, Li R, Zarowny D, (1993) Inadequate treatment of pain in ambulatory patients. *Clin J Pain 9*:279-283.

McMillan, SC (1996a). Pain and pain relief experienced by hospice patients with cancer. *Cancer Nursing, 19*, 298-307.

McMillan, SC (1996b). Quality of life of primary caregivers of hospice patients w. cancer. *Cancer Practice, 4*, 191-198.

McMillan, S.C. & Mahon, M. (1994a). A study of quality of life of hospice patients on admission and at week 3. *Cancer Nursing, 17*(1), 41-48.

McMillan, S.C. & Mahon, M. (1994b). Measuring quality of life in hospice patients using a newly developed Hospice Quality of Life Index. *Quality of Life Research, 3*, 437-447.

McMillan, S.C. & Mahon, M. (1994c). The impact of hospice services on the quality of life of primary caregivers. *Oncology Nursing Forum, 21*, 1189-1195.

McMillan, S.C. & Small, B. (2002, under editorial review). Symptom distress and quality of life in patients with cancer newly admitted to hospice homecare. *Oncology Nursing Forum.*

McMillan S.C. & Tittle, M. (1995). A descriptive study of the management of pain and pain-related side-effects in a cancer center and a hospice. *The Hospice Journal, 10*, 89-107.

McMillan, SC, Tittle, M, Hagan, S & Laughlin, J (2000a). Knowledge and attitudes of nurses in veterans hospitals about pain management in patients with cancer. *Oncology Nursing Forum, 27*(9), 1415-1423.

McMillan, SC, Tittle, M & Hagan, S (2000b). Management of pain and pain related symptoms in hospitalized veterans with cancer. *Cancer Nursing, 23*(5), 327-336.

McMillan, S & Weitzner, M (1998). Quality of life in cancer patients: A revised hospice index. *Cancer Practice, 6*, 282-8.

McMillan, S. & Williams, F. (1989). Validity & reliability of the CAS. *Cancer Nursing, 12*(3), 183-188.

Meyers, JL & Gray, LN. (2001). The relationship between family primary caregiver characteristics and satisfaction with hospice care, quality of life, and burden. *Oncology Nursing Forum, 28*(1), 73-82.

Morrison, RS, Siu, AL, Leipzig, RM, Cassel, CK & Meier, DE. (2000). The hard task of improving the quality of care at the end of life. *Archives of Internal Medicine, 160*(6), 743-47.

Ng, K. & von Gunten, CF (1998). Symptoms and attitudes of 100 consecutive patients admitted to an acute hospital palliative care unit. *Journal of Pain and symptom Management, 16*(5), 307-16.

Nijboer, C, Tempelaar, R, Triemstra, M. van den Bos, GAM, sanderman, R. (2001). The Role of Social and psychological resources in caregiving of cancer patients. *Cancer, 91*(5), 1029-1039.

Northouse, LL (1988). Social support in patients and husbands adjustment to breast cancer. *Nursing Res. 37*, 91-95.

Northouse, L, Peters-Golden, H. (1993).Cancer and family: Strategies to assist spouses. *Sem. Oncology Nsg, 9*. 74-82.

Owen, J.E., Goode, K.T., & Haley, W.E. (2001). End of life care and reactions to death in African-American and White family caregivers of relatives with Alzheimer's disease. *Omega, 43,* 349-361.

Oxman, A.D., Thomson, M.A., Davis, D.A. & Haynes, R.B. (1995). No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *Canadian Medical Association Journal, 153*(10), 1423-1431.

Oxman, T.E. (1998). Effective educational techniques for primary care providers: Application to the management of psychiatric disorders. *International Journal of Psychiatry in Medicine, 28*, 3-9.

Peruselli, C., Paci, E., Franceschi, P., Legori, T. & Mannuci, F. (1997). Outcome evaluation in a home palliative care service. *Journal of Pain and Symptom Management, 13*, 158-65.

Portenoy, RK, Thaler, HT, Kornblith, AB, et al. (1994). The Memorial Symptom Assessment Scale: An instrument for the evaluation of symptom prevalence, characteristics and distress. *European Journal of Cancer, 30A*,1326-1336.

Pond, C., Mant, A., Kehoe, L., Hewitt, H. & Brodaty, H. (1994). General practitioner diagnosis of depression and dementia in the elderly: Can academic detailing make a difference? *Family Practice, 11*, 141-147.

Prigerson, HG, Beirhals, AJ, Kasl, SV et al. (1997). Traumatic grief as a risk factor for mental and physical morbidity. *American Journal of Psychiatry, 154*, 616-623.

*Prigerson, H. O., & Jacobs, S. C. (2001). Traumatic grief as a distinct disorder: A rationale, consensus criteria, and a preliminary empirical test. In M. S. Stroebe & R. O. Hansson (Eds.), Handbook of bereavement research: Consequences, coping, and care (pp. 613-645). Washington, DC: American Psychological Association.*

Prigerson, H, Frank, E, Kasl, S et al. (1995a). Complicated grief and bereavement-related depression as distinct disorders: Preliminary empirical validation in elderly bereaved spouses. *American Journal of Psychiatry, 152*, 220-230.

Prigerson, HG, Maciejewski, CF, Reynolds, CF et al. (1995b). The Inventory of Complicated Grief: a scale to measure certain maladaptive symptoms of loss. *Psychiatry Research, 59*, 65-79.

Radloff, L. S. (1977). The CES-D scale: A self report depression scale for research in the general population. *Applied Psychological Measurements, 1*, 385-401.

Ramsey, P. H. (1982). Empirical power for procedures for comparing two groups on p variables. *Journal of Educational Statistics, 7*, 139-156.

Rhodes, VA, McDaniel, RW & Matthews, CA. (1998). Hospice patients' and nurses' perceptions of self-care deficits based on symptom experience. *Cancer Nursing, 21*(5), 312-19.

Ringdal, GI, Jordhoy, MS, Ringdal, K & Kaasa, S. (2001). The first year of grief and bereavement in close family members who have died of cancer. *Palliative Medicine, 15*, 91-95.

Rossi, FS, Zotti, AM, Zaccaria, S & Donner, CF (2001. Caregiver strain associated with tracheostomy in chronic respiratory failure. *Chest, 119*(5), 1498-1502.

Rost, K., Nutting, P., Smith, J., Werner, J. & Duan, N. (2001). Improving depression outcomes in community primary care practice: A randomized trial of the QUEST intervention. *Journal of General Internal Medicine, 16*, 143-149.

Sabo, D. (1990). Men, death and anxiety: Critical feminist interpretations of adjustment to mastectomy. In Clark, Fritz, Rieder (Eds.). *Clinical Sociological Perspectives on Illness and Loss.* Philadelphia: Charles Press, 71-84.

Sales, E. (1991). Psychosocial impact of the phase of cancer on the family. *Journal of Psychosocial Oncology, 9*, 1-9.

*Schafer, J. L. & Olson, M. K. (1998). Multiple imputation for multivariate missing-data problems: A data analyst's perspective. Multivariate Behavioral Research, 33, 545-571.*

Schonwetter, R.S., Teasdale, T.A., Storey, P., Luchi, R.J. (1990). Estimation of survival time in terminal cancer patients: An impedance to hospice admissions. *The Hospice Journal, 6*(4), 65-79.

*Schulz, R., Newsom, J. T., Fleissner, K., DeCamp, A. R., & Nieboer, A. P. (1997). The effects of bereavement after family caregiving. Aging and Mental Health, 1, 269-282.*

Schumacher, K.L., Dodd, M.J. & Paul, S.M. (1993). The stress process in family caregivers of persons receiving chemotherapy. *Research in Nursing and Health, 16*, 395-404.

Seigel, D. & Lopez, J. (1997). Trends in antihypertensive drug use in the United States: Do the JNCV Recommendations affect prescribing? *JAMA, 278*, 1745-1748.

Simon, G.E. & Ludman, E. (2000a). Lessons from recent research on depression in primary care. *Epidemiologia e Psichiatria Sociale, 9*(3), 145-151.

Simon, G.E., VonKorff, M., Rutter, C. & Wagner, E. (2000b). Randomised trial of monitoring, feedback, and management of care by telephone to improve treatment of depression in primary care. *BMJ 320*(7234), 550-554.

Skilbeck, J, Mott, L, Page, H. et al. (1998). Palliative care in chronic obstructive pulmonary disease: A needs assessment. *Journal of Palliative Medicine, 12*, 245-54.

Sloan, PA, Vandervere, BL, Snapp, JS, Johnson, M, & Sloan, DA. (1999). Cancer pain assessment and management recommendations by hospice nurses. *Journal of Pain and Symptom Management, 18*(2), 103-110.

*Soon, A.J., & Levine, M. (2002). Screening for depression in patients in long-term care facilities: A randomized controlled trial of physician response. Journal of the American Geriatrics Society, 50, 1092-1099.*

Sorenson, HM. (2000). Dyspnea Assessment. *Respiratory Care, 45*(11), 1331-1341.

Soumerai, S.B. (1998). Principles and uses of academic detailing to improve the management of psychiatric disorders. *International Journal of Psychiatry in Medicine, 28*(1), 81-96.

Stetz, KM (1987). Caregiving demands during advanced cancer: Spouse's needs. *Cancer Nursing, 10*, 260-268.

Stetz, KM & Brown, M (1997). Taking care: Caregiving to persons with cancer and AIDS. *Cancer Nursing, 20*, 12-22.

Stevens, J. (1986). *Applied multivariate statistics for the social sciences* (3rd ed.).Mahwah, NJ: Lawrence Erlbaum Assoc.

Stewart, A, Hays, R, & Ware, J. (1994). The medical outcomes study short-form general health survey. In J.E. Mezzich et al.(Eds.). *Psychiatric epidemiology: Assessment concepts & methods* (368-382). Baltimore: Johns Hopkins Press.

Syrjala, LK & Chapko, ME (1995). Evidence for a psychosocial model of cancer treatment-related pain. *Pain, 61*, 69-79.

Tabachnick, B. G. & Fidell, L. S. (2001). *Using multivariate statistics* (4th ed.). New York, NY: Harper Collins.

Tennstedt, S.L. (2001). Discussion: Research Design in end of life research. Presented at NIH Integrative Conference on End of Life Research: Focus on Aging, October 22, Bethesda, MD.

Thielemann, PA. (2001). Coping style and social support effects on depression in spousal caregivers of patients with advanced lung cancer. Unpublished doctoral dissertation, University of South Florida, College of Nursing.

Thomson, J(2000).The place of spiritual well-being in hospice patients' quality of life. *The Hospice Journal, 15*(2), 13-27.

*Tilden V. P., Tolle, S. W., Nelson, C. A., & Fields J. (2001). Family decision-making to withdraw life-sustaining treatments from hospitalized patients. Nursing Research, 50, 105-115.*

Tishelman,C, Degner, L. (2000). Measuring symptom distress in patients with lung cancer. *Cancer Nursing, 23*(2), 83-90.

Tittle, M. & McMillan, S.C. (1994). Pain and pain-related side effects in an ICU and on a surgival unit: Nurses' management. *American Journal of Critical Care, 3*, 25-30.

Toseland, R.W., Blanchard, C.G., McCallion, P. (1995). A problem solving intervention for caregivers of cancer patients. *Social Sciences and Medicine, 40*, 517-528.

Turvey, CL, Carney, C, Arndt, S et al. (1999). Conjugal loss and syndromal depression in a sample of elders aged 70 years and older. *American Journal of Psychiatry, 156*(10), 1596-1601.

Vachon, MLS, Lyall, WAL, Rogers, J. et al. (1980). A controlled study of self-help interventions for widows. *American Journal of Psychiatry, 137*, 1380-84.

Walsh, D, Donnelly, S, Rybicki, L. (2000). The symptoms of advanced cancer: Relationship to age, gender, and performance status in 1,000 patients. *Supportive Care in Cancer, 8*, 175-179.

Ware, J.E., Kosinski, M., Keller, S.D. (1994). *SF-36 Physical and Mental Health Summary Scales: A Users's Manual.* Boston: The Health Institute.

Ware, J.E., Snow, K.K., Kosinski, M., Gandek, B. (1993). *SF-36 Health Survey Manual and Interpretation Guide.* Boston: The Health Institute, New England Medical Center.

Weingarten, S. (1997).Practice guidelines & prediction rules subject to careful clinical testing. *JAMA, 277*, 1977-1978.

Weitzner, M., Meyers, C. Steinbruecker, S, Jacobsen, P. (1996b). Family caregiver quality of life (QOL): A preliminary report of a validational study. *Supportive Care in Cancer, 4*, 232.

Weitzner, M., Meyers, C., Steinbruecker, S., Saleeba, A. (1995b). Family caregiver quality of life (QOL): Comparing patient's vs. caregiver's views. *Proceedings of the American Society of Clinical Oncology, 14*(abst. 1642).

Weitzner, M., Meyers, C., Steinbruecker, S., Saleeba, A. & Sandifer, SD (1997a). Developing a caregiver quality of life instrument: Preliminary steps. *Cancer Practice, 5*, 25-31.

Weitzner, M., Moody, L. & McMillan, S.C. (1997b). Symptom management issues in hospice care. *American Journal of Hospice and Palliative Care, 14*, 190-195.

Wells, K, Sherbourne, C, Schoenbaum, M., et al. (2000). Impact of disseminating quality improvement programs for depression in primary care. *JAMA, 283*, 212-220.

Zarit, S & Zarit, J. (1998). Mental disorders in older adults: Fundamentals of assessment and treatment. New York: Guilford Press.