

THE RELATION OF SICK LEAVE BENEFITS, EMPLOYMENT PATTERNS,
AND INDIVIDUAL CHARACTERISTICS TO
RADIATION THERAPY-RELATED FATIGUE

A Dissertation Presented

by

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Submitted to the Office of Graduate Studies,
University of Massachusetts Boston, in partial fulfillment of the requirements for
the degree of

DOCTOR OF PHILOSOPHY

June 2005

Ph.D. in Nursing Program

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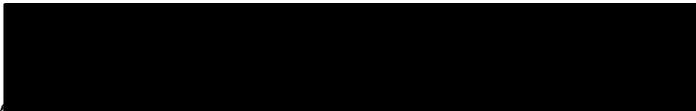
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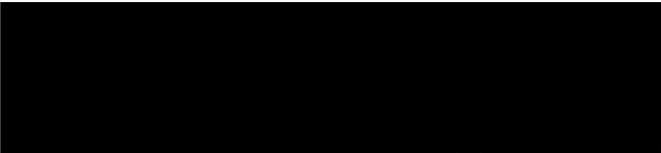
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ABSTRACT

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Fatigue has consistently been found to be the most common and distressing side effect of radiation therapy. This study examined the relation of a specific life-style behavior with many policy and economic implications, participation in the workforce, on radiation therapy-related fatigue. The aims of this longitudinal study were to: describe sick leave benefits available to patients undergoing radiation therapy; examine the relation between sick leave benefits, individual characteristics, and employment patterns in patients undergoing radiation therapy; and examine the relation between employment patterns, individual characteristics, and fatigue in patients receiving radiation therapy. The Conceptual Model of Nursing and Health Policy (CMNHP) and the Piper Integrated Fatigue Model (IFM) guided this study. Seventy-seven study participants receiving radiation therapy to the breast, chest, head and neck, pelvis, and prostate were recruited

from one community hospital. The revised Piper Fatigue Scale (PFS), the Brief Fatigue Inventory (BFI) and a single item 0-10 numeric scale were used to measure five dimensions of subjective fatigue. The study employed a prospective, longitudinal design. Data were collected at baseline prior to starting radiation therapy, weekly during treatment, and at the one month follow-up visit. Mean total fatigue scores on the PFS ranged from 0-4.77 at baseline (M = 0.46, SD = 0.93), 0-8.77 at the completion of treatment (M = 2.84, SD = 2.40), and 0-4.82 (M = 0.77, SD = 1.20) at one month post-treatment. Treatment-related side effects, education, living situation, age, treatment site, and work were associated with fatigue along the trajectory of radiation therapy. Study participants who were working at the end of radiation therapy had lower fatigue scores than those who were not working $t(75) = 4.85, p < .0001$. Age, pain, gender, side effects, availability of sick leave benefits, and fatigue were associated with work along the trajectory of radiation therapy. Only 49% of study participants had paid sick leave benefits available at the start of radiation. Study findings supported the credibility of the CMNHP and the Piper IFM, which can be used to guide and focus future research into employment and sick leave policies and their impact on cancer-related fatigue.

ACKNOWLEDGEMENTS

I would like to thank Kathy, Karol, and Barbara whose patience and understanding during these past six years was invaluable. Without you this would not have been possible.

I would also like to thank the Oncology Nursing Society and the Oncology Nursing Foundation for their financial and professional support. Participation in the inaugural FIRESM Course back in 1995 started me along the line of research leading to this dissertation. Thank you also to my Cancer Nursing Research Short Course faculty reviewers, Jean K. Brown, Ph.D., R.N., F.A.A.N. and Susan C. McMillan, Ph.D., A.R.N.P., F.A.A.N., for their input in the early stages of this study.

I would also like to thank my committee members, Nancy Lovejoy and Sybil Crawford, and especially my chair, Jacqueline Fawcett, for their patience, support, and encouragement during this process.

Finally I would like to dedicate this dissertation to all patients experiencing cancer-related fatigue. Hopefully cancer-related fatigue will soon be nothing more than a minor nuisance.

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CHAPTER 1

INTRODUCTION

The American Cancer Society (2005) estimated that 1,372,910 new cases of cancer would be diagnosed in the United States in 2005, with 33,030 new cases in Massachusetts, not including in situ (non-invasive) cancers and non-melanoma skin cancers. Approximately 60% of all persons diagnosed with cancer will receive radiation therapy at some point in their treatment (Hilderly, 1997).

Although radiation therapy plays a major role in the cure, control, or palliation of cancer, it also produces adverse effects. Haylock and Hart (1979) were among the first to describe fatigue as a result of radiation therapy for cancer. Since that time, much attention has been given to the subject of cancer-related fatigue. Fatigue, which has been reported in 65%-100% of patients receiving radiation therapy for cancer, has consistently been found to be the most common and distressing side effect (Munro & Potter, 1996; Oberst, Hughes, Chang, & McCubbin, 1991; Stone, Richards, A'Hern, & Hardy, 2001; Williams et al., 2001).

In 1995, the Oncology Nursing Society (ONS), in conjunction with a major pharmaceutical firm, launched FIRE, the Fatigue Initiative through Research and Education. The goals of this ongoing project are to increase awareness of the problem of cancer-related fatigue, promote specific research to identify factors related to fatigue, and to develop research-based interventions to help alleviate or modify cancer-related fatigue (Nail, 2002). Two separate rounds of funding have allocated \$650,000 for research into cancer-related fatigue (Nail). Other research awards were given for instrument development and for fellowships to promote research about cancer-related fatigue (Nail).

The ONS FIRE Excellence Award is given annually to an oncology nurse who “has made an outstanding and significant contribution to cancer-related fatigue clinical practice, education, or research” (ONS, 2005).

The FIRE model was chosen as the prototype for the Priority Symptom Management project (PRISM), launched in March of 2000 by the Oncology Nursing Society, to identify symptom management priorities for oncology nurses in the areas of patient and public education, research, nursing interventions, and health policy (Ropka & Spencer-Cisek, 2001). PRISM has resulted in professional education programs and a series of articles on symptom management, including fatigue (Nail, 2002; ONS, 2001),

The Oncology Nursing Society’s Year 2004 Research Priorities Survey was designed to determine the ONS research priorities for 2005-2008 for oncology nursing across the entire scope of cancer care, including prevention, detection, treatment, survivorship, and palliative care (Berger et al., 2005). Both the general membership group and a doctorally prepared group identified fatigue/lack of energy as one of the top twenty research priorities. In addition, the general membership group identified nurses as advocates as one of the top twenty research priorities (Berger et al.). The 2003-2005 ONS Research Agenda supports continued research in fatigue as well as research in health systems issues and policy related to symptom control (ONS, 2005).

Furthermore, the National Comprehensive Cancer Network (NCCN) has issued practice guidelines for cancer-related fatigue for both practitioners and patients (Mock et al., 2000; NCCN, 2003). These guidelines propose a treatment algorithm that includes screening all patients for cancer-related fatigue and then incorporating more in-depth assessments and interventions based on the initial screening. Moreover, the Advisory

Board Company of Washington D. C. (1999) encouraged its Oncology Roundtable members to incorporate simple screening for fatigue and then implementing an appropriate treatment algorithm.

Research has revealed an inconsistency between patients' and health care providers' perceptions of fatigue and fatigue management (Dillon & Kelly, 2003; Passik et al., 2002; Stone et al., 2003). In surveys done both in the United States and Ireland, a much larger percentage of health care providers reported providing information on fatigue management than patients reported receiving such information (Dillon & Kelly; Stone et al.). Patients frequently hesitate to report fatigue, citing doctors' failure to offer interventions, lack of awareness of effective treatments for fatigue, and a desire to treat fatigue without medications, as well as not wanting to bother the doctor as reasons (Dillon & Kelly; Passik). Interestingly, of those who reported fatigue in the Irish study, 46% discussed it with their doctor and 44% discussed it with their nurse (Dillon & Kelly). In a companion study of U.S. patients, 79% discussed fatigue with their doctor and only 28% spoke with their nurse (Curt et al., 2000). Ream, Browne, Glaus, Knipping, & Frei (2003) found, in focus groups conducted in the United Kingdom and Switzerland, that individuals voiced a common concern: fatigue had not been addressed in the clinical setting. Thus, in spite of recommendations from professional organizations to assess and manage fatigue, there is evidence that that is not happening. The findings of the present study will be used to advance policies about the clinical assessment and management of fatigue in patients undergoing radiation therapy.

Although fatigue in persons receiving radiation therapy has been well described, few investigators have examined the relation of specific life-style behaviors to the

prevalence and severity of cancer-related fatigue. Mock et al. (1997) studied the effect of exercise on fatigue related to radiation therapy for breast cancer. Other investigators have documented the benefits of exercise and increased physical activity on cancer-related fatigue (Dimeo, Stieglitz, Novelli-Fischer, Fetscher, & Keul, 1999; Dimeo et al., 1997; Sarna & Conde, 2001; Schwartz, 1999, 2000a; Young-McCaughan et al., 2003). Still other investigators have examined the effects of certain behavioral techniques, including group psychotherapy (Forester, Kornfield, Fleiss, & Thompson, 1991), relaxation therapy (Christman & Cain, 2004; Decker, Cline-Elsen, & Gallagher, 1992), guided imagery (Kolcaba & Fox, 1999), and energy conservation (Barsevick, Whitmer, Sweeney, & Nail, 2002) on radiation therapy-related fatigue. Many of these studies were supported by the Oncology Nursing Society's FIRE grants.

One life-style behavior with many policy and economic implications is participation in the workforce. The Department of Labor (DOL, 2005) estimated that 140,200,000 Americans over the age of sixteen were employed full- or part-time in January 2005, representing an employment-population ratio of 62.4%. Inasmuch as cancer affects persons of all ages and races, many persons with cancer are in the workforce. Longman, Braden, and Mishel (1996) found that most employees continued to work during treatment for breast cancer, taking sick time only when necessary. Financial necessity and the need to maintain health insurance coverage may force many persons with cancer to work during their treatment. Others may choose to work to maintain a sense of normalcy in their lives.

Treatment for cancer is an acceptable criterion for Family and Medical Leave Act (FMLA) benefits. However, even employees covered by the FMLA may not have

sufficient resources to afford to take unpaid leave. Employers cannot provide fewer benefits than required by law but may provide additional sick leave benefits at their discretion. Short-term disability and paid sick leave may supplement FMLA (Mock, 1998). Other employer benefits may include rearranging work flow, allowing shorter workdays, working part-time, rearranging tasks for periods of high energy, and allowing working from home (Mock).

Information on employment status is collected as demographic data in many studies of cancer-related fatigue but generally is not included in data analysis. Consequently, little is known about the availability of sick leave benefits to patients receiving cancer treatment. Even less is known about the utilization of those benefits to adjust employment status as a coping mechanism for cancer-related fatigue. And, the specific impact of radiation therapy-related fatigue on employment had not been studied. The findings of the present study will help to fill some of the gaps in knowledge about the relations among sick leave benefits, employment patterns and cancer-related fatigue and thus inform policymakers.

Specific Aims

The specific aims of this longitudinal study were to:

1. Describe the pattern of fatigue over time in patients undergoing radiation therapy for cancer.
2. Describe the sick leave benefits that are available to patients undergoing radiation therapy for cancer.

3. Examine the relation between sick leave benefits and employment patterns in patients undergoing radiation therapy for cancer at the beginning of treatment, weekly during treatment, and at the one month follow-up visit.
4. Examine the relation between individual characteristics and employment patterns in patients undergoing radiation therapy for cancer at the beginning of treatment, weekly during treatment, and at the one month follow-up visit.
5. Examine the relation between employment patterns and fatigue in patients receiving radiation therapy for cancer at the beginning of treatment, weekly during treatment, and at the one month follow-up visit.
6. Examine the relation between individual characteristics and fatigue in patients receiving radiation therapy for cancer at the beginning of treatment, weekly during treatment, and at the one month follow-up visit.

Conceptual Framework

The Conceptual Model of Nursing and Health Policy (Fawcett & Russell, 2001, 2002) and the Piper Integrated Fatigue Model (Berger & Walker, 2001; Piper et al., 1998; Piper, Lindsey, & Dodd, 1987; Sitton, 1997) guided the design of the study, the selection of variables, and the specification of the relations among the variables. (Figure 1).

Conceptual Model of Nursing and Health Policy (CMNHP). The CMNHP focuses on public, organizational, and professional policies. Public policies are those formulated by local, state, or federal governments. The particular public policy of interest in this study was the Family and Medical Leave Act (FMLA). Organizational policies are specific to a particular institution. According to Fawcett and Russell (2001), such policies are for the purpose of self-direction within an institution. Of interest in this

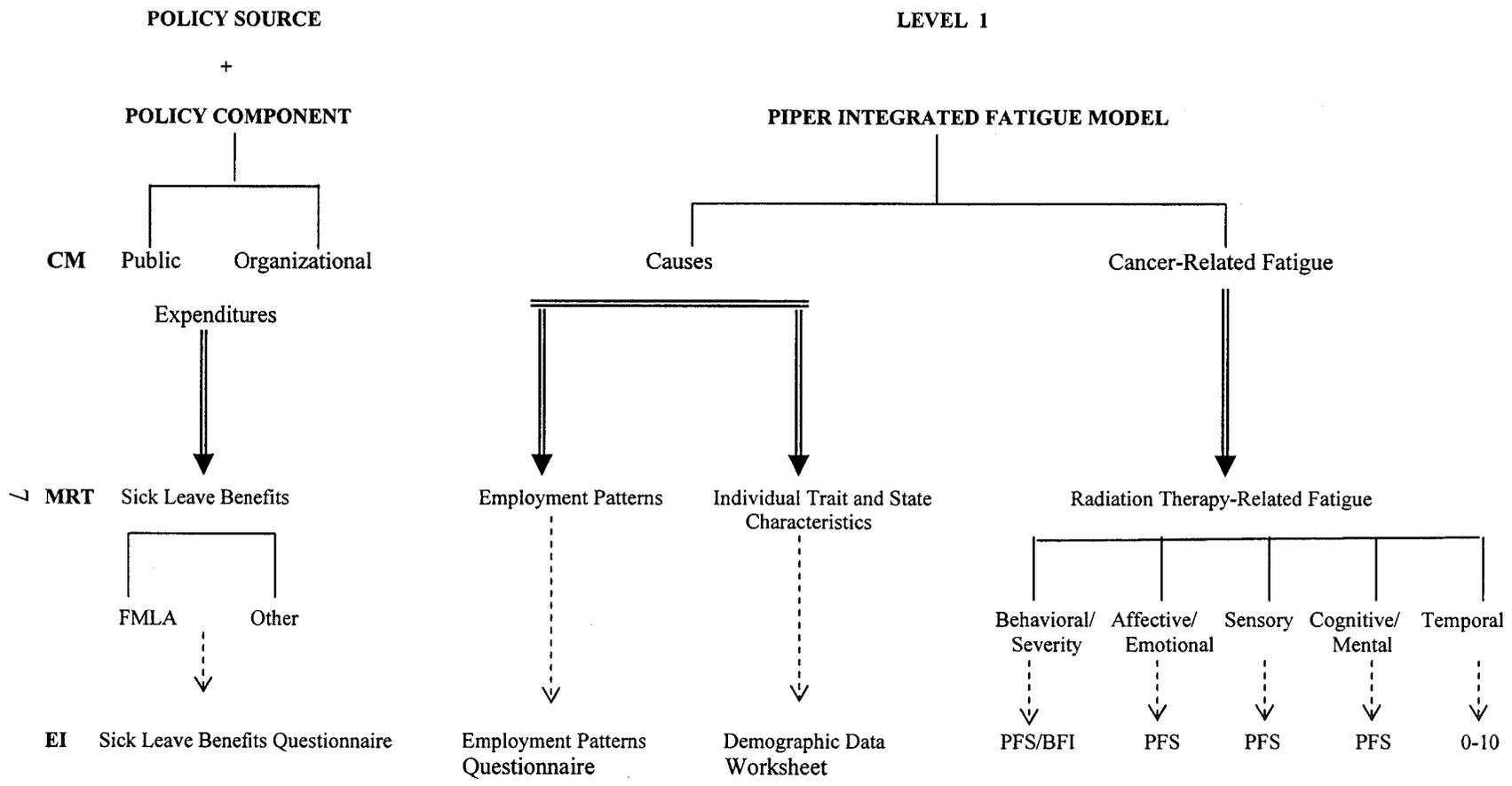


Figure 1. Conceptual model of nursing and health policy (CMNHP).

study were selected organizational sick leave policies that were available to employees in addition to the federally mandated FMLA. These policies included both formal benefits such as paid sick leave, earned time or short-term disability, and less clearly defined informal benefits such as flex time, working from home, benefit time donated by other employees, and reduction of work load. According to Fawcett and Russell, health policies address services, personnel, and expenditures. Both the FMLA and employer sick leave benefits address expenditures. Information on FMLA and sick leave benefits were obtained through study participant self-report.

The CMNHP consists of five increasingly broad levels that serve as the frame of reference for viewing nursing and health policy (Fawcett & Russell, 2001). This study used Level I as its frame of reference. According to Fawcett and Russell, Level I examines nursing practice processes and outcomes within an explicit conceptual model of nursing practice or nursing theory. The Piper Integrated Fatigue Model (IFM) was of particular interest in this study. The IFM explicitly addresses outcomes, with an assumption that practice processes are directed toward those outcomes. In addition, the IFM identifies variables that expand understanding of the influence of policies on outcomes. The unit of analysis for this study was individuals undergoing radiation therapy for cancer. The nursing and health policy outcome of interest was cancer-related fatigue. The impact of specific nursing practice processes on radiation therapy-related fatigue is a topic for future research.

Integrated Fatigue Model (IFM) (Figure 2). Fatigue eludes easy conceptualization (Blesch et al., 1991). There continues to be no universally accepted definition of cancer-related fatigue within either the nursing or allied health fields

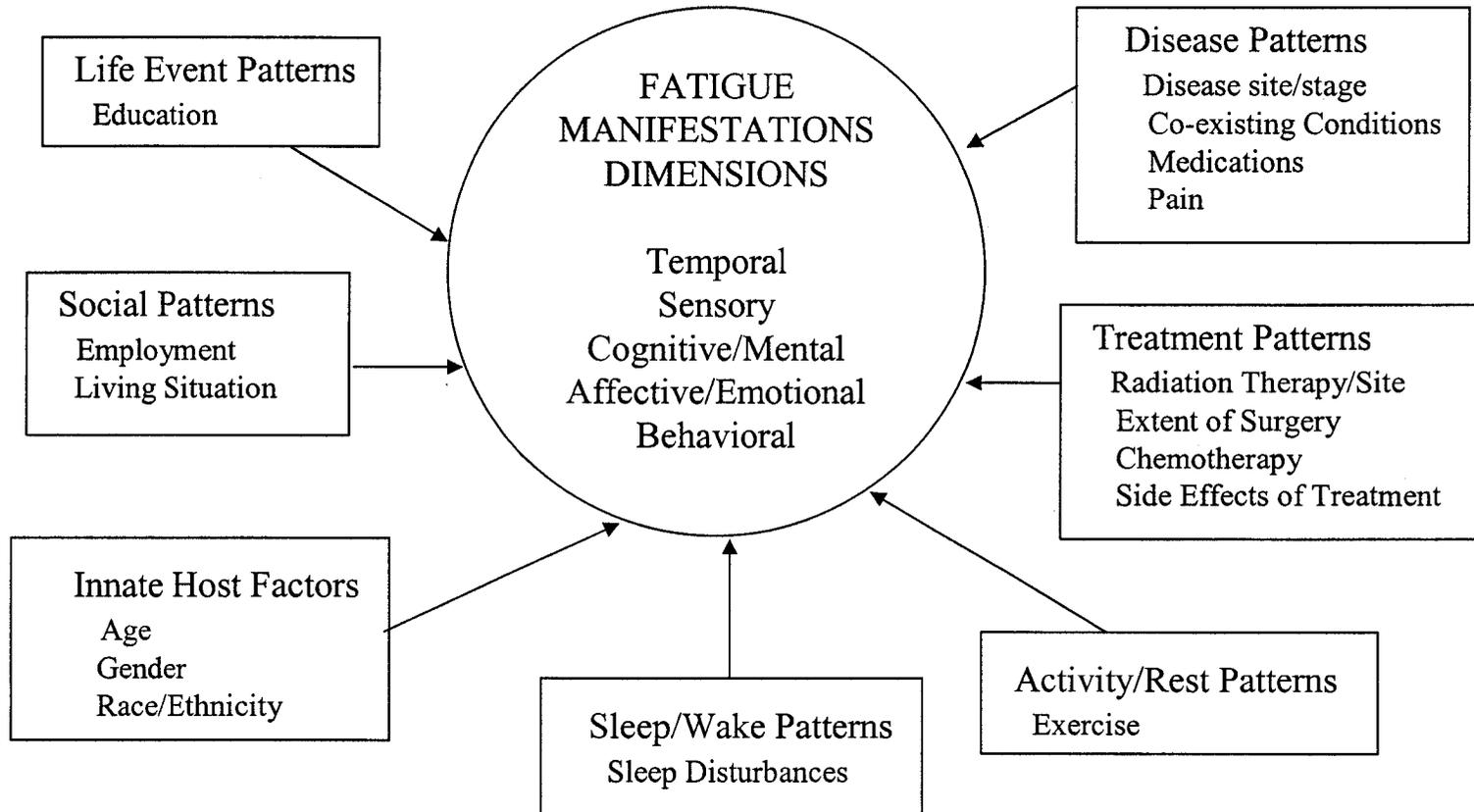


Figure 2. Integrated fatigue model (IFM). ©

From "Lets Take 'U' Out of Fatigue," by Oncology Nursing Society (2001).

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(Tiesinga, Dassen, & Halifens, 1996). The NCCN (2003) offers the following definition: “Cancer-related fatigue is a persistent, subjective sense of tiredness related to cancer or cancer treatment that interferes with usual functioning.” Cancer-related fatigue is acknowledged to be multidimensional and dynamic (Winningham et al., 1994).

The IFM is a synthesis of much of the available data on cancer-related fatigue (Berger & Walker, 2001). In the IFM, subjective perception is posited to be the key to understanding cancer-related fatigue (Piper et al, 1998). The IFM encompasses six manifestations or dimensions of subjective fatigue: temporal (timing and duration), sensory (physical), cognitive/mental, affective/emotional, behavioral/severity, and physiological (Piper et al., 1987; Sitton, 1997). Although researchers agree that cancer-related fatigue is a subjective phenomenon, there is no accepted measure to quantify subjective physiological fatigue (Berger et al., 2003). Determining and measuring physiological fatigue is currently an area of active research, as well as a source of controversy (B. Piper, personal communication, October 1, 2003). Physiological fatigue is a correlate or underlying mechanism of cancer-related fatigue and possible measures are expensive and inexact (B. Piper). Thus the physiological dimension of the IFM’s conceptualization of fatigue was not measured in this study; the other five dimensions were measured. In particular, the Revised Piper Fatigue Scale (PFS) was used to measure four dimensions of subjective fatigue: sensory, cognitive/mental, affective/emotional, and behavioral. A single item 0-10 numeric scale was used to measure the temporal dimension of fatigue. In addition, the Brief Fatigue Inventory (BFI) was used as a single-dimensional measure of the severity of radiation therapy-related fatigue.

The IFM delineates the multiple interrelated factors or causes that lead to fatigue in cancer patients, such as life event patterns, social patterns, environmental patterns, regulation/transmission factors, psychological patterns, symptom patterns, oxygenation patterns, innate host factors, accumulation of metabolites, energy/energy substrate patterns, activity/rest patterns, sleep/wake patterns, and disease and treatment patterns (Berger, et al., 2003; Piper et al., 1987; Sitton, 1997). Although the IFM does not directly imply a reciprocal relation between the multiple patterns and fatigue, there is a suggestion in the literature that this relation does indeed exist (Berger & Walker, 2001; Piper et al., 1987).

Employment patterns represent several of the patterns identified in the IFM as potential causes of fatigue: life event patterns, social patterns, and activity/rest patterns. Temporal aspects, e.g., days and hours of work, as well as job title and actual duties performed were used to define employment patterns and were measured by self-report.

Individual characteristics also represent several of the patterns in the IFM. The NCCN (2003) guidelines suggest assessment of specific individual characteristics, including medications, medical problems, nutrition/metabolic status, activities, and sleep patterns during a comprehensive fatigue assessment. For the purpose of this study, individual characteristics were defined as age, gender, and race/ethnicity (innate host factors); disease site and stage (disease patterns); extent of surgery, previous and concurrent chemotherapy, radiation dose and treatment field, and anatomic treatment-related side effects (treatment patterns); baseline hemoglobin, co-existing medical conditions, pain, and medication usage (disease patterns, oxygenation patterns); education (life event patterns); living situation (social patterns); exercise (activity/rest

patterns); and sleep disturbances (sleep/wake patterns). Individual characteristics were measured by a demographic data questionnaire. Standardized documentation tools used in radiation therapy departments were used to measure anatomical site-specific treatment-related side effects.

Individual characteristics included both trait and state characteristics. Trait characteristics are those that remain fairly constant for an individual and vary little if any over time (Knapp, Kimble, & Dunbar, 1998). Trait characteristics in the present study included age, gender, race/ethnicity, disease site and stage, extent of surgery, previous chemotherapy, radiation treatment field, baseline hemoglobin, co-existing medical conditions, medication usage, education, and living situation. State characteristics are those that are less enduring and may vary significantly over time (Knapp et al.). State characteristics in the present study included radiation dose, treatment-related side effects, concurrent chemotherapy, pain, exercise, and sleep disturbances.

Figure 3 depicts the proposed relations between sick leave benefits, employment patterns, individual characteristics, and fatigue in patients receiving radiation therapy for cancer.

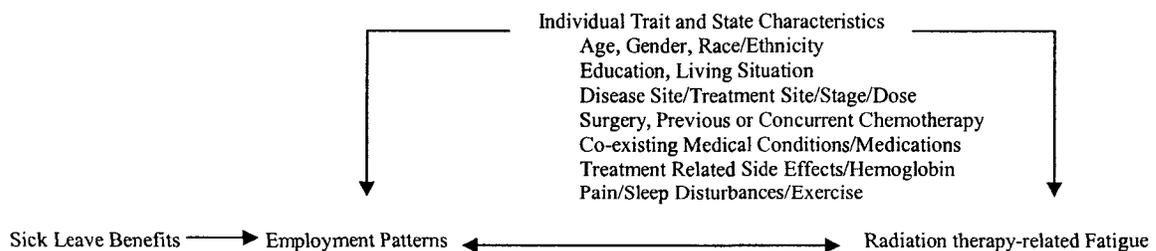


Figure 3. Diagram of proposed relational propositions.

Study aim 1 reflects the longitudinal design of the study as well as the temporal dimension of the IFM. Study aims 2 and 3 are grounded in the CMNHP. Aim 2 focuses on the health policy of sick leave benefits. Aim 3 focuses on the effect of a health policy on factors thought to be related to the outcome of interest, i.e., radiation therapy-related fatigue. Study aims 4, 5, and 6 specify relational propositions that are inherent in the IFM. Specific hypotheses derived from the study aims, conceptual framework and supporting literature are given in Chapter 2.

CHAPTER 2

INTEGRATED REVIEW OF THE LITERATURE

Radiation Therapy

Radiation therapy is the use of ionizing radiation in the treatment of cancer.

Radiation therapy may be used for curative intent, such as in the treatment of early stage laryngeal or prostate cancer (Hilderly, 1997). Radiation therapy also may be used as an adjuvant treatment, where radiation precedes or follows definitive surgery to increase local control (Hilderly). Examples of adjuvant use include radiation following lumpectomy for early stage breast cancer or radiation along with chemotherapy after surgery for rectal cancer. Radiation therapy also may be used in a palliative setting to help relieve symptoms of advanced cancer, such as pain or bleeding.

Radiation therapy may be administered externally, via treatment machines known as linear accelerators, or internally, via a radioactive implant. Only external beam radiation therapy was considered in the present study.

Prior to actually initiating external beam treatment, patients undergo a process of treatment planning, also referred to as simulation. This process is for the purpose of accurately defining the treatment field and ensuring accurate treatment reproducibility (Hilderly, 1997). The nurse's role in treatment planning is primarily to perform a comprehensive assessment of patient and family coping strategies and learning needs in order to design a plan of nursing care (Hilderly). In most radiation therapy departments, the nurse meets in a formal session with the patient and family either immediately after the treatment planning session or just prior to the first treatment to perform this

assessment and then provide in-depth patient and family education regarding expected side effects and strategies for managing those side effects.

Generally, a treatment course for palliation is shorter than a treatment course for curative or adjuvant intent. Curative or adjuvant radiation therapy also frequently requires higher doses and complex treatment planning. Thus, in order to detect trends in radiation therapy-related fatigue over time, the present study included only patients receiving radiation therapy for curative or adjuvant intent.

The most common method of delivering radiation therapy is by external beam, where radiation treatment is delivered by electromagnetic energy from a machine placed at a defined distance from the target site. The radiation treatment is given in divided doses or fractions. Fractionation allows for maximum tumor kill and minimum damage to normal healthy tissue (Hilderly, 1997). The standard fractionation schedule for curative or adjuvant intent is a daily fraction delivered five days a week for a period of four to seven weeks. The dose of radiation is prescribed in units called grays (Gy) or centigrays (cGy).

Patients meet at least once a week with the physician and nurse for the purpose of ongoing assessment, education, and initiation of interventions to manage side effects. The present study collected data at each of these planned weekly visits. Fatigue and skin changes occur in the majority of patient undergoing radiation therapy (Sitton, 1997). Other side effects are specific to the part of the body being treated, e.g., diarrhea during pelvic radiation or esophageal irritation during chest radiation, and generally begin after doses of 1500 to 3000 cGy, which generally are reached after the second or third week of treatment (Knopp, 1997; Maher, 1997; Manzanek, 1997). As the effects of radiation

doses are cumulative, acute side effects generally increase in severity as treatment progresses and then resolve within two to four weeks after completion of a course of radiation therapy (Knopp; Manzanek; Sitton).

Follow-up after completion of a course of radiation therapy varies widely by institution. However, the majority of patients are seen in follow-up at least once, generally four weeks after completion of their course of radiation. At that time, patients are assessed for resolution or continuation of acute side effects. The one month follow-up visit was included in the present study.

Radiation Therapy-Related Fatigue (Study Aim 1; Hypothesis 1)

The present study tested the hypothesis (derived from study aim 1) that radiation therapy-related fatigue follows a predictable pattern in patients receiving radiation therapy for cancer, beginning in approximately the second week of treatment, increasing as treatments progress, and returning to near pre-treatment levels by one month post-treatment.

The fatigue associated with radiation therapy appears to follow a pattern of increasing over the course of treatment and declining after completion of treatment (Christman, Oakley, & Cronin, 2001; Geinitz et al., 2001; Greenberg, Sawicka, Eisenthal, & Ross, 1992; Irvine, Vincent, Graydon, & Bubela, 1998; Schwartz et al., 2000). Onset of radiation therapy-related fatigue is generally expected to occur by the end of the second week of radiation (Greenberg; Greenberg, Gray, Mannix, Eisenthal, & Carey, 1993; Irvine), although other patterns have been found.

Irvine et al. (1998) measured fatigue in 76 women receiving radiation for breast cancer at six points in time: prior to starting treatment, at one and two weeks after

initiation of treatment, at the completion of treatment, and at three and six months post treatment. The researchers found a curvilinear relation between fatigue and cumulative radiation dose with a significant increase in fatigue at weeks one and two. Fatigue plateaued from week two to the end of treatment and returned to pretreatment levels by three months after completion of treatment.

Christman et al. (2001) found a similar curvilinear relation in 49 women with cervical or uterine cancer. Fatigue increased significantly by week two of treatment and continued a more gradual increase through the end of treatment. Fatigue then gradually decreased after completion of treatment. Findings from an earlier study by Greenberg et al. (1992) of 15 women also revealed a curvilinear relationship between fatigue and radiation fraction. However, those researchers found that fatigue decreased in the first two weeks of treatment, increased as treatment progressed, plateaued after week four, and began to decrease in the third week after treatment. Geinitz et al. (2001) found, in a group of 41 patients receiving radiation therapy for breast cancer, that scores on a fatigue visual analog scale (VAS) increased until treatment week four and remained elevated until week five. Values fell to pre-treatment levels by two months after treatment. Physical and cognitive subscores of the investigator-developed Fatigue Assessment Questionnaire were significantly elevated during weeks four and five (Geinitz et al.).

Magnan and Mood (2003) found, in a secondary analysis of 384 patients with diverse ethnic, educational, social, and economic backgrounds and heterogeneous cancer diagnoses and treatment sites, that the average onset of radiation therapy-related fatigue was halfway through the second week of treatment ($M=7.69$ treatment days; $SD=6.89$). Seventy-six percent of patients reported fatigue by the end of the second week of

treatment. However, an additional 43% of patients reported fatigue onset during the first week of treatment.

Not all studies included measures of fatigue at multiple points in time; rather, several studies compared pre-treatment levels to end-of-treatment levels. Irvine, Vincent, Graydon, Bubela, and Thompson (1994) compared 54 patients receiving radiation therapy to a group of healthy controls. There were no differences in mean levels of fatigue experienced by cancer patients prior to starting treatment and the mean levels of fatigue experienced by healthy volunteers. There was a significant increase in levels of fatigue experienced by the cancer patients at the end of treatment compared to their pre-treatment scores and to scores of the controls. No effort was made, however, to match controls. Monga, Kerrigan, Thornby, and Monga (1999) found that fatigue scores on the Piper Fatigue Scale were significantly higher at completion of treatment than at pre-treatment in a sample of 36 men receiving radiation therapy for localized prostate cancer. Janda et al. (2000) found that symptoms of fatigue increased significantly from baseline to end of therapy in a study of 43 patients undergoing external beam radiation therapy for prostate cancer. In contrast, Barsevick et al. (2002) found, in their study of energy conservation for cancer-related fatigue, that men receiving radiation therapy for early stage prostate cancer could not be included in data analysis due to low levels of reported fatigue at 88% of the data points. Monga et al. (1997) did not find any significant increase in psychological-subjective fatigue from pre-treatment to the end of treatment as measured by the PFS in a study of 13 men undergoing radiation therapy for prostate cancer. The researchers did, however, find a significant increase in neuromuscular fatigue from pre-treatment to end of treatment.

Most of these studies of radiation therapy-related fatigue have small sample sizes, ranging from 13 to 76 patients (an exception is the Mangan and Mood study [2003], with a sample size of 384). They are observational studies, using convenience samples of patients receiving radiation therapy at the study sites. There was no consistency in instruments used to measure fatigue. Thus it is difficult to make comparisons across studies. However, the majority of studies do point to a predictable pattern of fatigue in patients receiving radiation therapy for cancer, beginning in the second week of treatment, generally increasing as treatments progress, and returning to pretreatment levels by two to three months post treatment. The present study included measures of fatigue at baseline, weekly during radiation therapy, and at the one month follow-up study. Long-term follow-up will be considered as a future study.

Sick Leave Benefits and Employment Patterns (Study Aims 2 & 3; Hypothesis 2)

The present study tested the hypothesis (derived from study aims 2 and 3) that availability of sick leave benefits is associated with changes in employment patterns in patients undergoing radiation therapy for cancer.

The 1993 FMLA guarantees 12 weeks of unpaid leave for employees for medical care for a serious health condition, childbirth, adoption, or care for an ill family member (Cantor et al., 2001; DOL, 2000; DOL, n.d.; McGovern & Cossi, 1996). Employees must have been employed by their current employer for at least 12 months and have 1,250 hours of service with that employer during the previous twelve-month period. Employers with fewer than 50 employees within a 75 mile radius do not fall under FMLA. State and federal government employees are covered even if they do not meet the size or

geographic criteria (Cantor). Cancer and cancer-treatment qualify as serious health conditions for purposes of FMLA.

The FMLA requires unpaid leave, but permits use of paid leave benefits for any portion of the covered leave (Cantor et al., 2001). The FMLA requires employers to maintain group health insurance for eligible employees on the same terms that coverage would be provided if the employees were still working (Cantor). Leave provided under FMLA is job-protected; that is, an employee must be returned to the same (or equivalent) job upon return from the FMLA (Cantor). There are exceptions to the job-requirement, however. Reinstatement can be denied if the employee is terminated, if the employee's shift is eliminated, or if the employee is designated a "key" employee (HRTools, n.d.). The FMLA also established a bipartisan committee to study legally required and voluntary leave policies and their impact on workers and employers (Cantor et al., 2001). The first survey was conducted in 1995. In the year 2000, the DOL commissioned an update to the 1995 survey. Between July and October 2000, a list-assisted random digit dialing telephone survey was conducted on a sample of United States residents who had been employed at any time since January 1. A total of 2,558 interviews were completed for a weighted response rate of 58% (Cantor). Population weights were used to estimate actual numbers.

Cantor et al. (2001) estimated that between 18.5 million and 24.4 million Americans work for covered employers but are not eligible to take leave. An additional 30 to 37 million Americans work for non-covered employers. Overall, 62% of American workers are not covered under the FMLA (Albelda, Clayton-Matthews, & Manuel, 2002). Non-covered or non-eligible employees are more likely to be under age 25 or

over age 65, to have never been married, to have less than a high school diploma, and to have lower annual incomes (Cantor).

Another component of FMLA requires covered employers to provide employees with notification of their rights under the FMLA (Cantor et al., 2001). In the 2000 survey, 40.9% of all employees reported not having heard of the FMLA (Cantor). General awareness of FMLA increased slightly, but statistically significantly, since 1995.

Overall, the DOL estimated that 23.8 million Americans used the FMLA in 1999 (Cantor et al., 2001). Nearly two-fifths (37.8%) of those leaves were for the employee's own health (Cantor). Most frequent reasons cited were heart attack, cancer, depression, and surgery (Cantor). Interestingly, few intermittent leaves were taken for the employee's own health. Cantor et al. had expected that people receiving treatments such as chemotherapy, which is given in cycles, might benefit from intermittent leave.

Three and a half million Americans reported needing leave but being unable to take it (Cantor et al., 2001). More than three-quarters (77.6%) indicated they did not take leave because they could not afford it (Cantor). Slightly more than one-fifth (20.8%) stated their employer denied their leave request (Cantor). When asked what they did to take care of the situation when they did not take the desired leave, 44% stated they just lived with it/suffered with it, 25% got help from others, and 12% altered their work schedule (Cantor). Those reporting needing leave were more likely to be separated, divorced, or widowed than those reporting not needing leave (Cantor).

Cantor et al. (2001) hypothesized that some workers eligible for leave may not take it for a variety of reasons. Albelda et al. (2002) estimated that over two million workers in the United States who needed a leave but did not take one would have done so

if it were a paid program. Of those surveyed who took leave in 1999, more than one-half (53.6%) expressed worries about being able to pay their bills on time (Cantor). More than one-third (34.2%) of leave-takers reported receiving no pay during their longest leave (Cantor). Those receiving no pay were more likely to be female, hourly workers, younger (ages 18-24), have less than a high school education, and have annual salaries less than \$20,000 (Cantor).

Use of sick leave benefits by persons with cancer has only been minimally described in the literature. Policy implications specific to cancer and employment tend to focus on difficulty obtaining insurance (Fawcett & Buhle, 1995; Hoffman, 1999; Stewart et al., 2001) and the potential for discrimination related to a cancer diagnosis (Maunsell, Brisson, Dubois, Lauzier, & Fraser., 1999; Maunsell et al., 2004; Rothstein, Kennedy, Ritchie, & Pyle, 1995; Schultz, Beck, Stave, & Sellin, 2002).

Patients with cancer, then, can use the FMLA if they are eligible or covered and can afford it. Because of limitations of the FMLA, advocates of paid leave have placed this policy issue high on their legislative agenda (Albelda et al. 2002; AWHONN, 2002). Several countries, notably Canada, Italy, and Norway, provide at least partial paid leave under the unemployment insurance system (AWHONN). In 2000, the DOL issued rules that allow states to use unemployment insurance to provide paid leave under FMLA but only for the birth or adoption of a newborn child, although this legislation has been recently rescinded (Albelda, 2004). Five states (California, New York, New Jersey, Hawaii, and Rhode Island), Puerto Rico, and the railroad industry have mandatory temporary disability insurance (TDI) (Albelda; Social Security Administration [SSA], n.d.). The first TDI legislation was passed in 1942 and the last in 1969 (SSA). TDI

covers most commercial and industrial workers in private employment (SSA). Principal occupational groups excluded include domestic workers, family workers, government employees, and the self-employed (California permits elective coverage for self-employed and Hawaii covers state and local government employees) (SSA).

Administrative costs are met from payroll taxes with employers and employees generally cost-sharing. Benefits vary by state but generally begin after seven days of disability. In many cases, the employee cannot receive any wages during the period of TDI. TDI is not job-protected (Albelda). Albelda et al. argue that paid leave shifts costs to a more equitable distribution and reduces the burden on families. With no paid policy in place, businesses and states also pay in lost productivity, increased turnover, increased benefits costs, loss of payroll taxes, and increase in use of public assistance programs and Medicaid (Albelda).

Individuals with a serious health problem, such as cancer, are more likely to adjust their employment patterns if they have sick leave benefits available to them. Individuals may use the FMLA or other sick leave benefits in order to stop working altogether or to alter work schedules (Curt et al., 2000; Curt & Johnston, 2003; Longman et al., 1996; Mock, 1998). Little formal information is available on the relation of sick leave benefits and employment patterns, other than the FMLA. Curt et al. (2000) and Curt and Johnston (2003) found that both U.S. and Irish patients accepted fewer responsibilities, reduced working hours, took additional leave, and stopped working altogether due to cancer-related fatigue.

The findings of several studies suggest that there are psychological and perhaps physiological benefits, such as emotional support from colleagues and maintenance of

physical activity, to working during cancer treatment (Berry, 1993; Carter, 1994; Chan, Molassiotis, Yam, Chan, & Lam, 2001; Hilton, 1996; Maunsell et al., 1999; Wengstrom, Haggmark, & Forsberg, 2001). Few investigators have examined employment patterns during cancer treatment (Burnie, 2000; Curt et al., 2000; Longman et al., 1996). Instead, most investigators have studied employment patterns of cancer survivors. Most cancer survivors who were working prior to diagnosis are able to return to work, although some adjustments may need to be made due to disability, and many survivors consistently report problems with employment (Bradley & Bednarck, 2002; Bushunow, Sun, Raubertas, & Rosenthal, 1995; Fawcett & Buhle, 1995; Hensel, Egerer, Schneeweiss, Goldschmidt, & Ho, 2002; Satariano & DeLorenze, 1996; Schultz et al., 2002). Spelten et al. (2003) found, in a study of 235 patients in the Netherlands, that 64% of cancer survivors returned to work within 18 months of the first day of sick leave. Fatigue levels predicted the return to work, with fatigue at 6 months predicting a longer sick leave, with a hazard ratio of 0.71 (95% Confidence Interval 0.59-0.85) adjusted for diagnosis, treatment type, age, and gender (Spelten).

The DOL 2000 survey estimated that more than nine-tenths (94.4%) of Americans who used the FMLA in 1999 returned to the same employer after the leave (Cantor et al., 2001). Major reasons cited for return to work were no longer needed to be on leave, could not afford to take any more time off, just wanted to get back to work, and used up all the leave time allowed (Cantor).

Individual Characteristics and Employment Patterns (Study Aim 4; Hypotheses 3)

The present study tested the hypothesis (derived from study aim 4) that selected individual trait characteristics (age, gender, race/ethnicity, disease site and stage, extent

of surgery, previous chemotherapy, radiation treatment field, baseline hemoglobin, co-existing medical conditions, medications, education, and living situation) are associated with changes in employment patterns in patients undergoing radiation therapy for cancer. In addition, selected individual state characteristics (radiation dose, concurrent chemotherapy, treatment-related side effects, pain level, exercise, and sleep disturbances) also are associated with changes in employment patterns in patients undergoing radiation therapy for cancer.

The DOL (2005) estimated that in January of 2005, approximately 140,200,000 Americans were employed full- or part-time in non-farm occupations, which amounts to an overall civilian employment-population ratio of 62.4% (DOL). Americans worked an average of 33.7 hours per week in January 2005 (DOL). In 2004, Americans who consistently worked less than 35 hours per week for non-economic reasons, such as health or medical, worked an average of 21.4 hours per week (DOL). The FMLA eligibility criteria requiring an employee to have worked 1250 hours in the previous twelve months (DOL) averages to 24.4 hours per week. This means that individuals who decrease work hours due to health or illness might invalidate their eligibility for the FMLA in the next calendar year.

Selected trait and state individual characteristics are thought to be associated with employment patterns. Americans working full-time are more likely to be White rather than Black or Hispanic (DOL, 2005). Employed Americans also are more likely to be married than divorced or never married (DOL). Black, never married Americans are the most likely to be unemployed (DOL). Santariano and DeLorenze (1996) found that Black women were twice as likely as White women to be on medical leave from work

three months after treatment for breast cancer. Need for transportation assistance, limitations in upper-body strength, and employment in jobs requiring physical activity accounted for much of the difference. Thus the present study included race, ethnicity, and living situation as individual trait characteristics that may be related to employment patterns.

Age is another individual trait characteristic that may be associated with employment patterns, especially retirement. The traditional age for retirement, age 65, no longer provides full social security benefits for persons born after 1937 (SSA, n.d.). The age for full social security benefits has gradually increased over time until it is now age 67 for persons born after 1959 (SSA). In addition, individuals may choose to delay retirement until age 70 and receive increased benefits (SSA). The present study enrolled adults ranging from 18 to 67 years, the current retirement age for receipt of full social security benefits.

Although women represented less than one-half (46.3%) of the U.S. workforce in 2004, they represented more than one-half of technical (56%) and service (55.6%) workers (DOL, 2005). The service industry especially is noted for lower wages and health and sick time benefits (Cantor et al., 2001). In addition, the median weekly income for women in 2004 was less than 78% of the median weekly income for men (\$573 for women compared to \$713 for men) (DOL). Thus female workers are at higher risk for lower wages and fewer benefits than their male counterparts. The present study considered gender as an individual trait characteristic that may be associated with specific employment patterns.

Level of educational attainment is still another individual trait characteristic that has a major impact on employment. Participation in the workforce progressively increases with increased education and the unemployment rate progressively decreases. In 2004, the participation rate was 41.2% for individuals with less than a high school diploma (DOL, 2005). This increased to 60% for individuals with a high school diploma or equivalent but no college, to 73.8% for individuals with an associate degree, and to 75.8% for individuals with a bachelor's degree or higher (DOL). Conversely, the unemployment rates in 2004 ranged from 8.5% for individuals with less than a high school diploma to 2.7% for individuals with a bachelor's degree or higher (DOL). Education also is associated with the type of work an individual is qualified for. Thus the present study included education level as an individual trait characteristic that may be associated with specific employment patterns.

The physical and mental capacity to perform one's job also affects employment patterns. Nearly three percent (2.6%) of individuals who usually worked full-time reported working between 1 and 34 hours in 2004 for non-economic reasons including medical and disability (DOL, 2005). Individuals between the ages of 25 and 54 were the most likely to report not working due to ill health (DOL). Individual trait characteristics that influence physical health that were examined in the present study included disease site and stage, radiation treatment field, extent of surgery, previous chemotherapy, co-existing medical conditions, and baseline hemoglobin. In addition, individual state characteristics that influence physical health that also were examined in the present study included radiation dose, concurrent chemotherapy, medications, pain level, and anatomic site-specific treatment-related side effects.

As the effects of radiation doses are cumulative, radiation dose was considered as an individual state characteristic in the present study. Acute side effects of radiation may occur earlier and be more severe in patients receiving concurrent chemotherapy (Knopp, 1997; Poirier, 1991). Thus, concurrent chemotherapy was considered an individual state characteristic in the proposed study.

Although the diagnosis of cancer may have an impact on employment, most individuals with cancer are able to return to some form of work. Many survivors, however, continue to report problems with employment. The specific impact of radiation therapy on current and future employment has not been studied. The present study will help to fill the gap in knowledge regarding the impact of radiation therapy and radiation therapy-related fatigue on study participants' current employment.

Employment Patterns and Fatigue (Study Aim 5; Hypothesis 4)

The present study tested the hypothesis (derived from study aim 5) that a reciprocal relation exists between employment patterns and radiation therapy-related fatigue.

Few studies of employment status as a contributing factor to cancer-related fatigue have been conducted. Employment status was considered as a demographic variable in several studies (Akechi, Kugaya, Okamura, Yamawaki, & Uchitomi, 1999; Bower et al.; Irvine et al., 1998). Irvine et al., who studied women with breast cancer receiving radiation therapy, did not find any differences in fatigue scores by education or employment status. They did find a statistically significant correlation between fatigue and disruption of usual activities. Those investigators did not, however, state whether employment status changed during treatment. Bower et al. also did not find employment

status to be associated with fatigue. In contrast, Akechi et al. found that housewives experienced less fatigue than persons working full time. They did not, however, differentiate among types of cancer or types of cancer treatments. Two other studies (Berger & Farr, 1999; Mock et al., 1997) included collection of demographic data for employment but did not include these data in the analyses.

Curt et al. (2000) conducted a telephone survey of 379 cancer patients having a prior history of chemotherapy to confirm the prevalence and duration of fatigue and to assess the physical, mental, social, and economic impact on the lives of patients and their families. Fifty-three percent of patients received chemotherapy alone, and 47% received a combination of chemotherapy and radiation therapy. The researchers found that 59% ($n=177$) of the patients who experienced fatigue were working at the time of diagnosis. Of these patients, three quarters changed their employment as a result of fatigue. An average of 4.2 sick days was taken per month during and immediately after treatment. Twenty-eight percent of patients discontinued work altogether, 23% went on disability, and 11% used unpaid family or medical leave because of fatigue. The researchers did not differentiate patients who received chemotherapy alone from those who received both chemotherapy and radiation therapy. This study is distinctive in the fatigue literature in that it is one of the few studies with a random sample. Patients were recruited from a nationally representative panel of 575,000 households in the United States who had previously indicated they would be willing to be contacted for research purposes. From this panel, attempts were made to contact a randomly chosen subset of 6,125 households identified as having a member diagnosed with cancer. Ultimately, 379 patients completed the telephone interview. The researchers did not discuss how they arrived at

their final sample size nor did they state whether there were differences between the patients who completed the interview and those who either could not be contacted or chose not to participate.

The impact of cancer-related fatigue on employment status is not unique to the United States samples. The All Ireland Fatigue Coalition (AIFC) was established to examine cancer-related fatigue among Irish patients ($N= 1000$) undergoing active treatment. In order to define the economic impact of cancer-related fatigue, the survey addressed patient employment status at the time of cancer diagnosis (Curt & Johnston, 2003). The Irish sample was compared to the U.S. sample described in Curt et al. (2000). There were differences between the two samples. U.S. patients were more than twice as likely as Irish patients to be working full time. Irish patients were more likely to be self-employed or retired. Overall, 36% of Irish patients were actively working at the time of diagnosis compared to 59% of U.S. patients. However, the impact of cancer-related fatigue on work was greater on Irish patients. Sixty-three percent of Irish patients accepted fewer work responsibilities during treatment compared to thirty-five percent of U.S. patients. Fifty-two percent of Irish patients reduced hours of work compared to 34% of U.S. patients. Forty-eight percent of Irish patients working at the time of diagnosis stopped working altogether during treatment. In contrast, 28% of U.S. patients stopped work during treatment. Caregivers in both the U.S. and Irish samples also changed their employment as a result of patients' fatigue. Caregivers took days off, accepted fewer responsibilities, reduced working hours, and stopped working altogether (Curt et al., 2000; Curt & Johnston, 2003). In the Irish study, one caregiver lost a business.

Burnie (2000), in a qualitative study of 25 women with breast cancer, found that nearly half experienced a change in employment as a result of their diagnosis, either taking sick leave or, in the case of one woman who was self-employed, recruiting help from others. Women who continued to work expressed concerns about their ability to meet their employment needs: “I felt I did my job as well as I could;” “It would be very stressful if I continued to teach” (Burnie, p. 124). In the report of another qualitative study, Witt and Murray-Edwards (2002) quoted a cancer survivor: “At work, I negotiated for my needs. No matter how much I wanted to be actively involved at work, I had to pay attention to how much my body could do” (p. 30).

Although fatigue itself was not specifically mentioned, work was found to have beneficial effects on coping with stresses of cancer. Maunsell et al. (1999) identified several themes in the responses of employed women diagnosed with breast cancer, including possible positive effects of learning about the diagnosis while at work. In an exploratory study, Wengstrom et al. (2001) found that women identified support from colleagues at work as an effective strategy for coping with side effects of radiation therapy. Chan et al. (2001) found that social networks, including work and colleagues, were important in coping with treatment and treatment-related effects in a group of Chinese women with gynecologic cancer. Hilton (1996) identified resuming normal activities as an effective coping strategy for women with breast cancer. Berry (1993) and Carter (1994) noted that work and career may be a source of self-esteem and identity during a life event that threatens these components of self, such as cancer. Sehlen et al. (2002) found that being employed during radiation therapy for head and neck cancer was positively correlated with quality of life after treatment.

Employment, then, may have beneficial effects for persons being treated for cancer but frequently is affected by the side effects of cancer treatment, such as fatigue, which in turn may be affected by employment. Patients may stop working altogether, take sick leave, or accept fewer responsibilities due to cancer-related fatigue. Some patients who continue to work may feel that they are not fully meeting their employment responsibilities. On the other hand, patients who continue to work during treatment may experience increased emotional support and a more positive quality of life. Employment factors including hours of work and adjustments made during treatment were considered as individual state characteristics in the present study.

Individual Characteristics and Fatigue (Study Aim 6; Hypotheses 5)

The Piper IFM identifies several individual characteristics that may be associated with cancer-related fatigue. Selected individual state characteristics (anatomic site-specific treatment-related side effects, pain, sleep disturbances, exercise patterns, and concurrent chemotherapy) and selected individual trait characteristics (age, gender, race/ethnicity, living situation, education, disease site, anatomic treatment site, disease stage, extent of surgery, previous chemotherapy, co-existing medical conditions, baseline hemoglobin, and medications) are related to radiation therapy-related fatigue.

The proposed study tested the hypothesis that the following individual trait and state characteristics are related to radiation therapy-related fatigue.

Age. Jacobsen et al. (1999) and Irvine et al. (1998) found no significant relation between age and cancer-related fatigue. Woo, Dibble, Piper, Keating, and Weiss (1998) found, in a study of 322 cancer survivors, that younger women experienced higher levels of fatigue than older women. Bower et al. (2000) found that women in their study who

experienced higher levels of fatigue were more likely to be younger. Hickok, Morrow, McDonald, and Belig (1996), in a retrospective review of 50 patients who had received radiation therapy for lung cancer, found that fatigue was more frequent in the youngest (<51) and oldest (>70) patients than in those aged 51-70 years, suggesting a curvilinear relation between age and radiation therapy-related fatigue.

Curt et al. (2000) found, in a sample of 379 patients drawn from a randomly selected subset of 6,125 households identified as having a family member with cancer, that persons aged 55 to 64 were more likely than younger patients to experience fatigue that lasted longer than one week after their most recent chemotherapy. Cimprich (1998) found, in a study of 74 women with breast cancer, that older women experienced greater attentional fatigue, as manifested by decreased capacity to direct attention, than younger women. Thus there is a suggestion that age may influence cancer-related fatigue although the exact relation is unclear. Age then, was considered as an individual trait characteristic in the present study.

Gender, education, and race/ethnicity. Akechi et al. (1998) measured fatigue in 455 ambulatory cancer patients in Japan. The researchers found that female cancer patients and patients with higher levels of education had higher fatigue scores than men and patients with lower levels of education. The investigators did not indicate what types of treatment patients were receiving. In a small sample of patients undergoing biochemotherapy, Fu, Anderson, McDaniel, and Armer (2002) found that female patients reported higher total fatigue scores and higher fatigue scores in the dimensions of behavioral/severity and cognitive/mood than male patients. Gender was not a significant factor in radiation therapy-related fatigue in a study of lung cancer patients by Hickok et

al. (1996). Curt et al. (2000) found, in a random sample of 379 cancer patients, that women tended to be more likely than men to report experiencing daily fatigue. However, men were more likely than women (43% versus 24%, $p < .05$) to stop working altogether because of fatigue. Bower et al. (2000) did not find ethnicity or educational attainment to be significantly associated with fatigue.

Thus there is a suggestion that gender and education may influence cancer-related fatigue. Race and ethnicity do not appear to be related to cancer-related fatigue although the majority of the study participants were White, which limits the ability to draw conclusions about other racial or ethnic groups. The present study attempted to enroll a culturally diverse sample; however the final sample only included 4 (5%) study participants of racial/ethnic groups other than non-Hispanic White. Gender, education, and race/ethnicity were considered as individual trait characteristics in the present study.

Co-existing medical conditions/pain/medications. The presence of co-existing medical conditions may exacerbate or mask cancer-related fatigue. Fibromyalgia, chronic heart or lung disease, infection, hypothyroidism, renal or hepatic dysfunction, and chronic neurologic disorders are all associated with fatigue (Berger et al., 2003; Landis et al., 2003; NCCN, 2003). Hwang, Chang, Rue, and Kasimis (2003) found, in a study of 180 cancer patients, that pain independently predicted fatigue. According to NCCN, pain, whether cancer-related or not, is often a causative element of fatigue and thus should be specifically assessed. Medications and medication interactions including over-the-counter medications, vitamins, and herbal remedies may contribute to worsening of fatigue. For example, certain cardiac medications, such as beta-blockers, may cause bradycardia and subsequent fatigue (NCCN). Certain classifications of medications, such

as narcotics, antidepressants, antiemetics, and antihistamines, are known to contribute to fatigue (NCCN). Stone, Hardy, Huddart, A'Hern, and Richards (2000) found an increase in fatigue after three months in 62 men with prostate cancer receiving hormone therapy. The present study then, in order to incorporate a full fatigue assessment as suggested by the NCCN, included assessment of the individual trait characteristic, co-existing medical conditions, and the individual state characteristics, pain and medication usage.

Previous/concurrent treatment. The majority of patients with cancer are treated with a combined modality treatment rather than a single modality. Patients may have undergone surgery prior to initiating chemotherapy and/or radiation therapy. Chemotherapy may be administered prior to a course of radiation as well as concurrently with radiation therapy. The increased use of fatigue-inducing multimodal treatments has exacerbated the problem of cancer-related fatigue (NCCN, 2003). Schwartz (1998) recruited 219 physically active cancer survivors through an advertisement in a sports magazine. Patients had received surgery alone (30%), chemotherapy alone (11%), radiation therapy alone (3%), surgery and chemotherapy (20%), surgery and radiation therapy (20%), chemotherapy and radiation therapy (4%), or surgery, chemotherapy, and radiation therapy (15%). When asked about their level of cancer-related fatigue during treatment, the seven patients who received a combination of chemotherapy and radiation reported the highest levels of the following characteristics of cancer-related fatigue: intensity, distressing, depressing, incapacitation, and fatigue change from pre to post cancer. Patients who received a combination of surgery, chemotherapy, and radiation therapy had the second highest scores. Berger et al. (2003) found, in their study of 25 women receiving their first cycle of doxorubicin-based chemotherapy, that mean fatigue

intensity scores remained mild (< 4). However, half of the study participants' scores were in the moderate (4-6.9) to severe (7-10) range at each measurement point. The investigators speculated that this finding is explained by the fact that almost half of the sample was receiving radiation therapy at the times of moderate to severe fatigue (Berger). In contrast, Donovan et al. (2004) assessed fatigue in 134 women receiving either chemotherapy and radiation or radiation alone for early stage breast cancer. Fatigue increased over the course of treatment only in women receiving radiation alone. The researchers suggested that women's perception of fatigue may have changed as a function of having received prior chemotherapy.

Christman et al. (2001) found, in their sample of 52 women receiving radiation therapy for cervical or uterine cancer, that postoperative women experienced a greater incidence of fatigue than women who had not had surgery. Cimprich (1998) found, in a study of 74 women with breast cancer, that women who underwent more extensive surgery experienced greater levels of attentional fatigue, as measured by decreased capacity to focus attention, than women who underwent breast conservation surgery. Collectively, the study findings suggest that patients who received chemotherapy or major surgery prior to their radiation and those who received chemotherapy concurrently with radiation may experience greater fatigue than patients who receive radiation therapy alone. Thus, extent of surgery and previous chemotherapy were considered as individual trait characteristics and concurrent chemotherapy was considered as an individual state characteristic in the present study.

Disease site and stage/radiation treatment site. Several researchers found no relation between fatigue and the individual trait characteristic, stage of disease, in women

with breast cancer (Irvine et al., 1998; Jacobsen et al., 1999; Mast, 1998; Okuyama, Akechi, & Kugaya, 2000). Hickok et al. (1996) similarly found no relation between fatigue and stage of disease in a sample of patients with lung cancer who underwent radiation therapy. Gift, Stommel, Jablonski, and Given (2003) did find, in a secondary analysis of 112 patients with newly diagnosed lung cancer, that stage of cancer at diagnosis was the most predictive of the number of cluster symptoms (fatigue, weakness, poor appetite, weight loss, altered taste, nausea, vomiting) reported. Fatigue was reported more frequently in late stage ($n=49$) lung cancer than in early stage ($n=54$) lung cancer at diagnosis and at three months and six months post-diagnosis (Gift et al.).

Treatment site is an individual trait characteristic that may influence radiation therapy-related fatigue. Most of the studies of radiation therapy-related fatigue were conducted with women with breast cancer or men with prostate cancer, which is consistent with the diagnoses of the majority of patients treated with radiation therapy. However, there is a suggestion in the literature that fatigue is problematic and may actually be higher in people with other diagnoses (Blesch et al., 1991; Christman et al., 2001; Haylock & Hart, 1979; Hickok et al., 1996; King, Nail, Kreamer, Strohl, & Johnson, 1985; Piper et al., 1989).

King et al. (1985) found, in a sample of 96 patients, that patients receiving radiation therapy to the chest or female pelvis had higher levels of fatigue in the first week of treatment than patients receiving radiation therapy to the head and neck region or male pelvis. Olt (2003) identified fatigue as a major issue in women with gynecologic cancer. However, only three studies were found of women with gynecologic cancer receiving radiation therapy (Ahlberg, Ekman, & Gaston-Johansson, 2004; Ahlberg,

Ekman, Wallgren, & Gaston-Johansson, 2004; Christman et al., 2001). Two other studies included gynecologic cancer along with other diagnoses (Haylock & Hart; 1979; King et al., 1985). Ahlberg, Ekman, Wallgren et al. found that 60 women with uterine cancer scheduled to begin a course of radiation therapy experienced a low grade of fatigue prior to starting their radiation. Ahlberg, Ekman, and Gaston-Johansson found the degree of fatigue increased during radiotherapy in a pilot study of 15 women with uterine cancer. Christman et al. found nearly 50% of women in her study who were receiving radiation therapy for a gynecologic malignancy reported fatigue within the first week of treatment. King et al. found higher levels of fatigue in patients with gynecologic and lung cancers than in patients with cancer of the head and neck or prostate. Haylock and Hart found similar patterns of fatigue across several diagnoses (breast, lung, colon, soft palate, spine, testicle, cervix, and lymphoma).

Several studies were found that included an examination of fatigue in patients receiving radiation therapy for lung cancer (Beach, Siebeneck, Buderer, & Ferner, 2001; Blesch et al, 1991; Borthwick, Knowles, McNamara, Dea, & Stroner, 2003; Ekfors & Petersson, 2004; Hickok et al., 1996). Ekfors and Petersson found, in a qualitative study of 15 patients with lung cancer, that fatigue was a major experience, sometimes leading to social isolation. Hickok et al. found that fatigue developed in 78% of the 50 patients in their sample. Blesch et al. found that fatigue was present in 99% of the 77 patients in their sample of patients with breast or lung cancer receiving radiation therapy. In contrast, Beach et al., in a prospective study of a convenience sample of 45 patients with lung cancer receiving radiation therapy, did not find a significant change in overall or subscale scores on the Piper Fatigue Scale from pre-treatment to either the four week

point or the end of treatment. The researchers did find that change in fatigue over the course of treatment varied quite a bit from person to person. Borthwick et al. conducted a prospective study of 53 patients undergoing radiation therapy for lung cancer. The study findings confirmed the progression of fatigue over the course of treatment. However, levels of distress and interference with daily living were not found to be as overwhelming as expected. Tishelman, Degner, and Mueller (2000) found, in a pilot study of 15 patients with lung cancer receiving a variety of treatments, that fatigue received the highest score in intensity of symptoms but was second lowest in perceived importance. Breathing was the prime symptom in terms of importance. The researchers suggested that results may be related to a general deterioration in overall physical condition of the study participants. In addition, the findings from an experimental study by Given et al. (2002) revealed that the interventions for fatigue had the least effect on patients with lung cancer, suggesting that patients with lung cancer may have more advanced and complex disease, making their fatigue less amenable to intervention.

Magnan and Mood (2003) found that the mean level of fatigue onset did not differ by treatment site. However, fatigue duration was longer in patients with gynecologic cancers than prostate cancer ($p=0.017$, mean difference = -9.22 days) and fatigue distress was greater in patients with lung cancer than prostate cancer ($p=0.034$, mean difference = -0.63).

The findings of some studies suggested that the area of the body being treated and the size of the treatment field influence the duration of radiation therapy-related fatigue (Devlen, Maguire, Phillips, Crowther, & Chambers, 1987; Fobair et al., 1986; King et al., 1985). For example, patients treated for non-Hodgkin's lymphoma may experience

fatigue up to a year post-treatment. Patients treated with radiation therapy to the breast generally revert to pre-treatment levels by three months after completion of treatment. Due to time constraints, the present study did not include examination of the relation of sick leave benefits and employment patterns to fatigue that persisted beyond the one month follow-up visit. This is a subject for future study; present study participants were asked if they would be willing to be contacted at a later date for a long-term follow-up study.

Contradictory findings regarding the relation between disease site and stage and radiation therapy-related fatigue suggest that it is useful to include these variables in future studies. Inasmuch as there is a suggestion that fatigue is more problematic in other diagnoses than in breast or prostate cancer, it is important to recruit patients with a variety of cancer diagnoses receiving radiation to various anatomical sites. An attempt was made to oversample diagnoses other than breast or prostate cancer in order to obtain a sufficient sample of individuals with other diagnoses. Thus, disease site and stage and radiation treatment site all were considered as individual trait characteristics in the present study.

Anatomic site specific treatment-related side effects. Studies suggest that the individual state characteristic, site-specific side effects of treatment, may contribute to radiation therapy-related fatigue (Cella, Lai, Chang, Peterman, & Slavin, 2002; Guren et al., 2003; Wang, et al., 2001). Wang et al. found, in a study of 72 patients receiving preoperative chemotherapy and radiation therapy for rectal cancer, that uncontrolled diarrhea was predictive of increased fatigue ($p < 0.01$). In a prospective study of 42

patients, Guren et al. found that mean scores of diarrhea and fatigue increased significantly by the end of radiation therapy.

Bansal et al. (2004) found, in a prospective longitudinal study of 45 patients with head and neck cancers receiving radiation therapy, that Grade II acute morbidities led to an increase in fatigue symptom scores during the course of radiation therapy. This increase in symptom scores led to a significant decline in global health status ($p < .001$). Scores improved after one month of therapy but did not reach pre-treatment values. Lai et al. (2003) studied 113 patients with nasopharyngeal cancer currently undergoing radiation therapy ($n = 33$), within one year post-treatment ($n = 44$), or more than one year post-treatment ($n = 38$). The researchers found greater symptom distress, including fatigue, in patients undergoing radiation therapy than in the other two groups.

No relation was found between fatigue and nutritional status over time in patients with lung cancer receiving radiation therapy (Beach et al., 2001). The relation between degree of esophagitis (an expected side effect of radiation to the lung) and fatigue was not examined. Fatigue also has not been studied in relation to level of hydration (Nail, 2002).

There is a suggestion then, that fatigue may be related to other side effects of treatment in patients undergoing radiation therapy. It would be useful to explore the potential relation of site-specific side effects to fatigue. The present study was designed to examine the relation of the individual state characteristic, site-specific treatment-related side effects, to radiation therapy-related fatigue.

Hemoglobin. Contradictory findings exist for a relation between hemoglobin and cancer-related fatigue. Several investigators have found no relation (Bartsch, Weis, &

Moser, 2003; Blesch et al., 1991; Glaus, 1993; Greenberg et al., 1992; Irvine et al., 1994). Others have found a moderate relation (Cella et al., 2002; Holzner et al., 2002; Hwang et al., 2003; Magnan & Mood, 1993). Cella et al. compared anemic cancer patients to non-anemic cancer patients and to the general United States population. Fatigue scores of the anemic cancer patients were significantly worse than those of the non-anemic cancer patients, which, in turn, were significantly worse than those of the general population ($p < 0.001$). Within the group of anemic cancer patients, the degree of anemia was predictive of the degree of fatigue ($p < 0.001$). Hwang et al. found, in a study of 180 cancer patients, that hemoglobin was a unidimensional independent predictor of fatigue. Magnan and Mood found decreased hemoglobin consistently associated with higher levels of fatigue distress and earlier onset of fatigue. Ahlberg, Ekman, and Gaston-Johansson (2004) found a significant decrease in hemoglobin during radiation therapy in 15 women with uterine cancer. However, there was no correlation between hemoglobin and general fatigue during or at the completion of treatment. Harrison, Shasha, and Homel (2002) speculated that one-half of cancer patients undergoing radiation therapy are anemic prior to or during treatment. Only baseline hemoglobin levels were considered as individual trait characteristics in the present study as it is not standard practice to obtain routine laboratory analyses for patients receiving radiation therapy.

Living situation. Akechi et al. (1998) found that housewives and patients living with relatives had lower fatigue scores than patients living alone. Bower et al. (2000) found that patients with higher fatigue scores were less likely to be married or in a significant relationship. The present study was designed to test the hypothesis that the

individual trait characteristic, living situation, is related to radiation therapy-related fatigue.

Exercise and sleep. Exercise has found to be the one effective intervention for relief of cancer-related fatigue (Dimeo et al., 1997; Dimeo et al., 1999; Mock, 2001; Mock et al., 1997; Mock et al., 2001; Schwartz, 1999, 2000a; Young-McCaughan et al., 2003). Mock et al. (1997) enrolled 46 women receiving radiation therapy for early stage breast cancer into either an experimental walking exercise group or a control group receiving usual care. The exercise group scored significantly lower on symptom intensity especially fatigue. Although the sample size was small, this is one of the few studies of cancer-related fatigue to use random assignment. Although not specifically measuring fatigue, Young-McCaughan et al. found, in a study of 62 cancer patients either undergoing or having completed cancer treatment, that subjects who completed a 12-week exercise program reported less difficulty sleeping and more energy on the Cancer Rehabilitation Evaluation System-Short Form questionnaire. On the other hand, patients enrolled in exercise interventions often drop out of the study for a variety of reasons, including fatigue (Dimeo et al., 1997; Dimeo et al., 1999; Mock; Mock et al., 2001; Pickett et al., 2002; Schwartz; Young-McCaughan). Patients who actively exercised prior to their diagnosis and treatment frequently report that they have to reduce the frequency or intensity of their exercise due to fatigue. Thus, exercise may help to reduce radiation therapy-related fatigue but may also be adversely influenced by fatigue. Exercise then, was considered as an individual state characteristic in the present study.

Sleep disturbances have been found to be related to increased levels of fatigue in cancer patients and in other chronic diseases such as fibromyalgia (Anderson et al., 2003;

Berger & Farr, 1999; Bower et al., 2000; Davidson, MacLean, Brundage, & Schuttze, 2002; Holzner et al., 2002; Landis et al., 2003; Lee, 2001). Berger and Farr found that a group of 72 women with breast cancer receiving chemotherapy who were less active during the day and had more nighttime awakenings, as measured by wrist actigraphs, reported greater cancer-related fatigue. The researchers suggested that performing usual daytime activities might help maintain lower levels of fatigue. Bower et al. found sleep disturbances to be a strong predictor of fatigue in a study of 1,957 breast cancer survivors even after controlling for other factors such as depression and pain. Lee linked sleep disturbances in cancer patients to fatigue, pain, wound healing, immune function, and mental health. Anderson et al. found, in a sample of 354 cancer patients, 72 psychiatric patients, and 290 non-patient volunteers, that sleep disturbance scores of both the cancer patients and the non-patient volunteers were significantly correlated with fatigue severity. Many patients reported that they slept increased amounts during the day and went to bed earlier at night due to cancer-related fatigue.

Miaskowski and Lee (1999) found an interesting pattern of higher fatigue scores in the evening and lower scores in the morning in a pilot study of 24 cancer patients receiving radiation therapy for bone metastases. This finding suggests that sleep may mediate radiation therapy-related fatigue. Alternatively, fatigue may lead to sleep disturbances. Sleep disturbances then, were considered as individual state characteristics in the present study.

In summary, individual characteristics appear to be related to cancer-related fatigue. The individual trait characteristics of age, gender, education, living situation, previous chemotherapy, extent of surgery, disease and treatment site, dose of radiation,

stage of disease, co-existing medical conditions, baseline hemoglobin, and medications all have been found in at least one study to be related to radiation therapy-related fatigue. The literature also suggests that the individual state characteristics of anatomic site-specific treatment-related side effects, pain level, sleep disturbances, exercise patterns, and concurrent chemotherapy are related to radiation therapy-related fatigue. Accordingly, the present study included these selected trait and state individual characteristics.

In conclusion then, the literature suggests that there are limitations to the use of sick leave benefits by persons with cancer. No information is available of the use of sick leave benefits by persons undergoing radiation therapy. The decision to work or not to work during radiation therapy may be influenced by the availability of sick leave benefits. Working during therapy may contribute to radiation therapy-related fatigue. Alternatively, work may provide emotional and physical benefits to the person with cancer. Individual characteristics may contribute to the degree of fatigue experienced by patients undergoing radiation therapy for cancer. Appendix A provides a summary of selected references included in this review.

Establishing the presence or absence of relations among the factors that may contribute to radiation therapy-related fatigue will provide a foundation for further policy decisions concerning sick leave, such as the alternatives for paid family and medical leave proposed by Albelda et al. (2002). Information from this study also may be used to affect policy regarding reimbursement for cancer-related fatigue assessment and management as recommended by the Advisory Board Committee (1999) and the NCCN (2003).

Hypotheses

Study hypotheses to be tested were derived from the study aims, the conceptual framework that guided the study, and the review of the pertinent literature. This study, then, tested the following hypotheses:

1. Radiation therapy-related fatigue follows a predictable pattern in patients receiving radiation therapy, beginning in approximately the second week of treatment, increasing as treatments progress, and returning to near pre-treatment levels by one month post-treatment.
2. Availability of sick leave benefits is associated with employment patterns in patients undergoing radiation therapy for cancer.
- 3a. Selected trait individual characteristics (age, gender, race/ethnicity, education, living situation, disease site and stage, radiation treatment site, extent of surgery, previous chemotherapy, baseline hemoglobin, co-existing medical conditions, and medications) are associated with employment patterns in patients undergoing radiation therapy for cancer.
- 3b. In addition, selected state individual characteristics (concurrent chemotherapy, radiation dose, site-specific treatment-related side effects, pain, exercise, and sleep disturbances) also are associated with employment patterns in patients undergoing radiation therapy for cancer.
4. A reciprocal relation exists between employment patterns and radiation therapy-related fatigue in patients undergoing radiation therapy for cancer.

- 5a. Selected state individual characteristics (age, gender, race/ethnicity, education, living situation, disease site and stage, radiation treatment site, extent of surgery, previous chemotherapy, baseline hemoglobin, co-existing medical conditions, and medications) are associated with radiation therapy-related fatigue in patients undergoing radiation therapy for cancer.
- 5b. In addition, selected state individual characteristics (concurrent chemotherapy, radiation dose, site-specific treatment-related side effects, pain, exercise, and sleep disturbances) also are associated with employment patterns in patients undergoing radiation therapy for cancer.

CHAPTER 3

METHODS

Sample

Seventy-seven study participants were recruited from one community hospital radiation oncology department. All individuals who were approached agreed to participate in the study. One study participant did not complete the one month follow-up assessment due to disease progression but completed all other visits. The original plan, which was to enroll approximately 150 study participants, was based on an expectation of a medium effect size (ES), using Cohen's (1988, p. 446) formulas. Findings, however, revealed large ESs when data had been collected from 77 study participants.

The actual ES for the sample was first calculated from a *t*-test of the differences in mean fatigue scores between the working and non-working groups at the end of radiation therapy. Using a formula given by Cohen (1988, p. 40), the observed ES was $d = 1.12$. Inasmuch as directionality was not specified, Cohen's (1988, p. 34) power table for a two-tailed *t*-test was used. With an ES of 1.12, obtained alpha $< .001$, and *N* of 77, the estimated power was .97.

Power was then calculated for multiple regression, using the obtained values. Power was first calculated for cross-sectional linear regression of variables predicting hours of work at the end of treatment. Using Cohen's (1988, pp. 415, 424) formulas and power tables (p. 416), with an Adjusted $R^2 = .3735$, an obtained alpha $< .001$, 6 independent variables, and *N* of 77, the estimated power was .99. Similar powers also were estimated for cross-sectional linear regressions of variables predicting work at each of the other measurement points during treatment. Next, power was calculated for a

cross-sectional linear regression of variables predicting mean total fatigue score at the end of radiation. Using Cohen's formulas (pp. 415,424) and power tables (p.417), with an Adjusted $R^2=.5684$, an obtained $\alpha <.001$, with 10 independent variables and N of 77, the estimated power was .99. Similar powers also were estimated for cross-sectional linear regressions of variables predicting mean total fatigue at each of the other measurement points during treatment. Thus, the sample of 77 study participants yielded powers of .97-.99.

The sample was limited to study participants who were receiving radiation therapy for either curative or adjunctive intent (thus receiving at least four weeks of radiation therapy); were between the ages of 18 and 67 years (the "usual" age of members of the workforce); had no unstable medical or psychiatric co-existing medical conditions as determined by medical history and chart review; were not receiving radiation therapy to the brain; had a Karnofsky Performance Status (KPS) greater than or equal to 70; were able to speak and read English; and were able to give written informed consent. Study participants with unstable medical or psychiatric co-existing conditions, such as uncontrolled hypertension, uncontrolled diabetes, or severe depression, were excluded to avoid confounding radiation therapy-related fatigue with the fatigue that may be associated with those conditions. Study participants with a KPS score of less than 70 would not be able to work, and frequently are hospitalized or reside in a rehabilitation facility (Yates, Chalmers, & McKegney, 1980). Both study participants who were currently working and those who were not currently working were recruited into the study as long as they were working prior to the diagnosis of cancer. The inclusion and exclusion criteria for the study are summarized in Table 1.

Table 1

Inclusion and Exclusion Criteria

| Inclusion Criteria | Exclusion Criteria |
|--|--|
| RT for curative or adjunctive intent: ≥ 4 weeks of treatment | RT for palliation: < 4 weeks of treatment |
| RT to chest/lung, breast, abdomen, pelvis, head and neck, extremities | RT to brain |
| Age 18-67 | Age < 18 or > 67 |
| KPS ≥ 70 | KPS < 70 |
| Absence of unstable medical or psychiatric co-morbidity | Presence of unstable medical or psychiatric co-morbidity, e.g., uncontrolled hypertension, uncontrolled diabetes, severe depression |
| Able to speak and read English | Unable to speak or read English |
| Able to give written informed consent | Unable to give written informed consent |
| Employed prior to diagnosis of cancer | Not employed prior to diagnosis of cancer |

The majority of the study participants were female (58%) and White non-Hispanic (95%). The participants ranged in age from 29-67 years ($M= 53.95$, $SD= 8.44$). The most common treatment site was breast (44%), followed fairly equally by the remaining four treatment sites (chest, pelvis, prostate, and head and neck). Table 2 summarizes the individual characteristics for the sample.

Table 2

Sample Characteristics (N=77)

| | Range | <i>M</i> | SD |
|--------------------------|-----------|----------|--------|
| Age (years) | 29-67 | 53.95 | 8.44 |
| Education (years) | 8-18 | 14 | 2.21 |
| Radiation Dose (cGy) | | | |
| Chest | 4400-6600 | 6046 | 744.55 |
| Pelvis | 4400-5940 | 4876 | 481.64 |
| Head/Neck | 4600-6600 | 6300 | 674.95 |
| Prostate | 6600-7200 | 6964 | 294.19 |
| Breast | 5040-6400 | 6093 | 363.80 |
| | <i>n</i> | Percent | |
| Gender | | | |
| Male | 32 | 42% | |
| Female | 45 | 58% | |
| Race/Ethnicity | | | |
| Non-Hispanic White | 73 | 95% | |
| Non-Hispanic Black | 2 | 2.5% | |
| Hispanic White | 2 | 2.5% | |
| Living Situation | | | |
| Alone | 18 | 23% | |
| Family/Significant Other | 59 | 77% | |
| Stage of Disease | | | |
| I | 27 | 35% | |
| II | 21 | 27% | |
| III | 16 | 21% | |
| IV | 8 | 10% | |
| Other | 5 | 6.5% | |

| | <i>n</i> | Percent | |
|---------------------------|----------|---------|--|
| Medical Conditions | | | |
| None | 21 | 27% | |
| 1 or 2 | 39 | 51% | |
| >2 | 17 | 22% | |
| Surgery | | | |
| Major | 21 | 27% | |
| Minor | 29 | 38% | |
| Biopsy Only/None | 27 | 35% | |
| Medications | | | |
| None | 23 | 33% | |
| 1 or 2 | 31 | 40% | |
| > 2 | 21 | 27% | |
| Treatment Site | | | |
| Chest | 13 | 17% | |
| Lung | 9 | | |
| Esophagus | 3 | | |
| Other | 1 | | |
| Pelvis | 9 | 12% | |
| Rectal | 5 | | |
| Bladder | 1 | | |
| Uterus | 2 | | |
| Pancreas | 1 | | |
| Head/Neck | 10 | 13% | |
| Prostate | 11 | 14% | |
| Breast | 34 | 44% | |
| Chemotherapy | | | |
| Prior Only | 19 | 25% | |
| Concurrent Only | 3 | 4% | |
| Both | 17 | 22% | |
| None | 38 | 49% | |

Instruments

The revised Piper Fatigue Scale (PFS) , the Brief Fatigue Inventory (BFI) and a single item 0-10 numeric scale were used to measure five dimensions of subjective fatigue: behavioral/severity, affective/emotional, sensory, cognitive/mental, and temporal. Physiological fatigue was not measured in this study. An investigator-developed sick leave benefits questionnaire, an employment patterns questionnaire, and a demographic questionnaire were used to measure other variables. These instruments were piloted tested with five volunteers: two healthy individuals, one cancer expert, and two former cancer patients. Only minor changes were made to the wording of the questions. The KPS was used as an exclusion/inclusion criterion for entry into the study.

Instruments to measure fatigue need to minimize staff and patient burden during assessment. Varricchio (2000) pointed out that choice of a tool to measure fatigue must consider its potential burden on the patient, should not make the fatigue worse, and needs to be understood by the patient. The instruments chosen to measure fatigue in this study were able to be completed quickly, were easy to administer, and were readily incorporated into routine assessments, thus minimizing staff and study participant burden. Instruments used to measure employment patterns, individual characteristics, and use of sick leave benefits also were designed to minimize study participant burden.

Karnofsky Performance Status Scale (KPS) (Appendix B). The KPS is a widely used measure of performance status in cancer study participants, especially those receiving radiation therapy (Karnofsky & Burchenal as cited in Padilla & Stromborg, 1997). The KPS measures performance of activities of daily living (Mor, Laliberte, Morris, & Weimann, 1984; Yates et al., 1980). Scores range from 0 (Moribund) to 100

(Normal, no evidence of disease). Mor et al. and Yates et al. reported KPS inter-rater reliability estimates of, $r=.69-.97$, and kappa=.53; Cronbach's alpha for internal consistency was estimated at .97 and test-retest reliability was estimated to be $r=.66$. Correlational analyses revealed the KPS to be correlated with other variables related to physical functioning, such as pain ($p = .006$) and sleep ($p=.050$) (Yates et al.). KPS scores also were correlated with physical quality of life (Kendall's tau=.35; $p < .001$) (Mor et al.). Akechi et al. (1999) found performance status as measured by the KPS to be significantly associated with fatigue. Although generally scored by the health care provider, one researcher used the KPS as a subjective measure by having study participants rate their own performance status (Waterhouse & Metcalf, 1984). In the present study, the KPS was used in the traditional manner, having the attending physician, primary nurse, or investigator assign a KPS value to potential study participants, with study participants required to have a KPS score of 70 or greater. The KPS was assigned at the time of initial consult before approaching the patient about participating in the study. Physicians, primary nurses, and the researcher each independently assigned a KPS score to five potential study participants. Inter-rater reliability of .99 was achieved for the KPS.

Numeric Scale (Appendix C). A single-item numeric scale was used to measure the temporal dimension of fatigue and as a screening measure for fatigue prior to administering the PFS. The instrument used the same 0-10 scale as the quantitative items of the PFS. Study participants were asked to rate the degree of fatigue they were currently experiencing on a scale of 0 (no fatigue) to 10 (a great deal of fatigue). If the rating was greater than 0, study participants then were assessed with the PFS. If the study

participant rated his or her fatigue as 0 on the single-item numeric scale, indicating no fatigue, all items of the PFS were rated 0. The numeric scale is effective and time-efficient in clinical practice (Piper, 1997). Although the 0-100 visual analog scale (VAS) is more sensitive, the 0-10 numeric scale is more consistent with clinical assessment instruments for other symptoms, such as pain, and the supposed increase in measurement sensitivity does not appear to be clinically significant (Piper et al., 1998). Both the VAS and the numeric scale correlate well with other unidimensional, multiple-item measures of intensity such as the Profile of Moods States (Pickard-Holley, 1991). In the present study, the correlation between the numeric scale and the PFS was .84; the correlation between the numeric scale and the BFI was .86.

Piper Fatigue Scale (PFS) (Appendix C). The PFS was used to measure four dimensions of subjective fatigue: behavioral/severity, affective/emotional, sensory, and cognitive/mental. The PFS requires only 5 to 10 minutes to complete and is useful for both screening and outcome assessments (Schwartz, 2002). The original PFS contained 40 items that measured four dimensions of subjective fatigue (temporal, severity, sensory, affective) and three open-ended questions that measure perceived causes of fatigue, relief measures, and associated symptoms (Piper et al., 1989). The PFS is regarded as one of the best-validated and best-developed multidimensional measures of cancer-related fatigue (Gledhill, Rodary, Mahe, & Laizet, 2002; Piper, 1997; Wu & McSweeney, 2001). However, some researchers have criticized this instrument as too complex and lengthy and based on the assumption that all respondents were experiencing fatigue (Wu & McSweeney). Factor analysis was used to reduce the original scale to its current 22 items, which measure four dimensions of subjective fatigue (behavioral/severity,

affective/emotional, sensory, and cognitive/mental) and five open-ended questions that provide additional qualitative information on contributing and relieving factors to cancer-related fatigue (Piper et al., 1998). Internal consistency reliability coefficients for the subscales ranged from .92-.96; the standardized alpha for the entire revised 22-item scale was .97 (Piper et al., 1998). A French version of the revised PFS yielded Cronbach's alpha coefficients ranging from .85 to .92 for the various subscales, indicating good subscale reliability (Gledhill et al.).

The 22 items of the revised PFS were scaled from 0 to 10, with 0 being no fatigue and 10 being severe fatigue. A mean total fatigue score then was calculated by adding the scores of items 1 through 22 together and dividing by 22 (Piper et al., 1998). Items 1 through 6 measure behavioral/severity dimensions of fatigue; items 7 through 11 measure affective/emotional meaning; items 12 through 16 measure sensory dimensions of fatigue; and items 17 through 22 measure cognitive/mental dimensions. The five open-ended questions of the revised PFS provided qualitative data that was used in this study to supplement the qualitative data provided by the other items.

Cronbach's standardized alpha coefficient for the entire scale was .98 in the present study. Standardized alpha coefficients for the subscales in the present study were: behavioral/severity--.79, affective/emotional--.98, sensory--.96, and cognitive/mental--.93. One item, distress, did not "fit" with the rest of the scale, having much lower item-test and item-rest correlations than the remainder of the items (STATA, 2001). If this item were dropped from the calculation, the standardized alpha coefficient for the behavioral/severity subscale increased to .87. Thus overall, the PFS demonstrated good reliability in the present study. The lack of fit of the distress item might be

indicative of lower distress levels in the current sample. Inasmuch as fatigue distress is regarded as a significant issue (Munro & Potter, 1996; Williams et al., 2001), the distress item was maintained for data analyses in the present study.

Brief Fatigue Inventory (BFI) (Appendix D). The BFI was developed by Mendoza and colleagues to assess the severity and impact of fatigue on patients with cancer and is described as a unidimensional measure of the severity of fatigue (Mendoza et al., 1999; Wu & McSweeney, 2001). The BFI is useful for screening to identify those patients with severe fatigue (Mendoza), but has limited ability to distinguish between mild and moderate fatigue (Schwartz, 2002). Japanese and German versions of the BFI have been validated (Okuyama et al., 2003; Radbruch et al., 2003). Validation studies are currently ongoing for Arabic, Korean, Russian, and Taiwanese versions (ProQolid, 2004). Based on the Brief Pain Inventory, the BFI consists of nine items rated from 0-10; the first three questions evaluate present, usual, and worse fatigue over the past 24 hours; the remainder evaluate interference with usual functioning (Schwartz; Wu). Cronbach's standardized alpha coefficients for the BFI have ranged from .89-.96 (Mendoza; Okuyama; Radbruch). Cronbach's standardized alpha coefficient for the BFI was .98 in the present study.

Sick Leave Benefits Questionnaire (Appendix E). Use of sick leave benefits were measured by an investigator-developed questionnaire originally designed for a survey research course requirement. Two focus groups were held, one with oncology nurses and one with former radiation oncology patients, to discuss staff and patient perceptions of sick leave benefits prior to the actual development of the questionnaire. Questions then were drafted and subjected to cognitive interviews with two oncology nurses, two non-

patient and non-medical persons, and two former patients. Additional options were added as a result of the interviews. The questionnaire was then pre-tested with three graduate students (Poirier, 2002). The Sick Leave Benefits Questionnaire asks study participants about their knowledge and utilization of available sick leave benefits, including FMLA, sick time, other benefit time, and informal benefits, such as decreased work load and working from home.

Employment Patterns Questionnaire (Appendix F). Study participants were asked about their hours and days of work as well as their job title and actual duties performed. A well-established survey, the Boston Area Survey (Center for Survey Research, 2002) was used as a source of questions about employment patterns. Study participants' actual perceptions were used to define jobs as physical/nonphysical. In addition, study participants were asked to rate the degree of stress they experienced at work on a 0 to 10 scale with 0 being no stress and 10 being a great deal of stress. Study participants also were asked to rate the amount of support they received from co-workers and supervisors on a 0 to 10 scales with 0 being a great deal of support and 10 being no support.

Demographic Data Sheet (Appendix G). Individual state and trait characteristics on the investigator-developed Demographic Data Worksheet obtained by study participant self-report included age, gender, race/ethnicity, education, living situation (alone, spouse/domestic partner, roommate, dependent children, grown children, elderly parents, other relative), usual exercise patterns, sleep disturbances, cancer/treatment site, previous treatment for cancer (type and extent of surgery, chemotherapy), concurrent chemotherapy, and concomitant medications. Other demographic data were obtained from the medical record, i.e., stage of disease, co-existing medical conditions, and

baseline hemoglobin. Site-specific treatment-related side effects and cumulative radiation dose were obtained from the Radiation Therapy Patient Care Record (Appendix H) currently used in the hospital's radiation therapy department. This tool grades side effects on a 0 to 4 scale consistent with the Common Toxicities Scoring Scale used in oncology (National Cancer Institute, 2003).

Weekly Assessment Tool (Appendix I). Study participants were assessed weekly for any change in their use of sick leave benefits or employment patterns. In addition, state characteristics (sleep disturbances, exercise patterns, living situation, and anatomic treatment-related site-specific side effects) also were updated weekly.

Procedures

Protection of human subjects. The study procedures were approved by the community hospital's and University of Massachusetts Boston's Institutional Review Boards. Potential study participants were identified by the attending radiation oncologist or primary nurse at the time of initial consultation and referred to the investigator. Study participants were then asked by the investigator to participate in the study at the time of initial nursing assessment and education done after the treatment planning session.

The investigator obtained written informed consent at the time of the nursing assessment and education done after the treatment planning session or immediately preceding the first radiation treatment. Study participants were given an explanation of the purpose of the study, how confidentiality would be maintained, their right to withdraw from the study at any time, and the time required for their participation in the study. Potential study participants were assured that participating or not participating in the study would not affect their medical or nursing care during their radiation therapy.

They were told that their fatigue would be assessed and managed, regardless of their participation in the study, with interventions such as moderate exercise, pacing activities and distraction offered. Study participants who agreed to participate in the study then signed the informed consent form. Study participants signed an authorization form for use of protected health information to allow the investigator to review their medical records.

Study participants were identified only by code numbers. All research instruments were marked only with the code number to maintain patient confidentiality. A master list was maintained with the names of study participants and their assigned code numbers. The master list was kept in a locked cabinet in the investigator's office and only the investigator and the research assistants had access to the cabinet. No code numbers were placed on informed consent forms. The master list will be destroyed at the earliest possible time after completion of the study. No reference to individual study participants will be made in any published or unpublished report of the proposed study.

Risks to study participants were minimal. Study participants may have found it stressful to answer questions regarding employment and benefits. Study participants were assured that they need not answer any question if it made them uncomfortable. No study participant refused to answer any question. An additional 15 to 20 minutes of time above that usually spent in the initial nursing assessment and education was required to obtain baseline data. An additional 10 minutes was required at each routine weekly assessment visit. Study participants did not need to make any additional visits to the department. No specific benefits to study participants were expected from participation in this study, although study participants who reported difficulties managing sick leave

benefits or employment issues were referred to social service or their specific employee assistance programs or human resources departments.

Design. The study employed a prospective, longitudinal design. Data were collected at baseline prior to starting radiation therapy, weekly during treatment, and at the one month follow-up visit. Each study participant was interviewed at six to eight different points in time. There were only occasional delays in assessments due to weather or illness. Extra work for study participants who agreed to be part of the study was minimized by doing data collection at the same time as routine assessments conducted on all patients receiving radiation therapy.

The investigator obtained baseline data for all study participants. After a training session in the use of the instruments, registered nurse research assistants obtained the weekly assessment data during the routine weekly visit. The investigator was available to provide direction and guidance as needed as well as to also obtain weekly assessment data. Each research assistant and the investigator followed a particular cohort of study participants.

Demographic data, use of sick leave benefits, and employment data were collected at baseline and updated during weekly assessments. During the baseline assessment, study participants were asked about their knowledge and utilization of sick leave and other employment benefits available to them during treatment. Study participants also were asked about their employment patterns prior to the diagnosis of cancer as well as their current employment patterns. Both currently working and nonworking study participants were interviewed weekly by the investigator or a research assistant for any changes in employment or use of sick leave benefits as a result of their

treatment. State characteristics such as sleep disturbances, exercise patterns, and treatment-related side effects also were assessed weekly.

Fatigue was assessed for all study participants at baseline, weekly during radiation therapy including the last week of treatment, and at the one month follow-up visit. The single-item numeric scale was administered at each visit. If the level of fatigue on this scale was greater than 0, the PFS then was administered. The BFI was administered at baseline and at the end of treatment.

Data Analysis

STATA, intercooled, version 7.0 and SAS Learning Edition 2.0 were used to analyze the quantitative data. STATA was used to conduct cross-sectional analyses and regression diagnostics. SAS was used to conduct longitudinal or time-series regression analyses.

Variables. Data included both continuous and categorical variables. A categorical variable was created for the individual trait characteristics, sick leave benefits: sick leave benefits available/not available. Other sick leave information was reported qualitatively, e.g., type of adjustments made at work to accommodate treatment-related side effects.

The individual state characteristics, employment patterns, were both continuous and categorical. Hours of work were used as a continuous variable, with non-working study participants assigned 0 hours. Hours of work also were categorized as working/non-working and full time/part time. Employment also was categorized as physical/nonphysical. Study participants also were categorized as working at beginning of treatment/not working at beginning of treatment, working at end of treatment/not

working at end of treatment, and changed employment during treatment/did not change employment during treatment.

Categorical variables also were created for individual trait and state characteristics: gender, race/ethnicity, disease/treatment site, stage of disease, extent of surgery, previous chemotherapy, concurrent chemotherapy, co-existing medical conditions, medications, and living situation. Individual trait and state characteristics, age, number of years of education, and site-specific side effect scores, were analyzed as continuous variables. Individual state characteristics, sleep disturbances and pain, were categorized as present/not present at each measurement point. Fatigue scores, as measured by the PFS, the BFI, and the single-item numeric scale, are continuous variables.

Tests of hypotheses. All hypotheses were tested at the .05 level of significance.

Hypotheses 1. Radiation therapy-related fatigue follows a predictable pattern in patients receiving radiation therapy, beginning in approximately the second week of treatment, increasing as treatments progress, and returning to near pre-treatment levels by one month post treatment.

Mean total fatigue scores for the entire sample and for groups categorized by treatment site were graphed for each measurement point. Paired *t*-tests were used to test for significant differences in mean fatigue scores at each point in time. Shi (1997) recommended at least three measures on the same instrument to draw conclusions regarding trends over time. The present study measured fatigue at a minimum of six points in time. Longitudinal analysis is able to account for differences in numbers of measurement points among study participants.

Hypothesis 2. Availability of sick leave benefits is associated with employment patterns in study participants undergoing radiation therapy for cancer.

Descriptive statistics were used to summarize employment patterns. A series of *t*-tests for independent samples then was used to compare study participants who had sick leave benefits with those who did not on the basis of working at the beginning and end of treatment, making changes in employment during treatment, and stopping work during treatment.

Hypothesis 3. Selected individual trait and state characteristics (age, gender, race/ethnicity, education, living situation, disease site and stage, extent of surgery, previous and concurrent chemotherapy, radiation treatment site, co-existing medical conditions, medications, baseline hemoglobin, radiation dose, exercise, treatment-related side effects, sleep disturbances, and pain) are associated with changes in employment patterns in patients undergoing radiation therapy for cancer.

Both cross-sectional multiple regression analyses and longitudinal regression analyses were used to test this hypothesis, modeling work as a function of individual characteristics. Confirmatory regression analysis was conducted using the simultaneous regression procedure (Burns & Grove, 2001). All independent variables supported by the integrated literature review were entered into the regression model at the same time. Variables were retained or eliminated based on individual probability levels, R^2 and adjusted R^2 of the model, results of regression diagnostic tests, and the strength of the supporting literature. Cross-sectional multiple regression was performed for the dependent variable, hours of work, at each of the measurement points. Actual hours worked at each measurement point was used in longitudinal analyses. Inasmuch as the

study consisted of repeated observations of work over time for the same set of participants, longitudinal analysis would be able to capture changes with time as the single within-subjects factor (Der & Everitt, 2002). Table 3 summarizes the longitudinal design for the dependent variable hours of work.

Table 3

Longitudinal Design for Dependent Variable Hours of Work

| Time | Time 0= Baseline | Time 1= Week 1 | Time 2= Week 2 | Time n= Week n | Time 6= End | Time 7= F/U |
|--|--------------------------------------|------------------------------------|------------------------------------|------------------------------------|---------------------------------|---------------------------------|
| DV: Hours of Work | Hours Baseline | Hours Week 1 | Hours Week 2 | Hours Week n | Hours End | Hours F/U |
| IV: Mean Total Fatigue Score | Mean Total Fatigue Baseline | Mean Total Fatigue Week 1 | Mean Total Fatigue Week 2 | Mean Total Fatigue Week n | Mean Total Fatigue End | Mean Total Fatigue F/U |
| IV: | Side Effects Baseline | Side Effects Week 1 | Side Effects Week 2 | Side Effects Week n | Side Effects End | Side Effects F/U |
| IV: | Pain at Baseline | Pain at Week 1 | Pain at Week 2 | Pain at Week n | Pain at End | Pain at F/U |
| IV: | Age | Age | Age | Age | Age | Age |
| IV: | Gender | Gender | Gender | Gender | Gender | Gender |
| IV: | Sick Leave | Sick Leave | Sick Leave | Sick Leave | Sick Leave | Sick Leave |

Hypothesis 4. A reciprocal relation exists between employment patterns and radiation therapy-related fatigue in study participants undergoing radiation therapy for cancer.

A *t*-test for the difference of means was first conducted comparing working and non-working groups on the basis of mean total fatigue scores at the end of radiation therapy.

The hypothesis then was tested both cross-sectionally at the end of treatment and longitudinally using the simultaneous regression procedure. Mean total fatigue scores on the PFS were used in all regression models. The dependent variable, hours of work, was first modeled as a function of mean total fatigue score, individual characteristics, and availability of sick leave benefits. The dependent variable, mean total fatigue score, then was modeled as a function of hours worked, individual characteristics, and availability of sick leave benefits.

Hypothesis 5. Selected trait and state individual characteristics (age, gender, race/ethnicity, education, living situation, disease site and stage, extent of surgery, previous and concurrent chemotherapy, radiation treatment site, co-existing medical conditions, medications, baseline hemoglobin, radiation dose, exercise, treatment-related side effects, sleep disturbances, and pain) are associated with radiation therapy-related fatigue in individuals undergoing radiation therapy for cancer.

Both cross-sectional multiple regression analyses and longitudinal regression analyses using the simultaneous regression procedure were used to test this hypothesis, modeling fatigue as a function of individual characteristics. Cross-sectional multiple regression was performed for the dependent variable, mean total fatigue score, at each

measurement point. Mean total fatigue scores at each measurement point also were used in longitudinal analyses. Table 4 summarizes the longitudinal design for the dependent variable mean total fatigue score.

Table 4

Longitudinal Design for Dependent Variable Mean Total Fatigue Score

| Time | Time 0= Baseline | Time 1= Week 1 | Time 2= Week 2 | Time n= Week n | Time 7= End | Time 8= F/U |
|--|--------------------------------------|------------------------------------|------------------------------------|--|-----------------------------------|---------------------------------|
| DV: Mean Total Fatigue Score | Mean Total Fatigue Baseline | Mean Total Fatigue Week 1 | Mean Total Fatigue Week 2 | Mean Total Fatigue Week n | Mean Total Fatigue End | Mean Total Fatigue F/U |
| IV: Hours of Work | Hours Baseline | Hours Week 1 | Hours Week 2 | Hours Week n | Hours End | Hours F/U |
| IV: | Side Effects Baseline | Side Effects Week 1 | Side Effects Week 2 | Side Effects Week n | Side Effects End | Side Effects F/U |
| IV: | Visit=0 Dose=0 | Visit=1 Dose= 900- 1000 | Visit=2 Dose= 1800- 2000 | Visit=n Dose= n ₁ -n ₂ | Visit=6 Dose= 4400- 7200 | Visit=7 Dose=0 |
| IV: | Age | Age | Age | Age | Age | Age |
| IV: | Ed | Ed | Ed | Ed | Ed | Ed |
| IV: | Living Sit | Living Sit | Living Sit | Living Sit | Living Sit | Living Sit |
| IV: | Rx Site | Rx Site | Rx Site | Rx Site | Rx Site | Rx Site |

CHAPTER 4

RESULTS

Employment Patterns

All 77 study participants were employed at the time of their diagnosis of cancer. Fifty-six (73%) of the participants were working at the start of radiation therapy. Of the 21 not working at the start of radiation, reasons were: unable to work because of surgery or chemotherapy ($n=9$), retired prior to start of radiation ($n=3$), laid off or temporarily unemployed ($n=3$), and chose not to work during radiation ($n=6$). Twenty-five (45%) of the 56 study participants employed at the start of radiation made some changes in their employment during their radiation. Changes included stopping work altogether ($n=14$), changing type of duties/work from home ($n=4$), decreasing hours worked per week ($n=2$), and taking an occasional day or half-day off during therapy ($n=5$). In addition, four participants who were not working at the start of radiation therapy resumed employment during radiation. In all, 45 (58%) of the 77 study participants were working full- or part-time at the end of radiation, and 32 (42%) study participants were not working at the end of radiation.

Sixty-two (82%) of the 76 study participants assessed at the one month follow-up visit had continued or resumed their previous employment. Of the 14 study participants not working at the one-month visit, 5 were retired (2 in addition to the 3 study participants who had retired prior to the start of their radiation), 1 study participant chose to go back to school and start a new career, 1 study participant's job was eliminated at the end of his treatment, and 7 study participants remained too ill to work or were undergoing additional cancer therapy.

Twenty-one (27%) of the 77 study participants described their work as “primarily physical labor,” e.g., construction work, supermarket cashier, landscaping, nursing assistant in long-term care, postal employee. Fifteen (19%) of the 77 study participants described their work as “primarily mental,” e.g., financial planner, counseling, supervisor, computer analyst. The remainder described their work as a combination of physical and mental activities, e.g., teacher, dog trainer, secretary, clinical supervisor. Twenty (26%) of the 77 study participants stated that their job was stressful (greater than 5 on a scale of 0-10). Only 4 (5%) of the 77 study participants stated that they received little or no support from their co-workers or supervisors. Employment patterns are summarized in Table 5.

Table 5

Summary of Employment Patterns (N=77)

| | <i>n</i> | Percent |
|-----------------------------------|----------|-----------|
| Working , Full- or Part-Time | | |
| at Diagnosis | 77 | 100% |
| at Start of Treatment | 56 | 73% |
| at End of Treatment | 45 | 58% |
| at Follow-up | 62 | 82% |
| Full-Time (≥ 36 hours/week) | | |
| at Diagnosis | 44 | 57% |
| at Start of Treatment | 36 | 47% |
| Part-Time (12-35 hours/week) | | |
| at Diagnosis | 20 | 26% |
| at Start of Treatment | 10 | 13% |
| Self-Employed, Currently Working | | |
| at Diagnosis | 13 | 17% |
| at Start of Treatment | 10 | 13% |
| | <i>M</i> | <i>SD</i> |
| Hours Worked per Week | | |
| Diagnosis Range 12-60 | 37 | 7.99 |
| Baseline Range 0-60 | 26 | 18.19 |
| End of Treatment Range 0-48 | 19 | 17.85 |
| Follow-up Range 0-48 | 28 | 15.30 |

Sick Leave Benefits

Forty-five (58%) of the 77 study participants stated they had some paid sick leave benefits (sick time, vacation time, earned time off, or short-term disability), although 7 (16%) of the 45 had no benefits remaining at the start of their radiation therapy. Study participants who were employed full-time were more likely to have sick leave benefits than study participants who were employed part-time or self-employed, $t(75) = -8.90$, $p < .001$. Of the 21 study participants not working at the beginning of radiation, only 9 (43%) received any income--3 had sick leave benefits, 3 received a retirement pension, and 3 received unemployment compensation. However, of the 14 study participants who stopped work altogether during their radiation, 11 (79%) had sick leave benefits and thus continued to receive some income.

Twenty-eight (37%) of the 77 study participants stated they were eligible for the FMLA, 41 (53%) stated they were not eligible, and 18 (10%) did not know whether they were eligible. Reasons for ineligibility included self-employed, too small an employer, and not working sufficient hours. Employees of health-care facilities and supervisors were most likely to be able to articulate the provisions of the FMLA. Table 6 summarizes sick leave benefits.

Fatigue

Study participants completed the single item numeric fatigue scale at each visit. If the score was greater than 0, study participants then completed the Piper Fatigue Scale (PFS). Mean change in fatigue scores for the entire sample on the single item numeric scale was 3.14 for baseline to the end of treatment. Schwartz et al. (2002) defined the minimally important clinical difference in fatigue to be 2.4 points for the single item

Table 6

Summary of Sick Leave Benefits (n=77)

| | <i>n</i> | Percent |
|-------------------------|----------|---------|
| Eligible for FMLA | | |
| Yes | 28 | 37% |
| No | 41 | 53% |
| Don't Know | 18 | 10% |
| Paid Benefits Available | | |
| At Diagnosis | 45 | 58% |
| At Start of Radiation | 38 | 49% |

numeric scale. In addition, the Brief Fatigue Inventory (BFI) was administered at the baseline and end of treatment visits. The PFS and BFI mean scores were highly correlated ($r = .92, p < .001$ at baseline; $r = .95, p < .001$ at end of treatment). These findings support the construct validity of the PFS. Only the PFS was used in subsequent data analyses.

As can be seen in Table 7, at baseline, 37 (48%) of the 77 study participants reported some fatigue. Thirty-six of those participants reported only mild fatigue (<4) and only one reported moderate fatigue at baseline (4-6.9). At the completion of therapy, 75 (97%) of the study participants reported some degree of fatigue. Fifty-three (69%) of the study participants reported mild fatigue, 15 (19%) reported moderate fatigue, and only 7 (9%) reported severe (7 or >) fatigue at the end of treatment. However, 47 (61%) of the study participants reported a maximum fatigue intensity score of moderate to severe at least once during their therapy. Interestingly, 50 (65%) of the 77 study

Table 7

Overall Summary of Reported Fatigue

| | <i>n</i> | Percent |
|---|----------|---------|
| Mean Fatigue at Baseline (<i>N</i> =77) | | |
| None | 40 | 52% |
| Mild (<4) | 36 | 47% |
| Moderate (4-6.9) | 1 | 1% |
| Severe (≥7) | 0 | 0 |
| Mean Fatigue at End of Treatment (<i>N</i> =77) | | |
| None | 2 | 3% |
| Mild | 53 | 69% |
| Moderate | 15 | 19% |
| Severe | 7 | 9% |
| Mean Fatigue at One Month Follow-up (<i>N</i> =76) | | |
| None | 34 | 45% |
| Mild | 39 | 51% |
| Moderate | 3 | 4% |
| Severe | 0 | 0 |
| Maximum Fatigue Distress Score (<i>N</i> =77) | | |
| Mild or None | 50 | 65% |
| Moderate | 15 | 19.5% |
| Severe | 12 | 15.5% |

participants reported no or only mild distress from the fatigue, 15 (19.5%) reported moderate distress, and 12 (15.5%) reported severe distress. At the one month follow-up visit, 42 (55%) of the 76 study participants who reported fatigue, the majority reported only mild fatigue. At this one month follow-up visit, 27 (35%) of the 76 study

participants reported that a substantial increase in fatigue had occurred at 1.5 to 2 weeks post-treatment, which then began to resolve by the one month visit.

Mean total fatigue scores on the PFS for the entire sample ranged from 0-4.77 at baseline ($M = 0.46, SD = 0.93$). Those scores increased to a range of 0-8.77 at the completion of treatment ($M = 2.84, SD = 2.40$). At follow-up, mean fatigue scores ranged from 0-4.82 ($M = 0.77, SD = 1.20$). Table 8 provides a summary of fatigue scores at each point in treatment.

Table 8

Summary of Radiation Therapy-Related Mean Total Fatigue Scores at Each Point in Treatment

| Treatment Point | <i>n</i> | Range | <i>M</i> | <i>SD</i> |
|---------------------|----------|--------|----------|-----------|
| Baseline | 77 | 0-4.77 | 0.46 | 0.93 |
| Week One | 77 | 0-5.11 | 0.66 | 1.13 |
| Week Two | 77 | 0-6.57 | 1.15 | 1.60 |
| Week Three | 77 | 0-6.45 | 1.50 | 1.62 |
| Week Four | 77 | 0-7.39 | 1.97 | 1.95 |
| Week Five | 77 | 0-7.50 | 2.15 | 2.08 |
| End of Treatment | 77 | 0-8.77 | 2.84 | 2.40 |
| One Month Follow-up | 76 | 0-4.82 | 0.77 | 1.20 |

Mean total fatigue scores were highly negatively correlated with the ability to perform usual activities ($r = -0.77, p < .001$) at the completion of treatment; study participants with higher fatigue scores were less able to continue to perform their usual activities than their

counterparts with lower fatigue scores. There were no differences in mean total fatigue scores at either baseline or end of treatment by type of work (primarily physical, primarily mental, or combination).

Mean fatigue scores on the subscales also increased over the course of treatment reaching peak levels at the end of treatment and then diminishing by the one month follow-up visit (Table 9). The behavioral/severity and affective/emotional subscales had higher mean fatigue scores at each measurement point than the sensory and cognitive/mental subscales.

Table 9

Summary of Mean Fatigue Scores at Each Point in Treatment by Subscale

| Treatment Point | N | Behavioral/ Severity | | Affective/ Emotional | | Sensory | | Cognitive/ Mental | |
|---------------------|----|-------------------------|------|-------------------------|------|---------|------|----------------------|------|
| | | M | SD | M | SD | M | SD | M | SD |
| Baseline | 77 | 0.63 | 1.23 | 0.63 | 1.40 | 0.59 | 1.15 | 0.47 | 1.29 |
| Week One | 77 | 0.75 | 1.29 | 0.69 | 1.40 | 0.66 | 1.23 | 0.50 | 1.12 |
| Week Two | 77 | 1.27 | 1.96 | 1.25 | 1.96 | 1.20 | 1.60 | 0.94 | 1.66 |
| Week Three | 77 | 1.58 | 1.99 | 1.69 | 2.09 | 1.51 | 1.55 | 1.09 | 1.71 |
| Week Four | 77 | 2.01 | 2.31 | 2.19 | 2.37 | 2.02 | 1.95 | 1.59 | 2.0 |
| Week Five | 77 | 2.32 | 2.73 | 2.34 | 2.43 | 2.16 | 2.04 | 1.78 | 2.10 |
| End of Treatment | 77 | 3.14 | 3.05 | 3.09 | 2.60 | 2.72 | 2.19 | 2.34 | 2.50 |
| One Month Follow-up | 76 | 0.84 | 1.50 | 0.92 | 1.50 | 0.68 | 1.19 | 0.60 | 1.14 |

Individual Characteristics

Sleep disturbances. Thirty-five (45%) of the study participants reported sleep disturbances at one or more points in treatment. Sleep disturbances were moderately correlated with fatigue ($r = .38, p = .0007$) and weakly correlated with hours of work ($r = .26, p = .02$) by the end of treatment.

Pain. Sixteen (21%) of the participants reported the presence of pain at one or more points in treatment. The presence of pain was moderately correlated with both fatigue ($r = .43, p < .0001$) and hours of work ($r = .41, p = .0002$) by the end of treatment.

Site-specific treatment-related side effects. Site-specific treatment-related side effects increased over the course of treatment from a range of 0-7 ($M = 1.14, SD = 1.56$) by week two to a range of 0-15 at the end of treatment ($M = 3.71, SD = 3.00$) on the Common Toxicities Scoring Scale (National Cancer Institute, 2003). Side effects diminished by the one month follow-up visit to a range of 0-7 ($M = 0.85, SD = 1.58$). Study participants receiving radiation therapy to the breast ($M = 2.21, SD = 1.38$) and the prostate ($M = 2.77, SD = 1.58$) had the lowest maximum side effect scores followed by study participants receiving radiation therapy to the pelvis ($m = 4.89, SD = 2.57$), chest ($M = 5.0, SD = 2.93$), and head and neck region ($M = 7.45, SD = 4.36$). Beginning in week two, side effect scores were substantially correlated with mean fatigue scores at each measurement point ($r = .52-.59, p < .001$).

Data for other individual characteristics are summarized in Chapter 3.

Tests of Hypotheses

Hypothesis 1. Radiation therapy-related fatigue follows a predictable pattern in patients receiving radiation therapy, beginning in approximately the second week of

treatment, increasing as treatments progress, and returning to near pre-treatment levels by one month post treatment.

The data support Hypothesis 1. Figure 4 graphically displays the increase in mean total fatigue scores over time for all study participants and for study participants divided by treatment site (chest, pelvis, head and neck, breast and prostate). It can be clearly seen that fatigue begins to increase after week one of treatment, peaks at the end of treatment, and returns to near baseline at the one month follow-up visit.

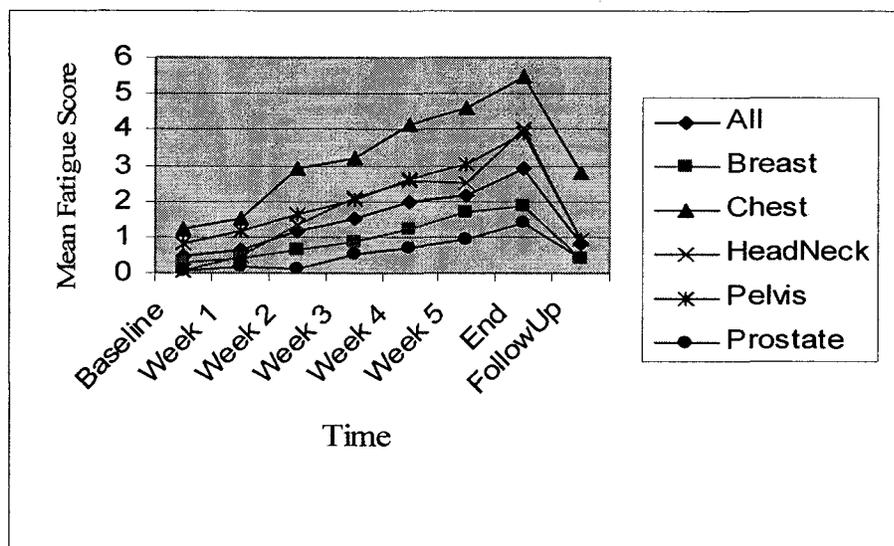


Figure 4. Mean total fatigue score by treatment site.

Mean fatigue scores for subscales also increased as treatments progressed and then decreased by the one month follow-up visit. Figure 5 graphically displays the mean fatigue scores over time by subscale. Only mean total fatigue scores were used for the remainder of the data analyses in the present study.

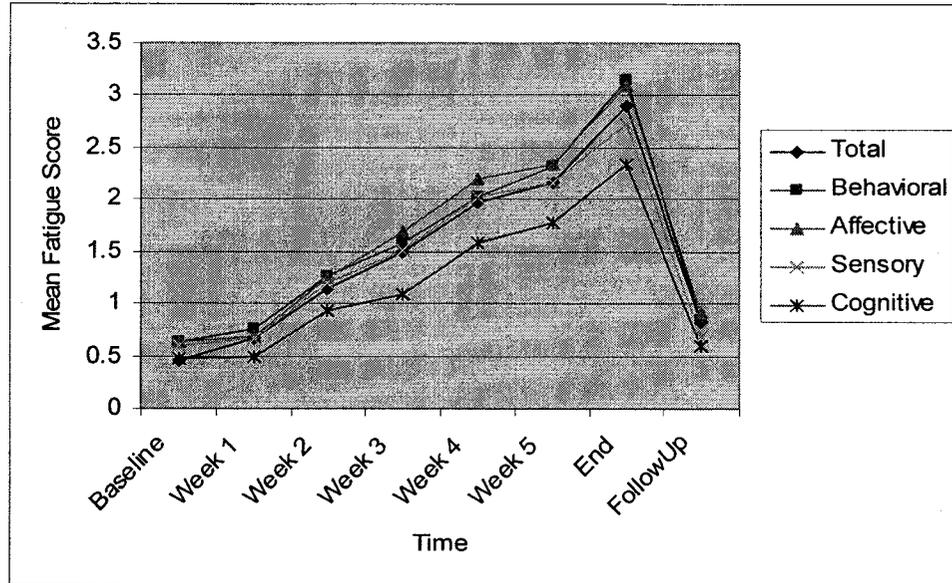


Figure 5. Mean fatigue scores by subscale.

Table 10 presents a summary of differences in mean total fatigue scores for baseline compared to each point in treatment and for baseline compared to the one month follow-up visit. Differences in mean total fatigue scores at baseline compared to the end of treatment were statistically significant for the entire group and for all treatment sites. Differences in mean total fatigue scores at baseline compared to week one were statistically significant for the entire group and for study participants receiving radiation therapy to the breast and pelvis. Differences in mean total fatigue scores for participants receiving radiation therapy to the chest and the head and neck region became statistically significant at the end of week two. Differences in mean total fatigue scores for participants receiving radiation therapy to the prostate did not become statistically significant until the end of week four. Study participants receiving radiation therapy to the head and neck area and chest still had significantly increased fatigue at the one month follow-up visit as compared to baseline.

Table 10

Paired T-Tests of the Differences in Mean Fatigue Scores Baseline to Each Data

Collection Point

| | Week 1 <i>p</i> | Week 2 <i>p</i> | Week 3 <i>p</i> | Week 4 <i>p</i> | End <i>p</i> | Follow-up <i>p</i> |
|---------------------------------|--------------------|--------------------|--------------------|--------------------|-----------------|-------------------------|
| Total Sample (<i>N</i> =77) | .004 | < .0004 | <.0001 | <.0001 | <.0001 | .004 (<i>N</i> =76) |
| Breast (<i>n</i> =34) | .01 | .003 | < .0001 | < .0001 | <.0001 | .56 (<i>n</i> =34) |
| Pelvis (<i>n</i> =9) | .03 | .003 | .001 | .001 | .0004 | .78 (<i>n</i> =9) |
| Head/Neck (<i>n</i> =10) | .23 | .02 | .008 | .004 | .0007 | .04 (<i>n</i> =10) |
| Chest (<i>n</i> =13) | .06 | .007 | .0002 | .0001 | <.0001 | .04 (<i>n</i> =12) |
| Prostate (<i>n</i> =11) | .19 | .24 | .08 | .05 | .05 | .30 (<i>n</i> =11) |

Study participants receiving radiation therapy to the chest had statistically higher mean fatigue scores than study participants receiving radiation therapy to other sites, both at baseline, $t(75) = -3.36, p < .0001$ and at the end of treatment, $t(75) = -4.64, p < .0001$.

Hypothesis 2. Availability of sick leave benefits is associated with changes in employment patterns in patients undergoing radiation therapy for cancer.

The data support Hypothesis 2 both in making adjustments in employment patterns and in stopping work altogether during radiation therapy. Eighty-seven percent of study participants with paid sick leave benefits were working at the beginning of

radiation; in contrast, only 55 % of study participants without paid sick leave benefits were working at the beginning of radiation. Study participants with sick leave benefits were more likely to be working at the beginning of treatment than those without sick leave benefits, $t(75) = -3.33, p = .001$. Forty-eight percent of study participants with sick leave benefits made changes in their employment during treatment; in contrast, only 26% of study participants without sick leave benefits made changes in their employment during treatment. Study participants with sick leave benefits were more likely than study participants without sick leave benefits to make adjustments in their employment during radiation therapy, $t(75) = -1.97, p = .05$. In addition, study participants with sick leave benefits were more likely than study participants without sick leave benefits to stop work altogether during radiation therapy, $t(75) = -3.10, p = .003$.

Hypothesis 3. Selected individual trait and state characteristics (age, gender, race/ethnicity, disease site and stage, extent of surgery, previous and concurrent chemotherapy, radiation treatment field, baseline hemoglobin, co-existing medical conditions, medications, education, living situation, radiation dose, treatment-related side effects, pain, exercise, and sleep disturbances) are associated with changes in employment patterns in patients undergoing radiation therapy for cancer. Hypothesis 3 could not be tested as originally proposed. Several individual characteristics were eliminated from the analysis: race/ethnicity due to unavailability of a culturally diverse population, baseline hemoglobin due to unavailability of data, and exercise due to few study participants who reported any exercise. A time ID variable was created to conduct longitudinal analyses. The time ID variable specified the variable that was used to assign time periods to the observations; in this case the actual measurement points (SAS, 2004).

Visit was created to correspond to the eight measurement points: baseline, weeks one through five, end of treatment, and the one-month follow-up visit. Visit, the time ID variable, was also used in longitudinal analyses as a proxy for radiation dose. All study participants have a radiation dose of 0 at visit one (baseline), which then increases at a constant rate for each study participant at each subsequent visit. Radiation dose and visit were highly correlated ($r = .96, p < .001$). In addition, disease site was not used in the data analysis; there were too few study participants in each category to evaluate by disease site. Rather, radiation treatment site was used in the data analysis. Radiation efficacy and toxicity are specific to anatomic region treated rather than to the actual disease. Chest treatment site included study participants with lung cancer, esophageal cancer, and sarcoma. Pelvis treatment site included study participants with rectal cancer, endometrial cancer, bladder cancer, and pancreatic cancer. Head and neck treatment site included study participants with various types of cancers of the head and neck region, as well as study participants with lymphoma receiving consolidation treatment to the neck region. Thus, the individual state and trait characteristics that were included in the analyses were: age, gender, education, living situation, stage of disease, extent of surgery, previous and concurrent chemotherapy, radiation treatment site, co-existing medical conditions, medications, treatment-related side-effects, visit, pain, and sleep disturbances (Table 11).

Both cross-sectional and longitudinal regression analyses were conducted.

Diagnostic tests were run on cross-sectional regression models to determine if the models met the assumptions of the classic linear regression model (Table 12). STATA Intercooled 7 was used to test the cross-sectional models for omitted variables, heteroscedasticity, multicollinearity, and normality of fitted residuals. The *ovtest* in

Table 11

Actual Versus Planned Individual Characteristics Used in Data Analyses

| Planned | Actual |
|--------------------------------|----------------------------------|
| Trait | Trait |
| Age | Age |
| Gender | Gender |
| Race/Ethnicity | Education |
| Education | Living Situation |
| Living Situation | Stage of Disease |
| Disease Site | Extent of Surgery |
| Stage of Disease | Previous Chemotherapy |
| Extent of Surgery | Radiation Treatment Field |
| Previous Chemotherapy | Co-existing medical conditions |
| Radiation Treatment Field | State |
| Baseline Hemoglobin | Concurrent Chemotherapy |
| Co-existing medical conditions | Medications |
| State | Visit (Proxy for Radiation Dose) |
| Concurrent Chemotherapy | Treatment-Related Side Effects |
| Medications | Pain |
| Radiation Dose | Sleep Disturbances |
| Treatment-Related Side Effects | |
| Pain | |
| Exercise | |
| Sleep Disturbances | |

Table 12

Regression Diagnostics for Cross-Sectional Analyses

| | Hours of Work at End of Treatment | Mean Total Fatigue Score at End of Treatment |
|--|-----------------------------------|--|
| <i>ov test (F, prob>F)</i> | 1.75, .17 | 0.98, .41 |
| <i>Hetest (chisq, prob>chisq)</i> | 0.68, .41 | 0.07, .79 |
| <i>VIF (mean, maximum)</i> | 1.41, 1.71 | 1.73, 2.79 |
| <i>Swilk residuals (z, prob>z, V)</i> | 1.15, .13, 1.69 | -0.16, .56, 0.93 |

STATA performs the Ramsey RESET test for omitted variables. The null hypothesis that there are no omitted variables was accepted. The STATA *hettest* performs the Cook-Weisberg test for heteroscedasticity of the fitted residuals. The null hypothesis that there is constant variance was accepted. After predicting values for residuals, the *swilk* test in STATA performs the Shapiro-Wilk W test for normality of fitted residuals. STATA (2001) recommends using both the *p* value and the *V* value to assess for normality of the data. The median value for *V* is 1.0 for normally distributed data. Very large values of *V* indicate non-normality (STATA). The null hypothesis that the data are normally distributed was accepted. The *kdensity* graph (Figure 6) shows that the residuals are fairly but not perfectly normally distributed. The *vif* command in STATA calculates the variance inflation factors to test for multicollinearity of the independent variables. Hamilton (2003) suggests that collinearity becomes a problem if the largest *vif* is greater than 10 or the mean *vif* is significantly larger than 1. Mean and maximum *vif* values indicated that multicollinearity was not a problem in the models.

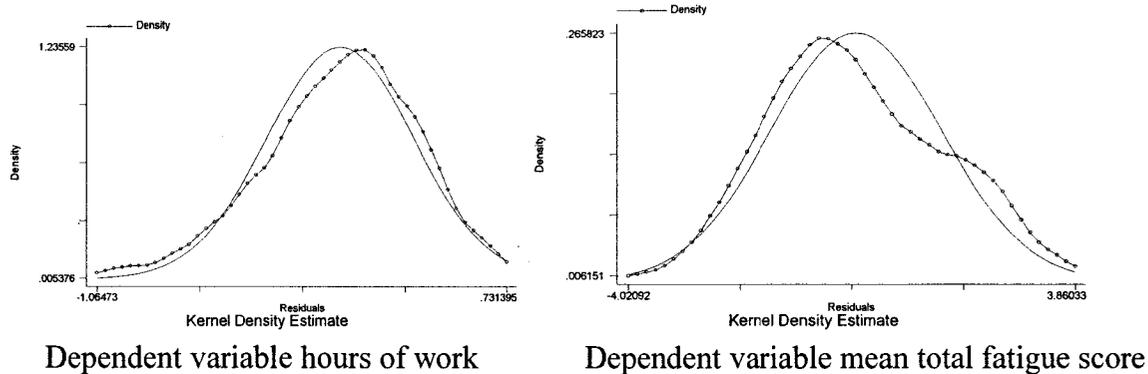


Figure 6. KDensity graphs of fitted residuals compared to normal curve for dependent variables hours of work at end of treatment and mean total fatigue score at end of treatment.

All independent variables in the longitudinal models also were tested for multicollinearity. Correlations between variables ranged from .00-.60. According to Burns and Grove (2001), multicollinearity exists if a bivariate correlation is greater than .65. Thus, multicollinearity was not an issue in this study. The SAS command regression analysis of panel data (the command for longitudinal analysis) also performs a Hausman test for random effects. This tests the null hypothesis that there is no correlation between random effects and the regressors. The Hausman *p* values were .09 for the dependent variable hours of work and .76 for the dependent variable mean total fatigue score. Thus the null hypothesis was accepted. The various regression diagnostics suggested that the models met the assumptions of the classic linear regression model in so far as could be tested in the computer software used.

Separate cross-sectional multiple regression analyses were run for each point in treatment. Gender, presence of pain, and side effects, as well as mean total fatigue score, predicted hours of work at the end of treatments (Table 13). Men were more likely than

women to be working at the end of treatment. The presence of pain and increase in site-specific side effects led to fewer hours worked at the end of treatment. The analysis indicated that 37 % of the variance in working was accounted for by mean fatigue at end of treatment, gender, presence of pain, and side effects. Each of the other data collection points during treatment yielded similar results with the exception that side effects did not become significant until week 4. Education, living situation, previous or concurrent chemotherapy, extent of surgery, radiation treatment site, stage of disease, sleep disturbances, co-existing medical conditions, and medications were not associated with hours of work at any measurement point in this study.

Table 13

Summary of Linear Regression of Hours of Work at End of Treatment (N=77)

| | Coefficient, Unstandardized | <i>t</i> value | <i>p</i> | <i>Beta*</i> |
|----------------------|-----------------------------|----------------|----------|--------------|
| Age | -0.36 | -1.65 | .10 | -.17 |
| Pain | -10.91 | -1.99 | .05 | -.21 |
| Gender (Male) | 10.95 | 2.92 | .005 | .30 |
| Fatigue at End | -2.31 | -2.67 | .01 | -.31 |
| Maximum Side Effects | -1.87 | -2.67 | .01 | -.30 |
| Sick Leave Benefits | 6.46 | 1.88 | .065 | .18 |

$R^2=.4230$; Adj $R^2=.3735$

*Standardized Beta coefficient

Longitudinal analysis produced similar findings. Inasmuch as work varied over the course of the treatment as did several of the independent variables, including pain and

side effects, longitudinal analysis made use of more data. Age, the presence of pain, gender, side effects, availability of sick leave benefits, and living situation, as well as mean total fatigue score, were predictive of hours of work along the trajectory of radiation therapy (Table 14).

Table 14

Summary of Longitudinal Regression of Hours of Work at Each Point in Treatment

(N=77)

| | Coefficient | t value | p |
|---------------|-------------|---------|--------|
| Age | -0.50 | -2.18 | .030 |
| Pain | -13.53 | -2.53 | .012 |
| Gender (Male) | 10.83 | 2.87 | .004 |
| Mean Fatigue | -0.12 | -6.79 | <.0001 |
| Side Effects | -1.37 | -4.42 | <.0001 |
| Sick Leave | 11.11 | 3.23 | .001 |

$R^2=.2052$; Adj $R^2=.17$

Younger study participants and men were more likely to be working during radiation treatments. The presence of pain and increase in side effects were inversely associated with hours of work. Availability of sick leave benefits was positively associated with hours of work. The analysis thus indicated that 17% of the variance in hours of work during the course of radiation therapy was accounted for by fatigue, age, pain, gender, side effects, and sick leave benefits. Education, living situation, previous or concurrent chemotherapy, extent of surgery, radiation treatment site, stage of disease,

sleep disturbances, co-existing medical conditions, and medications were not associated with hours of work in this study.

Hypothesis 4. A reciprocal relation exists between employment patterns and radiation therapy-related fatigue in study participants undergoing radiation therapy for cancer. This hypothesis was tested both cross-sectionally and longitudinally and was accepted.

A two-tailed *t*-test for independent samples was first calculated to determine if there was any difference in mean fatigue scores for the working versus non-working groups at the completion of radiation therapy. Study participants who were working at the end of radiation has lower fatigue scores than those who were not working, $t(75) = 4.85, p < .0001$. More in-depth analyses then were conducted.

Work was first modeled as a function of fatigue. As seen in Tables 13 and 14, hours of work were negatively associated with mean total fatigue scores. That is, study participants with higher fatigue scores worked fewer hours than participants with lower fatigue scores.

Fatigue then was modeled as a function of hours of work (Tables 15, 16). In a cross-sectional analysis, mean total fatigue scores at the end of treatment were negatively associated with hours of work at the end of treatment. Again, longitudinal analysis revealed results similar to results of the cross-sectional analysis. Fatigue was negatively associated with hours of work at each point in treatment. That is, increase in hours of work at each point in treatment (visit) led to lower total fatigue scores.

Thus, the data support the hypothesis that there is a reciprocal relation between employment patterns (hours of work) and fatigue. Increased fatigue is negatively

associated with hours of work and hours of work also are negatively correlated with fatigue.

Table 15

Summary of Linear Regression of Mean Fatigue at End of Treatment (N=77)

| | Coefficient, Unstandardized | t value | p | Beta* |
|-----------------------------------|-----------------------------|---------|--------|-------|
| Hours of Work at End of Treatment | -0.03 | -2.27 | .027 | -.20 |
| Maximum Side Effects | 0.20 | 2.19 | .032 | .23 |
| Age | -0.06 | -2.50 | .015 | -.21 |
| Living Situation | -1.85 | -3.90 | .0008 | -.32 |
| Years of Education | 0.17 | 1.97 | .05 | .16 |
| Breast | -3.01 | -4.99 | <.0001 | -.62 |
| Prostate | -2.49 | -3.39 | .001 | -.36 |
| Head and Neck | -2.52 | -3.55 | .001 | -.35 |
| Pelvis | -1.43 | -2.00 | .05 | -.19 |
| Chest | Reference | -- | -- | |

$R^2=.6195$; Adj $R^2=.5684$

*Standardized Beta coefficient

Table 16

*Summary of Longitudinal Regression of Mean Fatigue at Each Point in Treatment**(N=77)*

| | Coefficient | <i>t</i> value | <i>p</i> |
|------------------|-------------|----------------|----------|
| Side Effects | 0.30 | 10.36 | <.0001 |
| Education | 0.16 | 2.34 | .02 |
| Living Situation | -0.76 | -2.16 | .031 |
| Age | -0.04 | -1.90 | .05 |
| Head and Neck | -1.76 | -3.45 | .0006 |
| Prostate | -1.54 | -3.04 | .002 |
| Breast | -1.65 | -4.16 | <.0001 |
| Pelvis | -0.90 | -1.74 | .08 |
| Chest | Reference | -- | -- |
| Hours of Work | -0.03 | -6.91 | <.0001 |
| Visit | 0.21 | 2.59 | .01 |

R²=.3312; Adj R²=.25

Hypothesis 5. Selected trait and state individual characteristics (age, gender, race/ethnicity, disease site and stage, extent of surgery, previous and concurrent chemotherapy, radiation treatment field, baseline hemoglobin, co-existing medical conditions, medications, education, living situation, radiation dose, treatment-related side effects, pain, exercise, and sleep disturbances) are associated with radiation therapy-related fatigue in individuals undergoing radiation therapy for cancer. Hypothesis 5

could not be tested as originally proposed as not all individual characteristics could be included in the analysis as previous explained in Hypothesis 3.

As seen in Table 15, side effects, age, living situation, education, and treatment site, as well as hours of work, were all associated with fatigue at the end of treatment. Increased side effects, younger age, living alone, and higher education were associated with increased fatigue at the end of treatment. A quadratic term was included in the models for age, as some of the literature suggests that age has a curvilinear relation with fatigue (Hickok et al., 1996). That did not appear to be the case in this study, where a linear relation was found between age and radiation therapy-related fatigue. However, due to exclusion criteria, there were no elderly participants in this study, which might explain the discrepancy in findings. Study participants receiving radiation therapy to the breast, prostate, head and neck region, and pelvis had less fatigue at the end of radiation than study participants receiving radiation therapy to the chest. The analysis thus indicated that 57 % of the variance in mean fatigue at the end of treatment was accounted for by hours of work at the end of treatment, side effects, age, living situation, education, and treatment site. Cross-sectional analyses of each of the other points in treatment yielded similar results, with the exception that age did not become significant until week 4.

Again longitudinal analysis revealed similar findings to findings of the cross-sectional analyses, as can be seen in Table 16. Side effects, education, living situation, age, and treatment site, and visit, as well as hours of work, were all associated with mean total fatigue scores at each point in treatment (visit). Increase in side effects was associated with increased fatigue at each point in treatment. Younger study participants,

more highly educated study participants, and study participants who lived alone had increased fatigue during radiation therapy. Study participants who received radiation therapy to the head and neck region, breast, pelvis, and prostate had higher fatigue scores than study participants who received radiation therapy to the chest. Visit was positively associated with fatigue; as visit increased (and thus as radiation dose increased) fatigue increased. The analysis thus indicated that 25 % of the variance in mean fatigue during the course of radiation therapy was accounted for by hours of work, side effects, age, living situation, education, visit (radiation dose) and treatment site. Both cross-sectional and longitudinal analyses revealed that gender, previous or concurrent chemotherapy, extent of surgery, stage of disease, pain, sleep disturbances, co-existing medical conditions, and medications were not associated with fatigue at any of the measurement points in this study.

Figure 6 depicts the actual relations between sick leave benefits, employment patterns, individual characteristics, and radiation therapy-related fatigue found in this study.

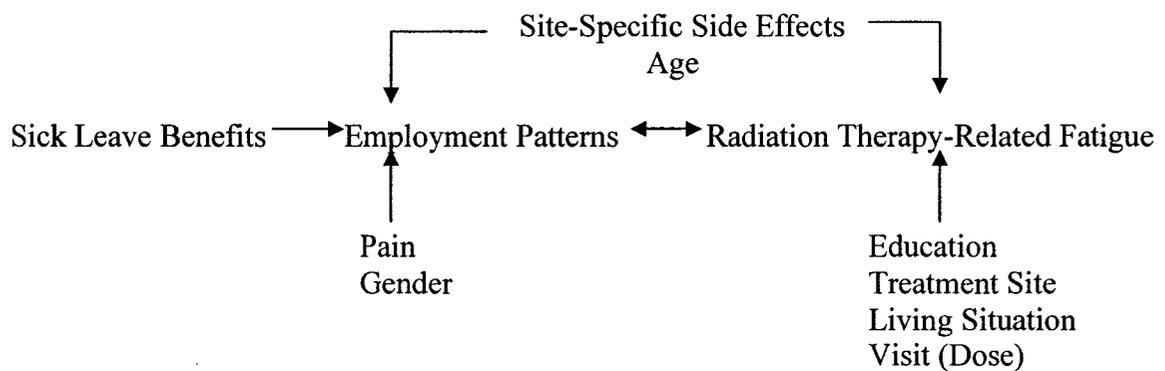


Figure 6. Diagram of relational propositions supported by study data.

CHAPTER 5

DISCUSSION

The findings supported the credibility of the CMNHP and the Piper IFM. The final middle range theory was, however, more parsimonious than that originally proposed. Furthermore, effect sizes were greater than had been anticipated.

The study findings are in keeping with the literature that specific individual trait and state characteristics (age, gender, presence of pain, and site-specific treatment-related side effects), as well as availability of sick leave benefits and radiation therapy-related fatigue are associated with employment patterns in patients receiving radiation therapy for cancer (Curt et al., 2000; Curt & Johnston, 2003; DOL, 2005; Longman et al., 1996; SSA, n.d.). Men were more likely than women to be working at each measurement point in this study. Societal pressures and financial concerns may be greater for men to continue working than for women. Younger participants were more likely to continue working during treatment than older participants. Younger workers may have fewer accrued benefits and less savings than older workers and thus have fewer resources to draw on.

Other individual trait and state characteristics (education, living situation, stage of disease, surgery, previous or concurrent chemotherapy, sleep disturbances, co-existing medical conditions, and medications) were not associated with employment patterns in the present study. Several of these characteristics may have an impact on employment if they have an association with performance status. All participants in the present study were required to have a KPS of at least 70 in order to be included. Baseline KPS at entry in the study actually was > 80 for all participants. The high level of performance may

explain why characteristics such as surgery, chemotherapy, and co-existing medical conditions, which are often associated with decrease in performance status (Ackechi et al., 1999; Cimprich, 1998; Landis et al., 2003), were not associated with working in this study. Other factors not measured in this study, e.g., desire to maintain “normalcy” or to “save” sick time for when it is really needed, may have had a greater impact on employment patterns.

The study findings also are in keeping with the literature that specific individual state and trait characteristics (age, education, living situation, treatment site, radiation dose (visit) and site-specific treatment-related side effects) as well as work are associated with radiation therapy-related fatigue (Ackechi et al., 1998; Bansal et al., 2004; Barsevick et al., 2002; Bower et al., 2000; King et al., 1985; Wang et al., 2001; Woo et al., 1998). The present study did not yield evidence of any association between gender, surgery, previous or concurrent chemotherapy, stage of disease, medications, or sleep disturbances and radiation therapy-related fatigue. In contrast, other researchers have reported an association between these individual characteristics and cancer-related fatigue (Ackechi et al., 1998; Christman et al., 2001; Cimprich, 1998; Curt et al., 2000; Fu et al., 2002; Gift et al., 2003; Hickok et al., 1996)

Several researchers have reported increased fatigue in women receiving cancer therapy as compared to men (Ackechi et al., Anderson et al., 2002). There was no evidence in the present study of increased fatigue in women. One possible explanation may be the distribution of the sample across treatment sites. Although women comprised 58% of the study sample, they only comprised 37 % of the high fatigue treatment sites (chest, pelvis, head and neck). In contrast, men comprised only 42% of the total sample

but 63% of the high fatigue treatment sites. Stage of disease was not associated with fatigue in this study. Stage of disease may have more of an impact on fatigue in later phases of illness when patients experience more symptoms of disease than in earlier treatment phases. The present study also did not yield evidence of any association between the presence of other medical conditions and radiation therapy-related fatigue, although this was to be expected as the presence of uncontrolled co-existing medical conditions was an exclusion criterion for the study.

Both the Revised PFS and the BFI demonstrated adequate reliability for the study sample. Study participants reported lower fatigue distress scores than had previously been reported in the literature (Munro & Potter, 1996; Williams et al., 2001). Although the present study was not designed as an intervention, it is possible that simply participating in the study served as an intervention. Allowing participants the opportunity to fully explore and address their fatigue may have helped to reduce distress. Another possible explanation is the Hawthorne effect, whereby study participants change their behavior simply because they are part of a study (Burns & Grove, 2001).

Policy Implications

Sick leave benefits were available to some but not all of the participants in this study. Study participants working full-time were more likely to have paid benefits than those working part-time or those who were self-employed. Yet, even some study participants with paid benefits did not have any benefits remaining by the time they started their radiation therapy, having used time for surgery and chemotherapy. Eligibility for the FMLA was not a factor in this sample. Consistent with figures reported by Albelda et al. (2002), only 37% of the sample stated they were eligible for FMLA.

Comments made by study participants suggested that they were much more concerned with receiving pay during their radiation therapy than they were with having their job protected. Nearly all study participants stated that there was little risk of losing their jobs even if they needed to take time off but they feared how they would manage without income.

Of the 21 study participants not working at the start of their radiation therapy, only 3 were receiving paid sick leave benefits; 6 others were receiving unemployment compensation or a retirement pension. Fifty-seven percent of the non-working study participants thus were not receiving any pay at the start of the radiation therapy. In contrast, Albelda et al. (2002) found that just 35.4% of Massachusetts workers took leave with no wage replacement. Four study participants who were not working at the start of their radiation returned to work during treatment, citing financial concerns as their primary reason for returning to work.

Interestingly, contrary to what would have been expected, study participants with paid sick leave benefits were more likely to be working at the beginning of radiation therapy than those without sick leave benefits. Study participants with paid benefits were correspondingly more likely to make changes in employment during radiation than those without benefits. Changes included stopping work altogether but also included less drastic measures such as working from home, decreasing hours worked per week, and taking an occasional sick day during treatment. Perhaps participants with paid sick leave had more flexibility in adjusting their schedules to meet the needs of their treatment. Thus, the availability of paid sick leave appears to support continuing to work during radiation therapy as well as stopping work if necessary.

Paid leave policies advocated by Albelda et al. (2002) and AWHONN (2002) would benefit some workers requiring radiation therapy or other cancer therapies. However, many workers who are not currently covered by the FMLA or unemployment compensation, such as those employed by small businesses, work less than 24 hours per week, or are self-employed, might not benefit by these proposed policies. In the current study, 17% of study participants were self-employed and 13% worked less than 24 hours per week. Proposed policies would expand the FMLA by making it a paid program rather than an unpaid program through the use of unemployment insurance to cover temporary disability. Consideration needs to be given in future proposals to working Americans not eligible for the FMLA or unemployment compensation. Inasmuch as mandatory TDI is available only in five states and Puerto Rico, this should be expanded to all 50 states.

State and federal budget cuts and the rescinding of a Federal bill allowing use of unemployment benefits to pay for sick leave has led to decreased attention to a policy of paid leave (Albelda, 2004). Yet, fears that such programs are too expensive are unfounded. According to Albelda, the average annual cost to cover an employee for all types of leaves would be just \$90.00 per employee. For leaves for an employee's own health, the average annual cost would be only \$56.00 per employee. These modest costs are easily overshadowed by the potential savings related to lower employee turnover and the potential lower productivity of employees who attempt to work when they are not feeling well but need the income. Albelda hypothesized that a paid leave program in Massachusetts would reduce the number of employees taking leave with no wage replacement from 35.4% to 22.4%.

Little information is available regarding employment during cancer treatment for workers who are self-employed. In the current study, 17% of participants described themselves as self-employed. Self-employed study participants expressed greater variety of work-related issues than other participants. They were not only concerned about income during treatment (as one study participant stated, “No work, no money.”) but also about the solvency of their businesses if they were not able to work. One self-employed study participant also was concerned about loyalty to his customers. He declared, “Many of them are elderly and have no one else to take care of their yards.” In other parts of the country, concerns of the self-employed might be even greater, for example, in mid-western dairy communities or coastal fishing villages. Treatment decisions might potentially be influenced by the ability to take needed time off from work. For example, a mid-western dairy farmer or a Maine lobsterman with prostate cancer might not elect radiation therapy as an option due to the need to receive 35-40 treatments on a daily basis at a center located many miles away. Of the five states that have TDI, only California allows self-employed workers to voluntarily participate in the program (SSA, n.d.). Giving all self-employed workers the option to pay into an unemployment insurance program and then using unemployment compensation during cancer treatment might increase their options for treatment.

In summary, the options proposed by paid leave advocates such as Albelda et al. (2002) and AWHONN (2002) are an improvement over the policies currently in place. However, those options would still leave a significant percentage of American workers uncovered. Future policies need to be expanded to provide options for small businesses and individuals who do not currently pay unemployment insurance. One option would be

to allow these workers and businesses to pay into an unemployment insurance pool that could then be used to provide paid sick leave. If only high risk workers bought into the program, leading to adverse selection, this option could potentially be cost-prohibitive (Jacobs, 1996). However, if the program was appealing enough and the majority participated, then costs could be kept down. Small businesses and individuals would need to be able to purchase unemployment insurance as a group rather than as individuals, similar to what is being done with health insurance.

Workers requiring cancer treatments need to be supported in their choices to work or not to work during treatment. Paid leave policies would increase options relative to receiving income. However, work has other than financial benefits to individuals with cancer. Participants in the current study who were working were less fatigued than those who were not working. Several study participants who were not working expressed the loss of purpose and social support. One participant who was not working at the start of radiation therapy began to exhibit signs of depression, including higher scores on the depression item of the PFS. These scores dropped substantially when he returned to work. Other study participants would have worked but their job did not allow for adjustments to schedules or hours worked. For example, several study participants stated that their employer would rather they not work at all than work an altered schedule. Proposed paid leave policies do not allow for working part-time during disability. Thus individuals may be forced into not working to receive adequate income. Current sick leave benefits (for those who had paid sick leave benefits) did support patients working if they so chose. Thus a universal program of paid leave should not counteract the ability

of patients to work part time during cancer treatment and still receive an adequate income.

The ideal program of paid leave would be one that would allow all workers to participate either through their employer or by purchasing the insurance themselves. Paid leave should replace lost income for those who could not work at all due to treatment, and supplement income for those who are unable to work a full schedule. Paid leave policies should encourage employers to make adjustments whenever possible to accommodate workers. This is especially important for low wage earners, especially those in the service industries. For example, one administrator of a long-term care facility offered an employee the job of folding linen when she was unable to maintain her duties as a licensed nursing assistant. Paid leave policies would benefit employers by allowing workers the opportunity to remain in their current positions or return to them following a course of cancer treatment. Thus employers would avoid the costs of recruitment and orientation of a new employee. Cantor et al. (2001) found that 94.4% of all persons who used the FMLA in 1999 returned to the same employer. The present study revealed that 82% of participants were working for the same employer as prior to diagnosis by the one month follow-up visit.

Nursing Practice Implications

The current study revealed several findings important to nursing care of patients receiving radiation therapy. First, the study confirmed previous study findings that radiation therapy-related fatigue increases over the course of treatment and returns to near baseline by one month post-treatment (Christman, Oakley, & Cronin, 2001; Geinitz et al., 2001; Greenberg et al., 1992; Irvine et al., 1998; Schwartz et al., 2000). Thus nursing

education, assessment, and interventions addressing radiation therapy-related fatigue need to change as treatment progresses. Patients need to be assessed for level of fatigue at baseline and educated as to expected patterns. Preventive interventions such as moderate level exercise can be initiated at this time (Mock, 2001; NCCN, 2003; Ream & Richardson, 1999; Stricker, C. T., Drake, D., Hoyer, K., & Mock, V., 2004). Re-assessment needs to be done at each nursing visit and interventions tailored to the degree of fatigue experienced. Patients can be reassured that in most cases fatigue will diminish by the one month follow-up visit. An unexpected finding in this study was that approximately 35% of study participants who reported mild to moderate fatigue at the completion of radiation therapy, noted a severe increase in fatigue at two weeks post-treatment. Fatigue then diminished by the one month visit. This information was volunteered by study participants when they came in for the one month follow-up visit; fatigue was not formally assessed at two weeks post-treatment, as this pattern had not been previously reported in the literature. One possible explanation for this pattern might be that many patients experience a “let down” at the end of a course of radiation treatments. Patients receive daily support and encouragement from nurses and radiation therapists during treatment, which is suddenly withdrawn once treatment ends. Symptoms, such as fatigue, may then become more apparent. This pattern of increased fatigue at two weeks post-treatment is a subject for further study. Patients need to be informed of the possibility of fatigue increasing before it returns to baseline.

Mean fatigue scores for the entire study sample increased from 0.46 at baseline to 2.91 at the end of treatment. However, for study participants receiving radiation therapy to the chest, head and neck, and pelvic areas, mean fatigue scores at the end of treatment

increased to 5.45, 4.04, and 3.89, respectively. According to the NCCN (2003) and ONS (2005), fatigue scores greater than 3.0 require intensive nursing assessment and intervention. Nursing interventions to manage radiation therapy-related fatigue need to be tailored to treatment site, anticipating the greater fatigue experienced by patients receiving radiation to the chest, head and neck, and pelvic areas.

Younger study participants experienced higher levels of fatigue than older study participants. Younger study participants may potentially have greater demands on their time. Work, caring for young children or elderly parents, school, and community activities all may play a role in fatigue in younger patients. Nurses can intervene by conducting a thorough assessment of these activities and assisting younger patients with time management and prioritization.

Study participants living alone experienced higher levels of fatigue than those who lived with family or significant others. Patients living alone may have no one to assist with household chores and other activities such as cooking meals. The present study revealed that as fatigue increased, participants were less able to carry out their usual activities. Nurses need to conduct an in-depth assessment of performance of activities of daily living and how these activities might be influenced by increasing levels of fatigue. Interventions such as Meals-on-Wheels might be appropriate for these patients. Nurses in radiation oncology are in a unique position to provide emotional support to patients who live alone and may not have outside sources of support especially if they are not working.

Study participants who were more highly educated experienced higher levels of fatigue than those with less formal education. Patients with higher levels of education

may work in more stressful jobs and also may be involved in more outside activities. In addition, they may have higher expectations of themselves and thus are more affected by cancer-related fatigue. The study sample was relatively highly educated, with only two participants having less than a high school diploma and a mean of 14 years of education, that is, two years of college or an associate degree. Nurses can anticipate increased fatigue in more highly educated patients and offer additional resources such as internet sites for education and support.

Sleep disturbances have been fairly consistently found to be associated with cancer-related fatigue (Anderson et al., 2003; Berger & Farr, 1999; Bower et al., 2000). The present study, however, revealed only a moderate linear association between sleep disturbances and fatigue. Participants who reported sleep disturbances at baseline continued to report sleep disturbances as treatment progressed. It is possible that these study participants had already adjusted to sleep disturbances prior to starting radiation and thus the interference with sleep had little impact on subsequent fatigue.

Hwang et al. (2003) found that pain predicted fatigue in cancer patients. The present study revealed only a moderate correlation between pain and radiation therapy-related fatigue. Anecdotally, however, one study participant whose arthritis pain had been well-controlled on Vioxx noted an increase in fatigue when the drug was taken off the market and she needed to explore less effective alternatives. Only 21% of participants reported pain at one or more points in treatment. Pain levels were generally mild to moderate (< 5 on a 0-10 scale). None of the participants was receiving radiation therapy to relieve pain. It is possible that patients with severe pain receiving palliative radiation therapy might have experienced more fatigue. Pain, however, was associated

with a lower likelihood of working in this study. Thus a thorough assessment of pain and implementation of appropriate pain relieving strategies might help keep individuals in the workforce.

The number and type of medications taken was not associated with fatigue in this study. Specifically, men receiving hormone therapy during radiation therapy for prostate cancer did not experience greater fatigue than men not receiving hormone therapy. Stone et al. (2000) had found that men receiving hormone therapy for prostate cancer experienced increased fatigue after three months of treatment. In the present study, hormone therapy was initiated at the beginning of radiation therapy. Thus, men had only been on hormones for a maximum of two months. Longer follow-up might reveal an increase in fatigue over time.

One individual characteristic that was highly associated with both radiation therapy-related fatigue and employment in this study was the presence of site-specific treatment-related side effects. Increase in side effects led to both an increase in fatigue and a decreased likelihood of working during treatment. A major role for nurses in a radiation therapy department is side effect management (Moore-Higgs et al., 2003). Aggressive side effect management has the potential for reducing radiation therapy-related fatigue and helping to keep patients in the workforce. Side effect management should focus on diarrhea, pain, esophagitis, skin reaction, and oral mucositis, which were the major side effects experienced by the participants in this and other studies (Bansal et al., 2004; Christman et al., 2001; Gift et al., 2003; Guren et al., 2003; Janda et al., 2000; King et al., 1985). Concurrent chemotherapy was not directly associated with radiation therapy-related fatigue in this study but was associated with an increase in side effects.

This finding supports previous findings by Poirier (1991). Concurrent chemotherapy may indirectly contribute to radiation therapy-related fatigue. Nurses need to anticipate the potential for increased side effects in patients receiving concurrent chemotherapy and be prepared to intervene earlier and more aggressively with these patients.

Limitations of the Study

A major limitation of the study is the small number of participants receiving treatment to sites other than breast, which limits generalizability of findings for specific treatment sites. Another limitation of the study is the homogeneous racial and ethnic make-up of the sample; only two of the study participants were non-White, and only two were Hispanic. This limits the ability to generalize to populations other than non-Hispanic White. There is a suggestion in the literature that fatigue and employment may differ by racial group (DOL, 2005; Santariano & DeLorenze, 1996). The sample for this study did not permit a test for such differences. The sample was a convenience sample recruited from a single treatment facility in central New England. Employment patterns and sick leave benefits may differ by geographic region. For example, results of the study might have been quite different if it were conducted in one of the five states that has mandatory TDI.

Threats to Internal and External Validity. Several threats to validity can be identified in the study. Threats to internal validity can lead to false-positive or false-negative conclusions (Burns & Grove, 2001). One possible threat to internal validity may be history- events that are not related to the study but occur during the time of the study and could potentially influence the response of study participants. This is especially true in repeated measures design because external events could differentially

affect study participants (Burns & Grove; Polit & Beck, 2003). Another threat to internal validity in a repeated measures design is testing itself. Repeated exposure to the study instrument may influence the study participants to change attitudes or responses to the items (Burns & Grove). Attrition was not a threat to internal validity in this particular study as all but one participant completed all planned measurements. The one participant only missed one measurement point. As the sample was a convenience sample from only one institution, selection bias was a potential threat to internal validity. Threats to external validity affect the generalizability of the study (Burns & Grove; Polit & Beck). One potential threat to external validity may be the Hawthorne effect as mentioned earlier. Participants may change their behavior simply because they are participating in a study. Experimenter expectations (Rosenthal effect) may be another potential threat to external validity in the present study (Burns & Grove; Polit & Beck). The researcher may have unconsciously communicated the expectation of fatigue and thus influenced participants' responses to the questions. The interaction of history and treatment effect may be a potential threat to external validity as well as internal validity. Inclusion of major demographic variables identified through a systematic review of the literature helped reduce the effects of extraneous variables and thus reduce threats to validity (Burns & Grove; Polit & Beck). A repeated measures or longitudinal design such as used in the present study also helped reduce threats to validity by having study participants serve as their own controls (Burns & Grove, Polit & Beck). Consistency of delivery of radiation therapy (field size and dose) within each treatment sites also helped reduce threats to validity (Burns & Grove).

Suggestions for Future Research

Replication of the study using multiple sites from diverse geographic and demographic regions would allow for greater numbers of participants receiving radiation to treatment sites other than breast, greater racial and ethnic diversity, and a greater variety of employment patterns and sick leave benefits. This heterogeneity would allow further exploration of the various factors influencing the association between work and radiation therapy-related fatigue. A larger total sample size would permit more sophisticated statistical tests of the reciprocal relation between work and radiation therapy-related fatigue. An example is structural equation modeling (SEM), which can be used to analyze nonrecursive models (i.e., models with two-way paths) (Munro, 2004). SEM would require a minimum of 100-200 participants and perhaps up to 500 participants (Munro).

Further examination of employment patterns and sick leave benefits of patients receiving cancer therapy is warranted. Comparing use of sick leave in states with mandatory TDI to states without mandatory TDI would provide further insight into patients' need to work or not to work during treatment. In addition, further exploration of variables influencing work is warranted. Role theory or related theories regarding work behavior as well as quality of life theories can be used to identify pertinent variables that may influence working or not working during cancer treatment as well as utilization of sick leave benefits. Studies exploring work during cancer treatment can be conducted in employment settings as well as in the clinical settings. These studies would expand and strengthen policy implications by including other stakeholders such as employers and industrial nurses.

The current study was designed to examine employment patterns and use of sick leave benefits during radiation therapy, but not during chemotherapy. Chemotherapy and radiation therapy lead to different patterns of fatigue and administration schedules. The ability of patients to work during the various therapies also may differ. For example, patients receiving myelosuppressive chemotherapy may not be able to perform certain jobs due to potential toxicity of the chemotherapy but may be able to work during subsequent radiation therapy. A study designed to investigate work and sick leave use during chemotherapy would provide further data to inform policy makers.

The study did not include examination of employment or fatigue in caregivers of patients receiving cancer treatment. Hamilton et al. (2001) suggested that fatigue is a significant issue for caregivers. In large studies conducted both in the United States and Ireland, caregivers experienced changes in employment (Curt et al., 2000; Dillon & Kelly, 2003), including losing a business. Future studies of radiation therapy-related fatigue and employment should consider caregivers as well as patients.

Further investigation of the relation between treatment-related site-specific side effects and fatigue is warranted as this is a prime area for nursing intervention. Recruitment of larger numbers of study participants receiving radiation therapy to sites known for distressing side effects, such as the chest, head and neck region, and pelvis, will allow for better examination of the relations. Intervention studies then can be designed to examine the impact of aggressive nursing management of side effects such as diarrhea, esophagitis, and oral mucositis on radiation therapy-related fatigue. These outcome studies will add to the body of knowledge regarding the impact of nursing care on patients receiving radiation therapy.

Another area for future investigation is the previously undescribed pattern of increased fatigue two weeks after the completion of radiation therapy. Patients are generally not seen by any providers at that time. However, nurses could conduct assessments and offer interventions via telephone at that time.

Conclusions

In conclusion then, the current study added to the body of knowledge of the employment patterns and the use of sick leave benefits in patients receiving radiation therapy for cancer and their relation to radiation therapy-related fatigue. The study findings are a catalyst for several new areas of investigation. The National Institutes of Health State-of-the-Science Panel (2002) recommended developing conceptual models to direct systematic research into pain, depression, and fatigue. The panel also recommended conducting prospective studies of populations, health care plan members, and cohorts of sufficient sample sizes to provide more accurate estimates of the incidence and prevalence of pain, depression, and fatigue. According to the panel, those estimates also are needed for subgroups of patients within the context of sociodemographic and medical characteristics, including age, sex, race, ethnicity, acculturation, and cancer type and stage at diagnosis. The IFM can continue to be used as a guide by both researchers and clinicians to identify relevant sociodemographic and medical characteristics, identify possible causes of fatigue, test interventions to reduce cancer-related fatigue, and evaluate outcomes of those interventions.

In addition, the panel recommended conducting research into system barriers to effective symptom control. Level 3 of the CMNHP, which focuses on a specific health care delivery system, and level 4, which guides examination of health care systems of

geopolitical communities, can be used to design and conduct broader studies (Fawcett & Russell, 2001, 2002). Policy analysis and evaluation of paid sick leave also can be guided by levels 3 and 4 of the CMNHP (Fawcett & Russell). Thus, both the CMNHP and the IFM can be used to guide and focus future research addressing paid leave policies and their impact on the relation between work and cancer-related fatigue. All significant stakeholders need to be included in future studies including cancer patients, cancer survivors, families and friends, employers, supervisors and co-workers, oncology nurses, industrial nurses, advocacy groups and professional organizations such as the American Cancer Society and the Oncology Nursing Society, and policy makers.

| APPENDIX A | | | | | | |
|-------------------------------------|--------|---------------------------|-------------------|------------------------|---|--|
| <i>Table of Selected References</i> | | | | | | |
| <i>Fatigue</i> | | | | | | |
| Citation | Sample | Design | Site/Modality | Instruments | Results | Conceptual Model |
| Ahlberg et al. (2004) | 15 | Pilot Study | GYN/RT | MFI-20 | Increased fatigue with RT ; Hgb not associated with fatigue | Conceptual Model of Symptom Management |
| Ahlberg et al. (2004) | 60 | Descriptive correlational | GYN/RT | MFI-20 | Low fatigue before RT | Conceptual Model of Symptom Management |
| Akechi et al. (1999) | 455 | Correlational | All/All | POMS | Female, higher education living alone increased fatigue | None |
| Anderson et al. (2003) | 716 | Instrument validation | All/All | BFI | Carcer, depression, community have different fatigue | None |
| Bansal et al. (2004) | 45 | Prospective longitudinal | HN/RT | QOL | Increase in symptoms and fatigue during RT | None |
| Barsevick et al. (2002) | 38 | Pretest/posttest | All/RT & CT | POMS-SF | Intervention result in no increase in fatigue during RT | Common Sense Model |
| Bartsch et al. (2003) | 144 | Correlational | All/All | EORTC-QLQ-C30/MFI | 22% patients had significant symptoms of fatigue | None |
| Beach et al. (2001) | 45 | Correlational | Lung/RT | PFS | No difference in fatigue from beginning to end of RT | IFM |
| Berger et al. (2003) | 21 | Correlational | Breast/CT | PFS | High adherence to sleep plan | IFM |
| Berger & Farr (1999) | 72 | Correlational | Breast/CT | PFS | Night awakenings associated with increased fatigue | None |
| Berger & Walker (2001) | 60 | Theory testing | Breast/CT | PFS | Need to develop interventions to reduce distress and promote health | IFM |
| Blesch et al. (1991) | 77 | Correlational | Breast & Lung/All | RFS | Positive correlation between pain and fatigue | IFM |
| Borthwick et al. (2003) | 53 | Qualitative | Lung/RT | Diary | Fatigue increased over course of treatment low distress | NA |
| Bower et al. (2000) | 1957 | Survey | Breast/All | RAND health survey | RT alone lowest fatigue | None |
| Cella et al. (2002) | 3492 | Survey | All/All | FACIT | Anemia associated with increased fatigue | None |
| Christman & Cain (2004) | 76 | Correlational | GYN;HN;Lung/RT | SDS | Relaxation associated with increased physical activity | None |
| Christman et al (2001) | 49 | Descriptive | GYN /RT | Investigator-developed | 50% reported fatigue | None |
| Cimprich (1998) | 74 | Descriptive | Breast/All | Attention tests | Older & greater surgery had increased attention deficit | Fatigue of Directed Attention |
| Davidson et al. (2002) | 982 | Descriptive | All/All | Investigator-developed | Fatigue contributed to insomnia | None |
| Decker et al. (1992) | 82 | Experimental | All/RT | POMS | Intervention group had less fatigue, pain | None |
| Dillon & Kelly | 412 | Survey | All/All | Investigator-developed | 41% patients reported fatigue most impact | None |
| Dimeo et al. (1999) | 59 | Experimental | All/BMT | POMS | Aerobic exercise reduced fatigue | None |
| Dimeo et al. (1997) | 78 | Correlational | All/All | POMS | Fatigue associated with psychologic distress | None |
| Donovan et al. (2004) | 134 | Correlational | Breast/ RT & CT | | Increase fatigue only in RT patients | None Stated |
| Ekfors & Petersson (2004) | 15 | Qualitative | Lung/RT | NA | Fatigue described as general experience | NA |

| <i>Table of Selected References-Continued</i> | | | | | | |
|---|--------|----------------------------|-----------------|------------------------|---|--|
| Citation | Sample | Design | Site/Modality | Instruments | Results | Conceptual Model |
| Forester et al. (1993) | 24 | Experimental | All/RT | SADS | < Emotional and physical symptoms | None |
| Fu et al. (2002) | 12 | Descriptive | All/Biotherapy | PFS | Moderate to severe fatigue | None |
| Geinitz et al. (2001) | 41 | Longitudinal correlational | Breast/RT | VAS | Greater fatigue over course not related to labs | None |
| Gift et al. (2003) | 112 | Secondary data analysis | Lung/All | Symptom Experience | Symptoms exist in clusters | Theory of Unpleasant Symptoms |
| Given (2002) | 103 | Experimental | All/CT | Investigator-developed | Interventions associated with less pain and fatigue | None |
| Gledhill et al. (2002) | 229 | Instrument validation | All/All | PFS/VAS | French validation of instrument | None |
| Greenberg et al (1993) | 15 | Longitudinal | Prostate/RT | VAS/BDI | IL-1 increased with fatigue | None |
| Greenberg et al (1992) | 15 | Longitudinal | Breast/RT | VAS | Fatigue increase not linear | None |
| Guren et al. (2003) | 42 | Prospective correlational | Rectal/RT | EORTC-QLQ-C30 | End of treatment fatigue greater than population norm | None |
| Hamilton et al. (2001) | 36 | Interview | Lung/RT | Investigator-developed | Fatigue not major issue family also fatigued | None |
| Haylock & Hart (1979) | 30 | Correlational | All/RT | PBFFC | Greater fatigue by end of week end of treatment | None |
| Hickok et al. (1996) | 50 | Medical record review | Lung/RT | Symptom Checklist | High frequency of fatigue | None |
| Holley (2001) | 20 | Experimental | All/All | Fatigue Distress Scale | Decreased fatigue distress in rehabilitation group | None |
| Holzner et al. (2002) | 68 | Correlational | All/CT | MFI-20 | Pain, dyspnea, sleep, low hgb associated with fatigue | None |
| Hwang et al. (2003) | 180 | Correlational | All/All | BFI | Predictors of fatigue included pain,dyspnea | None |
| Irvine et al. (1998) | 76 | Longitudinal correlational | Breast/RT | PBFFC | Increased fatigue over course of treatment | None |
| Irvine et al. (1994) | 101 | Longitudinal correlational | All/RT & CT | PBFFC | Increased fatigue over time | Energy Analysis Model |
| Janda et al. (2000) | 43 | Descriptive | Prostate/RT | EORTC-QLQ-C30/SF-36 | Increased in fatigue baseline to end of treatment | None |
| King et al. (1985) | 96 | Descriptive | All/RT | Symptom Profile | > fatigue in chest & gyn | None |
| Kolcaba & Fox (1999) | 53 | Experimental | Breast/RT | RTCQ/SAI | Intervention helpful in early treatment | Kolcaba Comfort Theory |
| Lai et al. (2003) | 115 | Correlational | Nasopharynx/RT | SDS | Moderate fatigue distress | Appraisal Model of Stress and Coping |
| Landis et al. (2003) | 23 | Correlational | Fibromyalgia/NA | WWHD | Poor sleep quality > fatigue | None |
| Langendijk et al. (2002) | 46 | Prospective correlational | Lung/RT | EORTC-QLQ-C30 | Greater fatigue associated with deterioration role functioning | None |
| Magnan & Mood (2003) | 384 | Correlational | All/RT | Investigator-developed | Positive health outcomes associated with lower fatigue | None |
| Mast (1998) | 109 | Correlational | Breast/RT & CT | SDS | Chemotherapy associated with increased fatigue | Conceptualization of Illness Uncertainty |
| Mendoza et al. (1999) | 305 | Instrument validation | All/All | BFI | Reliable measure for fatigue severity | None |
| Miaskowski & Lee (1999) | 24 | Correlational | Bone Mets/RT | Lee Fatigue Scale | > evening fatigue; poor pain control | None |
| Mock et al. (2001) | 52 | Experimental | Breast/RT & CT | PFS | Exercise associated with decreased fatigue | Levine Conservation Model |
| Mock et al. (1997) | 46 | Experimental | Breast/RT | PFS | Exercise associated with decreased fatigue | Roy Adaptation Model |
| Monga et al. (1997) | 13 | Descriptive | Prostate/RT | PFS | Decline in neuromuscular efficiency | None |
| Monga et al. (1999) | 36 | Descriptive | Prostate/RT | PFS | Increase in fatigue pre- to post-treatment | None |

| <i>Table of Selected References-Continued</i> | | | | | | |
|---|--------|-------------------------|----------------------|----------------------------|--|--------------------------------------|
| Citation | Sample | Design | Site/Modality | Instruments | Results | Conceptual Model |
| Mor et al.(1984) | 47 | Instrument validation | All-Hospice/NA | KPS | Good inter-rater reliability construct validity | None |
| Munro & Potter (1996) | 110 | Instrument validation | All/RT | Investigator-developed | Increased tiredness during treatment | None |
| Oberst et al. (1991) | 72 | Correlational | All/All | SDS/Self Care Burden | Fatigue most distressing symptom | Appraisal Model of Stress and Coping |
| Okuyama et al. (2000) | 134 | Correlational | Breast/CT | Cancer Fatigue Scale | Fatigue prevalence 56% | None |
| Okuyama et al. (2003) | 252 | Instrument validation | All/All | BFI | Japanese version brief valid and feasible | None |
| Passik et al. (2002) | 200 | Descriptive | All/All | FACT-F/FMBQ | 34% spoke with MD about fatigue | None |
| Pickard-Holley (1991) | 24 | Descriptive | Ovarian/CT | RFS | Fatigue peaked at day 7 then declined | None Stated |
| Piper et al. (1998) | 382 | Instrument validation | Breast/All | PFS | Instrument reduced to 22 items | IFM |
| Radbruch et al. (2003) | 22 | Instrument validation | All-Pain/All | BFI | German version valid and reliable | None |
| Ream et al. (2003) | 15 | Focus Groups | All/All | NA | Fatigue not addressed in clinical setting | NA |
| Sarna & Conde (2001) | 7 | Pilot Study | All/RT | POMS/Linear Analog | Increased activity associated with decreased fatigue | None |
| Schag et al (1991) | | Instrument validation | Breast/All | CARES-SF | Demonstrated validity/reliability | None |
| Schwartz et al. (2002) | 103 | Repeated measures | All/All | SCFS/POMS/Single Item | Determine minimally important clinical differences | None |
| Schwartz (2000) | 72 | Pretest/posttest | Breast/CT | Diaries/Functional Ability | Exercise associated with decreased fatigue | None |
| Schwartz et al. (2000) | | Correlational | All/RT & CT | | Differing patterns of fatigue by type of treatment | None |
| Schwartz (1999) | 31 | Correlational | Breast/CT | VAS | Exercise program feasible | None |
| Schwartz (1998) | 219 | Survey | All/All | Investigator-developed | Benefits from exercise | None |
| Stone (2000) | 62 | Correlational | Prostate/Hormone | FSS | Fatigue increased with hormone therapy | None |
| Stone et al. (2001) | 62 | Correlational | Prostate & Breast/RT | FSS/BFS | Fatigue severity increased from pre to post treatment | None |
| Stone et al. (2003) | 3338 | Survey | All/All | Investigator-developed | Only 14% respondents reported treatment offered for fatigue | None |
| Tishelman et al. (2000) | 26 | Pilot Study | Lung/All | SDS | Fatigue high intensity but low low importance | None Stated |
| Wang et al. (2001) | 72 | Correlational | Rectal/RT | BFI | Uncontrolled diarrhea predictive of fatigue | None |
| Wengstrom et al.(2001) | 134 | Qualitative | Breast/RT | NA | Coping strategies used by women for fatigue | Lazarus Appraisal Concept |
| Williams et al. (2001) | 270 | Descriptive | All/RT & CT | TRSC | 13 symptoms differed by type of treatment | None |
| Woo et al. (1998) | 332 | Secondary data analysis | Breast/RT & CT | PFS | Combined modality greater fatigue than RT alone | IFM |
| Yates et al. (1980) | | Instrument validation | Breast/All | KPS | Good inter-rater reliability construct validity | None |
| Young-McCaughan et al. (2003) | 62 | Repeated measures | All/All | CARES-SF | Exercise is safe and provides benefits | Roy Adaptation Model |

| <i>Table of Selected References-Continued</i> | | | | | | | |
|---|--------|---------------------------|--------|----------|------------------------|--|------------------|
| <i>Work</i> | | | | | | | |
| Citation | Sample | Design | Site | Modality | Instruments | Results | Conceptual Model |
| Berry (1993) | 19 | Interview | All | All | NA | Work provides social support | Grounded Theory |
| Bradley & Bednarek (2002) | 253 | Survey | All | All | Investigator-developed | 67% employed 5-7 years after | None |
| Burnie (2000) | 25 | Qualitative | Breast | RT | NA | Relations and work important | NA |
| Bushnow et al (1995) | 76 | Retrospective Cohort | Breast | CT | Investigator-developed | Chemotherapy did not delay return to work | None |
| Carter (1994) | 1 | Case Study | Breast | CT | Investigator-developed | Gave up desire to return to work | Lived Experience |
| Chan et al. (2001) | 18 | Qualitative | GYN | All | NA | Family and work sources of support | None |
| Curt et al. (2000) | 379 | Survey | All | All | Investigator-developed | 75% change employment as result of fatigue | None |
| Devlen et al (1987) | 120 | Interview | HD | CT | Standardized | Difficulty returning to work | None |
| Fobair et al (1986) | 403 | Survey | HD | CT | Investigator-developed | 42% survivors reported difficulty at work | None |
| Hensel et al. (2002) | 238 | Survey | All | ASCT | EORTC QLQ-C30 | Rehab did not affect re-employment | None |
| Hilton (1996) | 55 | Qualitative | Breast | All | NA | Importance of work | Grounded Theory |
| Longman et al. (1996) | 307 | Descriptive | Breast | All | Side effect checklist | Most continued to work; fatigue a problem | None |
| Maunsell et al. (2004) | 646 | Survey | Breast | All | Investigator-developed | 79% employed 3 years after treatment | None |
| Maunsell et al. (1999) | 13 | Qualitative | Breast | All | NA | Work related problems continue | None |
| Rothstein et al. (1995) | 422 | Survey | All | All | Investigator-developed | Self-reported discrimination | None |
| Satariano & DeLorenze(1996) | 296 | Interview | Breast | All | Investigator-developed | Leave associated with physical labor | None |
| Sehlen et al. (2002) | 83 | Prospective correlational | HN | RT | FACT-G | Employment associated with > QOL | None |
| Schultz et al. (2002) | 4364 | Survey | All | All | Investigator-developed | Job descrimination not an issue | None |
| Spelten et al. (2003) | 235 | Prospective correlational | All | All | Return to Work/MFI | Fatigue levels predicted return to work | None |
| Stewart et al. (2001) | 378 | Survey | Breast | All | Investigator-developed | 40% reported cancer affected work | None |
| Instruments: BFI-Brief Fatigue Inventory; BFS-Biodimensional Fatigue Scale; CARES-SF-Cancer Rehabilitation Evaluation Systems-Short Form; CSSQ-Cancer Survivors Survey Questionnaire; EORTC-QLQ-30-European Organization for Research and Treatment of Cancer-Quality of Live Questionnaire; FACIT-Functional Assessment of Chronic Illness Uncertainty; FACT-F-Functional Assessment of Cancer Therapy-Fatigue; FACT-G-Functional Assessment of Cancer Therapy-General; FBC-Fatigue Body Checklist; FSS-Fatigue Severity Scale; KPS-Karnofsky Performance Scale; MFI-Multidimensional Fatigue Inventory; PBFFC-Pearson-Byars Fatigue Feeling Checklist; PFS-Piper Fatigue Scale; POMS-Profile of Moods States; RFS-Rhoten Fatigue Scale; RTCQ-Radiation Therapy Comfort Questionnaire; SADS-Schedule for Affective Disorders and Schizophrenia; SAI-State Anxiety Inventory; SCFS-Schwartz Cancer Fatigue Scale; SDS-Symptom Distress Scale; TRSC-Therapy Related Symptom Checklist; VAS-Visual Analog Scale; WWHD-Washington Women's Health Diary | | | | | | | |
| Modality: ASCT-autologous stem cell transplant; CT-chemotherapy; RT-radiation therapy | | | | | | | |

APPENDIX B

Karnofsky Performance Scale

- 100 Normal, no complaints, no evidence of disease
- 90 Able to carry on normal activity; minor symptoms of disease
- 80 Normal activity with effort; some symptoms of disease
- 70 Cares for self; unable to carry on normal activity or active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled, requires special care and assistance
- 30 Severely disabled; hospitalization is indicated, death not imminent
- 20 Very sick, hospitalization necessary; active supportive treatment necessary
- 10 Moribund, fatal processes progressing rapidly
- 0 Dead

Retrieved 11/23/02 from the World Wide Web:
<http://www2.mc.duke.edu/9200bmt/Karnofsky.htm>

APPENDIX C

Single-Item Numeric Scale (If 0 Stop; If >0 Continue with Revised Piper Fatigue Scale)

Please circle the degree of fatigue you are experiencing **right now**:

No fatigue A great deal of fatigue
0 1 2 3 4 5 6 7 8 9 10

Revised Piper Fatigue Scale

How long have you been feeling fatigued? (Check one response only)

- a. Minutes
- b. Hours
- c. Days
- d. Weeks
- e. Months

1. To what degree is the fatigue you are feeling now causing you distress?

No distress A great deal of distress
0 1 2 3 4 5 6 7 8 9 10

2. To what degree is the fatigue you are feeling now interfering with your ability to complete your work or school activities?

None A great deal
0 1 2 3 4 5 6 7 8 9 10

3. To what degree is the fatigue you are feeling now interfering with your ability to visit or socialize with your friends?

None A great deal
0 1 2 3 4 5 6 7 8 9 10

4. To what degree is the fatigue you are feeling now interfering with your ability to engage in sexual activity?

None A great deal
0 1 2 3 4 5 6 7 8 9 10

5. Overall how much is the fatigue, which you are experiencing now, interfering with your ability to engage in the kind of activities you enjoy doing?

None A great deal

0 1 2 3 4 5 6 7 8 9 10

6. How would you describe the degree of intensity or severity of the fatigue which you are experiencing now?

Mild Severe

0 1 2 3 4 5 6 7 8 9 10

7. To what degree would you describe the fatigue which you are experiencing now as being:

Pleasant Unpleasant

0 1 2 3 4 5 6 7 8 9 10

8. To what degree would you describe the fatigue which you are experiencing now as being:

Agreeable Disagreeable

0 1 2 3 4 5 6 7 8 9 10

9. To what degree would you describe the fatigue which you are experiencing now as being:

Protective Destructive

0 1 2 3 4 5 6 7 8 9 10

10. To what degree would you describe the fatigue which you are experiencing now as being:

Negative Positive

0 1 2 3 4 5 6 7 8 9 10

11. To what degree would you describe the fatigue which you are experiencing now as being:

Normal Abnormal

0 1 2 3 4 5 6 7 8 9 10

12. To what degree are you now feeling:

| | | | | | | | | | | | | |
|--------|---|---|---|---|---|---|---|---|---|---|----|------|
| Strong | | | | | | | | | | | | Weak |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

13. To what degree are you now feeling:

| | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|----|--------|
| Awake | | | | | | | | | | | | Sleepy |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

14. To what degree are you now feeling:

| | | | | | | | | | | | | |
|--------|---|---|---|---|---|---|---|---|---|---|----|----------|
| Lively | | | | | | | | | | | | Listless |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

15. To what degree are you now feeling:

| | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Refreshed | | | | | | | | | | | | Tired |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

16. To what degree are you now feeling:

| | | | | | | | | | | | | |
|-----------|---|---|---|---|---|---|---|---|---|---|----|-------------|
| Energetic | | | | | | | | | | | | Unenergetic |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

17. To what degree are you now feeling:

| | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|----|-----------|
| Patient | | | | | | | | | | | | Impatient |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

18. To what degree are you now feeling:

| | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|----|-------|
| Relaxed | | | | | | | | | | | | Tense |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

19. To what degree are you now feeling:

| | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|----|-----------|
| Exhilarated | | | | | | | | | | | | Depressed |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

20. To what degree are you now feeling:

| | | | | | | | | | | | | |
|---------------------|---|---|---|---|---|---|---|---|---|---|----|-------------------------|
| Able to Concentrate | | | | | | | | | | | | Not Able to Concentrate |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

21. To what degree are you now feeling:

Able to Remember

Not Able to Remember

0 1 2 3 4 5 6 7 8 9 10

22. To what degree are you now feeling:

Able to Think Clearly

Not Able to Think Clearly

0 1 2 3 4 5 6 7 8 9 10

Overall, what do you believe is most directly contributing to or causing your fatigue?

Overall, the best thing you have found to relieve your fatigue is:

Is there anything else you would like to add that would describe your fatigue better to us?

Are you experiencing any other symptoms right now?

(If yes, please describe)

| | | | |
|--|-------|---|-------|
| Total Fatigue Score (total items 1-22) | _____ | Mean Fatigue Score | _____ |
| Total Behavioral Fatigue Score (total items 1-6) | _____ | Total Sensory Fatigue Score (total 12-16) | _____ |
| Mean Behavioral Fatigue Score | _____ | Mean Sensory Fatigue Score | _____ |
| Total Affective Fatigue Score (total 7-11) | _____ | Total Cognitive Fatigue Score (total 17-22) | _____ |
| Mean Affective Fatigue Score | _____ | Mean Cognitive Fatigue Score | _____ |

Time of Assessment (circle one)

Baseline Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Last Rx One-month

APPENDIX D

Brief Fatigue Inventory (BFI)

1. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue **right now**
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
2. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **usual level of fatigue during the past 24 hours**
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
3. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **worst level of fatigue during the past 24 hours**
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
4. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your general activity
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
5. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your mood
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
6. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your walking ability
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
7. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your normal work (includes both work outside the home and daily chores)
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
8. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your relations with other people
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10
9. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your enjoyment of life
No fatigue As bad as you can imagine
0 1 2 3 4 5 6 7 8 9 10

APPENDIX E

Sick Leave Benefits Questionnaire

1. Are you eligible for FMLA?
Yes _____
No _____
Don't Know _____

2. Do you have paid sick leave benefits at your job?
Yes _____
No _____
Don't Know _____

3. Do you have short-term disability?
Yes _____
No _____
Don't Know _____

4. Have you taken any sick days since your diagnosis of cancer?
Yes _____ Number of Days _____
No _____

5. Does your job allow for adjustments (shorter day, change in duties) during your treatments?
Yes _____
No _____

6. If yes, what type of adjustments? (Check all that apply)
Decrease hours of work per day _____
Decrease number of days worked per week _____
Work from home _____
Reduce work responsibilities _____
Change type of duties performed _____
Other (please specify) _____

7. Can you financially afford to use any of your sick leave benefits?
Yes _____
No _____
Don't Know _____

APPENDIX F

Employment Patterns Questionnaire

1. Are you currently self-employed or employed at a job for pay?
Yes _____
No _____

2. If no, were you self-employed or employed at a job for pay prior to your diagnosis of cancer?
Yes _____
No _____

3. If not currently employed, which of the following best describes your reason for not working?
Homemaker _____
Retired _____
Short-term disability _____
Permanently disabled _____
Student _____
FMLA _____
Other (please specify) _____

4. If you are currently working, what is the usual number of hours you work per week? _____

5. Is this considered
Full-time _____
Part-time _____

6. If you are currently working, what is the actual number of hours you worked last week?

7. What is your job title? _____

8. What are your usual job duties? _____

9. If you are not currently working, do you plan to return to work after your treatments are completed?
Yes _____
No _____

10. If you are currently working, please rate the degree of stress you experience at work
No stress A great deal of stress
0 1 2 3 4 5 6 7 8 9 10

11. If you are currently working, please rate the degree of support you receive from work
A great deal of support No support
0 1 2 3 4 5 6 7 8 9 10

APPENDIX G

Demographic Data Worksheet

Age at last birthday _____
 Gender Male _____ Female _____
 Number of years of education completed (circle last year completed)
 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
 Elementary/Jr/Sr High School College Graduate School

Country of Birth _____
 Race
 American Indian or Alaska Native _____ Native Hawaiian or Other Pacific Islander _____
 Asian _____ White _____
 Black or African American _____ Other (please specify) _____
 Ethnicity Hispanic or Latino _____ Not Hispanic or Latino _____

Disease Site
 Breast _____ Lung _____
 Prostate/Male GU _____ GYN/Female GU _____
 Head and Neck _____ Hematologic _____
 Other (please specify) _____

Treatment Site
 Breast _____ Pelvis, Prostate _____
 Chest _____ Pelvis, Bladder or Rectum _____
 Head and Neck _____ Pelvis, Gynecologic _____
 Extremity _____

Stage of Disease Stage I _____ Stage II _____ Stage III _____ Stage IV _____ Other _____

Extent of Surgery
 None _____ "Minor" e.g. Lumpectomy _____
 Biopsy Only _____ "Major" e.g. Prostatectomy _____

Previous Chemotherapy Yes _____ No _____
 Concurrent Chemotherapy Yes _____ No _____

Present Living Situation (check all that apply) Relationship/Marital Status
 Alone _____ Single, Never Married _____
 Spouse/Domestic Partner _____ Married _____
 Dependent Children _____ Domestic Partner _____
 Grown Children _____ Separated _____
 Parent/In-Law _____ Divorced _____
 Sibling _____ Widowed _____
 Other Relative _____
 Non-related Roommate _____
 Other (please specify) _____
 Pets _____

Housing Arrangement
 Single-level _____ Multi-level _____

Average Number of Hours of Sleep per Night _____

Average Number of Hours of Exercise per Week _____

Co-Existing Medical Conditions (check all that apply)

High Blood Pressure _____

Heart Disease _____

Emphysema _____

Diabetes, Insulin-dependent _____

Diabetes, Non insulin-dependent _____

Thyroid Disease _____

Kidney Disease _____

Liver Disease _____

High Cholesterol _____

GERD _____

Other, Please Specify _____

Number of co-existing Medical Conditions _____

Concurrent Medications

Number of Concurrent Medications _____

Karnofsky Status _____

Baseline Hemoglobin _____

APPENDIX H

Radiation Therapy Patient Care Record (Maximum Anatomic Site-Specific Side Effect Scores)

| Side Effect | Base-line | One | Two | Three | Four | Five | Six | End | 1 mo | Max |
|--------------------|-----------|-----|-----|-------|------|------|-----|-----|------|-----|
| Skin Reaction | | | | | | | | | | |
| Fatigue | | | | | | | | | | |
| Esophagitis | | | | | | | | | | |
| Cough | | | | | | | | | | |
| SOB | | | | | | | | | | |
| Proctitis | | | | | | | | | | |
| Diarrhea | | | | | | | | | | |
| Urinary Frequency | | | | | | | | | | |
| Oral Mucositis | | | | | | | | | | |
| Taste Changes | | | | | | | | | | |
| Xerostomia | | | | | | | | | | |
| Nausea | | | | | | | | | | |
| Anorexia | | | | | | | | | | |
| Sleep Disturbances | | | | | | | | | | |
| Pain Rating | | | | | | | | | | |
| Total S/E Score | | | | | | | | | | |
| Radiation Dose | | | | | | | | | | |

Assessment Parameters (Anatomic Site-Specific Side Effects)

Skin Reaction

0- None

- 1- Faint or dull erythema; follicular reaction; dry desquamation
- 2- Moderate to brisk erythema; patchy moist desquamation; moderate erythema in skin folds
- 3- Moist desquamation other than skin folds; bleeding induced by minor trauma
- 4- Ulceration, hemorrhage, or necrosis

Esophagitis/Pharyngitis

0- None

- 1- Tolerates regular diet
- 2- Tolerates soft diet
- 3- Tolerates liquids only
- 4- Chokes and/or coughs when swallows liquids

Cough

0- None

- 1- Non-productive cough; <5x/hour
- 2- Productive cough; <5x/hour
- 3- Non-productive cough; >5x/hour
- 4- Productive cough; >5x/hour

Shortness of Breath

0- None

- 1- Dyspnea with exertion
- 2- Dyspnea with minimal effort; not at rest
- 3- Dyspnea at rest; intermittent oxygen/steroid
- 4- Continuous oxygen therapy

Urinary Frequency

0- None

- 1- Urinating less than once an hour
- 2- Urinating at least once an hour
- 3- Urinating more than once an hour
- 4- Catheter required

Diarrhea

0- None

- 1- Abdominal cramping; \leq two liquid BM/day
- 2- 3-5 soft/liquid BM/day
- 3- 6-8 soft/liquid BM/day
- 4- \geq 9 soft/liquid BM/day

Proctitis

0- None

- 1- Rectal pain with bowel movement; no medication
- 2- Rectal pain with bowel movement; meds required
- 3- Mucus or bloody discharge
- 4- Life threatening perforation

Oral Mucositis

0- None

- 1- Generalized erythema
- 2- Isolated small ulcerations and/or white patches
- 3- Confluent ulcerations and white patches
- 4- Hemorrhage or necrosis

Taste Changes

0- None

- 1- Loss of 1/4 taste sensations
- 2- Loss of 2/4 taste sensations
- 3- Loss of 3/4 taste sensations
- 4- Complete loss of taste

Xerostomia

0- None

- 1- Mild mouth dryness; slightly thick saliva
- 2- Moderate dryness; thick, sticky saliva
- 3- Complete dryness of mouth

Nausea

0- None

- 1- 1 or 2 episodes of nausea in 24 hours
- 2- 3 to 4 episodes of nausea in 24 hours
- 3- 5 to 6 episodes of nausea in 24 hours
- 4- Continuous feeling of nausea

Anorexia

0- None

- 1- Loss of appetite; normal amts food
- 2- Loss of appetite; small amts food/liquids
- 3- Unable to eat any food
- 4- Receiving alternate mode of nutrition

Sleep Disturbances

0- Able to sleep through night without waking

- 1- Awakens < 2x/night; awake < 60 minutes
- 2- Awakens >2x/night; awake > 60 minutes
- 3- Unable to sleep throughout the night

Pain Rating:

Patient's subjective rating of degree of pain ranging from 0 (no pain) to 10 (severe pain)

APPENDIX I

Weekly Assessment Tool

Week: One Two Three Four Five Six End of Treatment
Follow-up: One-Month Three-Month Six-Month

1. Employment Patterns

1. Has your employment changed in any way since your last visit?

Yes ____ No ____

2. If yes, how has your employment changed?

Stopped working altogether _____

Worked fewer hours _____

Returned to work _____

Worked more hours _____

Changed duties _____

Other (please specify) _____

3. How many hours did you actually work in the past week? _____

2. Sick Leave Benefits

1. Have you used any sick leave benefits since your last visit?

Yes ____ No ____

2. If yes, what benefits have you used?

Paid sick time _____

Unpaid sick time _____

Other (please specify) _____

3. Demographic Update

1. Average number of hours of sleep per night in the past week _____

2. Average hours of exercise per day in the past week _____

3. Any change in medications since the last visit? Yes ____ No ____

4. If yes, what are the changes? _____

5. Any change in living situation since the last visit? Yes ____ No ____

6. If yes, what are the changes? _____

4. Karnofsky Status _____

Weekly Assessment Summary

| | Base-line | One | Two | Three | Four | Five | Six | End | 1 Mo |
|---|-----------|-----|-----|-------|------|------|-----|-----|------|
| Change in Employment Patterns Yes No | | | | | | | | | |
| Change in SLB Yes No | | | | | | | | | |
| # Hrs Worked Past Week | | | | | | | | | |
| Av Hrs Sleep per Night | | | | | | | | | |
| Av Hrs Exercise per Day | | | | | | | | | |
| Change in Living Situation Yes No | | | | | | | | | |
| Karnofsky | | | | | | | | | |

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