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Pain and quality of life in cancer patients enrolled in a hospice program

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Pain and Quality of Life in Cancer Patients
Enrolled in a Hospice Program

A Thesis
Presented to
The Faculty of the School of Nursing
San Jose State University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science

by
Cindy Parks
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ABSTRACT

PAIN AND QUALITY OF LIFE IN CANCER PATIENTS ENROLLED IN A HOSPICE PROGRAM

by Cindy A. Parks

This research study examined pain and quality of life in cancer patients enrolled in a hospice program. Pain has been identified as the most prevalent and disturbing symptom experienced by hospice patients. Utilizing a descriptive study design, data were collected regarding pain in a sample of hospice patients (N= 11).

The Brief Pain Inventory was utilized to measure the most severe pain score. The City of Hope Quality of Life Scale was used to assess quality of life concerns. Patients were most satisfied with the psychological and spiritual aspects of quality of life. A correlational analysis was performed and no statistically significant relationship was found between the most severe pain score and quality of life. No evidence of a trend in the data was observed. Review of the findings generated the recommendations to develop interventions aimed at enhancing patients' social support and managing physical symptoms.

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May God bless you all.

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Chapter 1
INTRODUCTION
Background

Hospice care provides an environment that serves the needs of the terminally ill. It is not a place; however, some hospices do exist separately from the home setting. Hospice is a philosophy that stresses quality of life for the terminally ill (Kines & Levine, 1995). It is a philosophy that encompasses such ideals as comfort care and palliative care. These terms are used synonymously in the literature with regard to hospice care.

The hospice movement has grown partially in response to the dissatisfaction with traditional medical care in treating the terminally ill (Maddocks, 1990). With the advances in modern technology in the traditional acute and curative care system, many health care providers and subscribers feel little attention has been given to the care of terminally ill patients (i.e., patients who will no longer benefit from aggressive treatments and interventions or who decline to pursue such avenues). The increase in the number of deaths from cancer in populations with more aged people, the inadequate attention paid by conventional medicine to the basic needs of dying patients, and new

insights and techniques for managing and controlling symptoms effectively in terminal illness have contributed to the social movement of hospice care (Maddocks, 1990). A deeper spiritual meaning to life and death has evolved which confronts the dying with a calm sense of confidence that has historically been lacking in Western medicine.

In a hospice program, the emphasis is on palliative, not curative, care (Plumb & Ogle, 1992). The goal of hospice care is to improve the quality of the patient's life and death rather than to extend the length of life (Berry & Lynn, 1993). This is achieved through pain and symptom management as the hospice team strives to improve the quality of life of the dying patient. Therefore, the central focus of the hospice team is on comfort measures and the promotion of optimal quality of life as a terminal outcome for patient care.

The principles of hospice care further define the philosophy of the system. The patient and the patient's family, or caregivers, are considered the unit of hospice care because the caregiver's involvement in the plan of care is essential. Hospice acknowledges friends, neighbors, and significant others of all types to be part of the unit of care; therefore, everyone is integrated into the care plan. The interdisciplinary team approach considers the values, preferences, ideals, and wishes of the terminally ill

patient and that person's family in planning and providing services. A unique variety of physiologic, psychologic, social, spiritual, and economic problems and needs arise that are each addressed on an individualized basis.

Supportive care is provided to all participants with an emphasis on continuity of care, coordination of resources, and advocacy for both patient and family (Maddocks, 1990).

Cancer is diagnosed in over one million Americans every year, causing 1 of every 10 reported deaths worldwide (Stjernsward & Tech, 1988). Approximately 8 million Americans have cancer or a history of cancer; half of these diagnoses have been made within the last 5 years. According to the American Cancer Society (1994), the prevalence of cancer in the United States has increased causing 1 of 5 deaths, about 1,400 per day.

Pain has been identified as one of the greatest stressors for terminally ill clients, and pain control is one of the primary goals of hospice services (Kines & Levine, 1995). On average, 75% of patients with advanced cancer have pain. The World Health Organization (WHO) estimates that 3.5 million people suffer from cancer related pain each day (WHO, 1986). Of those cancer patients with pain, 40-50% report their pain as moderate to severe, while 25-30% describe their pain as very severe (Bonica, 1990). Approximately 90% of cancer pain can be controlled through

use of appropriate analgesics, yet a statement from the National Cancer Institute Workshop on Cancer Pain (1990) indicated that the "under treatment of pain and other symptoms of cancer is a serious and neglected public health problem" (as cited in U.S. Department of Health & Human Services, 1990). The Workshop concluded that "every patient with cancer should have the expectation of pain control as an integral aspect of his/her care throughout the course of the disease" (as cited in U.S. Department of Health & Human Services, 1990).

Because cancer pain control is a problem of international concern, the WHO has recommended that every nation give high priority to establishing a cancer relief policy (Ad Hoc Committee on Cancer Pain of the American Society of Clinical Oncology, 1992). With pain control identified as the cornerstone of hospice care, it is appropriate to study pain in hospice patients with cancer and how pain affects their quality of life.

Quality of life is a concept integral to hospice care. The "high tech" era of the 1980s when quantity of life was stressed has led to a shift toward quality of life. Unrelieved pain causes unrelieved and unnecessary suffering. Because pain impacts an individual both physically and emotionally, the overall effect of cancer pain can be devastating (Ferrell, Taylor, Sattler, Fowler, & Cheyney,

1993). Cancer patients with pain often believe that pain means the inevitable progression of a feared, destructive disease. Uncontrolled pain further prevents people from enjoying recreational leisure activities, from working productively, and from relating to family, friends, and society in general (Ferrell, Grant, Chan, Ahn, & Ferrell, 1995). Therefore, pain control warrants a high priority in all patients and especially terminally ill cancer patients.

The continued growth of the hospice movement in response to changes in the direction of care from a curative, quantity of life model to a caring, quality of life direction has opened the door for research into pain and its effect on quality of life in cancer patients. Knowledge of the relationship between pain and quality of life aids the continued research into this area by providing tools, interventions, and strategies for health care providers to implement in their practice. The development of such standards of care can improve the outcomes for cancer patients.

The Background Problem and Research Topic

"Pain has been described as an experience that overwhelms the individual and consumes every aspect of life. Clinicians, researchers, and certainly patients would agree that pain is a major influence on overall quality of life" (Ferrell, Grant, Padilla, Vemuri, & Rhiner, 1991, p.9). In

today's health care arena, managed care and outcome oriented goals are heavily emphasized. Therefore, in order to further the impetus for the growth of the hospice movement, by improving care and patient outcomes, continued research and study are warranted.

The research topic is: Pain and quality of life in cancer patients enrolled in a hospice program. The study assumes that understanding and knowledge of any relationship between pain and quality of life can improve the practice of health care providers serving the terminally ill as well as improve the outcomes for these clients.

Definition of Terms

For the purpose of this study, the following definitions apply: (Sources are cited when applicable otherwise definitions were developed by the researcher).

1. Comfort Care is supportive care of an individual, both physical and emotional that does not attempt to prolong or sustain one's life.

2. Palliative care is "treatment which increases well-being and relieves symptoms but does not effect cure" (Maddocks, 1990, p.535).

3. Quality of life is "the prevention and alleviation of physical and mental suffering, and the presence of a supportive network of informal relationships" (Morris, Suissa, Sherwood, Wright, & Greer, 1986, p.47).

4. Pain is a multidimensional phenomenon consisting of physiologic, sensory, affective, cognitive, behavioral, and sociocultural components. These six components are interrelated and influence one another, thus making pain a multidimensional experience for the individual (Yeager, Miaskowski, Dibble, & Wallhagen, 1995).

5. Well-being is a positive state of physical, mental, and emotional health.

6. Terminally ill is a state of illness for which there is no known cure and which results in death.

Assumptions

The underlying assumption of this study is that pain has a great impact on terminally ill patients, especially those suffering from cancer. Terminally ill patients experience a wide variety of symptoms as their bodies deteriorate and prepare for death. Pain has been identified as the most common and most highly feared symptom experienced by terminally ill patients (Rhymes, 1991a). As hospice programs strive to alleviate symptoms and help terminally ill patients achieve a high level of satisfaction and quality to their remaining lives, adequate pain management is a goal not only for the patient but also for the health care providers.

It is assumed that there is a relationship between pain and quality of life. Pain has been associated with physical

symptoms such as fatigue, nausea, and appetite disturbances, and psychological symptoms such as fear, anxiety, and depression. Quality of life has been associated with these physical and psychosocial symptoms (Padilla et al., 1983).

Summary

The hospice movement has evolved from dissatisfaction with traditional medical treatment of terminally ill patients. With the incidence of cancer increasing and pain identified as the most prevalent problem in cancer patients, the management of pain is of crucial importance. The emphasis of hospice services is on palliative care for the terminally ill as the hospice team works with the patient and family to enhance quality of life for the patient through pain and symptom management. The intent of this study is to describe the nature of the relationship between pain and quality of life in terminally ill cancer patients as well as any relationship between these variables. The goal is to improve the outcomes for this population.

Chapter Two

LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

In this chapter, a literature review of hospice, pain, and quality of life research is presented. The study's conceptual framework is also described.

Literature Review

Hospice

The hospice movement has been an important aspect in the development and advancement of palliative medicine. However, few research studies have been conducted in the area of hospice because there is not a long history of research and exploration into this newly developed specialty area (Maddocks, 1990). The literature on hospice care predominately revolved around journal articles which provided definitions of the philosophy of care, and descriptions of the services, organizational structure, funding, and eligibility criteria.

Until the 20th century many patients were allowed to die at home without the need for a special program (Rhymes, 1991b). The home was considered an appropriate and acceptable place to be cared for as medicine could not cure many serious illnesses. Therefore, terminally ill patients preferred to remain in the familiar surroundings of their homes, cared for by their families and friends. However, many Americans today die in institutions after prolonged,

painful efforts have been made to extend life, and in some cases, their suffering. Rhymes indicated that these efforts were appropriate in some instances, yet they were unrealistic, useless, and painful in the terminally ill. The hospice movement was begun in part due to the over treatment of terminally ill patients. The goal of this movement was to allow terminally ill patients to die at home, in peace, and without undue pain and suffering. Henceforth, this movement has evolved from a "grass-roots" volunteer experience to a Medicare regulated and funded program. Rhymes further discussed the ethical and legal aspects of hospice care emphasizing the inevitability of death and the importance of comfort and dignity for the patient.

Hospice is defined in terms of the services provided and as a philosophy of care by Plumb & Ogle (1992). Hospice care has evolved through history as a house of rest and entertainment for travelers. This historical image, was compared to the current concept of "a place for the terminally ill individual to rest on the journey from one life to the next" (Plumb & Ogle, 1992, p.811). Patient education, pain and symptom assessment and management, and the psychological problems that surround death and dying require a multi-disciplinary approach to hospice care.

Corless (1994) discussed hospice as a political movement which lead to the legitimizing of palliative care for the terminally ill. Symptom control, specifically pain management, was important, and further research into symptom control and quality of life was recommended.

Mor (1986) examined hospice outcomes in an attempt to identify what should be measured that would reflect the goals and values of the hospice care model. In this study, 1,457 terminally ill cancer patients were interviewed at the point of entry into a hospice program, 7 days later and every 14 days until death. These data measured patients' psychosocial status, quality of life, and physical conditions. The findings indicated the difficulty in assessing psychosocial status when the effects of distressing symptoms, fatigue, and medications hindered the patients' ability to respond. The study found that attention to the prevention of pain and symptom control was an area that should be emphasized because it has a great impact upon the lives of patients.

The specialty of hospice care is apparent throughout these articles. Yet, the "newness" of the hospice concept and philosophy is evident by the limited amount of research studies in the area of hospice care. This indicated a need for further research and study into this rapidly growing area of health care.

Pain

The research on pain is vast (Ferrell, Wisdom, Wenzl, & Brown, 1989). With the advent of new treatments and the expansion of technology, pain has received considerable attention, especially pain related to cancer.

According to Berry and Lynn (1993), pain management has historically received little attention in the education of health professionals. This has resulted in the widespread problem that the needs of patients with severe pain frequently go unmet. In order to ellicit change in the thinking and behavior of health care professionals, education must be offered and the establishment of standards for pain and symptom management must be instituted and followed if a significant change is to occur.

Due to the widespread awareness of cancer pain, the WHO (1990) has encouraged the establishment of a cancer pain relief policy. This has been given high priority which, in turn, has led to research directed toward defining and evaluating current pain management methods.

Many of these efforts have led to the education of health professionals in appropriate analgesic use and the need for individualized pain management regimens (Ferrell, Rhiner, & Ferrell, 1993). A pain education program was developed and implemented for 40 cancer patients and their family caregivers. The program demonstrated that both

cancer patients and their caregivers benefited from an educational program for the relief of cancer pain.

The meaning of pain among 30 terminally ill cancer patients, caregivers and home care nurses was studied by Ferrell, Taylor et al., 1993). Loss and change were identified and associated with the pain experience. Lifestyles and daily routines needed to be altered in order to accommodate pain. Pain went beyond the mere physical experience and took on a complex individualized meaning for each patient despite the commonalties that existed among the patients. In order to achieve the most desirable outcome for a patient, a thorough assessment of the meaning of pain, as identified by the patient, proved to be important. Appropriate interventions were identified and utilized based on the assessment findings. In order to effectively manage pain and suffering, an understanding of the meaning of pain from the patient's perspective and the nurse's perspective was needed to improve the outcomes for the patient.

In Strang's (1992) study, cancer patients with pain (N = 93) were surveyed and the results indicated that pain was a major source of anxiety and depression and had a profound impact on the general well-being of the patient. As anxiety and depression increased, the pain threshold lowered creating a vicious cycle. Even temporary pain relief was found to benefit these patients. Unrelieved pain

affected many dimensions of quality of life, such as the physical, emotional, intellectual, and social dimensions. Strang therefore recommended that pain management and treatment should be considered a high priority in palliative care.

The literature supported the viewpoint that pain was often mismanaged and uncontrolled. According to Hagen, Young, and MacDonald (1995), under treatment occurred frequently despite the availability of pain assessment techniques, potent analgesics, and algorithms for interventions. Health care providers, as well as caregivers, needed more education on how to adequately manage cancer related pain. This lack of knowledge and understanding was particularly significant in view of the current trend toward outpatient care and home hospice settings.

The Hagen et al. (1995) report was based on the results of a symposium on improving the standards of care for patients with cancer. Participants included experts on control of cancer pain, cancer patients, and representatives from different regulatory agencies. Recommendations from the symposium were: (a) documentation of cancer pain treatment and outcomes is required for health care institutions seeking accreditation; (b) care facilities that treat cancer patients must have expert, multidisciplinary

programs for pain control with adequate psychosocial support for patients suffering from cancer pain; (c) further research and public education campaigns should be conducted to increase public awareness and knowledge of cancer pain; and (d) a continuing process of review of pain research protocols was suggested. It was further recommended that physicians play a pivotal role in the treatment of cancer pain and in eliciting the necessary changes to effectively manage cancer pain (Hagen et al., 1995).

In a retrospective study of 76 hospice patients affected by pain, patterns of pain, analgesic use, and barriers to pain control were studied (Morgan, Lindley, & Berry, 1994). Lifestyle changes in response to pain were investigated. Patient fear and resistance were identified as barriers to adequate pain control. Fear of side effects and dependence was identified by the caregivers in the study. Many patients and their families felt that pain and the need for analgesia was a sign of weakness or that it signified a worsening of their condition. The patients therefore remained silent in their suffering.

Additional factors identified by the Morgan et al. (1994) study have contributed to "the recognition that the basis for under treatment of cancer pain is multifactorial in nature, which has prompted complex strategies to address some of the issues surrounding cancer pain control" (p.18).

Health professionals' lack of knowledge regarding the pharmacology and appropriate dosages of analgesia, physician fear of promoting tolerance and addiction among patients, and fear of liability due to stringent governmental regulation over the availability of opioid drugs were identified as additional barriers to adequate pain management.

Pain control in hospice patients was found to be compromised by concerns about overuse of drugs, especially narcotics. McCormack et al. (1992) conducted a retrospective chart audit on the medical records of cancer patients ($N = 100$) receiving hospice care at home. Individual variability was demonstrated with marked variation in the amount of analgesia used. This study stressed the importance of assessing the patient's response to analgesia as a factor in determining dosing and route of administration.

The significance of improved pain management was summarized by Spross (1985) who stated, "I believe we must apply the science and art of pain relief as though a life depended on it. Certainly the quality of life does" (p.23).

In a descriptive study of 75 cancer patients with chronic pain, Ferrell and Schneider (1988) identified pain management as having critical importance as it was a crucial factor in determining functional ability and quality of

life. This study compared and evaluated the pain experience and management of pain in the hospital versus pain at home 7 to 10 days after discharge. The findings from this study suggested that pain is not effectively managed by cancer patients at home. A variety of reasons were suggested such as fears and misconceptions regarding pain management. Concerns of addiction, tolerance, and the use of routine analgesia were identified. The holistic approach of palliative care in treating pain was recommended for the home care setting.

According to Lee, McPherson, and Zuckerman (1992), pain occurred in at least 80% of terminally ill cancer patients. In this study, 11 hospice patient charts were reviewed for adequacy of documentation of pain status on initial and all subsequent follow-up visits. The results indicated a need for improvement of pain status documentation and a standardized documentation process.

In a retrospective study of terminally ill cancer patients ($N = 96$), pain control and management were studied (Austin, Cody, Evers, Hefferin, & Krasnow, 1986). Less than 50% of the patients were compliant with their pain medication regimens. These findings demonstrated the enormity and complexity of the problem of pain control in home hospice care cancer patients. It was recommended that the approach to pain control be individualized based on the

patients' perspectives and assessment of their own pain experiences.

Quality of Life

Quality of life has been examined from different perspectives. Quality of life assessment has emerged as an outcome variable to be measured in cancer treatment and clinical trials (Ferrell, Wisdom, & Wenzl, 1989). Cancer clinical trials have traditionally looked at duration of survival, retardation of the disease process, and control of major physical symptoms (Aaronson, Bullinger, & Ahmedzai, 1988). However, with the recent attention focused on quality of life versus quantity of life, the end points or outcomes of treatments are viewed differently. No longer is it enough to look merely at survival rate. Therefore, new tools have been developed and research studies conducted in order to attempt to define and measure quality of life.

Aaronson et al. (1988) developed a modular approach to quality of life assessment to be used in cancer clinical trials. This approach broke down the construct of quality of life into its component parts for measurement. The following quality of life dimensions were identified from their research study of 750 nonresectable lung cancer patients: (a) functional status, (b) physical symptoms common to many malignancies and/or treatment modalities, (c) psychological distress, (d) social interaction,

(e) financial/economic impact, (f) perceived health status, and (g) overall quality of life. The development of this modular approach to quality of life assessment contributed to the existing literature on quality of life assessment and further provided attributes that define the content domain of quality of life.

McMillan and Mahon (1994a, 1994b, 1994c) conducted three research studies of hospice patients and their quality of life. In the first study by McMillan and Mahon (1994a), the effects of hospice services on the quality of life of the caregiver were evaluated. Also, the reliability and validity of a newly revised instrument were tested. The sample consisted of 68 caregivers of cancer patients enrolled in a hospice program and 62 noncaregiving adults. The Caregiver Quality of Life Index (CQLI) and the Hospice Quality of Life Index (HQLI), created by the researchers, were administered to the subjects on admission into the hospice program and at 4 weeks post admission. The results suggested that caregivers of terminally ill cancer patients enrolled in a hospice program were able to maintain their quality of life. Caregiver quality of life did appear to be related to the caregiver's perception of the patient's quality of life indicating a need to assess both the patient's and caregiver's needs. In addition, the study

provided evidence of the reliability and validity of the CQLI to evaluate the quality of life of hospice caregivers.

The second research study by McMillan and Mahon (1994b) was part of a larger project involving the study of patients and caregivers. The purpose of this portion of their study was to evaluate the effects of hospice services on the quality of life of primary caregivers and to evaluate the reliability and validity of a newly developed Hospice Quality of Life Index (HQLI). Sixty-eight patient/caregiver pairs from a hospice program were asked to fill out the HQLI at admission and after 3 weeks of services. Hospice experts evaluated the items on the tool for content validity. "The content validity index (0.83) and the alpha coefficients (α = 0.87 and 0.83) supported the validity and reliability of the HQLI" (McMillan & Mahon, 1994b, p.437). The authors suggested the need for further study because this was a newly developed tool.

The third study evaluated the quality of life of hospice patients on admission and after 3 weeks of hospice care (McMillan & Mahon, 1994c). The sample was composed of 31 patient/caregiver pairs. The Sendera Quality of Life Index (SQLI) was given to both patients and caregivers at admission and at 3 weeks after hospice services were started. The findings indicated that hospice services may have a positive influence on some aspects of quality of life

for some patients as they neared death. The study also indicated that pain needed continual assessment and monitoring. Recommendations for an instrument that is specifically designed for hospice patients were made as well as a method for data collection from patients who were debilitated so that the sample could be more representative of the population.

Another McMillan (1996) research study evaluated the quality of life for 118 cancer patients receiving hospice care. The factors that affect the quality of life of cancer patients were explored using the newly refined HQLI. The HQLI was administered to the patients and their caregivers within 24 hours of admission and after 3 weeks of hospice care. The results indicated that quality of life remained stable during the study period when measured by the tool. The reliability and validity of this tool were further confirmed. Factor analysis confirmed four subscales: (a) physical/functional well-being, (b) emotional well-being, (c) social well-being, and (d) financial well-being. The alpha reliability coefficients for the HQLI were considered high. Alphas were the same at admission and after 3 weeks of hospice care with an $\alpha = 0.88$ and a $p = .001$ for the total scale. Overall, the findings revealed the quality of life of hospice patients to be relatively stable over the course of 3 weeks of care, thereby,

supporting the outcomes of care in these two hospices. Pain relief was found to be far from adequate in this study, and given that comfort is a main goal of hospice care, this finding suggested the need for greater focus on pain management.

A number of studies have developed tools to measure quality of life in patients managing cancer pain. Ferrell, Wisdom, Wenzel, and Brown (1989) conducted a study to assess the reliability and validity of the City of Hope Medical Center Quality of Life Survey, a tool designed to evaluate quality of life as a measure of pain management outcomes. Three groups were studied, each consisting of 50 subjects: (a) cancer patients with pain, (b) cancer patients without pain, and (c) healthy subjects without cancer. The statistical analysis of the results indicated that the instrument had test-retest reliability, internal consistency, and interrater reliability, as well as content and construct validity for some of the major factors. The major quality of life constructs represented in this study were: (a) psychological well-being, (b) physical well-being, (c) general and specific symptom control, and (d) degree of social support. These results were part of a four phase project with the goal of improved pain management for cancer patients at home. Further revision of the instrument was recommended and suggestions for further testing were made.

Ferrans (1990) conducted a study which developed the Quality of Life Index (QLI) to measure the quality of life for patients with cancer ($N = 111$). The construct of quality of life was depicted with four domains: (a) health and functioning, (b) socioeconomic, (c) psychological/spiritual, and (d) family. Each domain was further broken down and conceptualized as a multidimensional construct. Reliability, validity, and internal consistency reliability were supported.

Pain and Quality of Life

In a study of 85 caregivers for cancer patients, with and without pain, the quality of life for the cancer patients with pain was significantly worse than that of cancer patients without pain (Ferrell, Rhiner, Cohen, & Grant, 1991). The pain experience impacted the role functions and relationships of the caregiver as well as the patient, interrupting the physical and psychological well-being of both.

A series of studies examined the relationship between the concepts of pain and quality of life (Ferrell, 1995). Through this extensive work, the relationship between pain and quality of life was validated and expanded upon.

Ferrell participated in a four phase research study to explore pain management as it exists in the home. In the first phase by Ferrell and Schneider (1988), 75 cancer

patients with chronic pain were interviewed in the hospital and 7-10 days post discharge to compare responses on the McGill-Melzack Pain Questionnaire (MPQ) and the Pain Experience Measure. The findings indicated that 70% of the patients experienced more intensive pain at home. This suggested that pain was not effectively managed by cancer patients at home and that pain management was critical to functional ability (Ferrell & Schneider, 1988).

In the second phase of this four-phase study, Ferrell, Wisdom, and Wenzl (1989) refined a quality of life tool for use in measuring pain management outcomes. In this study, 50 subjects were surveyed including cancer patients with pain, cancer patients without pain, and healthy subjects. Four instruments were used to evaluate the quality of life of patients in pain and to provide scales for concurrent validity. The demographic, pain, and quality of life tools were developed by the researchers (Ferrell & Schneider, 1988). The first tool was a demographic data tool used to describe the study sample. The second was a pain assessment tool developed to describe the patients' pain and their pain management strategy. The third was the Karnofsky Performance Status Scale used for the establishment of concurrent validity, and the fourth instrument was the primary focus of this study, the City of Hope Medical Center Quality of Life Survey. The results indicated that the

instrument had test-retest reliability, internal consistency, and interrater reliability (Ferrell, Wisdom, & Wenzl, 1989). The correlations indicated a moderate to strong relationship between quality of life and measures of pain and functional status. The researchers concluded that through the use of quality of life as a measure of outcome in pain research, a given treatment can be evaluated not only with regard to its effect on pain, but also with regard to its effect on the total individual. Like pain, quality of life was an individual experience that could best be evaluated by the person experiencing it.

In the third phase of the four phase study, the impact of pain on quality of life was validated as was the reliability and validity of the City of Hope Medical Center Quality of Life Instrument (Ferrell, Wisdom, Wenzl, & Brown, 1989). In this study, 83 cancer patients with pain were randomly assigned in a clinical trial of short-acting analgesia versus long-acting analgesia. Data were collected every 2 weeks for a 6 week period. The tool was found to be internally consistent ($\alpha = 0.82$) and demonstrated construct validity and content validity (Ferrell, Wisdom, Wenzl, & Brown, 1989). An improvement in pain intensity and pain distress was experienced with the use of the controlled-release analgesic, MS Contin, versus the short-acting analgesics. Findings indicated the important

relationship between pain, functional status, and overall quality of life. This study suggested that through appropriate pain management with pain therapies such as controlled-released analgesia, tremendous opportunities existed to influence and enhance quality of life. In addition, this study contributed to the conceptual development of quality of life. The fourth phase of this research program is being planned to test interventions to improve pain management for patients in the home setting.

In a study of 41 cancer patients with pain, Padilla, Ferrell, Grant, & Rhiner, (1990) identified attributes that define the content domain of quality of life. Subjective data were collected about the relationship between pain and quality of life. Four open-ended questions were asked in the interview about quality of life. The questions asked were: (a) What does the term quality of life mean to you?, (b) What contributes to a good quality of life for you?, (c) What contributes to a poor or bad quality of life for you?, and (d) How does pain influence your quality of life? From this study, three categories of attributes were revealed that encompassed the quality of life domain. The categories were: (a) physical well-being, (b) psychological well-being, and (c) intrapersonal well-being. The investigators presumed that the content domain of quality of life expressed in this sample applied to other cancer

patients with pain, and that the content domain may expand as future studies were undertaken to include cancer patients with other problems (Padilla et al., 1990).

In a prospective study of pain with 84 cancer patients, pain and its influence on physical, emotional, cognitive, and social quality of life were studied (Strang & Ovarner, 1990). The patients ranged in age from 32-82 years old; 47 were female and 37 were males. The most common types of malignancies were breast cancer ($n = 20$), prostate cancer ($n = 11$), and lung cancer ($n = 10$). The mean intensity of pain was 3.9 indicating a mild level of pain with a possible range of 1-9. Of the patients surveyed, 73% experienced two or more different types of pain. "Anxiety and depressive feelings correlated with the intensity of pain ($p = 0.0003$ and ($p = 0.0004$)" (Strang & Ovarner, 1990, p. 109). Pain had a negative influence on activities of daily living (ADL) in 76% of the subjects and 56% experienced a decrease in their ability to concentrate. Social activities such as visits and conversations decreased significantly with increasing pain ($p = 0.0001$). It was therefore concluded from this study that unrelieved pain caused not only physical suffering but also negatively influenced different aspects of quality of life.

Conceptual Framework

The concepts of hospice, pain, and quality of life are discussed. A conceptual model of the relationship between the variables of pain and quality of life is presented.

Hospice

Hospice is a concept of care that has been established to improve the overall quality of life of the terminally ill. Therefore, the ultimate goal of hospice care is to enhance the quality of life of patients with terminal illness.

Gurfolino and Dumas (1994) found that the term hospice as it is known today borrows from medieval times when it referred to a place of shelter for weary, tired travelers returning from the crusades who sought respite and comfort at the "hospice." The ideas of respite and comfort remain today but the main concept of palliative care of the dying is the basis for hospice care.

Throughout the nineteenth century, care of the dying became delegated to the family in the home setting where the themes of respite and comfort remained. Dying was viewed as a normal part of living and the focus was on palliative care of the dying as hospice programs assisted patients and families to prepare for death (Maddocks, 1990). Providing comfort, both physical and emotional, enabled dying patients to face death in a peaceful, comfortable way while living

the remainder of their lives to the fullest (Gurfolina & Dumas, 1994).

According to Berry and Lynn (1993), the hospice philosophy emphasizes quality of life not quantity and caring rather than curing. Therefore, central to the mission of hospice from its beginning in Great Britain has been the control of pain in order to maximize quality of life. It was Dame Cicely Saunders (1967), founder of the modern hospice movement, who broadened the concept of hospice to include the management of a dying patient's total pain combined with the spiritual, emotional, and psychological care of the individual.

The foremost goal in the delivery of hospice care is the optimal control and the management of symptoms during the often difficult course of dying (Rhymes, 1991b). Although other symptoms are problematic in the management of the dying patient, pain is identified as the most common occurrence and the one which requires skilled management for terminal hospice patients. As hospice care delivery has evolved to predominately serve the home care cancer patient, effective pain control has become a critical component of hospice care (Rhymes, 1991b).

Pain

"Pain has been described as a physiologic event, as a personal sensation of hurt, and as a source of suffering"

(Ferrell, 1995, p.609). Suffering can include physical pain but by no means is limited to it. Suffering is an experience that threatens the intactness of a person as he exists as a complex social and psychological entity (Cassel, 1982). Pain is always accompanied by dimensions far beyond those of mere physical suffering, and the fear of this adds to the total suffering (Strang, 1992).

Pain has been identified as probably the most feared and common symptom in terminal illness, occurring in 50% to 80% of cancer patients and disturbing their overall quality of life (WHO, 1986). Yet, frequently pain has remained undermanaged despite the recognition that pain can successfully be controlled in 90% of cancer patients with appropriate analgesic therapy (Morgan et al., 1994).

Pain is a difficult complex phenomenon composed of multiple facets. It affects the multi-system being at the physical, sensory, cognitive, behavioral, and social levels thereby adding to its complexity. A great deal is known about the physical dimension of pain, but it is only one aspect of this highly complex symptom. Psychological and spiritual pain are known to exist yet are sometimes more difficult to assess, manage and relieve (Kines & Levine, 1995). Physical suffering, emotional distress, social impairment, and altered family roles are just a few of the consequences of pain.

Pain not only affects the individual patient but also can cause distress in the entire family (Ferrell & Schneider, 1988). Pain interferes with roles and relationships, sexuality and intimacy, and the ability to interact with others. Isolation is common as patients tend to withdraw from social interactions of any kind so as not to let others see them in pain.

Quality of Life

The concept of quality of life has been pondered for years and numerous contributions have been made to its definition. Works from such authors as Illich (1976), Tolstoy (1960), and Frankl (1984) have discussed life's meaning and the meaning of suffering. Yet the subjectivity of the concept makes it difficult to define. Many possibilities have been derived from the endless studies in an attempt to define the concept. Grant, Padilla, Ferrell, & Rhiner, (1990) defined quality of life as a personal statement of the positive or negative attributes that characterize one's life.

According to Fowlie, Berkeley, & Dingwall-Fordyce (1989):

- (a) quality of life is a construct of individual design for each patient, which changes with time and circumstances;
- (b) it may not be readily nor usefully measured;
- and (c) it may be amenable to improvement

only for individuals in individual ways and therefore it is not useful for policy making, other than a policy which allows for greater flexibility in patient care.

(p.55)

The essential character of any life is difficult to define, and in the case of the terminally ill cancer patients, there exist special considerations (Morris, Suissa, Sherwood, Wright, & Greer, 1986). For those who are dying, life takes on a new shape, a new focus. Oftentimes it narrows, sometimes to a single room, as working and running a household seem insignificant. Family and friends are seen differently. Values change as what was once important becomes trivial, while things once ignored become highly valued. Therefore, the concept of quality is viewed dynamically as it constantly changes, from week to week, day to day, and possibly minute to minute.

Quality of life can be an elusive concept, but it has continued to be the focus in the issues of death with dignity (McGinnis, 1986). Quality of life can be conceptualized to include both objective and subjective factors. Objective factors include the amount of physical activity, capacity for self-care, degree of pain, energy for activities, and socioeconomic factors such as employment and financial security. Subjective factors include a sense of personal worth and well-being, and satisfaction in personal

life experiences with family, society, occupation, and sexuality. Therefore, to attain or maintain quality of life, the patient needs to be able to engage in important roles that one perceives as worthwhile, achieve a sense of independence, a feeling of satisfaction, and have a sense of well-being.

The growing attention to quality of life with cancer reflects a changing attitude on the part of health care personnel. The value of cancer treatment is judged not only on survival and quantity, but on the quality of that survival. If one is kept alive by treatment merely to continually suffer from devastating symptoms, one must reevaluate and decide if that treatment is really worth it. An inscription on the entry gate of the City of Hope National Medical Center, bears the words of its former director, "There is no profit in curing the body if in the process we destroy the soul" (Ferrell, Grant et al., 1991, p.11).

The concept of quality of life is represented as having four major domains: (a) physical well-being, (b) psychological well-being, (c) social well-being, and (d) spiritual well-being (Ferrell, 1995). These domains are further constructed of multiple aspects of life. Hence, quality of life is conceptualized as a multidimensional concept. The multidimensional aspects of quality of life

and the profound influence of pain on each aspect illustrate the importance of aggressive interventions to manage cancer pain.

Pain and Quality of Life

It is assumed that pain and quality of life are closely related. These concepts have emerged over the last 10 years as central to hospice and palliative care; however, the nature of the relationship between the variables has only recently been examined. Pain has been identified as a significant problem that affects 50%-80% of patients with cancer and disturbs overall quality of life (Ferrell, Rhiner et al., 1993). Pain is associated not only with physical symptoms, such as fatigue, nausea, and sleeplessness, but also with psychological symptoms including anxiety, fear, and depression. Pain can further exacerbate suffering by worsening helplessness, anxiety, and depression. Collaterally, quality of life has been associated with the physical as well as the psychological domains. Although pain is obviously a physical event, pain has a primary influence on all of the quality of life domains. Knowledge and understanding of each has been broadened through clinical experience and research studies.

According to the WHO (1986), approximately 70% of patients with advanced cancer suffer from moderate to excruciating pain and in the terminal stage severe pain is

found in up to 90% of patients, depending on the type of cancer. As cancer remains a life threatening disease, pain is a constant reminder of the growth and progression of the disease process thereby creating a negative, frightening experience with psychological, social, and existential dimensions (Strang & Ovarner, 1990). Ferrell (1995) has indicated that pain has a significant impact on coping and the ability to enjoy and participate in leisure activities. Pain decreases concentration and cognitive abilities. Fear is also identified as a contributing factor as pain is considered a very frightening experience, which patients and their families believe would worsen over time. Therefore, pain has the greatest overall influence on psychological well-being. For treatment plans to be optimally effective in the management of pain, it is essential to recognize the influence the experience of pain has on all aspects of quality of life.

The relationship between pain and quality of life has led to the development of a conceptual model. Through the conceptual model of pain and quality of life, the relationship between the interrelated concepts of pain and suffering is depicted indicating the enormity of the influence pain plays on quality of life.

A quality of life model (see Figure 1) was developed by Ferrell (1995) based on previous research studies exploring

the experience of pain and perceptions of quality of life. The model of the relationship between pain and quality of life identified the impact of pain on quality of life. Quality of life was conceptualized as including four dimensions of well-being: (a) physical well-being, (b) psychological well-being, (c) social well-being, and (d) spiritual well-being.

Figure 1. The impact of pain on the quality of life.

Note. From "The Impact of pain on quality of life. A decade of research," by B. Ferrell, 1995, Nursing Clinics of North America, 30, p. 611. Reprinted with permission.

Each dimension is comprised of several concepts. The dimension of physical well-being encompasses the impact of pain on physical function and related symptoms. Pain is known to create or increase many physical symptoms, such as fatigue/strength, appetite and sleep disturbances, constipation and nausea. In general, functional ability is hindered as each of these symptoms is increased when pain is not controlled (Ferrell, 1995).

The second dimension of the pain quality of life model is psychological well-being. This dimension includes anxiety, depression, coping, control, sense of usefulness, fear, and enjoyment/happiness. Pain is associated with psychological symptoms, such as anxiety and depression. These symptoms results in psychological effects, such as the sense of loss of control or the feeling of uselessness. Fear is cited as an extremely powerful aspect of psychological well-being hindering quality of life. Pain is a very frightening experience that virtually all patients face. The fear of worsening pain best explains the overall influence of pain on psychological well-being (Ferrell, 1995).

The third dimension of quality of life is social well-being. Research has revealed that pain not only affects the patient, but it also has a profound influence on the entire family. Pain creates distress in family members,

influencing family support. Sexuality and affection are affected as intimacy is inhibited by pain. Employment is impacted as many patients become isolated and do not leave their homes in response to pain, leading to financial burden. Many described pain as an embarrassing experience, thereby affecting one's overall appearance. Many patients prefer not to be seen while in pain, adversely affecting roles and relationships with others.

The fourth dimension is spiritual well-being. This encompasses religiosity, uncertainty, positive changes, sense of purpose, hopefulness, suffering, meaning of pain, and transcendence. The aspect of spirituality has proven to be very important and includes many issues in regard to pain. "Pain has a tremendous influence on spirituality and particular religious traditions influence pain" (Ferrell, 1995, p.612). Pain creates a sense of uncertainty and is considered a metaphor by many for death for both the patient and family members. Pain is viewed as a sign that disease is worsening and advancing, and thus that death is approaching. Many patients derive positive meaning from their pain and suffering, which results in positive changes in their lives as an enhanced sense of purpose was identified (Ferrell, 1995). However, for other patients pain creates a sense of hopelessness as patients feel their lives are not worth continuing if they must live in pain.

Pain further creates a separate existential dimension of transcendence and suffering as the meaning of pain and what it represents is reflected upon by the individual.

This conceptualization suggests factors that contribute to pain perception and experience and how they relate to pain and the expression of pain. The quality of life conceptual model is the result of intensive interaction with patients in pain in order to best understand their perspectives on pain and quality of life. "The model illustrates the influence of pain on the four major dimensions of quality of life. It demonstrates that pain is not simply an isolated phenomenon, but an experience that influences all dimensions of quality of life" (Ferrell, Grant et al., 1991, p.13).

Summary

The literature has indicated the enormity of the problem hospice patients face when confronted with pain and quality of life issues. Pain and quality of life have evolved over the last decade as central themes in hospice and palliative care. Knowledge of pain and its management has expanded through clinical experience and an abundance of literature. Interest and knowledge of quality of life issues, especially with the advent of many new treatments, procedures, and medications, have also escalated. Outcomes are being scrutinized and weighed against quality of life issues as

technology continues to advance. Quantity and quality of life are issues nurses and other health care professionals struggle to balance. The pain and quality of life conceptual framework has provided a means for viewing the relationship between these variables.

Chapter 3

RESEARCH DESIGN AND METHODOLOGY

In this chapter, the methodology for this research study is described. This chapter discusses the research design, subjects and setting, human subjects approval, data collection methods, instruments, and data analysis strategy.

Research Design

This pilot study utilized a descriptive, correlational research design. It explored pain as it affected the quality of life of terminally ill cancer patients enrolled in a hospice program.

Subjects/Setting

A convenience sample of 11 participants were selected from a hospice program in a Health Maintenance Organization in Santa Clara County. To be eligible for this study the participants had to be enrolled members of the program for at least 2 weeks, have a diagnosis of cancer, have pain, be alert, be able to respond in English, and live in a home setting. The participants were contacted in person in order to explain the research study and provide a written copy of the research protocol. If the patient or caregiver thought this study would be too taxing or difficult, or if either should change their mind and decide not to participate, they could withdraw from the study without any repercussions.

The participants were selected from those who had identifiable pain. The evidence of pain was initially determined by the assessment findings of their hospice nurse through the initiation of a nursing care plan for alteration in comfort.

The hospice program averaged from 30 to 50 enrolled members. Diagnoses included cancer, heart and lung diseases, neurologic diseases, and AIDS. Cancer diagnoses were the most prevalent. Thus, patients with cancer diagnoses were the focus of this study. To be eligible for admission into the hospice program, certain criteria needed to be met. The patient had to have a terminal diagnosis with a life expectancy of 6 months or less and a 24 hour caregiver willing to provide the necessary care or arrange a plan of care provided by someone else.

Enrollment varied depending on the time of year as statistics indicated that enrollment was cyclical. The summer months tended to have a low patient census while the fall and winter months generally had a higher census. The average patient remained in the program for 2 months before they expired. However, a few patients remained on service for 1 to 2 years while others died almost immediately.

Instruments

Demographic information was collected by using a demographic tool developed by this researcher

(see Appendix A). Data collected through chart review were gender, age, marital status, caregiver, race, primary diagnosis, and types of metastases.

The Brief Pain Inventory (see Appendix B), a 9 question shortened version of the Pain Inventory developed by the Pain Research Group in the Department of Neurology at the University of Wisconsin - Madison was utilized in this study (Cleeland & Ryan, 1994). This tool had been used previously with cancer patients. Permission to use this tool was obtained in writing from the author (see Appendix C). It established the presence of pain and measured both the intensity and interference of pain in the patient's life. The tool also inquired about pain relief, pain quality, and the patient's perception of the cause of pain.

According to Cleeland & Ryan (1994), this tool had demonstrated both reliability and validity across different cultures and languages, and it was frequently used in clinical trials for pain assessment and the effectiveness of pain control treatments. This tool used a numeric rating scale to measure pain severity from 0 to 10. The numbers run along a horizontal line with 0 indicating "no pain" and 10 indicating "pain as bad as you can imagine." The range of scores possible were 0-90. The most severe pain score was used in this study.

The Quality of Life Instrument (see Appendix D), a 40 item ordinal scale, was utilized in this study. This tool was developed by The City of Hope National Medical Center and proved to be useful in clinical practice and in research studies (Ferrell, 1995). Permission to use this tool was obtained in writing from the author (Appendix E). In a study of 686 participants, this tool was found to be reliable and valid. The two measures of reliability tested were test-retest and internal consistency. Several measures of validity were used to determine the extent to which the instrument measured the concept of quality of life in cancer survivors: (a) a panel of quality of life researchers and nurses with expertise in oncology, and (b) multiple regression to determine factors most predictive of overall quality of life in cancer survivors.

The 40 items in this instrument represented the four domains of quality of life including physical well-being, psychological well-being, social concerns, and spiritual well-being. The participant was asked to read each question and decide if he/she agreed with the statement or disagreed. The patient was then asked to circle a number to indicate the degree to which he/she agreed or disagreed with the statement. The scoring was based on a scale of "0" indicating a positive, favorable response, to "10" indicating a negative response. Several items had reverse

anchors and, therefore, when coded the scores of those items needed to be reversed. For example, if a subject circled "3" on an item, $(10-3 = 7)$ thus a score of 7 would be recorded. A range of possible scores would be 0-400.

Human Subjects Approval

Approval for conducting this research study was obtained by the Kaiser Foundation Research Institute (see Appendix F). Additional approval was obtained from the Human Subjects-Institutional Review Board at San Jose State University (see Appendix G).

Data Collection

To identify appropriate study participants, a list of potentially eligible subjects was compiled during a hospice team conference in which the enrolled members were reviewed for their appropriateness for the study. Once they were selected based on meeting the participant criteria, they were contacted via the telephone by the researcher. The researcher explained the purpose of the study inquiring at that time if the patient wished to participate. Once they agreed to participate, a follow up appointment was arranged. Each participant was provided with a copy of their "Rights as a Research Subject" as well as two consent forms, one from Kaiser Santa Clara (see Appendix H) and the other from San Jose State University (see Appendix I). After signing the consents, the participants were asked to complete The

Brief Pain Inventory and The Quality of Life Instrument, either on their own or with the assistance of the researcher. Patient caregivers were not asked to help in answering the questions or filling out the tools. Data collection was conducted in the privacy and comfort of the patients' homes. The researcher was the only person involved in the data collection.

The confidentiality of the subjects interviewed was maintained. All data collected were locked in a file accessible to only the researcher. Patient data forms were given a code number to provide further confidentiality.

Analysis of the Data

Descriptive statistics were used to analyze the demographic data. Frequencies and percentages were used to describe gender, marital status, caregiver, and race, primary diagnosis, and metastases. Statistics used to analyze the age of the subjects were frequencies, means, and ranges. The Pearson's Product Moment Correlation was computed to describe the relationship between the two variables, pain and quality of life. A scattergram was done in order to visualize the relationship between the variables, most severe pain score and overall quality of life concerns score. The mean and standard deviation for the Worst Pain Score and the Quality of Life Instrument were reported.

Chapter Four

FINDINGS AND INTERPRETATION

This chapter contains a summary of the data collected from the 11 hospice patients regarding pain and quality of life. The demographic data for the sample ($N = 11$) were analyzed using descriptive statistics. In addition, data were analyzed to determine if a correlation existed between pain and quality of life. A discussion of the findings and a comparison to other studies is also included.

Demographic Characteristics

The sample consisted of 7 (64%) men and 4 (36%) females. The sample's mean age was 52.72 years with a range of 38 - 86 years. The ethnic groups represented were 72% Caucasian, 9% African American and, 9% Hispanic. Most of the subjects were married ($n = 9$) (see Table 1).

In most cases ($n = 9$) the spouse served as caregivers. The diagnoses for this population were as follows: (a) 18% prostate cancer with metastases to the bone, (b) 9% colon cancer with metastases to the liver, (c) 18% lung cancer and no metastases, (d) 9% liver cancer and no metastases, (e) 9% abdominal cancer with metastases to the pancreas, (f) 9% Multiple Myeloma, (g) 9% Hodgkin's Lymphoma with metastases to the brain, lung, and spine, (h) 9% ovarian cancer with no metastases, and (i) 9% brain cancer with no metastases (see Table 2).

Table 1

Demographics of Cancer Patients (N = 11)

Variable	Frequency	Percent
<u>Gender</u>		
Male	7	64
Female	4	36
<u>Age</u>		
35-45	2	18
46-55	4	36
56-65	2	18
66-75	1	9
76-85	1	9
86-95	1	9
<u>Race</u>		
Caucasian	8	73
Filipinos	1	9
African American	1	9
Hispanic	1	9

Table 2

Relationships and Diagnoses of Cancer Patients (N = 11)

<u>Variable</u>	<u>Frequency</u>	<u>Percent</u>
<u>Marital Status</u>		
Married	9	82
Not Married	2	18
<u>Caregiver</u>		
Wife/Husband	9	82
Siblings	1	9
Children	1	9
<u>Diagnosis/Metastases</u>		
Prostate/bone	2	18
Colon/liver	1	9
Lung/none	2	18
Liver/none	1	9
Abdominal/pancreas	1	9
Multiple Myeloma	1	9
Hodgkin's Lymphoma/ brain, lung, spine	1	9
Ovarian/none	1	9
Brain/none	1	9

Pain

The mean for the most severe pain score was 6.27 and the standard deviation was 2.86, indicating a moderately high level of pain from a possible range of 2.00 to 10.00. The scoring was based on a scale of 0 = no pain to 10 = most severe pain. Since one of the main goals of hospice services is to effectively manage pain, it would appear that this population did not have adequate pain relief.

Quality of Life

The overall mean total quality of life score was 4.76 with a standard deviation of 1.05 from a possible range of 0 (positive) to 10 (negative) indicating a moderate rating of satisfaction with quality of life. The mean subscale score for physical well-being was 5.28 with a standard deviation of 1.54. The psychological well-being mean was 4.83 with a standard deviation of 1.34. The social concerns mean was 5.56 with a standard deviation of 1.58. The mean score for spiritual well-being was 3.37 with a standard deviation of 2.04 (see Table 3). These findings indicated that the overall quality of life of this hospice population was generally satisfactory with an average mean subscale score of 4.76. The social and physical subscales indicated a slightly less than satisfactory level of quality of life. Whereas, the psychological and spiritual subscales indicated a higher level of satisfaction with quality of life.

Table 3

Quality of Life Overall and Subscale Scores (N = 11)

Category	Mean	Standard Deviation
Quality of Life Overall	4.76	1.05
Subscales of Quality of Life Concerns		
Physical Well-Being	5.28	1.54
Psychological Well-Being	4.83	1.34
Social Well-Being	5.56	1.58
Spiritual Well-Being	3.37	2.04

Note. Possible quality of life scores ranged from 0 (most positive) to 10 (most negative) for overall and each subscale.

The highest subscale means were found in the social well-being subscale (5.56) indicating a higher than average degree of social concern. In this subscale, 9 questions were asked. When asked to what degree has your illness or treatment interfered with your activities at home, a mean score of 8.09 was tabulated, which indicated a high degree of interference. The question how distressing has your illness been for your family also rated highly with a mean score of 8.00. Interference with sexuality rated 7.80 and employment 7.09, both indicative of a moderately high level of interference. The amount of support received from others was very positive and considered sufficient in meeting the needs of the patient.

The next highest subscale score 5.28 was found in the physical well-being subscale indicating a moderate level of interference with physical functioning and well-being. Surprisingly, this category of physical well-being did not score the lowest, indicating patients were able to see and acknowledge positive aspects in their lives despite their failing physical health. Of the 8 questions in this subscale, those items that fell away from the midpoint on the 1-10 item scale related to fatigue 7.50, appetite changes 5.90, and constipation 6.10, indicating a moderately high level of interference. When asked to what degree has your illness or treatment interfered with your activities at

home a mean score of 8.09 was reported indicating a severe impact.

The psychological well-being subscale had the next to lowest mean score of the quality of life subscales. This subscale had the largest proportion of questions totaling 16. The mean score for this subscale was 4.83 indicating a moderate level of satisfaction with psychological well being. Happiness ranked 4.72 with coping as a result of one's disease a 4.90, both on the positive side. Generally, satisfaction with life was positive 4.81 and, surprisingly, the amount of depression 3.18, was also lower than anticipated indicating a more positive response. Conversely, usefulness 6.63, anxiety 5.54, and ability to concentrate or remember things 5.36 indicated a more negative effect.

The most positively scored subscale was the spiritual well-being. These 7 questions referred to such items as religious activities, personal spiritual activities, uncertainty, and purpose in life. The amount of spiritual support church activities provided such as attending church and temple was positive, yielding 1.72. Only a moderate amount of uncertainty existed with a mean score of 5.60 which coincides with the high amount of spiritual support, adequate enough to decrease one's feelings of uncertainty. Most of the respondents were still hopeful (3.81) and

indicated they still felt a sense purpose or mission for their lives (4.27).

Correlations

Pearson's Correlation coefficients were computed between (a) the most severe pain score and (b) the quality of life concerns overall and subscales scores (see Table 4). No statistically significant relationship was found between the worst pain score and the quality of life scores. Although one correlation reached 0.28 it was not in the direction anticipated. Since a lower pain score indicates less pain and a lower quality of life concerns score indicates fewer concerns, correlations would be expected to be positive. This analysis was limited by the sample size.

To further analyze the relationship between pain and quality of life a scattergram was done using the overall quality of life concerns data and the most severe pain score (see Figure 2). The analysis shows upon observation no trend was obvious as the results of the scattergram indicate. However, in a larger sample population it is possible that a trend could exist. Research has found that for the majority of patients, quality of life declines rapidly near the end of life (Morris, et al., 1986). However, the mean quality of life score for this patient population remained at 4.76 even though the level of pain was higher than anticipated at 6.27.

Table 4

Correlation of Worst Pain with Quality of Life Concerns
Scores (N = 11)

Category	Correlation
Quality of Life Overall	-0.08
Subscales of Quality of Life Concerns	
Physical Well-Being	0.13
Psychological Well-Being	-0.00
Social Well-Being	-0.28
Spiritual Well-Being	-0.05

Note. All correlations were not significant.

Figure 2. Relationship of Overall Quality of Life Concerns and the Most Severe Pain Score.

Summary

The results of this study were similar and consistent with previous results in that the quality of life of hospice patients was reasonably good, supporting the outcomes of care in this hospice population. Pain was above the midpoint, averaging 6.30, indicating inadequate pain control. This finding suggests that greater efforts should be focused on pain management.

It is encouraging to note that in spite of the high pain rating, the patients felt their quality of life was acceptable. This result might suggest that hospice services were effective and contributed to this result.

Chapter Five

CONCLUSIONS AND RECOMMENDATIONS

Introduction

Limited knowledge about the quality of life of terminally ill hospice patients was reported. The purpose of this study was to examine pain and quality of life and determine if a correlation existed. A quality of life model was used in this study to conceptualize the effects of pain on quality of life in cancer patients. This chapter summarized the conclusions reached in this study, limitations of the study, implications for nursing practice, and recommendations for further research.

Conclusions

In this study, the City of Hope Quality of Life Scale findings indicated that the quality of life of the 11 hospice cancer patients was generally satisfactory regardless of the impact of pain. Although none of the correlations reached statistical significance the physical well-being concerns subscale was positive while the other 3 subscales were negative, as was the overall quality of life score.

This sample population was similar to those in previous studies. The subjects were predominately male and the caregivers were predominately female family members. The most common relationship was spouse. The higher rate of

male subjects with female caregivers was consistent with McMillan & Mahon, (1994a). The tendency for females to live longer and the cultural value placed on women as caregivers could possibly explain these findings. The types of cancer in the sample are reflective of the incidence in the United States. Lung, prostate, and colorectal cancers are the most common. However, breast cancer, which is also ranked highly, was not represented in this sample for reasons unknown.

The mean for the worst pain score was 6.27 indicating a higher than moderate level of pain. This result was similar to the findings of McMillan's (1996) study. The range of pain score from McMillan's study were 5.70 to 6.30 indicating a moderate level of pain. Given that comfort is a goal of hospice services, these findings suggest that more focus be placed on pain management.

In a similar study by Strange and Ovarner (1990) of 84 patients with cancer related pain, the influence of pain on quality of life was evaluated. The mean intensity of pain for this population was 3.90 with a range of 1-9. This low pain score could possibly be attributed to the difference in the sample populations. Strang and Ovarner's study was comprised of cancer patients that were not necessarily terminal and dying from their disease, whereas this study

and McMillan's (1996) study consisted of terminally ill hospice patients with varying degrees of end-stage disease.

However, the level of pain experienced by the hospice patients in this and McMillan & Mahon's studies (1994a, 1994b, 1994c, 1996) appeared to be greater than that experienced by the cancer patients from Strang and Ovarner's (1990) study, yet, did not appear to adversely effect their overall quality of life. Although it was not indicated in this study whether an increase in quality of life was experienced as a result of hospice services, it is encouraging to note that the quality of life for this population was overall satisfactory despite the level of perceived pain. Further research is needed to support these findings.

Patient quality of life in this study, on average, was higher than anticipated given that the patients were all known to be terminally ill. The possible range of scores on the quality of life scale was 0 to 10 points with a theoretical midpoint of 5. An average mean score was derived at 4.8. McMillan (1996) found similar results in her study of quality of life in hospice patients as did McMillan and Mahon, (1994a, 1994b). No explanation for these relatively high scores is indicated. The possibility does exist that the quality of life of terminally ill patients enrolled in a hospice program is higher due to the

hospice services provided; however, a different research design is necessary to study that relationship.

This sample of hospice patients identified having social concerns, physical, psychological, and lastly spiritual well-being problems as depicted by the Quality of Life conceptual framework. Social concerns were mentioned most frequently followed by physical, psychological, and spiritual. Aspects most problematic for patients related to worries and distress about family and friends. The amount of enjoyable activity they experienced, and how masculine or feminine they felt also were sources of concern. However, the support patients perceived from family and friends, physicians, and the hospice team provided a high level of satisfaction for the patients. Findings from McMillan's (1996) study were similar.

Physical problems most troublesome were fatigue, appetite changes, and constipation. These findings were consistent with findings from McMillan's (1996) study, which indicated a level of dissatisfaction with their ability to perform their usual daily activities (housework, chores, job) due to fatigue. These were the most problematic areas. These findings were further consistent with those from Strang and Ovarner's (1990) study, which indicated that 76% of the cancer patients surveyed reported pain significantly reduced their ability to perform activities of daily living.

Psychological well-being was generally not a major problem for this population. Similar findings were indicated in McMillan's (1996) study indicating a psychological well-being of 5.1 at admission into a hospice program and 5.9 after 4 weeks of hospice services. These results indicated that the psychological well-being of the hospice patients possibly improved in response to the hospice services, thereby supporting the care provided by the hospice.

Spiritual well-being proved to be the most positive aspect of quality of life for this population. This finding was similar to McMillan's (1996) study of quality of life in hospice patients. In McMillan's study the highest subscale mean score was also in the social/spiritual subscale indicating a satisfactory, rewarding quality of life. It is apparent from the conclusions from both studies that spiritual well-being was rated fairly high and encourages a positive quality of life.

Implications drawn from this study suggest that hospice services are successful in fostering and possibly improving, the overall quality of life in terminally ill cancer patients. Patients felt supported by their hospice staff and surprisingly suffered less anxiety, depression, and hopelessness than anticipated. Although pain relief does warrant greater attention and management. An important

question for further research would be to evaluate patients' quality of life before and after hospice services to determine if the care and services made a difference.

Scope and Limitations

This study attempted to isolate pain and quality of life from many other experiences terminally ill patients encountered. Many of the experiences overlapped and became difficult to separate and examine. The multidimensional character and subjective nature of both pain and quality of life add to the complexity of this study. The quality of life conceptual model illustrated the profound influence of pain on the four dimensions of quality of life and the multidimensional experience of pain. It can therefore be reiterated that pain is an "experience that overwhelms the individual and consumes every aspect of life" (Ferrell, 1995, p.609).

Several limitations of this study are acknowledged. The small sample size was a major limitation of this study and did not allow the results to be generalized to a larger population. The lack of statistical significance may also be attributed to the small sample size. However, the results could contribute to the body of research involving pain in terminally ill cancer patients, hospice, and quality of life. A strength of this study was its reliance on the patient as a self-reporter.

The deteriorating medical condition of the subjects also proved to be a limitation. Finding a sample of hospice patients willing and able to fill out the rigorous 40 item quality of life tool proved to be difficult as medical conditions changed rapidly. Many patients too ill or in a semi-conscious state were not eligible for the study, thereby not providing a representative sample of the hospice population.

Finally, the lack of appropriate measurement tools for this fragile population was another limitation. The City of Hope Quality of Life Scale recommended and used for cancer patients, however, was not specifically designed for the hospice population. A tool specific for hospice patients has recently been developed since this study began, which would be more appropriate for further studies in this area.

Implications for Nursing Practice

During the past 10 years, hospice care has evolved and grown into a vital aspect of the continuum of care. As health care continues to change so does nursing practice. As society moves toward a caring model of care for terminally ill patients, the needs of this growing population must be met. Quality of life as an outcome must be viewed as highly as treatment and cure; therefore, pain and suffering must be eliminated whenever possible. Health professionals' teamwork enhances support of patients and

caregivers as they strive for an acceptable quality of life. Hospice patients with quality of life concerns suggest a need for nurses to work together in a multidisciplinary team approach to enhance the support of patients' social network.

It is further recommended that interventions and strategies be developed to better assess the status of patients physically, emotionally, socially, and spiritually. Assessment, planning, implementation, and evaluation of care for hospice patients should address the four dimensions of quality of life - physical, psychological, social, and spiritual.

Recommendations

Continued research in the area of hospice care and quality of life issues is needed. Subsequent hospice quality of life studies should include the number of days from death as quality of life is assumed to decline as death approaches. Other possibilities for study include the needs of hospice patients without family caregivers, ethnic minorities, and young children. Our society is one of vast cultural diversity; the multitude of issues surrounding care of terminally ill patients from different cultures certainly warrants investigation.

This study has provided knowledge about the perceived quality of life of cancer patients with pain. The valuable insight that patients can provide will lead to better

understanding of their experience and provide a further impetus for aggressive care and treatment for terminally ill patients in pain.

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APPENDIX A
Demographic Tool

Demographic Tool

1. What is your gender?
2. What is your age?
3. What is your marital status?
4. Who is your caregiver?
5. What is your race?
6. What is your primary cancer diagnosis?
7. Do you have any metastases?

Note: Developed by Cindy Parks, R.N., 1997

Appendix B
Brief Pain Inventory

STUDY ID# _____

HOSPITAL# _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

Date ____/____/____

Time _____

Name _____

Last

First

Middle-Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes

2. No

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

3) Please rate your pain by circling the one number that best describes your pain at its **worst** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

4) Please rate your pain by circling the one number that best describes your pain at its **least** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **average**.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **right now**.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

7. What treatment(s) or medication(s) are you receiving for your pain?

8. In the last 24 hours, how much **relief** have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No										Complete
Relief										Relief

9. Circle the one number that describes how, during the past 24 hours, **pain has interfered** with your

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not										Completely
interfere										interfere

APPENDIX C
Letter of Permission

PAIN RESEARCH GROUP

February 7, 1996

Cindy Parks
2520 Lodi Lane
San Jose, CA 95124

Dear Ms. Parks:

You have my permission to use the Brief Pain Inventory, as it would be appropriate for your study. I'm enclosing copies of the Brief Pain Inventory, long and short forms, and an article entitled Pain Assessment: Global Use of the Brief Pain Inventory. Good luck with your research.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles S. Cleeland".

Charles S. Cleeland, Ph.D.
Director, Pain Research Group
Professor, Neurology

Enclosures

APPENDIX D
Quality of Life Scale

QOL Scale/Patient

QOL Scale - Cancer

Directions: We are interested in knowing how your experience of having cancer affects your Quality of Life. Please answer all of the following questions based on your life at this time.

Please circle the number from 0 - 10 that best describes your experiences:

Physical Well Being

To what extent are the following a problem for you:

1. **Fatigue**

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

2. **Appetite changes**

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

3. **Pain or aches**

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

4. **Sleep changes**

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

5. **Constipation**

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

QOL Scale/Patient

6. Nausea

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

7. Fertility changes

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

8. Rate your overall physical health

extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

Psychological Well Being Items

9. How difficult is it for you to cope as a result of your disease and treatment?

none at all 0 1 2 3 4 5 6 7 8 9 10 extremely

10. How good is your overall quality of life?

extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

11. How much happiness do you feel?

none at 0 1 2 3 4 5 6 7 8 9 10 complete
all

12. Do you feel like you are in control of things in your life?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

QOL Scale/Patient

13. How satisfying is your life?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

14. How is your present ability to concentrate or to remember things?

extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

15. How useful do you feel?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

16. How distressing was the initial diagnosis for you?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

17. How distressing were your cancer treatments (i.e. chemotherapy, radiation, BMT or surgery) for you?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

18. How distressing has the time been since your treatment ended?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

19. How much anxiety do you have?

none at all 0 1 2 3 4 5 6 7 8 9 10 severe

20. How much depression do you have?

none at all 0 1 2 3 4 5 6 7 8 9 10 severe

QOL Scale/Patient

21. Are you fearful of a second cancer?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

22. Are you fearful of recurrence cancer?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

23. Are you fearful of the spreading (metastasis) of cancer?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

24. Rate your overall psychological well being?

extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

Social Concerns

25. How distressing has illness been for your family?

not at all 0 1 2 3 4 5 6 7 8 9 10 extremely

26. Is the amount of support you receive from others
sufficient to meet your needs?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

27. To what degree has your illness or treatment interfered
with your personal relationships?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

QOL Scale/Patient

28. To what degree has your illness or treatment interfered with your sexuality?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

29. To what degree has your illness or treatment interfered with your employment?

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

30. To what degree has your illness or treatment interfered with your activities at home?

no problem 0 1 2 3 4 5 6 7 8 9 10 severe problem

31. How much isolation is caused by your illness or treatment?

none 0 1 2 3 4 5 6 7 8 9 10 completely

32. How much financial burden resulted from your illness or treatment?

none 0 1 2 3 4 5 6 7 8 9 10 extreme

33. Rate your overall social well being

extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

Spiritual Well Being

34. Is the amount of support you receive from religious activities such as going to church or temple sufficient to meet your needs?

not at all 0 1 2 3 4 5 6 7 8 9 10 completely

QOL Scale/Patient

35. Is the amount of support you receive from personal spiritual activities such as prayer or meditation sufficient to meet your needs?
- not at all 0 1 2 3 4 5 6 7 8 9 10 completely
36. How much uncertainty do you feel about your future?
- none at all 0 1 2 3 4 5 6 7 8 9 10 extreme
37. Has your illness made positive changes in your life?
- none at all 0 1 2 3 4 5 6 7 8 9 10 extreme
38. Do you sense a purpose/mission for your life or a reason for being alive?
- not at all 0 1 2 3 4 5 6 7 8 9 10 completely
39. How hopeful do you feel?
- not at all 0 1 2 3 4 5 6 7 8 9 10 extremely
40. Rate your overall spiritual well being
- extremely 0 1 2 3 4 5 6 7 8 9 10 excellent
poor

APPENDIX E
Letter of Permission

City of Hope

N A T I O N A L M E D I C A L C E N T E R

MAYDAY PAIN
RESOURCE CENTER

MEMORANDUM

To: Cindy Parks

From: Betty R. Ferrell, PhD, FAAN
Associate Research Scientist
Co-Director

Marcia M. Grant, DNSc, FAAN
Associate Research Scientist
Co-Director

Jane C. Roach
Project Coordinator

Date: February 6, 1996

Enclosed is the information you requested. Thank you for your interest in our materials from The Mayday Pain Resource Center. We hope you will find this useful in your research or clinical practice. If you should require any additional information, please let us know.

1500 EAST DUARTE ROAD, DUARTE, CALIFORNIA 91010-0269 (818) 359-8111 x 3829
(818) 301-8941 FAX

A National Cancer Institute Designated Clinical Cancer Research Center

mmmmmm2:95

APPENDIX F
Letter of Approval

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTER-OFFICE MEMORANDUM

TO: C. Parks, R.N.
S. Hadland, M.D.
Hospice - Santa Clara

DATE: June 20, 1996

FROM: Lisa Blanco

Lisa Blanco

COPY TO: C. Chow, M.D.

AT: KFRI Administration
1800 Harrison Street
Sixteenth Floor
Oakland

SUBJECT: Institutional Review and Approval of Research Study
Entitled: "What is the Relationship Between Pain and
Quality of Life in Cancer Patients Enrolled in a
Hospice Program?"

On June 15, 1996, the Institutional Review Board (IRB) for the protection of human subjects reviewed the above-subject research study. The study was approved as presented, subject to receipt and approval of a letter of approval from San Jose State University. Please provide this letter as soon as possible.

The revised consent form was also approved by the IRB. A copy of the approved consent form is enclosed for your use. Do not retype the consent form. If you need to change the consent form, please contact Gayle McCartney, (510) 967-3241 and she will make the changes for you.

Also enclosed is a statement entitled "Information About Rights of Medical Research Participants." A copy of this statement must be given to each prospective participant in order to satisfy statutory requirements.

All continuing projects and activities must be reviewed and reapproved at least annually by the Board. Board approval of any project is for a maximum period of one year. It is the responsibility of the investigator to resubmit the project for periodic review as determined by the Board. You will be reminded of the scheduled follow-up review date for your project.

If this proposal is used in conjunction with any other human experimentation or if it is modified in any way, it must be reapproved for these special circumstances. In addition, the Board must be promptly notified of unanticipated problems involving risks to human subjects or any complications which may occur during any experimental procedure.

If you have any questions, please call me at (510) 967-3240.

LB/mlm
Enc.

APPENDIX G
Letter of Approval

A campus of The California State University

Office of the Academic Vice President • Associate Academic Vice President • Graduate Studies and Research
One Washington Square • San Jose, California 95192-0025 • 408.924-2480

TO: Cindy Parks
2520 Lodi Lane
San Jose, CA 95124

FROM: Serena W. Stanford *Serena W. Stanford*
AAVP, Graduate Studies & Research

DATE: July 31, 1996

The Human Subjects-Institutional Review Board has approved your request to use human subjects in the study entitled:

"What is the Relationship Between Pain and Quality of
Life in Cancer Patients Enrolled in a Hospice Program"

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The Board's approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Serena Stanford, Ph.D., immediately. Injury includes but is not limited to bodily harm, psychological trauma and release of potentially damaging personal information.

Please also be advised that all subjects need to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate, or withdrawal will not affect any services the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

APPENDIX H
Consent to Participate

Kaiser Permanente Medical Center
900 Kiely Boulevard
Santa Clara, California 95051-5586
(408) 236-6400

Carol J. Kiecker
Vice President and Area Manager
South Bay Service Area

Robert M. Pearl, M.D.
Physician-in-Chief
Donna M. Young
Medical Group Administrator

Consent to Participate in a Medical Research Study

FORMAL TITLE : WHAT IS THE RELATIONSHIP BETWEEN PAIN AND QUALITY OF LIFE IN CANCER PATIENTS ENROLLED IN A HOSPICE PROGRAM?

PURPOSE OF THE STUDY

You are invited to participate in a study to determine how pain affects you quality of life. We hope to learn to what extent pain has on the quality of your life, with the hope of improving pain control, thereby enhancing care provided to Hospice patients. You were selected as a possible participant because you are an enrolled member in Santa Clara Kaiser's Hospice program and have identifiable pain.

STUDY PROCEDURE

If you decide to participate in this study you will be asked to complete a pain assessment tool. Of you identified pain as a symptom in which you are currently experiencing, you will then complete a quality of life assessment tool. Estimated time to complete both tools is 20-30 minutes.

RISK/DISCOMFORTS

No risks are anticipated, however, unforeseeable risks could occur and would be managed appropriately as determined by the investigator and the participant. If you should experience fatigue as a result of completing these assessment tools, the investigator will either assist you in filling out the tool or you may choose not to continue.

POSSIBLE BENEFITS

No tangible benefits are promised as a result of this study, however, the positive effects of participating in research to potentially help yourself and others could be viewed as a benefit.

CONFIDENTIALITY

Any information obtained during this study which could identify you will remain confidential. Summary information obtained in this study may be published in scientific journals or presented at scientific meetings, but you will not be identified.

Kaiser Permanente Medical Center
900 Kiely Boulevard
Santa Clara, California 95051-5386
(408) 236-6400

Carol J. Kiecker
Vice President and Area Manager
South Bay Service Area

Robert M. Pearl, M.D.
Physician-in-Chief

Donna M. Young
Medical Group Administrator

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WITHDRAWAL FROM STUDY

Participation in this study is voluntary. Your decision whether or not to participate will not harm your future relations with Kaiser Permanente or your Hospice caregivers. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

COSTS/PAYMENT

There will be no cost for participation, nor will there be any payment.

QUESTIONS

If you have questions, we want and expect you to ask them. If you think of any questions later, Cindy Parks, Santa Clara Hospice program at (408) 236-5317, will be happy to answer them.

Questions about your rights as a study participant, comments or complaints about the study also may be presented to the Institutional Review Board for the Protection of Human Subjects, Kaiser Foundation Research Institute, 1800 Harrison Street, Oakland, CA 94612-3433, telephone (510) 987-3236.

I have read the above and am satisfied with my understanding of the study, its possible benefits, risks, and alternatives. My questions about the study have been answered. I hereby voluntarily consent to participate in the medical research study as described. I have been offered copies of this two-page consent form and of the "Experimental Subject's Bill of Rights."

Signature of Participant

Date

Name of Participant, printed

Witness (not a physician)

APPENDIX I
Consent to Participate

College of Applied Sciences and Arts • School of Nursing
One Washington Square • San Jose, California 95192-0057 • 408/924-3130 • Fax 408/924-3135

CONSENT TO PARTICIPATE IN A MEDICAL RESEARCH STUDY

FORMAL TITLE : **WHAT IS THE RELATIONSHIP BETWEEN PAIN AND QUALITY OF LIFE IN CANCER PATIENTS ENROLLED IN A HOSPICE PROGRAM?**

PURPOSE OF THE STUDY

You are invited to participate in a study to determine how pain affects you quality of life. We hope to learn to what extent pain has on the quality of your life, with the hope of improving pain control, thereby enhancing care provided to Hospice patients. You were selected as a possible participant because you are an enrolled member in Santa Clara Kaiser's Hospice program and have identifiable pain.

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A campus of The California State University

College of Applied Sciences and Arts • School of Nursing
One Washington Square • San José, California 95192-0057 • 408/924-3130 • Fax 408/924-3133

Page 2 of 2

WITHDRAWAL FROM STUDY

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QUESTIONS

If you have questions, we want and expect you to ask them. If you think of any questions later, Cindy Parks, Santa Clara Hospice program at (408) 236-5317, will be happy to answer them.

Questions about your rights as a study participant, comments or complaints about the research may be presented to the Department of Nursing, Dr. Ginny Young at (408)924-3163. Questions or complaints about research, subjects' rights, or research-related injury may be presented to Serena Stanford, Ph.D., Associate Academic Vice President for Graduate Studies and Research, at (408)924-2480.

I have read the above and am satisfied with my understanding of the study, its possible benefits, risks, and alternatives. My questions about the study have been answered. I hereby voluntarily consent to participate in the medical research study as described. I have been offered copies of this two-page consent form and of the "Experimental Subject's Bill of Rights."

Signature of Participant

Date

Name of Participant, printed

Witness (not a physician)