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FATIGUE, SELF-EFFICACY, AND PHYSICAL FUNCTIONAL STATUS IN PERSONS WITH LUNG CANCER

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Amy Jude Hoffman

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ABSTRACT

FATIGUE, SELF-EFFICACY, AND PHYSICAL FUNCTIONAL STATUS IN PERSONS WITH LUNG CANCER

By

Amy Jude Hoffman

Cancer-related fatigue (CRF) is a prevalent and severe symptom that is inadequately managed and accompanied by other unpleasant symptoms that negatively impact the physical functional status (PFS) of persons with cancer and especially those with lung cancer (LC). Symptom management occurs through self-directed action, with perceived self-efficacy (PSE) being a key factor. Existing theories and studies do not address the key role PSE plays in a person's ability to manage symptoms and improve their PFS, making the current study unique in persons with LC and other cancer (OC) diagnoses.

Secondary data analyses from baseline observation of two randomized control trials were performed on 63 persons with LC and 235 persons with OC diagnoses who were undergoing a course of chemotherapy. For the total sample and in the LC and OC groups separately, the hypothesis of mediation from CRF to PFS through PSE for fatigue management was tested showing significant support for partial mediation. In the total sample, the magnitude of the relationship between CRF and PFS was reduced after PSE for fatigue management was controlled, with the mediation accounting for 12% of the variance (t = -2.59; p = .009). Consequently, CRF severity directly influences PFS and indirectly influences PFS by its effect on PSE for fatigue management. Further, on a 0-10 scale (10 = most severe), similar levels of CRF severity were reported by persons with LC (M = 5.88; SD = 2.00) and OC (M = 5.83; SD = 2.29) diagnoses (t = -.161; df = 296; p = .872). However, through blockwise, hierarchical multiple regression, similar levels of

CRF severity were found to significantly worsen the PFS of persons with LC as compared to OC diagnoses (t = -3.78). In addition to type of cancer diagnoses, five other factors in the total sample were identified through blockwise, multiple hierarchical regression as the most important factors accounting for 47.7% of the explained variance in PFS [F (28, 295) = 8.68, p = .000]. Specifically, higher levels of PSE for fatigue management (t = 3.55) were found to be one of the strongest predictors of greater PFS, while lower levels of PFS were predicted by greater total CRF severity (t = -5.39), greater number of co-morbid conditions (t = -4.20), greater total symptom severity (t = -2.46), and having surgery prior to chemotherapy (t = -2.31).

Lower levels of PSE for fatigue management were identified through best of all subset regression to be a predictor of greater CRF severity in the total sample and in the LC and OC groups. Persons with LC (M = 4.99; SD = 1.43) as compared to OC (M = 4.54; SD = 1.60) diagnoses reported higher levels of total severity of the other unpleasant symptoms (t = -1.99; df = 294; p = .047). Through path analyses, the CRF severity had a direct effect on increasing the total symptom severity of the other unpleasant symptoms (t = 9.69) which lowered the PFS (t = -2.71) for persons with LC and OC diagnoses.

The findings indicate that CRF is related to the presence of other symptoms, and PSE is an important factor in optimizing CRF management and PFS. This study provides the foundation for future intervention studies to increase PSE to achieve optimal symptom management and PFS in persons with cancer.

This work is dedicated to my Grandfather, William D. Lawton, who was a surgical technician overseas in World War II, and who died on February 19, 1976, after being diagnosed with lung cancer. I was only 10 years old at the time, and a Girl Scout, but I remember it as though it were yesterday. He was brave in his fight against the disease even though he had multiple occurring, severe symptoms of the disease and its treatment. As a little girl, I do remember the horror of the symptoms he experienced and how the symptoms robbed him of his dignity and quality of life. My hope is that this work will lead to improved symptom management and quality of life for persons with lung cancer so they will not have to suffer as my dear Grandfather did.

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CHAPTER ONE

INTRODUCTION

Persons with cancer report many troublesome symptoms. This is particularly true for persons with lung cancer (LC) who report even more symptoms than persons with other cancer (OC) diagnoses (A. Doorenbos, C. Given, B. Given, & N. Verbitsky, 2006b; B Given, Given, Azzouz, & Stommel, 2001). Fatigue is an especially prevalent and distressing symptom in the cancer population (Chan, Richardson, & Richardson, 2005; Cooley, 2000; Cooley, Short, & Moriarty, 2003; de Jong, Kester, Schouten, Abu-Saad, & Courtens, 2006; Hickok et al., 2005; Irvine, Vincent, Graydon, Bubela, & Thompson, 1994; Oi-Ling, Man-Wah, & Kam-Hung, 2005; Okuyama et al., 2001; Sarna & Brecht, 1997; Schwartz et al., 2000; Visser et al., 2006). Fatigue is accompanied by many other severe symptoms that are poorly managed by patients and professionals (Degner & Sloan, 1995; Gift, Jablonski, Stommel, & Given, 2004; C Given, Given, Azzouz, Kozachik, & Stommel, 2001; McCorkle & Benoliel, 1983). In some populations, a positive relationship between a person's perceived self-efficacy (PSE) (perception of ability) and his/her actual ability to manage symptoms has been shown (Barnason et al., 2003; Cheng & Boey, 2002; Federman, Arnstein, & Caudill, 2002; Gardner et al., 2003; King, Wessel, Bhambhani, Sholter, & Maksymowych, 2002; Lorig et al., 2001; Mathiowetz, Matuska, & Murphy, 2001; Pariser, O'Hanlon, & Espinoza, 2005; Wassem & Dudley, 2003; K. Wong, Wong, & Chan, 2005).

Symptoms are one of the major determinants of physical functional status (PFS) (D Brown, McMillan, & Milroy, 2005; Byar, Berger, Bakken, & Cetak, 2006; Dodd, Miaskowski, & Paul, 2001; A. Doorenbos, B. Given, C. Given, & N. Verbitsky, 2006a;

B. Given et al., 2001; Handy et al., 2002; Kurtz, Kurtz, Stommel, Given, & Given, 1999a, , 2000; Scott et al., 2003). Poorly managed symptoms impair daily functioning, interfere with cancer treatment, reduce quality of life, and jeopardize survival possibilities (Cleeland, 2000, , 2001; Vogelzang et al., 1997). However, to date, no research has been conducted studying the relationships between fatigue, PSE, and PFS in the cancer population. Demonstrating a relationship between increased PSE and the management of cancer-related fatigue (CRF), will support the designing of nursing interventions that help persons living with cancer increase their PSE so they can better manage their CRF and maintain their optimal PFS.

The National Comprehensive Cancer Network (NCCN) together with other researchers substantiate that gaps in knowledge exist for the effective management of CRF (Ahlberg, Ekman, Gaston-Johansson, & Mock, 2003; Cleeland, 2001; Curt et al., 2000; Dean & Stahl, 2002; Ferrell, Grant, Dean, & Funk, 1996; V Mock, 2001; V Mock et al., 2001; Stricker, Drake, Hoyer, & Mock, 2004). The NCCN defines CRF as "a distressing persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning" (National Comprehensive Cancer Network, 2006). The inadequacy of CRF management continues to impact a person's PFS (Lutz et al., 2001; V. Mock et al., 2000; Passik et al., 2002; Stone et al., 2003). This inconsistency between the state-of-the-science and the enormity of the problem was noted by the panel of experts at the "State-of-the-Science Conference on Symptom Management in Cancer: Pain, Depression, and Fatigue" held at the National Institutes of Health (NIH) in July 2002. The panel of experts recognized the limited scope of research and advocated that more study needs to

be devoted to the definition, occurrence, assessment, and treatment of CRF (National Institutes of Health, 2003). This study is unique since few descriptive and interventional studies have been dedicated to the LC population regarding fatigue and its accompanying unpleasant symptoms (Ahlberg et al., 2003; Carr et al., 2002; Okuyama et al., 2001).

Currently, most CRF management is carried out by patients via self-care strategies (Curt et al., 2000; Stone et al., 2003). These strategies are often impacted by the person's level of fatigue and PSE. In order to manage fatigue, it is critical to know what the person thinks of his/her ability to manage fatigue and how it impacts their self-directed action. Perceived self-efficacy forms the basis of any decision to act, the course of action selected, the degree of effort exerted, and the perseverance to continue in the face of obstacles and adversity (Bandura, 1997). Thus, the ability to exercise control over self-directed action is fundamental to symptom management and other actions which underpin the day-to-day responsibility of living with a life threatening chronic illness such as cancer. If the relationships between CRF, PSE, and PFS are found to be significant, they will provide the foundation for future intervention studies to increase PSE to achieve optimal symptom management and PFS in persons with cancer, and particularly for those with LC.

CHAPTER TWO

THEORETICAL FRAMEWORK AND REVIEW OF THE LITERATURE

Background

This year approximately 1.5 million Americans will learn they have cancer and 600,000 will die from the disease. The five-year survival rate for all cancers diagnosed between 1996 and 2002 is 66%, up from 51% from 1975 to 1977 due to earlier detection of cancer and advances in treatment. The National Cancer Institute estimates that approximately 10.5 million Americans with a history of cancer were alive in 2003 (American Cancer Society, 2007). Additionally, this year in the United States among men, solid tumors of the prostate, lung, and colon will account for approximately 54% of all newly diagnosed cancers. For women in 2007, the three most commonly diagnosed types of cancer will be breast, lung, and colon accounting for about 52% of all new estimated cases (Jemal et al., 2007). Consequently, many Americans in 2007 will learn they have been diagnosed with cancer, die from cancer, and will be living longer with the effects of the disease and its treatment. Regrettably, one of the major effects of cancer and its treatment is the burden of multiple concurrent symptoms (Miaskowski et al., 2006; Walsh & Rybicki, 2006).

A panel of experts at the National Institutes of Health State-of-the-Science Conference on Symptoms Management in Cancer concluded that despite the fact that research is producing novel approaches to the causes and cures of cancer, research used to diagnose, treat, and manage even the most common symptoms such as pain, fatigue, and depression lag behind (National Institutes of Health, 2003). The effects of these symptoms and the inadequacy of symptom management are one of the major

determinants of functional status and the inadequacy of symptom management affects a person's functional status. In light of these facts, managing symptoms related to the effects of cancer and cancer treatment is important to optimize patient physical functional status (PFS).

In the United States and throughout the world, lung cancer (LC) is the most common type of newly diagnosed cancer affecting both men and women (American Cancer Society, 2007; Jemal et al., 2007; Parkin, Bray, Ferlay, & Pisani, 2005; World Health Organization, 2003). Likewise, in the United States, LC is the most common cause of cancer-related mortality surpassing those of breast, prostate, and colorectal cancer deaths combined (American Cancer Society, 2007). The majority of persons with LC suffer from multiple concurrent severe symptoms (Chan et al., 2005; Cooley, 2000; Cooley et al., 2003; Cooley, Short, & Moriarty, 2002; Fox & Lyon, 2006; Gift et al., 2004; Gift, Stommel, Jablonski, & Given, 2003). It has been noted that persons with LC may suffer a disproportionate symptom experience in comparison to persons with other cancer diagnoses (OC). Persons with LC have more symptoms than other patients with solid tumors who are newly diagnosed and at the end-of-life (Doorenbos et al., 2006b; B. Given et al., 2001). Moreover, the level of symptom severity and distress has been reported to rise until death in persons with LC (Degner & Sloan, 1995; Sarna, 1993a, , 1998).

Lung cancer is classified clinically as small cell (13%) and non-small cell (87%) (American Cancer Society, 2006). While significant advances have been made in LC treatment, the five-year survival rate for all stages of non-small cell LC is a dismal 15%, and only 6% for small cell LC (American Cancer Society, 2003). Life extending and

palliative polychemotherapy regimens for persons with non-small cell LC have a one-year survival rate of 30% to 40% (Ramalingam & Belani, 2002). A recent, important study done by Winton et al. indicates greater length of survival for those with resected early stage non-small cell LC with adjuvant vinorelbine plus cisplatin (2005). However, greater survival length comes at a cost with the occurrence of multiple symptoms with fatigue being the most prevalent during chemotherapy which underscores the necessity for extending research to better manage the symptoms and improve functioning (Winton et al., 2005). Persons with small cell LC who present at diagnosis with extensive staged disease have a median life expectancy of 10 to 14 months (Ramalingam & Belani, 2002). The progressive decline for most persons with LC is due to the advanced stage of disease at diagnosis, the presence of pre-existing co-morbidities often associated with advancing age, and ineffective curative treatment.

Significance

The overall Healthy People 2010 objective for cancer supports this study stating its objective is: "To reduce the overall cancer death rate as well as illness, disability, and death by cancer "(Healthy People 2010, 2001). This study parallels the current research endeavors of the National Institute of Nursing Research and the Oncology Nursing Society in the area of symptom management, a key nursing-sensitive patient outcome for the promotion of the delivery of high-quality cancer care (B Given & Sherwood, 2005). Moreover, this research project stems from a larger randomized clinical trial that meets the core vision as articulated in the NIH Roadmap (National Institutes of Health, 2006). Consequently, given the enormity of the incidence of cancer, particularly LC, and the suffering of symptoms that corresponds with the disease trajectory, this research would

greatly benefit those living with LC by optimizing his/her ability to manage CRF and to improve his/her functional status.

Theoretical Framework

The theoretical framework for this study draws upon a synthesis of the Theory of Unpleasant Symptoms (TOUS) with Self-Efficacy Theory to examine the relationships among the variables within this study.

Introduction to the Theory of Unpleasant Symptoms

The TOUS, developed by Lenz, Pugh, Milligan, Gift, and Suppe (1997), demonstrates the complexity of the symptom experience. Most models of symptoms focus on one symptom and specifically on the intensity of the symptom, not the quality, distress, or duration. The TOUS was the first to portray multiple symptoms occurring together and relating to each other in a multiplicative manner (Gift, 2003). Symptoms occurring together are depicted as catalyzing each other. Thus, this theory uniquely allows for the presence of multiple symptoms and implies that management of one symptom will contribute to the management of other symptoms. The current literature refers to these co-occurring symptoms as symptom clusters. The three components of the TOUS are the patient characteristics influencing the symptoms, the symptoms themselves, and the performance outcomes. The three components are interacting, and each component influences every other component.

The first component, the patient characteristics are categorized as physiological, psychological, and contextual. Physiological characteristics are commonly what describe the severity of the disease, such as co-morbidities, abnormal blood studies, or other pathological findings. Psychological characteristics affecting the symptom experience

may include the person's mood, affective reaction to disease, degree of uncertainty regarding the symptoms, meaning ascribed to the symptoms, and knowledge about the symptoms. Contextual characteristics refer to the social and physical environment that may affect the person's symptom experience and their reporting of that experience, including social support, marital status, employment status, access to health care resources, lifestyle behaviors such as diet and exercise, and other resources.

Symptoms, the second component of the TOUS, can be considered alone or in combination. Symptoms have the dimensions of time (frequency and/or rate of occurrence; duration), severity (intensity), quality (description of qualifiers), and distress (bother). The quality dimension may be especially difficult, depending on the culture and language of the person, and the number of symptoms experienced at the same time.

The final component of the TOUS is performance, the "outcome" or "consequences" of the symptom experience. Symptoms affect performance. Performance includes functional (e.g., physical activity; ADLs; social activities and interaction; and role performance including work and other role-related tasks) and cognitive (e.g., ability to concentrate; problem solve and/or think) activities. Performance in this study emphasizes the functional performance, specifically PFS.

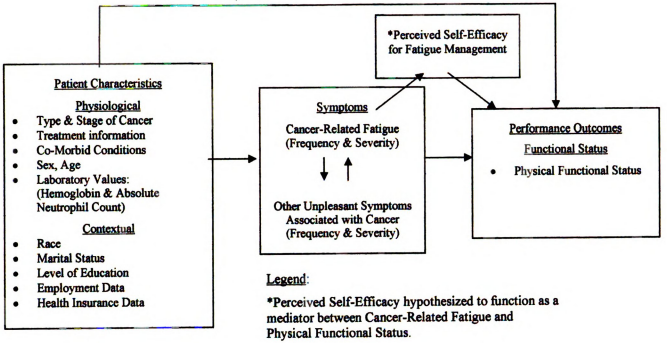
Introduction to Bandura's Self-Efficacy Theory

The addition of Bandura's Self-Efficacy Theory proposes that PSE serves as a possible mediator between symptoms such as CRF and functional status. Parallel to Bandura's definition, PSE is the person's perception of ability to execute behavior(s) to manage his or her symptoms such as CRF (1986). Bandura has identified PSE as a powerful mediator linked to successful outcome attainment (1997). According to Baron

and Kenny, mediators are defined most often as an internal property of a person that transforms the independent variable to explain how or why outcomes occur (1986). Bandura (1997) and Baron and Kenny (1986) stress the need to assess PSE for mediation rather than simply presuming such a link to develop a more precise understanding of the relationship between the independent and outcome variable.

Like the TOUS, Self-efficacy Theory posits interacting relationships among the factors in a given phenomenon; but, interactive relationships are not a focus of this study and are not included in the model for this study. The theoretical framework of this research is presented in Figure 1. For persons with cancer (LC and OC diagnoses), the patient characteristics were examined as they relate to CRF severity in order to identify which characteristics relate to CRF. Next, the symptom experience of persons with cancer (LC and OC diagnoses) was examined, specifically, the relationship between CRF and other unpleasant symptoms. Also, PSE for fatigue management was examined as a mediator between CRF and PFS. Lastly, the unique contribution of the physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE to the PFS of persons with cancer (LC and OC diagnoses) were examined.

Figure 1. Theoretical Framework



Review of the Literature

The review of the literature follows the components of the theoretical framework. A review of studies related to each component of the theoretical framework will be presented from left to right in the model.

Patient Characteristics

The challenge to managing CRF is its multidimensionality. The current literature provides limited evidence of the etiology of CRF in the general cancer population and even less for persons with LC. In this study, physiological (i.e., type and stage of cancer, treatment modalities, co-morbid conditions, sex, age, & laboratory values) and contextual (i.e., race, marital status, level of education, employment and health insurance data) characteristics that previous research has proposed were included in the study to be related to the subjective experience of CRF. These characteristics affect the PFS of a person with cancer, particularly LC when faced with CRF and other unpleasant symptoms.

Physiological Characteristics

Given that persons with LC experience greater numbers of symptoms in comparison to other cancer (OC) diagnoses, one might expect a difference by the type of cancer diagnosis in the CRF experience. Additionally, among patients 65 years of age and older persons with LC were found to be at more risk of reporting pain and/or fatigue as compared with persons with breast cancer (C. Given et al., 2001). For stage of cancer, within a diverse type of cancer population, data indicate that advanced cancer is more likely to be related to both pain and fatigue when compared with pain alone (C. Given et al., 2001). Fatigue has been identified as a highly prevalent and most distressing

symptom over time during various types of treatment for LC, such as chemotherapy, surgery, radiation therapy, and combined treatment (Cooley et al., 2003). Within a varied type of cancer population, data showed that patients with three or more co-morbid conditions reported increased fatigue (C. Given et al., 2001).

For sex, when compared with men, women were more likely to report fatigue (C. Given et al., 2001). However, for both sex and age, women 60 years of age or greater with metastatic cancer found fatigue to be more disruptive than men. Recommendations for further investigation of the relationship between CRF and laboratory values have been advised (V Mock, 2001; National Institutes of Health, 2003). Since associations between cancer treatment (e.g., chemotherapy, radiation) and symptoms have been found (Cooley et al., 2003), this study examined the respective associations of absolute neutrophil count (ANC) and hemoglobin levels with CRF. Hemoglobin was selected since it is a protein in the red blood cell that carries oxygen. Low levels of hemoglobin cause a reduction in the amount of oxygen that can be carried to tissues in the body. A decreased delivery of oxygen has been related to fatigue (National Comprehensive Cancer Network, 2006). Absolute neutrophil count represents a subset of the white blood cell count and neutrophils are responsible for fighting infection. Neutropenia is an abnormal decrease in the number of neutrophils and has been established as a strong predictor of infection in persons with cancer (National Comprehensive Cancer Network, 2005). The Infectious Disease Society of America defines neutropenia as an ANC less than 500 cells/mm^3 or an ANC of 500 to 1000 cells/mm^3 in patients where further decline is expected (Hughes et al., 2002). It is important to note that neutropenia can occur when the total white blood cell count is within a normal range of (4000-10,000 cells/mm^3). Consequently,

quantifying ANC is essential to achieving a correct assessment of neutrophil status. Pathophysiological processes leading to energy imbalance such as infection as indicated by the ANC level may be related to the report of fatigue (Fortner, Tauer, Okon, Houts, & Schwartzberg, 2005; Gutstein, 2001; Molassiotis & Chan, 2000).

Contextual Characteristics

There is a paucity of evidence concerning how the contextual characteristics, race, marital status, level of education, employment and health insurance data impact CRF in the general and lung cancer populations (Montazeri, Gillis, & McEwen, 1998). The burden associated with LC requires great amounts of support through contextual characteristics to sustain the patient and his/her family (Sarna & McCorkle, 1996). These need further investigation.

Symptoms

The management of unpleasant symptoms is a foremost priority for those suffering from LC. According to Gift et al., in a sample of 220 persons newly diagnosed with LC, a mean of 11 symptoms was reported per person (2004). These multiple distressing symptoms were related to severity and limitations. Additionally, B. Given et al. report among persons with cancer who were 65 years and older, those with LC reported a greater number of symptoms than those with other tumors of solid composition (2001). Symptoms place an additional burden on the lives of persons with LC (Cleeland & Reyes-Gibby, 2002). Cooley et al. found in a secondary longitudinal analysis that while many symptoms improve over time, some persons recently diagnosed with LC experience increasing levels of distress from pain frequency and fatigue (2003). Moreover, other studies report for persons with LC, the level of symptom severity and

distress rises until death (Degner & Sloan, 1995; Sarna, 1993a, , 1998). This increased symptom severity negatively impacts a person's PFS. However, few studies have been conducted focusing on the relationship between symptoms and functional status for persons with LC.

Symptoms are the "perceived red flags of threats to health" (Hegyvary, 1993). Symptoms are the experience of the person. The TOUS highlights four dimensions that characterize the person's symptom experience: timing (frequency and/or rate of occurrence; duration), severity (intensity), quality (description of qualifiers), and distress (bother). This study focuses on two dimensions of the person's symptom experience: frequency or rate of occurrence and severity. Furthermore, the TOUS addresses not only one symptom, but multiple symptoms and their interactions. This is important to this study since during the course of their illness trajectory, persons with cancer, particularly LC, not only present with CRF, but with other concurrent symptoms. The concurrence of symptoms are likely to catalyze each other worsening the overall level of symptom severity (Cleeland & Reyes-Gibby, 2002; Lenz et al., 1997). Therefore, the determination of the total symptom severity is critical to fully understand the symptom experience of the person with LC with fatigue and other concurrent symptoms. Given that persons with LC experience greater numbers of symptoms in comparison to other cancer (OC) diagnoses (B. Given et al., 2001), this study compared and described the other unpleasant symptoms associated with CRF. This is a vital step in portraying the true fatigue symptom experience of the person with cancer, particularly LC, which will serve as a foundation to design future interventional studies to enhance PSE and increase PFS.

Perceived Self-Efficacy

Although not studied in the LC population, a contributing factor to the achievement of symptom management of CRF to attain maximum PFS may be a person's PSE. There is accumulating evidence that PSE expectations exert strong influence on behavior (Bandura, 1989). Self-efficacy contributes to health behavior change in chronic illness and is a key predictor of health promotion (Bandura, 1995, , 1997). Investigations substantiate that PSE plays a central role in producing positive health outcomes in symptom management and functional ability in people living with chronic conditions such as arthritis (Barlow, Turner, & Wright, 2000; Lorig, Ritter, & Plant, 2005; Lorig et al., 2001; Pariser et al., 2005), cardiac disease (Barnason et al., 2003; Cheng & Boey, 2002; Gardner et al., 2003; Hiltunen et al., 2005), chronic pain (Federman et al., 2002), COPD (K. Wong et al., 2005), diabetes (Howells et al., 2002), fibromyalgia (King et al., 2002), and multiple sclerosis (Mathiowetz et al., 2001; Wassem & Dudley, 2003). Attention to PSE is important in enhancing a positive perception of control over the challenging situations faced by persons with cancer (Merluzzi & Martinez Sanchez, 1997; Telch & Telch, 1985, , 1986).

Very few studies have been conducted relative to PSE and symptom management in the general cancer population and only one small study has been done concentrating solely on PSE in persons with LC (Porter et al., 2002). Using appropriate mesh terms, keywords and thesaurus terms via PubMed, MEDLINE, CINAHL, and PsycINFO (i.e., fatigue, cancer-related fatigue, symptoms, self-efficacy, and cancer), no studies have been conducted on the role PSE plays in the management of fatigue and other associated unpleasant symptoms to achieve optimal functional status for the LC population.

The few studies that have been conducted indicate that increased PSE has a positive impact on the lives of persons with cancer. For instance, Cunningham, Lockwood, and Cunningham reported in a convenience sample of 273 cancer patients (including 17 persons with LC) that an intervention involving implementation of coping skills led to a strong positive relationship between PSE, quality of life and mood state (1991). Likewise, Beckham, Burker, Lytle, Feldman, and Costakis found in a cross-sectional study of 42 male cancer patients (including 3 persons with LC) that PSE expectations relative to cancer symptoms accounted for a large proportion of the variance measures of cancer adjustment, psychological distress, positive and negative affect, and behavioral dysfunction (1997). Also, Lev, Paul, and Owen further substantiated these results through a longitudinal intervention study with a convenience sample of 307 general cancer patients (including 38 persons with LC) at baseline, 181 persons four months later, and 124 persons eight months later. In this study, patients reported that PSE affected their adjustment to cancer and without intervention their PSE and adjustment decreased over time (1999). In a later study, Lev et al. found in a randomized clinical trial of 56 women with breast cancer that PSE increased quality of life and decreased symptom distress (2001). Similar findings were found in a randomized clinical trial with 189 women with late stage breast cancer. Northouse et al. (2002) reported that PSE had positive effects on patients' and family members' quality of life. In a cross-sectional study with 63 men undergoing treatment for prostate cancer, Lev et al. (2004) found that psychosocial variables and physical symptoms were related to indicators of quality of life.

Lev et al. (2004) advised that these data support Bandura's (1997) assertion that psychosocial factors may determine quality of life, and using efficacy enhancing

interventions in persons with cancer may reduce a person's perception of stress and reported symptoms and increase a positive perception of quality of life. Weber et al. (2004) reported similar results through a randomized clinical trial of 30 men undergoing radical prostatectomy for prostate cancer. Here the treatment group receiving a support intervention had increased PSE, decreased depression, and greater improvement in physical functioning in comparison to the control group receiving usual care. Parallel to these findings, in a cross-sectional study with 85 advanced cancer patients (including 18 persons with LC), Hirai et al. (2002) reported that patients in good physical condition had high PSE, and patients with high PSE were less emotionally distressed. Thereby, the researchers stated that the findings imply that psychological interventions which emphasize PSE would be effective for advanced cancer patients. Most recently in 2006, two studies conducted over time report on the positive effects of PSE on patient outcomes. The first study conducted by Eller et al. evaluated the impact of PSE over time on the dimensions of quality of life in 159 men who were undergoing various treatments for prostate cancer (2006). Eller et al. reported that one subscale of PSE (positive attitude) was a significant predictor of two components of quality of life, social and functional well-being. The second study followed 95 women undergoing treatment for early stage breast cancer for one year. In this study, Manne et al. reported that cancer-related self-efficacy for activity management and self-satisfaction increased and remained relatively stable over the one year that participants were followed (2006).

To conclude, the only study pertaining to PSE in persons with LC, Porter et al. found that for a small convenience sample of 30 subjects, those who rated their PSE as higher had lower levels of pain and other symptom severity (2002). Although some of these

studies include small sample sizes, have methodological problems, and are mainly focused on the general, breast, or prostate cancer population, they provide the evidence to support further investigation and the development of PSE strategies to manage CRF and optimize the PFS of persons with LC.

Bandura posits that self-efficacy expectations are domain specific and are among the most effective mediators since they influence the initial decision to perform a behavior, the effort expended by the behavior, and the persistence of the behavior in the face of adversity (1997). Bandura distinguished outcome expectations, one's perception that a behavior could produce a particular outcome, from self-efficacy expectations, the perception of one's ability to execute this behavior successfully (1997). It is important to note that outcomes arise from actions, and the outcomes people anticipate depend largely on their perceptions of how well they will be able to perform in given situations (Bandura, 1997). In measuring PSE, people are presented with items describing different task demands and they rate the strength of their perception in their ability to execute behaviors. Items about PSE are phrased in terms of "can do" (perception of ability) rather than "will do" (perception of intention) (Bandura, 1997).

Parallel to Bandura's definition, PSE is the person's perception of ability to execute behavior(s) to manage his or her CRF (1986). This involves an evaluative process of the meaning of CRF and other associated unpleasant symptom(s); CRF's significance to a person's well-being; as well as the person's self-appraisal of his or her own PSE to manage fatigue. It is important to note that PSE is concerned with the judgments of what one can do with whatever knowledge and skills one possesses (Bandura, 1986). Perceived self-efficacy beliefs are developed and altered not only by direct mastery experiences, but

also by seeing people similar to oneself manage task demands successfully, social persuasion that one has the capabilities to succeed in given activities, and inferences from physiological and emotional states indicative of personal strengths and vulnerabilities (Bandura, 1997). Consequently, Self-Efficacy Theory is advantageous for use in research because influencing the development of sources of PSE provides direction for effective alteration of behavior (Lev, 1997).

According to Bandura, those persons with high levels of PSE are able to exert control over threats (1997) such as CRF and other unpleasant symptoms and strive to improve their PFS. Thus, it is both the fatigue and the person's PSE related to management of the fatigue that determines the degree to which the person is vulnerable or empowered to meet the demands of the fatigue and other unpleasant symptom(s) derived from LC and its treatment. As previously described, there is accumulating empirical evidence of the effectiveness of PSE positively impacting the management of symptom(s) and in turn the functional abilities of those suffering from various chronic conditions. However, using appropriate mesh terms, keywords and thesaurus terms via PubMed, MEDLINE, CINAHL, and PsycINFO (i.e., fatigue, cancer-related fatigue, symptoms, self-efficacy, and cancer), there is little published research in the area of PSE and its impact on symptom management for persons with life threatening, chronic illnesses such as cancer.

Functional Status

Although limited research exists describing the relationship between fatigue and the functional status for persons within the general cancer population (including persons with LC), studies have found CRF to adversely impact the functional status of older and younger persons. A study comprised of 826 persons 65 years of age and older with a new

diagnosis of cancer revealed that fatigue was 1 of 3 independent predictors of their physical functioning (B. Given et al., 2001). C. Given, Given, Azzouz, Stommel, and Kozachik (2000) reported from a study consisting of 907 patients age 65 or older with a new diagnosis of breast, colon, prostate, or lung cancer that patients who reported neither pain nor fatigue scored 15 points higher in physical functioning than those with pain or fatigue and 25 to 30 points higher than those with both symptoms. Similarly, in a study consisting of 93 persons with cancer 18 years of age or older receiving chemotherapy, both fatigue and pain were found to be the largest contributors to change in functional status of persons with cancer (Dodd et al., 2001). Last, a study reported that fatigue was the most prevalent and severe symptom among 47 persons with cancer who were in the final month of their lives resulting in great functional decline, especially in the areas of physical and role functioning (Sahlberg-Blom, Ternestedt, & Johansson, 2001).

Also, for persons with LC specifically, fatigue has been demonstrated to negatively affect their functional status when undergoing different treatment modalities. Handy et al. compared functional status in 139 persons with LC undergoing surgery with age-matched healthy patients. The results indicated that persons with LC had significantly lower scores in their level of energy and physical and role-emotional functioning with subsequent deterioration in functional status six months post-operatively (2002). Likewise, Langendijk et al. reported that 164 persons receiving radical radiotherapy reported fatigue as the most prevalent and distressing symptom and it increased in intensity over time during treatment (2001). This study also reported deterioration in physical and role functioning over time during radiotherapy and in the 6 to 12 months period after treatment ended.

Furthermore, fatigue has been shown to interfere with functioning activities for those with advanced-stage LC. Sarna and Brecht reported that among 60 women with advanced stage LC, fatigue was the most frequent distressing symptom with severe fatigue lowering physical functioning scores (1997). In another study by Sarna it was found that 79% of 24 persons with advanced staged LC experienced serious fatigue with 44% having subsequent difficulty with household chores, 52% losing interest in recreational activities, and 61% changing their recreational activities due to CRF (1993b). Additionally, Tanaka, Tatsuo, Okuyama, Nishiwaki, and Uchitomi reported that 50% of 171 persons with advanced stage LC reporting a low severity level of fatigue stated that this level of fatigue interfered with at least one daily activity (2002). Okuyama et al. similarly found that roughly half of their 157 persons with advanced LC reported fatigue interfered with at least one daily life activity (2001). In this group nearly one-third had interference with physical activities, and one-fifth reported CRF impacted emotional activities such as enjoyment with life and mood.

In a later study, Brown, McMillan, and Milroy (2005) compared functional status in 38 persons with metastatic or locally advanced LC with age and gender-matched persons. Brown et al. reported that persons with LC as compared to the control group had greater levels of fatigue and lower functional performance, poorer grip strength, and longer chair-rise time. In summary, the prevalence and distress from fatigue is high in persons with LC. Cancer-related fatigue alone or in conjunction with other symptoms heightens the total symptom impact adversely affecting the functional status of this population. Hence, management of fatigue and other associated symptoms of LC is a major element to optimal functioning.

Unpleasant symptoms such as CRF make it difficult for persons with cancer, particularly LC to maintain maximal functional status. The TOUS delineates the performance outcome component of the theoretical framework for this study (Lenz et al., 1997). According to the TOUS, performance outcomes are the consequences of symptom management which includes the PFS of the person with LC. Thus, the theoretical framework posits that multiple patient characteristics within the environment interact with each other and the symptom(s) allowing or restricting functional performance. In the face of the demands of CRF and other unpleasant symptoms, higher levels of functioning can be achieved by enhancing the PSE of the person with LC. Thus, PSE is an empowering mediator that enables the person with LC to achieve control over CRF and other unpleasant symptoms and enhance optimal functional performance.

Summary

Persons with LC have been found to experience more symptoms than those with OC diagnoses. Cancer-related fatigue is problematic and impacts the functional status of persons with LC. A contributing factor to symptom management of CRF is a person's PSE. Limited research has been conducted regarding the impact of CRF on symptom management to improve the functional status of persons with cancer, particularly LC. This research seeks to measure a person's fatigue self-efficacy and whether PSE relates to their ability to manage CRF and how this relates to their PFS. This study is important since it will lead to interventional research to improve functional status of persons with cancer, particularly LC when faced with fatigue.

CHAPTER THREE

METHODOLOGY

Design

This study is a cross-sectional descriptive design that employs baseline measures obtained from patients who were undergoing a course of chemotherapy from two larger randomized control trials currently underway: "The Family Home Care for Cancer: A Community-based Model for Symptom Management" (FHCC) project (R01 CA-079280) sponsored by Barbara A. Given, Ph.D., R.N., FAAN, Principal Investigator, and "The Automated Telephone Monitoring for Symptom Management" (ATSM) project (R01 CA-30724) sponsored by Charles W. Given, Ph.D., Principal Investigator (see Executive Summaries in Appendix A). The baseline measures were completed prior to the beginning of the intervention. This current study focuses on the baseline data and distinguishes itself from the larger study in that it focuses on the role perceived self-efficacy (PSE) plays in fatigue management and other unpleasant symptoms to achieve optimal physical functional status (PFS). Moreover, while the analyses of this study includes persons with other cancer (OC) diagnoses, the primary focus remains on persons with lung cancer (LC), a population that, when compared to other types of cancer diagnoses, has a greater number of symptoms (Doorenbos et al., 2006b; B. Given et al., 2001).

Purpose and Research Questions

The foremost purpose of this descriptive study was to examine fatigue and PSE in persons with LC and analyze how PSE in managing fatigue impacts PFS. Utilizing persons with OC diagnoses as a comparison group to persons with LC as well as to increase sample size assisted in answering the following research questions for the study:

1. What are the patient characteristics that relate to CRF severity in persons with cancer (LC and OC diagnoses)?
2. How does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of CRF severity?
3. What is the symptom experience of persons with LC and how does it compare to the symptom experience of OC diagnoses, including the relationships between CRF and other unpleasant symptoms?
4. Does PSE for fatigue management mediate the relationship between CRF severity and PFS in persons with cancer (LC and OC)?
5. Does mediation differ in persons with LC as compared to OC when evaluating PSE for fatigue management as a mediator between the relationship of CRF severity and PFS?
6. What is the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE to the PFS of persons with cancer (LC and OC)?
7. Considering the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE for fatigue

management to PFS, how does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of PFS?

8. Through the employment of a Path Model, is the PFS of persons with cancer (LC and OC) predicted through physiological and contextual patient characteristics, CRF, other unpleasant symptoms, and PSE for fatigue management?

Sample

The target sample for the study came from the baseline measures prior to the intervention of both the FHCC and ATSM studies (see Appendix A). Sample size included 63 persons with LC with a comparison group of 235 persons with OC diagnoses, which is composed of persons with breast cancer (n = 105); persons with colon cancer (n = 44); and persons with other sites of cancer (n = 86). As a result, the total sample size consists 298 persons with cancer, persons with LC (N = 63) and OC diagnoses (N = 235).

Study participants were recruited who were cognitively intact, speak English, able to hear and speak for telephone interviews, have new or recurrent disease, not receiving hospice care, receiving chemotherapy for breast, colorectal, or lung cancer, other solid tumors, and non-Hodgkin's lymphoma with at least two cycles remaining at time of enrollment, and may have been receiving concurrent radiation therapy. Thus, the baseline data for this study produced diversity in age, stage of cancer, and symptom severity. Exclusion criteria included those who were diagnosed with any hematological malignancy or whose treatment involved bone marrow transplant or stem cell rescue and for persons diagnosed with an emotional or psychological disorder for which they were currently under the care of a professional.

Setting

The data for the FHCC and ATSM studies were collected from seven different collaborating cancer sites (see Appendix B).

Operational Definitions

Operational definitions of the study's key variables are introduced below and are organized according to the theoretical framework guiding this study. The operationalization of the key variables is further discussed in the section that outlines the instruments used for this study.

Physiological Patient Characteristics

Physiological patient characteristics include type and stage of cancer; treatment information (radiation therapy and surgery); co-morbid conditions; sex; age; and laboratory values (hemoglobin and absolute neutrophil count). Type of cancer includes both LC (small cell or non-small cell) and OC (breast, colon, and other types) diagnoses. Stage of cancer is classified by the TNM system and a two-stage system. Treatment information included whether or not a patient was receiving radiation. Treatment information also included two variables regarding surgery: *surgery prior and surgery during*. *Surgery Prior* means that the surgery occurred prior to chemotherapy and prior to consent. *Surgery During* means that the surgery occurred during chemotherapy and the audit period which is from consent to last interview.

Contextual Patient Characteristics

Contextual patient characteristics include race; marital status; level of education; employment data; and health insurance data. Employment data included whether a person was retired, receiving disability, was on a temporary leave from employment, whether the

person had to quit employment, and annual combined household income. Health insurance data included whether or not a subject had health insurance and if so, who held the policy (patient or spouse), and the type of health insurance policy held (private, Medicare, or Medicaid).

Symptoms

Symptoms are the "perceived red flags of threats to health," (Hegyvary, 1993). Cancer-related fatigue and 15 other unpleasant symptoms were included in this study. The total CRF severity and total symptom severity from the other unpleasant symptoms were analyzed.

The total CRF severity score includes two items from the Brief Fatigue Inventory, the patient's current (now) and worst severity of CRF within the past 7 days. The total CRF severity score was calculated by summing each subject's response to severity scores for both of the two CRF severity items and dividing by two (the two items assessing CRF severity) to standardize the score on an 11-point scale.

The total symptom severity score from 15 other unpleasant symptoms (excludes CRF) associated with cancer and cancer treatment was calculated by summing each subject's response to severity scores for each symptom reported (i.e., a reported symptom is a symptom with a severity score greater than zero) and dividing by the total number of symptoms reported to standardize the score on an 11-point scale.

Perceived Self-Efficacy for Fatigue Management

Perceived self-efficacy for fatigue management is the person's perception of ability to execute behavior(s) to manage his or her CRF. The Self-Efficacy for Fatigue in Patients

with Cancer Scale measured how certain persons with cancer were in performing specified behaviors/goals in managing fatigue.

Performance Outcomes

Performance outcomes are the consequences of symptom management which includes the PFS of the persons with cancer which was measured via the Medical Outcomes Study Short Form-36 PFS subscale.

Instruments

Data for the study were collected in conjunction with the FHCC and ATSM studies at baseline via telephone interviews and medical record chart abstraction. The telephone interview for the study took approximately 15 minutes to complete. The following instruments include measures of patient characteristics; CRF, other unpleasant symptoms, PSE, and PFS (see Summary of Measures for Research, Appendix C).

Patient Characteristics (Physiological and Contextual)

Demographic Questionnaire and Medical Record Chart Abstraction

Patient characteristics were measured at baseline prior to the intervention using selected questions from a demographic questionnaire and medical record chart abstraction form developed for the FHCC and ATSM studies (see Appendix C). Most patient characteristics were self-report items. A demographic questionnaire was used for co-morbid conditions, sex, age, race, marital status, level of education, and employment data. Information on co-morbid conditions regards 15 chronic health conditions. Stage and type of cancer (LC or OC diagnoses), treatment information, hemoglobin, absolute neutrophil count, and health insurance data were obtained from the person's chart via a chart abstraction form. Information on the stage of cancer was classified according to the

TNM staging system of the American Joint Committee on Cancer for non-small cell LC and OC diagnoses that stages the cancer on a scale of 0 to IV. For small cell LC, a two-staged system was used: limited or early stage and extensive or late stage.

Symptoms (CRF and Other Unpleasant Symptoms)

The Brief Fatigue Inventory (BFI)

The BFI measures the severity from CRF (3 items), and the amount that CRF has interfered with aspects of the patient's life (6 items) (Mendoza et al., 1999). The investigators designed the BFI based upon the Brief Pain Inventory that has demonstrated successful assessment (successfully utilized in telephone interviews) of the severity of cancer pain in the United States and other countries (Cleeland et al., 1989; G. Wong et al., 2004). Items on the BFI were derived from the data in the Wisconsin Fatigue Study that utilized normal volunteers, psychiatric patients receiving treatment for depression, and cancer patients.

Appropriate psychometric properties were found using data on adult patients (N = 305) from the University of Texas M.D. Anderson Cancer Center consisting of inpatients and outpatients with varying types of cancer (including persons with LC), and control subjects (N = 290) from the Houston area (Mendoza et al., 1999). The BFI achieved a high internal consistency level of 0.96. Cronbach's coefficient alpha for each of the items (if deleted) was 0.95 for both interference in general activity and mood and 0.96 for the remaining items. Concurrent validity was established with two previously validated measures which are used for the assessment of fatigue, Profile of Mood States Fatigue Subscale ($r = 0.84, p < 0.001$) and the Functional Assessment of Cancer Therapy Fatigue Subscale ($r = -0.88, p < 0.001$) (Hwang, Chang, Cogswell, & Kasimis, 2002).

Furthermore, the BFI is sensitive in detecting severe from non-severe CRF at a cut score of 7 with a range of 7-10. Stability of the BFI to detect severity of CRF has been demonstrated (Hwang et al., 2002).

For the study, two items from the BFI measuring severity of CRF were used to calculate a total CRF severity score (see Appendix D). On an 11-point scale (0-10), these two items evaluated the patient's current (now) and worst severity of CRF within the past 7 days. The total CRF severity score was calculated by summing each subject's response to severity scores for both of the two CRF severity items and dividing by two (the two items assessing CRF severity) to standardize the score on an 11-point scale. For this study, internal consistency reliability of the total CRF severity revealed a Cronbach's alpha of 0.85 for the total sample, 0.81 for persons with LC, and 0.86 for persons with OC diagnoses.

The Symptom Experience Inventory

Frequency and severity of the other unpleasant symptoms were assessed using the Symptom Experience Inventory which was developed and used in previous studies (successfully utilized in telephone interviews) by Dr. Barbara Given (Gift et al., 2004; B Given et al., 2002; C. Given et al., 2001) (see Appendix E). The inventory is a self-report measure containing 16 symptoms related to cancer and its treatment (i.e., pain, dyspnea, insomnia, nausea, difficulty remembering things, lack of appetite, dry mouth, vomiting, numbness or tingling, diarrhea, fever, cough, constipation, weakness, alopecia, fatigue). Frequency was evaluated by asking the patient to indicate the number of days in the past week that they experienced the symptoms. On an 11-point scale (0-10), patients were asked to rate their current severity of their symptoms. Frequency of the symptoms and

both the individual symptom severity and total symptom severity scores were calculated for persons with LC and OC diagnoses. Individual symptom severity scoring was rated from a 0 to 10, with 0 being "symptom not present" and 10 being "worst it can be". The total symptom severity associated with each symptom was calculated by summing each subject's response to severity scores for each symptom reported (i.e., a reported symptom is a symptom with a severity score greater than zero) and dividing by the total number of symptoms reported to standardize the score on an 11-point scale. The total symptom severity score did not include the symptom of fatigue. For this study, evaluation of the internal consistency reliability resulted in a Cronbach's alpha for the total sample of 0.72, for persons with LC 0.77, and for persons with OC 0.69.

Perceived Self-Efficacy for Fatigue Management

Self-Efficacy for Fatigue in Patients with Cancer Scale (SEFPCS)

Review of the literature revealed that there was no existing tool to measure PSE for fatigue management in persons with cancer. In this study, PSE for fatigue management was measured using a six-item subscale adapted by the author from the Lorig Arthritis Self-Efficacy Scale (ASE). Lorig created the ASE to measure persons' PSE to cope with the consequences of chronic arthritis. The ASE has a 3-factor solution accounting for 61% of the variance in the dimensions of PSE. Internal coefficient alphas for each of the subscales ($N = 143$) are 0.76 for pain management, 0.89 for physical functioning, and 0.87 for coping with other symptoms (Lorig, Chastain, Ung, Shoor, & Holman, 1989).

Of interest is the Coping with Other Symptoms Lorig subscale, which has been minimally altered for the cancer population by replacing the word fatigue for other identified symptoms to create the SEFPCS (see Appendix F). In a similar manner to the

SEFPCS, the Lorig subscale has been successfully adapted in the past for three chronically ill populations which includes patient populations with chronic pain, cancer pain and HIV disease (Anderson, Dowds, Pelletz, Edwards, & Peeters-Asdourian, 1995; Keefe et al., 2003; Shively, Smith, Bormann, & Gifford, 2002), and successfully used to collect data via telephone interview (Keefe et al., 2003). These research studies with different chronically ill populations have demonstrated improved internal Cronbach's alpha with adaptation of the Lorig Coping with Other Symptoms subscale as compared to the internal Cronbach's alpha reported when used in the arthritis population. Note that the degree of manipulation performed in all three past studies is greater than what was done for the SEFPCS.

The SEFPCS is a self-report measure containing 6 items related to PSE for fatigue management. For this study, on an 11-point scale (0-10) with 0 being "very uncertain" and 10 "very certain", persons with cancer were asked to rate how certain they were in performing specified behaviors/goals in managing fatigue. The SEFPCS score was calculated by summing the responses for each item and dividing that sum by six, the number of items in the SEFPCS. Scores ranged from 0-10, with higher scores indicating greater PSE for fatigue management. Content validity for the SEFPCS was reviewed by three nurse experts experienced in fatigue management of persons with cancer, and revisions were made prior to the SEFPCS use in the study (Nunnally & Berstein, 1994). For this study, evaluation of the internal consistency reliability resulted in a Cronbach's alpha for the total sample of 0.92, for persons with LC 0.91, and persons with OC diagnoses 0.92.

Performance Outcomes (Functional Status)

The Medical Outcomes Study Short Form-36 (SF-36)

The SF-36 is one of the most comprehensive, generic, multi-dimensional health-related quality of life measures for adults with chronic conditions which assesses various components of functional status (see Appendix G) (Maciejewski, 1997; Murdaugh, 1997; Ware, Snow, Kosinski, & Gandek, 1993). Eight subscales are contained within the instrument including physical functional status (10 items), role-physical functional status (4 items), bodily pain (2 items), general health perceptions (5 items), vitality (4 items), social functional status (2 items), role-emotional functional status (3 items), and mental health (5 items). Principle component analysis demonstrates that 80-85% of the variance in the eight subscales was accounted for by two factors, physical and mental health. It is standardized, validated, (McHorney, Ware, & Raczek, 1993) and shows internal consistency of the subscales ranging from .78 to .92 (Ware et al., 1993). Since symptoms are a major determinant of functional status, the physical functional status subscale from the SF-36 was used. The SF-36 Health Survey Manual and Interpretation Guide was used for scoring (Ware et al., 1993). The subscale scores of the SF-36 are linearly transformed to range from 0 to 100, with higher scores representing better levels of functional status (Ware et al., 1993). For this study, evaluation of the internal consistency reliability resulted in a Cronbach's alpha for the total sample of 0.91, for persons with LC 0.91, and persons with OC diagnoses 0.91.

Procedures

Recruitment and Data Collection

Data were obtained for the study from the baseline measures of the FHCC and ATSM studies. The baseline measures were collected prior to the beginning of the intervention. Recruiters for the FHCC and ATSM studies were employees of the participating sites which facilitated their ability to access patient records and information without breach of confidentiality. Recruiters were trained at Michigan State University (MSU) following a procedure developed by the FHCC and ATSM projects. The eligibility (i.e., see inclusion and exclusion criteria, p. 24) of the patient was determined at the participating sites. If eligible to participate in the study, the recruiters met with the patients to describe the studies, discuss roles and expectations, explain patients' rights, obtain written consent, and enroll patients. Patient contact information was transmitted via a secure WEB-based server at the central site.

Once the patient was enrolled, the patient's symptoms were screened via completing twice weekly automated telephone calls, for up to six weeks. For the screening process of the FHCC study, symptoms were assessed until a symptom severity threshold of 2 out of 10 for both pain and fatigue was reached or a symptom severity threshold of 3 out of 10 on either pain or fatigue was reached. For the screening process of the ATSM study, symptoms were assessed until a symptom severity threshold of a 2 or higher out of 10 for one or more symptoms was reached. If after six weeks patients did not reach a symptom severity threshold level as designated by the FHCC or ATSM studies, they were sent a letter thanking them for participating. Patients reaching the symptom severity threshold were contacted by telephone by an interviewer to complete the baseline interview. The

interviewer received the patient's name and their telephone number from the MSU Project Coordinator once patient's fulfilled the eligibility, consent and enrollment process, and symptom assessment screening. The interviewer staff was trained and followed procedures developed by the research staff of the FHCC and ATSM studies. Interviews occurred based upon the convenience of the patient. Instruments for the proposed project were part of the FHCC and ATSM study consent form and part of the interview materials and were approved by the MSU IRB. Once the baseline interviews were completed, patients were randomly assigned to either FHCC or ATSM study. Trained by the FHCC and ATSM research staff, auditors completed medical record chart abstraction.

Inclusion of Women and Men

A person's sex was included in both the theoretical model and statistical models of the study. Eligible male and female adults age 21 years and older were enrolled in the study. Inclusion of both women and men were necessary because LC is the leading cause of cancer death in both women and men regardless of race (American Cancer Society, 2007). The LC incidence rate is declining significantly in men from a high of 102.1 per 100,000 in 1984 to 77.8 in 2002 (American Cancer Society, 2006). While there has been a dramatic increase in the number of LC cases in women, it has leveled off at 52.8 per 100,000 in 1998 and continues to remain stable (American Cancer Society, 2004, , 2006).

Inclusion of Minorities

Race was included in both the theoretical and statistical models of the study. Non-Caucasian participants were differentiated in the study by the following groups: Hispanic or Latino, American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific

Islander, and Black or African American. In past studies conducted by the Principal Investigators Drs. Given, accrual of minority subjects ranged between 8-10%. With the exception of the Detroit metropolitan area as a part of Wayne State University's Karmanos Cancer Center which has a higher percentage of minority patients, Community Clinical Oncology Programs in the state of Michigan have approximately this same percentage of minority participation (B. Given, 1998-2007; C. Given, 2003-2007).

Cooley reported in her systematic review of the empirical research examining symptoms in adults with LC the majority of studies were conducted with Caucasians and recommends special recruitment strategies to increase the likelihood of minority participation (2000). Nevertheless, recruitment efforts for minorities included strategies outlined in the literature as helpful to minority recruitment (D. R. Brown, Fouad, Basen-Engquist, & Tortolero-Luna, 2000; Holcombe, Jacobson, Li, & Moinpour, 1999; Pinto, McCaskill-Stevens, Wolfe, & Marcus, 2000). Examples of efforts to augment minority participation included having recruiters at each site attend a training session consisting of a two-hour didactic session on how to recruit minorities through role-playing opportunities and communication skills. Booster recruiter training sessions were planned annually with more scheduled when necessary. In addition, ethnically sensitive brochures about the benefits of participating in clinical trials were developed at a Flesch-Kincaid fifth grade level with a reading ease score above 70 on a 100 point scale with higher scores indicating greater ease of understanding. The pictures on the brochures and other participant information included a racial mix of people.

Inclusion of Children

Children under the age of 21 years were excluded from the study. It is extremely atypical for an individual under age 21 to suffer from LC. The sample would not contain enough participants of this age group to identify significant relationships. Instead, the majority of persons with LC were individuals in their sixth decade or older (National Cancer Institute, 2003). The focus of the research was a description of CRF and other unpleasant symptoms in adults with LC and how their PSE to manage their fatigue affected PFS.

Data and Safety Monitoring Plan

The Principal Investigator for this study received permission from the Principal Investigators of the FHCC and ATSM projects for the data for analysis of the study. To protect confidentiality, the data were placed on a computer disc without any patient names or health care system identifiers. The FHHC and ATSM Principal Investigators hold the master list of patient identifying information and the Principal Investigator for this study has no access to this master list. A codebook defining each variable and the range of permitted responses was obtained from the parent studies. The original copy of data from the disc was transferred to statistical analysis software and examined to ensure the prior editing of the variables were not missing, were within the permitted range, and were logically consistent with other variables. The codebook defined the basis for editing the data. Reliability analysis was performed to evaluate consistency of measures used in the target sample for the study as described for each instrument used in the study. The database will be completely edited and frozen before any final analyses for publication

begin. The disc containing the data for analysis for this study is stored in a secure area in a locked file cabinet.

Protection of Human Subjects

This study used a cross-sectional descriptive design that employed baseline measures taken from patients who were undergoing a course of chemotherapy prior to the beginning of the intervention from two randomized control trials: "The Family Home Care for Cancer: A Community-based Model for Symptom Management" (FHCC) project (R01 CA-079280) sponsored by Barbara A. Given, Ph. D., R.N., FAAN, Principal Investigator and "The Automated Telephone Monitoring for Symptom Management" (ATSM) project (R01 CA-30724) sponsored by Charles W. Given, Ph.D., Principal Investigator (see Executive Summaries in Appendix A). The FHCC and ATSM studies had Institutional Review Board (IRB) approval through the University Committee on Research Involving Human Subjects (UCHRIS) of MSU and collaborating sites, including approval for use of the measures being used in this study. Approval to conduct this study was obtained from MSU UCHRIS (February 24, 2006, July 26, 2006, and January 2007). The Principal Investigator for this study has adhered to all mechanisms for the protection of human subjects. Additionally, the Principal Investigator for this study will maintain the human subject certification administered by IRB at MSU throughout the study, analysis and publication of the data.

The parent studies started data collection in December 2003 and completed in April 2006. The FHCC and ATSM studies obtained consent, enrolled patients, and collected data for this study. Recruiters, trained by the FHCC and ATSM studies, determined eligibility at the collaborating sites (see inclusion and exclusion criteria). The recruiters

met with the patients to provide a description of the study, discussed roles and expectations, explained patients' rights, obtained written consent, and enrolled patients. Patients consented to this study as part of the parent studies consent. Data were collected by interviewer staff who were trained by the research staff of the FHCC and ATSM studies. Trained auditors completed medical record chart abstraction.

Sources of Material

Sources of research material obtained from individually identifiable living human subjects were acquired from self-report telephone questionnaires and medical record abstraction form. The data were obtained specifically for research purposes only. The sample for the study comes from the National Institutes of Health sponsored study, entitled FHCC (R01 CA-079280) and ATSM (R01 CA-30724) studies. The applicant obtained permission from Drs. Given to use the data. Institutional Review Board approval has been obtained. Subjects did not incur any expense as a result of their participation in the study. Data were obtained using measures described earlier in the Methodology section which include: 1) Patient Characteristic Questions from the Demographic Questionnaire and Medical Record Chart Abstraction Form, 2) Items from the Brief Fatigue Inventory, 3) the Symptom Experience Inventory, 4) Self-Efficacy for Fatigue in Patients with Cancer Scale, and 5) the Medical Outcomes Study Short Form-36 PFS subscale. Additional information about the measures can be found in the appendices. The data for the FHCC and ATSM studies were collected from seven different collaborating sites which provide cancer care (see Appendix B).

Potential Risks and Protection Against Risks

Since the study used a cross-sectional descriptive design not involving investigational intervention, patients were placed at very minimal risk by their participation in the study. Patients may have become fatigued while answering questions on the telephone for the baseline interview. The total respondent burden for instruments from the study took approximately 15 minutes. Great effort was made to limit the length of the interview. According to past research studies conducted by Drs. Given, it was found that older patients with cancer, even with persons who are quite ill, experience low respondent interview fatigue or burden and have little attrition. However, if patients experienced fatigue or were too ill to complete the questionnaires, they could have withdrawn from the study at any time. In the event a decision was made to skip and/or reschedule the interview, the Project Manager and Principal Investigators were notified. Another potential risk may have involved patients feeling apprehensive in sharing personal information. The interviewer was trained to introduce the patient to the interview questions, to recognize the patient's feelings, to refer patients to their physician if needed, and to be adaptable and gracious to patients regardless of their responses.

Breach of confidentiality was also a potential risk for patients. However, strict provisions to prevent this were in place. The patient was told by the recruiter and the interviewer that all demographic and health information conveyed in the interview was entirely confidential. None of the information provided to the phone interviewer would be shared with the nurse or their physicians. The research information would not be linked with them personally by name or other means that might identify them. However, all patients were told that clinical information obtained as part of the symptom

management content would be shared if this placed them at risk. Via an established protocol, this information would be shared with their oncologists to ensure optimal coordinated care. The patient was afforded the opportunity to ask questions about this process to ensure they understood the importance of this to their overall plan of care.

The confidentiality of patients was safeguarded in the following ways: 1) by use of subject identification numbers, 2) by release of research data in aggregate form only, 3) by omission of agency names and/or identification in all presentations and reports, and 4) by not providing confidential interview research data given by subjects back to the agencies or participating staff members.

Paper copies of all consent forms were transmitted via secure courier. These forms were retained in a locked file in the central MSU site. All computers that were used were double password protected. A password would be required to open Windows 2000 and a second, different password would be required to log on to the network. Interview data were stored on a secure web server and were password protected. Servers were scanned for viruses and systems were in place to detect attempts at unauthorized entry. Additional server logs record all persons accessing data files.

Safety monitoring procedures were in place for interviews. All interviewers were carefully trained in correct interviewing procedures; received regular monitoring by the Quality Assurance Manager and Principal Investigators to assure ethics, scientific integrity, and confidentiality of the research. Patients were frequently asked during the interview if they wanted to continue and were given a toll free number at the end of the interview to contact MSU if they had questions or concerns. The quality of the

interviewer and the interview process was monitored monthly by the Principal Investigators.

Patients were informed that they could freely withdraw from the study at any time without loss of benefits they would otherwise be entitled to and without penalty to their health care. A request by any patient to withdraw their consent and to discontinue participation in the study was promptly and unconditionally honored. Also, no financial costs to the patient resulted from their participation in the study.

Patient and Other Anticipated Benefits

It is unknown whether or not patients had directly benefited from participation in the study. Patients had their symptoms assessed and the patient's oncologist was notified of any symptoms reported by the patient that placed them at risk. Sharing of their thoughts and feelings may have provided therapeutic benefits. Patients may have felt good in being able to contribute to the state-of-the-science which may help future patients. The patient's oncologist was notified of any symptoms reported by the patient that may have placed them at risk. If CRF and other unpleasant symptoms along with PSE, physiological, and situational patient characteristics were found to impact functional status, strategies for treatment for CRF could be developed. As a result, benefits to health care professionals include an increased understanding of the fatigue phenomenon in persons with LC as well as OC diagnoses. The risk is small compared to the potential gain of these anticipated benefits from the study.

Importance of the Knowledge to be Gained

The importance of the knowledge to be gained is that this is one of few studies identified that examined CRF and other associated unpleasant symptoms in persons with

cancer and specifically LC. This study is unique in that it focused on persons with LC and explored specific patient characteristics that predict higher levels of CRF. Moreover, this research measured a person's PSE and whether PSE relates to their ability to manage their fatigue and to improve their PFS. Thus, this study is expected to lead to future interventional research to improve the PFS of persons with cancer, particularly LC when faced with fatigue.

Data Analysis Plan

The foremost purpose of this cross-sectional descriptive study was to examine fatigue in persons with LC and analyze how PSE in managing fatigue impacts PFS. Utilizing persons with OC diagnoses as a comparison group to persons with LC as well as to increase sample size assisted in answering the following research questions for the study. Data were analyzed using SPSS, Inc., 13.0 Version; LISREL 8.72 Version; and, SYSTAT, Inc., 11.0 Version (Point Richmond, CA). Tests were two-tailed with level of significance set at 0.05 for all tests.

Power

As discussed by Cohen (1988), power analysis was determined based upon regression using predictor variables utilizing Research Question #6 of the study [i.e., What is the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE to the PFS of persons with cancer (LC and OC)?]. Thus, power analysis of Research Question #6 was based on 28 possible predictors, and the selection was based on measures of tolerance, the independence of predictors (von Eye & Schuster, 1998). Given a sample size of 298 persons with cancer and utilizing all 28 predictors, a two-tailed test with a level of significance set at 0.05 and power set at 0.80

renders an effect size (ES) of 0.09 (Erdfelder, Faul, & Buchner, 1996). According to classification set by Cohen (1988), this value is within the small range of ES for multiple regression analysis (.02 - .15 small ES; .15 - .35 moderate ES; .35 > large ES). Rehse and Pukrop (2003) report a moderate ES is consistent in psychosocial studies provided to adult patients with cancer.

Analyses of Research Questions

The analyses of the research questions involved models in which the parameters are set equal for the comparison groups. For reason of sample size, the analysis plan included using the variable "type of cancer diagnoses" (LC and OC diagnoses) as a predictor in the models which incorporated the use of the total sample ($N = 298$).

Research questions and plans for analyses of baseline data were as follows:

1. What are the patient characteristics that relate to CRF severity in persons with cancer (LC and OC diagnoses)?

Regression was used to determine which patient characteristics predict variations of CRF severity for persons with cancer (LC and OC diagnoses), and whether having a cancer diagnosis of LC compared with OC diagnoses was a predictor of CRF severity. The model used was: Y (CRF) = b_0 + b_1 (type of cancer diagnoses) + b_2 (type of treatment variables requiring statistical control) + b_3 (stage of cancer) + b_4 (co-morbid conditions) + b_5 (sex) + b_6 (age) + b_7 (race) + b_8 (marital status) + b_9 (level of education) + b_{10} (employment data) + b_{11} (health insurance data) by von Eye and Schuster (von Eye & Schuster, 1998). A best of all subset regression using a backward elimination procedure was employed in a theoretically driven fashion with the goal of finding the most parsimonious model. In addition, all predictors were placed in the equation

simultaneously in an unconstrained regression. It is important to note that prior to employing all regression techniques, univariate and bivariate analyses were performed to assess the quality of the data to check for missing data, outliers and distribution of variables. An estimation algorithm using the maximum likelihood method was used to handle missing values (von Eye & Schuster, 1998). Inclusion of patient characteristics predicting CRF severity involved assessment for issues of multicollinearity employing such diagnostics as evaluation of tolerance levels, evaluation of effect sizes to ensure optimal use of power, and testing each predictor individually to ensure that the contribution made by that particular variable was statistically significant (von Eye & Schuster, 1998). Residual analysis was used to check the assumptions of normal distribution, homoscedasticity, and linear relationships between the statistically significant predictor variables and the criterion variable.

2. How does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of CRF severity?

Similar procedures were used for the separate group analysis of persons with LC and OC diagnoses as were used for the total sample of persons with cancer in Research Question #1. The exception being that "type of cancer diagnoses" (LC and OC diagnoses) was not entered into the initial model for group analysis.

3. What is the symptom experience of persons with LC and how does it compare to the symptom experience of OC diagnoses, including the relationships between CRF and other unpleasant symptoms?

Descriptive statistics were used to analyze the frequency and severity of the individual symptoms. Correlation analysis was employed to examine the relationship

between CRF severity (total CRF Severity score) and each of the individual symptom's severity level (Symptom Experience Inventory score) as well as the total symptom severity. The total symptom severity associated with each symptom was calculated by summing each subject's response to severity scores for each symptom reported (i.e., a reported symptom is a symptom with a severity score greater than zero) and dividing by the total number of symptoms reported to standardize the score on an 11-point scale. The individual and total symptom weighted mean severity scores were calculated. Individual symptom weighted mean severity scores were calculated by multiplying the mean score of each symptom by the number of persons who actually reported experiencing the symptom and dividing by the total number of persons in the sample. The total symptom weighted mean severity score was calculated by multiplying each symptom mean by the number of persons who reported the symptom. Next, the multiplied means were summed and divided by the total number of persons used for the multiplication.

4. Does PSE for fatigue management mediate the relationship between CRF severity and PFS in persons with cancer (LC and OC diagnoses)?

To test the mediation model, a series of three regression analyses specified by Baron and Kenny were performed (Baron & Kenny, 1986; Kenny, 2005). First, single order relationships among PSE, CRF and PFS (SF-36 PFS subscale) were established via Pearson correlations. Next, three regression analyses were estimated: 1) Y (PSE) = b_0 + b_1 (CRF); 2) Y (PFS) = b_0 + b_1 (CRF); and, 3) Y (PFS) = b_0 + b_1 (CRF) + b_2 (PSE). Mediation was established when the following conditions were met: 1) CRF affects PSE in the first equation; 2) CRF affects PFS in the second equation; and, 3) PSE affects PFS in the third equation. Mediation was established when these conditions all held in the

predicted direction, and the effects of CRF on PFS was less in the third equation than in the second. Further analysis was performed which involved significance testing of the mediation pathway via Sobel Test (Baron & Kenny, 1986; Dudley, Benuzillo, & Carrico, 2004; Kenny, 2005).

5. Does mediation differ in persons with LC as compared to OC diagnoses when evaluating PSE for fatigue management as a mediator between the relationship of CRF severity and PFS?

Similar procedures were used for the separate group analyses of persons with LC and OC diagnoses as were used for the total sample of persons with cancer in Research Question #4. Similar to the total sample, the Sobel Test was employed for both persons with LC and OC diagnoses. However, while the Sobel Test yields greater description of the mediation pathway, Hoyle and Kenny (1999) and Kenny (2005) identified a limitation of the Sobel Test is that the power of the test is low and the test is very conservative. Consequently, Hoyle and Kenny (1999) and Kenny (2005) recommend a minimum sample size when using the Sobel Test of at least 200 cases. This limitation is noted later in the mediation analysis of persons with LC since the sample size of this group falls short of the recommended sample size of 200 cases. The Sobel Test serves as an informal test for persons with LC due to the low sample size of this group. Thus, formal evaluation of whether PSE for fatigue management mediates the relationship between CRF and PFS was formally examined using regression analyses procedures outlined by Baron and Kenny (1986) and Kenny (2005).

6. What is the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE to the PFS of persons with cancer (LC and OC diagnoses

The analysis used incorporated hierarchical multiple regression model: Y (PFS) = b_0 + b_1 (contextual patient characteristics) + b_2 (physiological patient characteristics) + b_3 (type of treatment variables requiring statistical control) + b_4 (PSE) + b_5 (other unpleasant symptoms) + b_6 (CRF). In sequential order, the independent variables were entered in six separate blocks: contextual patient characteristics, physiological patient characteristics, type of treatment variables requiring statistical control, PSE, other unpleasant symptoms, and CRF. Consequently, after each block was entered, the contribution of each variable above and beyond the last was accounted for in the prediction of PFS of persons with cancer (LC and OC diagnoses).

7. Considering the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE for fatigue management to PFS, how does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of PFS?

Hierarchical multiple regression analysis was performed separately on groups of cancer patients, those with LC and OC diagnoses. Similar procedures used in Research Question #6 for the total sample was also used for persons with LC and OC diagnoses.

8. Through the employment of a Path Model, is the PFS of persons with cancer (LC and OC) predicted through physiological and contextual patient characteristics, CRF, other unpleasant symptoms, and PSE for fatigue management?

Final analysis included an exogenous-endogenous Path Model to test the hypothesis that PFS for persons with cancer (LC and OC diagnoses) is predicted through

physiological and contextual patient characteristics, CRF, other unpleasant symptoms, and PSE (Raykov & Marcoulides, 2006). This incorporated a sequence of predictions tested through a path model via LISREL Version 8.72 statistical software package.

In a first step, exogenous variables were selected through bivariate analyses with an inclusion criterion set at $p < 0.20$. Multiple regression analyses was then conducted within each group of variables (physiological patient characteristics; contextual patient characteristics; type of treatment variables requiring statistical control) with an inclusion criterion set at $p < 0.20$. These criteria were chosen to maintain as many variables as possible, given that they could eventually be significant in the final analysis. Consequently 16 out of 25 exogenous variables to the prediction of CRF severity were retained in the initial model.

All analyses were conducted using the Satorra-Bentler Robust Maximum Likelihood Method of parameter estimation to adjust model chi-square for non-normally distributed variables. Several model fitting measures were used to attain a parsimonious final solution which included evaluation of parameter estimates, modification indexes, theoretical considerations, and goodness-of-fit tests. Specific goodness-of-fit-tests included the Satorra-Bentler Scaled Chi-Square which reflects the degree of discrepancy between the observed covariance matrix derived from the data and that predicted by the model. A small, nonsignificant chi-square indicates that one cannot reject the null hypothesis that the tested model fits the data (Raykov & Marcoulides, 2006). Another goodness-of-fit test used was the Root-Mean Square Error of Approximation (RMSEA) which provides an estimate of the average absolute discrepancy between the model covariance estimates and the observed covariances (Raykov & Marcoulides, 2006). For

this index, values ≤ 0.05 indicates close approximate fit with a value of zero indicating the best fit. The 90% confidence intervals (CI) for population parameters estimated by the RMSEA reflects the degree of uncertainty associated with RMSEA as a point estimate at the 90% level of statistical confidence (Raykov & Marcoulides, 2006). If the lower bound of a 90% CI is ≤ 0.05, the model has close approximate fit in the population. Finally, the Comparative Fit Index (CFI) was used which indicates the amount of covariation in the data that can be reproduced by the given model (Raykov & Marcoulides, 2006). The CFI is more robust for deviations from normality. A CFI value above 0.90 indicates reasonably good fit of the model.

CHAPTER FOUR

RESULTS

Preliminary Examination of the Data

Normality

Continuous variables, namely age, co-morbid conditions, individual symptoms, total symptom severity of the other unpleasant symptoms, worst and least cancer-related fatigue (CRF) severity, total CRF severity, perceived self-efficacy (PSE) for fatigue management, and physical functional status (PFS) were examined for normality of distribution. Age was found to be normally distributed. Univariate analysis revealed that some of the individual symptoms were not normally distributed. When calculated, Fisher's Measure of Skewness Test showed the variables of pain, nausea, cough, difficulty remembering, and weakness had values greater than +1.96. Likewise, Fisher's Measure of Kurtosis showed that the individual symptoms of fatigue, nausea, insomnia, anorexia, dry mouth, constipation, weakness, and alopecia had values above +1.96 or below -1.96. However, the total symptom severity score of the other unpleasant symptoms which consists of a calculation utilizing the individual symptoms was normally distributed.

Co-morbid conditions and worst and least CRF had both skewed and kurtosed distributions with values above +1.96 or below -1.96. The skewness values for the summary scores of total CRF severity (-.759), PSE for fatigue management (-1.33), and PFS (-1.94) all had values indicating that that the distribution was not skewed. However, the kurtosis values for the summary scores of total CRF severity (-2.90), PSE for fatigue management (-2.87), and PFS (-3.63) was platykurtic. The finding of non-normal

distributions among the symptom-related and other health-related variables was expected and therefore considered normal.

Frequency and Missing Data

The data were examined for frequency and patterns of missing data via the Missing Analysis Program in SYSTAT Version 11.0 statistical software package (Point Richmond, CA). An estimation algorithm using the maximum likelihood factor of covariance was used for missing value analysis (von Eye & Schuster, 1998). A cut-off point determined at 50% or less missing cases was used to estimate incomplete data yielding 100% complete cases on data analyzed (von Eye & Schuster, 1998). All missing data were determined to be missing completely at random via The Little MCAR Test Statistic.

Descriptive Statistics for Patient Characteristics: Physiological

Type of Cancer

The analysis was performed on a sample of 298 persons with cancer, with persons diagnosed with lung cancer (LC) comprising 21% of the sample. Of the persons with LC, 78% (*N = 63*) were diagnosed with non-small cell LC, with 22% diagnosed with small cell LC. Persons with other cancer (OC) diagnoses comprised 79% (*N = 235*) of the total sample with breast cancer (45%), colon cancer (19%), urological cancer (11%), gynecological cancer (9%), and other cancers (16%) making up the OC diagnoses category.

Stage of Cancer

For stage of cancer, 26% of persons with cancer were diagnosed in early stage (Stage I, II, and limited disease) while 74% (Stage III, IV, and extensive disease) were found to

be in a late stage cancer. Most persons with LC (81%) and OC (72%) presented with late stage cancer (see Table 1). Among the total sample, there were no significant differences between early and late stage cancer between LC and OC diagnoses ($\chi^2 = 2.1$; 1 *df*; $p = .147$). There were more persons diagnosed with late stage cancer as compared to early stage cancer for both LC ($\chi^2 = 24.1$; 1 *df*; $p = .000$) and OC ($\chi^2 = 45.1$; 1 *df*; $p = .000$) diagnoses.

Treatment, Radiation Therapy

Most persons with cancer (84%) did not report receiving radiation therapy at the baseline interview. However, persons with LC (25%) had a significantly higher frequency of reporting receiving radiation therapy as compared to persons with OC (13%) ($\chi^2 = 5.6$; 1 *df*; $p = .018$) (see Table 1).

Treatment, Surgery

Out of the total sample, most persons with cancer (62%) had a surgical procedure prior to receiving chemotherapy as compared to not having a surgical procedure prior to chemotherapy ($\chi^2 = 35.4$; 1 *df*; $p = .000$). This included 71% of persons with OC, and 30% of persons with LC. The odds of having surgery prior to chemotherapy were 5.7 times higher in persons with OC as compared to LC (95% CI: 3.1 - 10.4) (see Table 1).

Similarly, out of the total sample, 32% of persons with cancer reported having a surgical procedure during chemotherapy which included 36% of persons with OC and 16% of persons with LC (see Table 1). The odds of having a surgical procedure during chemotherapy were 2.94 times higher for persons with OC as compared to LC (95% CI: 1.4 - 6.1).

Treatment, Chemotherapy Type at Consent

Out of the total sample, first line initial chemotherapy treatment was reported by the largest percentage of persons with cancer (47%) at time of consent of the study, which included 65% of persons with LC and 42% of persons with OC. The next most frequently reported treatment at the time of consent of the study by the total sample (21%) was second line chemotherapy because first line did not work or the disease had progressed. This included 16% of persons with LC and 22% of persons with OC. Another treatment regimen reported by the total sample included adjuvant chemotherapy with radiation therapy (20%), which comprised 16% of persons with LC and 20% of persons with OC. Adjuvant chemotherapy is given after primary treatment to increase the rate of cure. Neoadjuvant chemotherapy was the least frequent treatment regimen reported by 12% of all persons with cancer. Neoadjuvant chemotherapy is administered prior to the primary treatment of cancer. Two percent of persons with LC and 15% of persons with OC reported receiving neoadjuvant chemotherapy at the time of consent into the study.

Co-morbid Condition

The total sample reported a mean number of two co-morbid conditions with hypertension (45%), emotional problems (28%), other major health problems (21%), and other cancer diagnosis (20%) accounting for the most commonly reported co-morbid conditions respectively. Persons with LC ($M = 2.79$; $SD = 1.81$) had a significantly higher mean number of co-morbid conditions as compared to persons with OC ($M = 1.82$; $SD = 1.46$) ($t = -4.47$; $p = .000$). Hypertension and emotional problems remained the top two ranked co-morbid conditions respectively in both persons with LC and OC (see Table 1 and Table 2).

Sex

While not significantly different, women made up the majority (54%) of the LC group ($\chi^2 = .397$; 1 *df*; $p = .529$). There were significantly more women, 75%, than men in the OC group ($\chi^2 = 56.3$; 1 *df*; $p = .000$). As well, women significantly comprised the majority (70%) of the total sample ($\chi^2 = 9.97$; 1 *df*; $p = .002$). The odds of being a woman were 1.7 times greater in the OC group as compared to the LC group (see Table 1).

Age

In the total sample, the range for age was 25 to 90 years ($M = 57.10$; $SD = 11.88$). Those persons with LC were significantly older with a mean age of 62 years ($SD = 10$) as compared to persons with OC with a mean age of 56 years ($SD = 12$) ($t = -3.97$; $p = .000$) (see Table 1).

Laboratory Values

This study proposed to analyze the absolute neutrophil count and hemoglobin level of persons with cancer to the prediction of CRF and PFS. However, this was not possible since up to 85% of the data regarding the absolute neutrophil count and hemoglobin were not collected.

Table 1

Physiological Patient Characteristics by Percentage of the Total Sample and by Group

Characteristics	% Total Sample ($N = 298$)	% Lung Cancer ($N = 63$)	% Other Cancer ($N = 235$)
Stage of Cancer			
Early stage	26%	19%	28%
Late stage	74%	81%	72%
Treatment Use			
Radiation therapy	16%	25%	13%
Surgery prior to chemotherapy	62%	30%	71%
Surgery during chemotherapy	32%	16%	36%
Sex			
Female	70%	54%	75%
Male	30%	46%	25%
Co-morbid Conditions			
M (*SD*)	2.02 (1.59)	2.79 (1.81)	1.82 (1.46)
Minimum-Maximum	0-9	0-9	0-8
Age (years)			
M (*SD*)	57.10 (11.88)	62.30 (10.20)	55.72 (11.93)
Minimum-Maximum	25-90	37-82	25-90

Table 2

Co-morbid Conditions by Percentage of the Total Sample and by Group

Co-morbid Condition	% Total Sample ($N = 298$)	% Lung Cancer ($N = 63$)	% Other Cancer ($N = 235$)
Hypertension	45	60	40
Emotional problems	28	32	26
Other major health problems	21	21	20
Other cancer	20	16	20
Heart problem	17	25	15
Loss of urine beyond control	16	16	16
Diabetes	14	19	12
Cataract surgery	10	16	9
Arthritis, rheumatism	10	21	7
Emphysema	9	29	4
Wear a hearing aid	5	8	4
Surgical replacement of joint	4	6	3
Stroke	2	6	1
Angina	2	5	2
Fractured hip	.30	--	.40

Descriptive Statistics for Patient Characteristics: Contextual

Race

Racial composition of the total sample of persons with cancer was 87% Caucasian, 10% African American, and 3% other racial minorities. For persons with LC, 94% were Caucasian and 6% were African American. Similar findings were found for persons with OC with 85% reported being Caucasian, 11% African American, and 4% another racial minority (see Table 3).

Marital Status

The majority of the total sample were married (68.8%) followed by being divorced or separated (15.4%), never married (9.1%), widowed (5.4%), or living together (1.3%). A similar trend of marital status was found among the LC and OC groups (see Table 3).

Level of Education

Educational achievement for the total sample consisted of 24.5% graduated from high school, 28.9% with some college/technical training, 20.1% completing college, and 16.4% with graduate/professional education. Only 10% had some high school or less education (see Table 3).

Employment Data

For the total sample, 49.3% were retired, 21.8% were receiving disability, 20.1% were on a temporary leave from employment, and 13.8% reported that they had to quit employment. Similar findings concerning employment status were found by group for both persons with LC and OC cancer (see Table 3). Whether or not a change in employment status for the sample was due to cancer is not known.

Annual Combined Household Income

Information on the annual combined household income showed that most persons with cancer reported earning within the range of $50,000 to $74,999. More specifically, 27% of persons with LC and 32% of persons with OC diagnoses reported producing $50,000 to $74,999 annually (see Table 3).

Health Insurance Data

For the total sample, most persons with cancer possessed health insurance (99%) with the insurance policy being held by themselves (70%) versus their spouse (25%). The majority of the total sample possessed private insurance (81%) either by itself or in addition to being insured with Medicare. The total sample reported being insured through Medicare (28%) and Medicaid (10%) (see Table 3).

Most persons with LC (51%) held a Medicare policy in comparison to persons with OC (22%) diagnoses ($\chi^2 = 20.2$; $df = 1$; $p = .000$). The odds of a person with LC holding a Medicare policy was 3.6 times greater than for persons with OC (95% CI: 2.0 - 6.5). Persons with OC (85%) held a private insurance policy more often than persons with LC (68%) ($\chi^2 = 8.8$; $df = 1$; $p = .003$). The odds of a person with OC diagnoses holding a private insurance policy was 2.6 times greater than persons with LC (95% CI: 2.0 - 6.5).

Table 3

Contextual Patient Characteristics by Percentage of the Total Sample and by Group

Characteristics	% Total Sample ($N = 298$)	% Lung Cancer ($N = 63$)	% Other Cancer ($N = 235$)
Race			
Caucasian	86.9	93.7	85
African American	9.7	6.3	10.6
Native American Alaskan	2.0	--	2.6
Mexican American Hispanic	.70	--	.90
Oriental Asian Pacific Islander	.70	--	.90
Marital Status			
Married	68.8	66.7	69.4
Divorced/Separated	15.4	17.5	14.9
Never married	9.1	4.8	10.2
Widowed	5.4	7.9	4.7
Living together	1.3	3.2	.90
Level of Education			
High school or less	10	15.9	8.6
High school	24.5	23.8	24.7
Some college/Technical training	28.9	36.5	26.8
College	20.1	12.7	22.1
Graduate/Professional	16.4	11.1	17.9

Table 3 Continued

Characteristics	% Total Sample ($N = 298$)	% Lung Cancer ($N = 63$)	% Other Cancer ($N = 235$)
Employment Information			
Retired	49.3	58.7	46.8
Receiving disability	21.8	25.4	20.9
On a temporary leave from work	20.1	17.5	20.9
Quit work	13.8	11.1	14.5
Annual Combined Income			
< $24,999	14.4	20.6	12.8
$25,000 to $49,999	25.8	33.3	23.8
$50,000 to $74,999	28.2	31.7	27.2
$75,000 to $99,999	11.4	4.8	13.2
$100,000 to > $200,000	20.1	9.5	23.0
Type of Health Insurance Plan			
Private	81.2	68.3	84.7
Medicare	28.2	50.8	22.1
Medicaid	9.7	12.7	8.9

Descriptive Statistics for Symptoms: Cancer-Related Fatigue (CRF)

Fatigue Frequency

The total sample of persons with cancer reported experiencing fatigue on at least one of the seven days from their baseline interview. The mean number of days that all persons with cancer reported having fatigue was 5.14 ($SD = 2.02$), with 47% stating fatigue on all seven days. No significant differences ($t = -1.470$; $df = 296$; $p = .143$) were found in the frequency of the mean report of fatigue by persons with LC ($M = 5.48$; $SD = 1.81$) and OC diagnoses ($M = 5.10$; $SD = 2.07$). The most frequently rated number of days in which persons with LC (52%) and OC (45%) experienced fatigue was seven days. Lastly, the median number of days that persons with LC experienced fatigue was higher at 7 days as compared to 5 days for persons with OC diagnoses.

Current Fatigue Severity

During the baseline interview, 99% of the total sample of persons with cancer reported currently experiencing fatigue, with a mean fatigue severity score of 5.24 ($SD = 2.33$) for those who reported fatigue. There was no significant difference ($t = -.885$; $df = 292$; $p = .377$) in the current mean report of fatigue severity by persons with LC ($M = 5.47$; $SD = 2.19$) and OC ($M = 5.17$; $SD = 2.37$) diagnoses (see Table 4).

Worst Fatigue Severity

In addition, during the baseline interview, the total sample of persons with cancer rated their worst fatigue severity in the past seven days as a mean score of 6.52 (SD = 2.39). However, there was no significant difference ($t = .560$; $df = 113$; $p = .577$) in the worst fatigue severity score by persons with OC ($M = 6.55$; $SD = 2.46$) and LC ($M = 6.38$; $SD = 2.08$) (see Table 4).

Total CRF Severity

The total CRF severity score was calculated by summing each subject's response to the current and worst severity scores and dividing by two to standardize the score on an 11-point scale. The total CRF severity score reported by the total sample of persons with cancer ($N = 298$) was a mean of 5.84 ($SD = 2.23$). No significant difference was found ($t = -.161$; $df = 296$; $p = .872$) in the mean total CRF severity score report for persons with LC ($M = 5.88$; $SD = 2.00$) and OC ($M = 5.83$; $SD = 2.29$) (see Table 4).

Descriptive Statistics for Symptoms: Other Unpleasant Symptoms Associated with Cancer and Cancer Treatment

Frequency and severity of the other unpleasant symptoms associated with cancer and cancer treatment will be discussed in greater detail under research question #2. Of those persons ($N = 296$) who reported other unpleasant symptoms associated with cancer excluding fatigue, the total mean symptom severity score was 4.64 ($SD = 1.58$). Persons with LC ($M = 4.99$; $SD = 1.43$) had a significantly higher total symptom severity score as compared to persons with OC ($M = 4.54$; $SD = 1.60$) diagnoses ($t = -1.99$; $df = 294$; $p = .047$) (see Table 4). To assist in the interpretation of the significance of the findings, an effect size for the difference of the means between the two groups (LC and OC diagnoses) concerning the total symptom severity was small ($d = .30$). Cohen's (1988) thresholds for small, moderate, and large are respectively .20, .50, and .80. It should be remembered that Cohen (1988) defined these thresholds to reflect the typical effect sizes encountered in the behavioral sciences as a whole and that many effects involving clinical and psychological research as well as new areas of research are likely to be small.

Thus, interpretations of effect sizes are based upon not only the thresholds prescribed by Cohen, but also judgment of the clinical-research phenomenon.

Table 4

Comparison of Persons with Lung Cancer and Other Cancer Diagnoses Mean Scores on Symptom Severity Scores

Symptom Severity Scores	Total Sample *M* (*SD*)	Lung Cancer *M* (*SD*)	Other Cancer *M* (*SD*)	*t*	*df*	*p*
Current Fatigue Score	5.24 (2.33) *N* = 294	5.47 (2.19) *N* = 62	5.17 (2.37) *N* = 232	-.855	292	.377
Worst Fatigue Score	6.52 (2.39) *N* = 298	6.38 (2.08) *N* = 63	6.55 (2.46) *N* = 235	.560	113	.577
Total CRF Severity Score	5.84 (2.23) *N* = 298	5.88 (2.00) *N* = 63	5.83 (2.29) *N* = 235	-.161	296	.872
Total Symptom Severity Score	4.64 (1.58) *N* = 296	4.99 (1.43) *N* = 63	4.54 (1.60) *N* = 233	-1.99	294	.047

Descriptive Statistics for Perceived Self-Efficacy for Fatigue Management in Persons with Cancer

The mean score for the total sample for persons with cancer ($N = 298$) for PSE to manage fatigue was 6.43 ($SD = 2.25$). While the mean PSE to manage fatigue score was slightly higher in persons with LC ($M = 6.66$; $SD = 1.96$) as compared to persons with OC ($M = 6.37$; $SD = 2.33$), the difference was not statistically significant ($t = -1.028$; $df = 113$; $p = .306$) (see Table 5).

Descriptive Statistics for Performance Outcome: Physical Functional Status

The PFS mean score reported by the total sample of persons with cancer was 58.10 ($SD = 27.20$). Persons with LC ($M = 44.29$; $SD = 26.73$) had a statistically significantly lower PFS score when compared to persons with OC ($M = 61.81$; $SD = 26.16$) ($t = 4.70$; $df = 296$; $p = 0.000$) (see Table 5). An effect size for the difference of the means regarding PFS in persons with LC and OC was moderate ($d = .662$).

Table 5

Comparison of Persons with Lung Cancer and Other Cancer Diagnoses Mean Scores on Perceived Self-Efficacy for Fatigue Management and Physical Functional Status

	Total Sample	Lung Cancer	Other Cancer			
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*t*	*df*	*p*
PSE for Fatigue Management Score	6.43 (2.25) *N* = 298	6.66 (1.96) *N* = 63	6.37 (2.33) *N* = 235	-1.028	113	.306
Physical Functional Status Score	58.10 (27.10) *N* = 298	44.29 (26.73) *N* = 63	61.81 (26.16) *N* = 235	4.70	296	.000

Results of Research Questions

Research Question #1: What are the patient characteristics that relate to CRF severity in persons with cancer (LC and OC diagnoses)?

Prior to conducting analysis of Research Question #1, a total CRF severity score was calculated by summing each subject's response to current and worst severity of CRF items and dividing by two to standardize the score on an 11-point scale. This score was used in all regression analyses with total CRF severity as the criterion variable. Correlations between predictor variables and total CRF severity were calculated. The predictor variables that significantly correlated with total CRF severity were the patient's

stage of cancer ($r = .149$; $p = .01$), total number of co-morbid conditions ($r = .139$; $p = .016$), and sex ($r = .149$; $p = .010$).

A total of 25 patient characteristics were identified as important to the initial best of all subset regression model (Table 6). The following eight categories of Physiological Patient Characteristics included 11 out of 25 possible variables to the prediction of total CRF severity: 1) type of cancer; 2) stage of cancer; 3) receiving radiation therapy; 4) surgery prior to chemotherapy which includes four groups [yes had surgery; don't know if had surgery; this response choice was not selected; no surgery and this group served as the reference group when the groups were dummy coded (i.e., group left out)]; 5) surgery during chemotherapy which includes three groups [yes had surgery; this response choice was not selected; no surgery and this group served as the reference group when the groups were dummy coded (i.e., group left out)]; 6) co-morbid conditions; 7) age; and 8) sex. The six categories of Contextual Patient Characteristics included 14 out of 25 possible variables to the prediction of total CRF severity: 1) race; 2) marital status; 3) level of education achieved; 4) employment data including whether a person was retired, receiving disability, was on a temporary leave from employment, and whether they had to quit employment; 5) annual combined household income; and 6) health insurance data including whether or not a person with cancer had health insurance and if so, who held the policy (patient or spouse), and the type of health insurance policy held (private, Medicare, or Medicaid).

A backward elimination procedure was used in a theoretically driven fashion using the theoretical framework for the study to identify the patient characteristics that predict total CRF severity in persons with cancer. The first step began with computing the initial

model that included all 25 predictors. Having computed the first model, goodness-of-fit criterion was used in model selection that included examination of tests on individual regression coefficients (*t*-values) to remove the variables that contribute the least to the model (assuming that its contribution is not significant), and the model's multiple correlation coefficient alongside the *F*-statistic with its associated significance level (*p*-value). Additionally, all predictor variables entered into the model had to reach a tolerance level of 0.4 and a level of significance = 0.05.

Step1

The first step, the calculation of the initial model to find the best of all subset model to predict total CRF severity in persons with cancer, resulted in a model that was not statistically significant [$R^2 = .105$; $F(25, 272) = 1.274$; $p = .177$]. To improve the model, nine predictors with *t*-values < -/+.50 were eliminated in Step 2 (see Table 6).

Step 2

The elimination of 9 out of 25 predictors from the initial model resulted in a statistically significant model in Step 2 explaining 10.2% of the variance [$F(16, 281) = 2.0$; $p = .013$]. The model in Step 2 had only one statistically significant patient predictor to total CRF severity, the total number of co-morbid conditions. However, in this model, 9 out of 16 predictors had *t*-values $\geq$ -/+ 1.00. In an attempt to improve the model in Step 3, all predictors with *t*-values > -/+ 1.00 were retained which meant that seven predictors were eliminated (see Table 6).

Step 3

With the elimination of seven predictors, the explained variance in Step 3 decreased from 10.2% to 8.4%, but the model became more statistically significant in predicting

total CRF severity in persons with cancer [F (9, 288) = 2.932; p = .002]. In addition to the total number of co-morbid conditions, age became a statistically significant predictor to total CRF severity. Subsequently, to improve the model predicting total CRF severity, all predictors with t-values > -/+ 1.50 were retained (stage of cancer, total number of co-morbid conditions, age, and sex) and five predictors were eliminated in Step 4 (see Table 6).

Step 4

The elimination of five predictors identified in Step 3 resulted in a further decrease in the explained variance to 7.3%. Like the model in Step 3, the model in Step 4 became more statistically significant in predicting the total CRF severity in persons with cancer [F (4, 293) = 5.759; p =.000]. The total number of co-morbid conditions, age, and sex were all statistically significant predictors in the total CRF severity of persons with cancer. As in Step 3, stage of cancer remained not statistically significant in the prediction of total CRF severity in persons with cancer (t < -/+ 2.00). One more attempt to improve the model predicting total CRF severity in persons with cancer included eliminating the predictor, stage of cancer, from the model in Step 5 (see Table 6).

Step 5

The elimination of stage of cancer resulted in a slight reduction in the explained variance to the prediction of total CRF severity in persons with cancer, from 7.3% in Step 4% to 6.2% in Step 5 with a slight increase in the F-statistic. Additionally, the t-values and corresponding p-values for the statistically significant predictors (total number of co-morbid conditions, age, and sex) in Step 5 as compared to Step 4 increased in value. Consequently, as compared to the other four models, the model in Step 5 was selected as

the best model to represent the prediction of total CRF severity in persons with cancer (see Table 6).

Further Analysis, Step 6

The Theory of Unpleasant Symptoms (TOUS) predicts that patient characteristics, symptom dimensions, and interactions between symptoms have an effect on a person's performance outcome, PFS. Consequently, to depict a more comprehensive and truer picture of the fatigue phenomenon in persons with cancer, further analysis was conducted. This step added two components of the theoretical framework guiding this dissertation project that was not accounted for in the original prediction equation of total CRF severity in persons with cancer. Consequently, the patient characteristics of PSE for fatigue management and the other unpleasant symptoms from cancer and cancer treatment were accounted for in the final model predicting total CRF severity in persons with cancer as identified in Step 6. The PSE for fatigue management score and the total symptom severity score were the values added to the model in Step 5 to calculate the more comprehensive description of the fatigue phenomenon in persons with cancer as guided by the TOUS. Once added, the explained variance in the prediction of the total CRF severity in persons with cancer increased from 6.2% to 39.2% [F (5, 290) = 37.41; p = .000]. The predictors of total number of co-morbid conditions and sex remained statistically significant (t > 2.0); but age no longer remained a predictor of total CRF Severity (t = -1.67). Both PSE for fatigue management (t = -6.49) and the other unpleasant symptoms associated with cancer and its treatment (t = 9.77) were statistically significant in the prediction of total CRF severity in persons with cancer (see Table 6).

The Final Model

The initial model as identified in Step 1 demonstrated good apriori power at 0.80 to detect relationships with small effects (.085) while utilizing all 25 predictors with a two-tailed test and a level of significance set at 0.05 (Erdfelder et al., 1996). Therefore, at better-than-chance-levels, the final model as depicted in Step 6 for the prediction of total CRF severity in persons with cancer accounts for 39.2% of the variance [F (5, 290) = 37.41; p = .000]. This prediction of the actual value of total CRF severity was made with small residual variance. The standard error of the estimate shows that on average, the actual value will be +/- 1.76 of the predicted value 68% of the time, and will be within +/- (2) (1.76) 95% of the time. Tolerance levels for the predictors ran from a low of .810 for co-morbid conditions, .811 for age, and .957 and greater for all others.

Significance testing. In the final model depicted in Step 6 each predictor was tested to ensure that the contribution made by that particular variable was statistically significant (von Eye & Schuster, 1998). This involved comparing two nested models, the constrained model (c) and the unconstrained model (u) to calculate the F-statistic. As depicted in Table 7, the significance testing of each individual predictor demonstrates that they not only contribute to the model as a whole but also independently to the prediction of total CRF severity in persons with cancer.

Assumptions Met, the Model Confirmed

The mean of the predicted value in the final model of total CRF severity was 5.84 (SD = 1.40). Assessment of the histogram of the standardized residuals shows roughly a normal curve as validated by the range of the residual variance from -2.965 to 3.078. The normal probability plot shows a monotonic pattern and reasonable closeness of the cases

to the regression line, confirming a normal distribution. Additionally, the scatterplots of residuals for each statistically significant predictor variable and criterion variable reveals a pattern that is more dense in the center with decreasing density on the outer edges, thus demonstrating normal homoscedasticity.

Summary of Results for Research Question #1

In summary, for persons with cancer, the following predicts greater total CRF and the predictors are in the order of greatest to least strength of prediction: greater total symptom severity of the other unpleasant symptoms; lower PSE for fatigue management; greater number of co-morbid conditions; and women as compared to men. Note that in Step 5 when the two predictor variables, PSE for fatigue management and the other unpleasant symptoms were not accounted for in the model, the younger the age of a person with cancer, the greater the total CRF severity resulted.

Table 6

Results of Step 1-6 Identifying the Best Model Predicting Total CRF Severity In Persons with Cancer Using a Theoretically Driven Backward Elimination Regression Method

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
1	.105	1.27	25, 272	.177	Type of Cancer	.953 (.342)	Race	.512 (.609)
					Stage of Cancer	1.66 (.097)	Marital Status	-.942 (.347)
					Receiving Radiation Treatment	-.396 (.692)	Level of Education Achieved	-.379 (.705)
					Surgery Prior to Chemotherapy		Employment Data	
					Yes, had surgery	-.837 (.403)	Person retired	.352 (.725)
					Don't know if had surgery	1.21 (.227)	Receiving disability	-.134 (.894)
					No response choice selected	-.898 (.370)	Temporary leave from work	-.102 (.919)
					Surgery During Chemotherapy		Had to quit work	-.233 (.824)
					Yes, had surgery	.642 (.522)	Annual Combined Income	.355 (.723)
					No response choice selected	1.54 (.124)	Health Insurance Data	
					Co-morbid Conditions	2.64 (.009)	Possessed health insurance	-.896 (.371)
					Age	-1.00 (.317)	Patient held health insurance	.333 (.740)

Table 6 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
					Sex	1.43 (.155)	Spouse held health insurance	.911 (.363)
							Type of Health Insurance Held	
							Held Medicare	-.604 (.546)
							Held Medicaid	-.283 (.777)
							Held Private	-.781 (.436)
2	.102	2.0	16, 281	.013	Type of Cancer	.980 (.328)	Race	.518 (.605)
					Stage of Cancer	1.72 (.086)	Marital Status	-.939 (.349)
					Surgery Prior to Chemotherapy		Health Insurance Data	
					Yes, had surgery	1.06 (.288)	Possessed health insurance	-1.00 (.316)
					Don't know if had surgery	1.32 (.190)	Spouse held health insurance	1.00 (.318)
					No response choice selected	-.926 (.355)	Type of health insurance held	
					Surgery During Chemotherapy		Held Medicare	-.639 (.524)
					Yes, had surgery	.623 (.533)	Held Private	-.716 (.475)
					No response choice selected	1.57 (.117)		
					Co-morbid Conditions	2.77 (.006)		

Table 6 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
					Age	-1.29 (.198)		
					Sex	1.50 (.136)		
3	.084	2.93	9, 288	.002	Stage of Cancer	1.72 (.086)	Health Insurance Data	
					Surgery Prior to Chemotherapy		Possessed health insurance	-.864 (.389)
					Yes, had surgery	.751 (.453)	Spouse held health insurance	.556 (.578)
					Don't know if had surgery	1.14 (.254)		
					No response choice selected	-.720 (.472)		
					Co-morbid Conditions	3.24 (.001)		
					Age	-2.19 (.030)		
					Sex	1.74 (.084)		
4	.073	5.76	4, 293	.000	Stage of Cancer	1.84 (.067)		
					Co-morbid Conditions	3.27 (.001)		
					Age	-2.18 (.030)		
					Sex	2.12 (.035)		

Table 6 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
5	.062	6.50	3, 294	.000	Co-morbid Conditions	3.37 (.001)		
					Age	-2.36 (.019)		
					Sex	2.56 (.011)		
6	.392	37.4	5, 290	.000	Co-morbid Conditions	2.41 (.017)		
					Age	-1.68 (.095)		
					Sex	2.35 (.020)		
					PSE for Fatigue Management	-6.49 (.000)		
					Other Unpleasant Symptoms	9.77 (.000)		

Table 7

Significance Testing of the Predictors to Total CRF Severity In Persons with Cancer

Predictor Variable	*F*-Statistic	*df*
Co-morbid Conditions	6.0	4, 291
Age	3.0	4, 291
Sex	5.5	4, 291
PSE for Fatigue Management	44.0	4, 291
Other Symptoms Associated with Cancer & Cancer Treatment	100.5	4, 293

All predictors significant at a level of $p < .05$

Research Question #2: How does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of CRF severity?

In answering Research Question #1, the "type of cancer diagnosis", LC versus OC diagnoses, was 1 of 25 variables placed in the initial model to identify the predictors that relate to total CRF severity in persons with cancer. Subsequently, in Step 2 of the backward elimination regression to find predictors to total CRF severity in persons with cancer, the "type of cancer diagnosis" was found not to be a statistically significant predictor ($t = .980$; $p = .328$).

To continue furthering the science of the CRF phenomenon, predictors to total CRF severity were examined separately in both persons with LC and OC diagnoses. With one exception, similar procedures were used for the separate group analysis of persons with LC and OC diagnoses as were used for the total sample of persons with cancer. The

exception being that "type of cancer diagnoses" was not entered into the initial model for group analysis.

Persons with Other Cancer Diagnoses

Step 1

The first step, the calculation of the initial model to find the best of all subset model to predict total CRF severity in persons with OC diagnoses, resulted in a model that was not statistically significant [$R^2 = .126$; F (24, 210) = 1.26; $p = .194$]. To improve the model, 9 out of 24 predictors with t-values < -/+ 0.50 were eliminated (see Table 8).

Step 2

The elimination of 9 out of 24 predictors from the initial model resulted in a statistically significant model in Step 2 explaining 12.4% of the variance [F (15, 219) = 2.06; $p = .013$]. The model in Step 2 contained only two statistically significant patient predictors to total CRF severity, stage of cancer and co-morbid conditions. In an attempt to improve the model in Step 3, all predictors with t-values > -/+ 0.90 were retained which meant that six predictors were eliminated (see Table 8).

Step 3

With the elimination of six predictors, the explained variance in Step 3 decreased from 12.6% to 10.8%, but the model became more statistically significant in predicting total CRF severity in persons with OC diagnoses [F (9, 225) = 3.02; $p = .002$]. Once again there were only two statistically significant predictors to total CRF severity, stage of cancer and co-morbid conditions. To improve the model predicting total CRF severity, four predictors with t-values ≤ -/+1.19 were eliminated (see Table 8).

Step 4

The elimination of four predictors in Step 3 resulted in a further decrease in the explained variance to 9.4%. Like the model in Step 3, the model in Step 4 became more statistically significant in predicting total CRF severity in persons with OC diagnoses [F (5, 229) = 4.74; p = .000]. Stage of cancer and co-morbid conditions remained statistically significant. The predictor variable, age, converted to statistical significance (see Table 8). Another step, Step 5, was added to improve the model predicting total CRF severity in persons with OC diagnoses which included eliminating the most statistically insignificant predictor variable.

Step 5

The elimination of one predictor in Step 4 resulted in a slight reduction of the explained variance from 9.4% to 8.8% (see Table 8). However, the model continued to strengthen with three statistically significant predictors to CRF severity: stage of cancer, co-morbid conditions, and age [F (4, 230) = 5.53; p = .000]. Another step, Step 6, was added to improve the model predicting total CRF severity in persons with OC diagnoses which included eliminating the only nonsignificant predictor variable, sex.

Step 6

With the elimination of the predictor variable, sex, all three former predictors (stage of cancer, co-morbid conditions, and age) in Step 5 remained statistically significant. The model strengthened with an explained variance of 7.6% [F (3, 231) = 33.4; p = .000] (see Table 8). As in the model which included identifying the predictors to CRF severity in the total sample, PSE for fatigue management and the other unpleasant symptoms were accounted for in the final model as depicted in Step 7.

Further Analysis, Step 7

After PSE for fatigue management and the other unpleasant symptoms were added to the model in Step 6, the explained variance in the prediction of the total CRF severity in persons with OC diagnoses increased from 7.6% to 42.4% [F (3, 231) = 33.4; p = .000]. The predictors of stage of cancer and co-morbid conditions remained statistically significant (t > 2.0); but age (t = -1.40) no longer remained a predictor of total CRF severity in persons with OC diagnoses. Both PSE for fatigue management (t = -6.10) and the other unpleasant symptoms (t = 8.95) were statistically significant in the prediction of total CRF severity in persons with OC diagnoses (see Table 8).

The Final Model

The initial model as identified in Step 1 demonstrated good apriori power at .80 to detect relationships with small effects (0.11) while utilizing 24 predictors with a two-tailed test and a level of significance set at 0.05 (Erdfelder et al., 1996). Therefore, at better-than-chance-levels, the final model as depicted in Step 7 for the prediction of total CRF severity in persons with OC diagnoses accounts for 42.4% of the variance [F (3, 231) = 33.4; p = .000). This prediction of the actual value of total CRF severity is made with small residual variance. The standard error of the estimate shows that on average, the actual value will be +/- 1.77 of the predicted value 68% of the time, and will be within +/- (2) (1.77) 95% of the time. Tolerance levels for the predictor variables ranged from a low of .772 for age, .781 for co-morbid conditions, and .950 and greater for all others.

Significance testing. As depicted in Table 9, the significance testing of each individual predictor demonstrates that they not only contribute to the model as a whole

but also independently to the prediction of total CRF severity in persons with OC diagnoses.

Assumptions Met, the Model Confirmed

The mean of the predicted value in the final model of total CRF severity was 5.83 (SD = 1.50). Assessment of the histogram of the standardized residuals shows roughly a normal curve as validated by the range of the residual variance from -3.09 to 2.91. The normal probability plot shows a monotonic pattern and reasonable closeness of the cases to the regression line, confirming a normal distribution. Additionally, the scatterplots of residuals for each statistically significant predictor variable and criterion variable reveals a pattern that is more dense in the center with decreasing density on the outer edges, thus demonstrating normal homoscedasticity.

Summary of Results for Research Question #2 (Persons with OC Diagnoses)

In summary, for persons with OC diagnoses, the following predicts greater total CRF and the predictors are in the order of greatest to least strength of prediction: greater total symptom severity from the other unpleasant symptoms; lower PSE for fatigue management; earlier rather than later stage cancer; and greater numbers of co-morbid conditions. Note that in Step 6 when the two predictor variables, PSE for fatigue management and the other unpleasant symptoms were not accounted for in the model, the younger the person is with cancer, the greater the total CRF severity.

Table 8

Results of Step 1-7 Identifying the Best Model Predicting Total CRF Severity In Persons with Other Cancer Diagnoses Using a Theoretically Driven Backward Elimination Regression Method

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
1	.126	1.26	24, 210	.194	Type of Cancer--Not entered	---	Race	.426 (.671)
					Stage of Cancer	2.17 (.031)	Marital Status	-.621 (.535)
					Receiving Radiation Treatment	-.244 (.807)	Level of Education Achieved	-.819 (.414)
					Surgery Prior to Chemotherapy		Employment Data	
					Yes, had surgery	.335 (.738)	Person retired	-.108 (.914)
					Don't know if had surgery	.872 (.384)	Receiving disability	-.097 (.923)
					No response choice selected	-.849 (.397)	Temporary leave from work	-.032 (.974)
					Surgery During Chemotherapy		Had to quit work	-.732 (.465)
					Yes, had surgery	.853 (.395)	Annual Combined Income	.314 (.754)
					No response choice selected	1.69 (.092)	Health Insurance Data	
					Co-morbid Conditions	2.54 (.012)	Patient held health insurance	-.116 (.908)
					Age	-.997 (.320)	Spouse held health insurance	.708 (.480)

Table 8 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
					Sex	.884 (.378)	Possessed Health Insurance	-.942 (.347)
							Type of Health Insurance Held	
							Held Medicare	-.980 (.328)
							Held Medicaid	-.106 (.916)
							Held Private	-.545 (.586)
2	.124	2.06	15, 219	.013	Stage of Cancer	2.31 (.022)	Marital Status	-.582 (.561)
					Surgery Prior to Chemotherapy		Level of Education Achieved	-.788 (.432)
					Don't know if had surgery	.887 (.376)	Employment Data	
					No response choice selected	-1.04 (.298)	Had to quit work	-.728 (.468)
					Surgery During Chemotherapy		Possessed Health Insurance	-.910 (.364)
					Yes, had surgery	.856 (.393)	Health Insurance Data	
					No response choice selected	1.73 (.085)	Spouse held health insurance	1.08 (.281)
					Co-morbid Conditions	2.72 (.007)	Type of Health Insurance Held	
					Age	-1.09 (.279)	Held Medicare	-1.11 (.267)
					Sex	.931 (.353)	Held Private	-.648 (.518)

Table 8 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
3	.108	3.02	9, 225	.002	Stage of Cancer	2.15 (.032)	Possessed Health Insurance	-.822 (.412)
					Surgery Prior to Chemotherapy		Spouse Held Health Insurance	.725 (.469)
					No response choice selected	-1.11 (.269)	Insurance Held-Medicare	-.987 (.325)
					Surgery During Chemotherapy			
					No response choice selected	1.51 (.133)		
					Co-morbid Condition	2.99 (.003)		
					Age	-1.25 (.212)		
					Sex	1.19 (.234)		
4	.094	4.74	5, 229	.000	Stage of Cancer	2.14 (.033)		
					Surgery Prior to Chemotherapy			
					No response choice selected	1.23 (.220)		
					Co-morbid Conditions	3.04 (.003)		
					Age	-2.33 (.021)		
					Sex	1.75 (.081)		

Table 8 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
5	.088	5.53	4, 230	.000	Stage of Cancer	2.17 (.031)		
					Co-morbid Condition	3.22 (.001)		
					Age	-2.43 (.016)		
					Sex	1.75 (.088)		
6	.076	6.34	3, 231	.000	Stage of Cancer	2.67 (.008)		
					Co-morbid Conditions	3.15 (.002)		
					Age	-2.47 (.014)		
7	.424	33.4	5, 227	.000	Stage of Cancer	2.47 (.014)		
					Co-morbid Condition	2.25 (.025)		
					Age	-1.40 (.164)		
					PSE for Fatigue Management	-6.10 (.000)		
					Other Unpleasant Symptoms	8.95 (.000)		

Table 9

Significance Testing of the Predictors to Total CRF Severity In Persons with Other Cancer Diagnoses

Predictor Variable	*F*-Statistic	*df*
Stage of Cancer	8.0	4, 228
Co-morbid Condition	6.5	4, 228
Age	2.5	4, 228
PSE for Fatigue Management	47.5	4, 228
Other Symptoms Associated with Cancer & Cancer Treatment	102.0	4, 228

All predictors significant at a level of $p < .05$

Persons with Lung Cancer

Step 1

The first step, the calculation of the initial model to find the best of all subset model to predict total CRF severity in persons with LC, resulted in a model that was not statistically significant [$R^2 = .308$; $F(23, 39) = .756$; $p = .759$]. To improve the model, 8 out of 23 predictors with *t*-values < -/+ 0.50 were eliminated (see Table 10).

Step 2

The elimination of 8 out of 23 predictors from the initial model resulted in another model that was not statistically significant [$R^2 = .294$; $F(15, 47) = 1.30$; $p = .237$]. Subsequently, six predictors with *t*-values < -/+ 1.0 were removed (see Table 10).

Step 3

The elimination of 6 out of 15 predictors led to an improved model, but still not statistically significant [R^2 = .247; F (9, 53) = 1.93; p = .067]. Next, three predictors were removed with t-values < -/+1.2 (see Table 10).

Step 4

After the removal of three predictor variables, the model in Step 4 became statistically significant [R^2 = .201; F (6, 56) = 2.36; p = .042]. This model contained six variables. Having surgery prior to chemotherapy and sex were statistically significant variables to the prediction of total CRF severity. In an effort to improve the model, one predictor variable with the lowest nonsignificant t-value was eliminated (see Table 10).

Step 5

With the elimination of one predictor, the model strengthened with an explained variance from 20.1% to 18.3% [F (5, 57) = 2.56; p = .037]. Having surgery prior to chemotherapy and sex remained statistically significant in predicting total CRF severity. Once again, 1 out of 3 of the predictor variables with the lowest nonsignificant t-value was eliminated (see Table 10).

Step 6

The elimination of 1 of 3 nonsignificant predictor variables improved the model in Step 6 [R^2 = .165; F (4, 58) = 2.87; p = .031]. Having surgery prior to chemotherapy remained a statistically significant predictor to total CRF severity, but the variable sex converted to nonsignificance. This model had a total of 4 predictors with 3 of the predictors with nonsignificant t-values. Thus, the predictor with the lowest nonsignificant t-value was eliminated (see Table 10).

Step 7

The model in Step 7 depicts all three predictor variables in the model as statistically significant, having surgery prior to chemotherapy, sex, and holding a private health insurance policy. The model as a whole was strengthened from Step 6 explaining 15.1% of the variance in the prediction of total CRF severity in persons with LC [F (3, 59) = 3.51; p = .021]. The predictor variables, PSE for fatigue management and the other unpleasant symptoms were accounted for in the final model as depicted in Step 8 (see Table 10).

Further Analysis, Step 8

After PSE for fatigue management and the total severity from the other unpleasant symptoms were added to the model, the explained variance in the prediction of the total CRF severity in persons with LC increased from 15.1% to 34.8% [F (5, 57) = 6.08; p = .000]. In the following order of greatest to least prediction of total CRF severity in persons with LC, four predictors were statistically significant: total symptom severity from the other unpleasant symptoms; PSE for fatigue management; the patient holding an insurance policy; and, having surgery prior to chemotherapy. The predictor variable of sex, females as compared to males predicts greater total CRF severity, became statistically not significant (t = 1.52) (see Table 10).

The Final Model

The initial model as identified in Step 1 demonstrated good apriori power at .80 to detect relationships with large effects (0.52) while utilizing 24 predictors with a two-tailed test and a level of significance set at 0.05 (Erdfelder et al., 1996). Therefore, at better-than-chance-levels, the final model as depicted in Step 8 for the prediction of total

CRF severity in persons with LC accounts for 34.8% of the variance [F (5, 57) = 6.08; p = .000]. This prediction of the actual value of total CRF severity is made with small residual variance. The standard error of the estimate shows that on average, the actual value will be +/- 1.68 of the predicted value 68% of the time, and will be within +/- (2) (1.68) 95% of the time. Tolerance levels of the individual predictors ranged from .916 to .960.

Significance testing. As depicted in Table 11, the significance testing of each individual predictor demonstrates that they not only contribute to the model as a whole but also independently to the prediction of total CRF severity in persons with OC diagnoses.

Assumptions Met, the Model Confirmed

The mean of the predicted value in the final model of total CRF severity was 5.88 (SD = 1.18). Assessment of the histogram of the standardized residuals shows roughly a normal curve as validated by the range of the residual variance from -2.16 to 2.15. The normal probability plot shows a monotonic pattern and reasonable closeness of the cases to the regression line, confirming a normal distribution. Additionally, the scatterplots of residuals for each statistically significant predictor variable and criterion variable reveals a pattern that is more dense in the center with decreasing density on the outer edges, thus demonstrating normal homoscedasticity.

Summary of the Results for Research Question #2 (Persons with LC)

Thus, for persons with LC, the following predicts greater total CRF severity and the predictors are in the order of greatest to least strength of prediction: greater total symptom severity from the other unpleasant symptoms; lower PSE for fatigue

management; the patient holding the insurance policy; and, having surgery prior to chemotherapy. Note in Step 7 when the two predictor variables, PSE for fatigue management and the other unpleasant symptoms were not accounted for in the model, females as compared to males predicted greater total CRF severity.

Table 10

Results of Step 1-8 Identifying the Best Model Predicting Total CRF Severity In Persons with Lung Cancer Using a Theoretically Driven Backward Elimination Regression Method

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
1	.308	.756	23, 39	.759	Type of Cancer--Not entered	---	Race	-.280 (.781)
					Stage of Cancer	-.912 (.367)	Marital Status	-.720 (.476)
					Receiving Radiation Treatment	-.613 (.543)	Level of Education Achieved	.779 (.441)
					Surgery Prior to Chemotherapy		Employment Data	
					Yes, had surgery	2.06 (.047)	Person retired	.247 (.806)
					Don't know if had surgery	.477 (.636)	Receiving disability	-1.09 (.281)
						-.569 (.573)	Temporary leave from work	.430 (.670)
					Surgery During Chemotherapy		Had to quit work	1.07 (.292)
					Yes, had surgery	-1.03 (.311)	Annual Combined Income	.786 (.437)
					No response choice selected	-.393 (.696)	Health Insurance Data	
					Co-morbid Conditions	1.25 (.219)	Patient held health insurance	1.38 (.174)
					Age	.067 (.947)	Spouse held health insurance	-.044 (.966)

Table 10 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
					Sex	.888 (.380)	Type of Health Insurance Held	
							Held Medicare	-.219 (.828)
							Held Medicaid	-.688 (.496)
							Held Private	-.953 (.346)
2	.294	1.30	15, 47	.237	Stage of Cancer	-1.22 (.227)	Marital Status	-.962 (.341)
					Receiving Radiation Treatment	-.623 (.536)	Level of Education Achieved	.758 (.452)
					Surgery Prior to Chemotherapy		Employment Data	
					Yes, had surgery	2.20 (.033)	Receiving disability	-1.53 (.134)
					No response choice selected	-.453 (.653)	Had to quit work	1.35 (.183)
					Surgery During Chemotherapy		Annual Combined Income	-1.06 (.295)
					Yes, had surgery	-1.08 (.287)	Health Insurance Data	
					Sex	1.01 (.319)	Patient held health insurance	1.81 (.078)
					Co-morbid Conditions	1.55 (.128)	Type of Health Insurance Held	
							Held Medicaid	-.828 (.412)
							Held Private	-1.06 (.295)

Table 10 Continued

Step	R^2	F	DF	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
3	.247	1.93	9, 53	.067	Stage of Cancer	-1.34 (.185)	Employment Data	
					Surgery Prior to Chemotherapy		Receiving disability	-1.05 (.297)
					Yes, had surgery	2.66 (.010)	Had to quit work	1.35 (.184)
					Surgery During Chemotherapy		Health Insurance Data	
					Yes, had surgery	-1.02 (.313)	Patient held health insurance	1.88 (.065)
					Co-morbid Conditions	1.26 (.212)	Type of Health Insurance Held	
					Sex	1.59 (.118)	Held Private	-.932 (.355)
4	.201	2.36	6, 56	.042	Stage of Cancer	-1.24 (.222)	Employment Data	
					Surgery Prior to Chemotherapy		Had to quit work	1.13 (.265)
					Yes, had surgery	2.48 (.016)	Health Insurance Data	
					Co-morbid Conditions	1.42 (.160)	Patient held health insurance	1.83 (.073)
					Sex	2.08 (.042)		

Table 10 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
5	.183	2.56	5, 57	.037	Stage of Cancer	-1.13 (.262)	Health Insurance Data	
					Surgery Prior to Chemotherapy		Patient held health insurance	1.89 (.067)
					Yes, had surgery	2.35 (.022)		
					Co-morbid Conditions	1.32 (.191)		
					Sex	2.04 (.046)		
6	.165	2.87	4, 58	.031	Surgery Prior to Chemotherapy		Health Insurance Data	
					Yes, had surgery	2.11 (.039)	Patient held health insurance	1.76 (.084)
					Co-morbid Conditions	.972 (.335)		
					Sex	1.97 (.053)		
7	.151	3.51	3, 59	.021	Surgery Prior to Chemotherapy		Health Insurance Data	
					Yes, had surgery	2.03 (.047)	Patient held health insurance	2.12 (.038)
					Sex	2.13 (.038)		

Table 10 Continued

Step	R^2	F	df	p	Physiological Characteristics	t (p)	Contextual Characteristics	t (p)
8	.348	6.08	5, 57	.000	Surgery Prior to Chemotherapy		Health Insurance Data	
					Yes, had surgery	2.04 (.046)	Patient held health insurance	2.08 (.042)
					Sex	1.52 (.135)		
					PSE for Fatigue Management	-2.29 (.026)		
					Other Unpleasant Symptoms	3.24 (.002)		

Table 11

Significance Testing of the Predictors to Total CRF Severity In Persons with Lung Cancer

Predictor Variable	*F*-Statistic	*df*
Had Surgery Prior to Chemotherapy	4.0	4, 58
Patient Held Health Insurance	4.17	4, 58
Sex	2.17	4, 58
PSE for Fatigue Management	5.0	4, 58
Other Symptoms Associated with Cancer & Cancer Treatment	10.0	4, 58

All predictors significant at a level of $p < .05$

Research Question #3: What is the symptom experience of persons with LC and how does it compare to the symptom experience of OC diagnoses, including the relationships between CRF and other unpleasant symptoms?

Out of 16 possible symptoms including fatigue, the total mean number of symptoms reported by persons with cancer at the baseline interview was 7.43 ($SD = 2.60$). While not statistically significant ($t = -.858$; $df = 87.50$; $p = .393$), persons with LC had a slightly higher mean number of symptoms ($M = 7.71$; $SD = 2.95$) as compared to persons with OC diagnoses ($M = 7.37$; $SD = 2.51$).

Symptom Frequency

At the baseline interview, fatigue was the most frequently reported symptom occurring 100% of the time over a period of the past seven days prior to the baseline interview in both persons with LC and OC diagnoses. While not statistically different (t = -1.470; df = 296; p = .143), persons with LC had a slightly higher mean number of days of fatigue (M = 5.48; SD = 1.81) than persons with OC (M = 5.05; SD = 2.07). After fatigue, the most frequently reported symptoms in the past seven days prior to the baseline interview by all persons were insomnia (77%), lack of appetite (63%), weakness (60%), dry mouth (60%), pain (55%), and nausea (53%) (see Table 12). However, for persons with LC, dyspnea, weakness, dry mouth, lack of appetite, and cough were the next most common symptoms after fatigue and insomnia, whereas persons with OC reported lack of appetite, weakness, dry mouth, pain, and nausea more frequently occurring after fatigue and insomnia (see Table 12).

Differences in Symptom Frequency

As compared to persons with OC, persons with LC reported a greater frequency in the mean number of days of dyspnea (3 days as compared to 1 day; t = -5.47; df = 296; p = .000) and cough (3 days as compared to 1 day; t = -4.418; df = 296; p = .000). While not statistically significant, note that persons with LC trended towards experiencing greater frequency of weakness as compared to persons with OC (3 days as compared to 2 days; t = -1.71; df = 296; p = .088). However, persons with OC experienced significantly more days of difficulty remembering as compared to persons with LC (1.9 days as compared to 1.2 days; t = 2.07; df = 116; p = .04).

Table 12

Rank, Frequency, and Percentage of Symptoms Reported by the Total Sample and by Group in the Past Seven Days from the Baseline Interview

Symptom	Total Sample $N = 298$		Lung Cancer $N = 63$		Other Cancer $N = 235$	
	Rank	*N* (%)	Rank	*N* (%)	Rank	*N* (%)
Fatigue	1	298 (100)	1	63 (100)	1	235 (100)
Insomnia	2	229 (77)	2	44 (70)	2	185 (79)
Lack of Appetite	3	187 (63)	6	37 (59)	3	150 (64)
Weakness	4	180 (60)	4	40 (63)	4	140 (60)
Dry Mouth	5	178 (60)	5	39 (62)	5	139 (59)
Pain	6	164 (55)	7	31 (49)	6	133 (57)
Nausea	7	159 (53)	7	31 (49)	7	128 (54)
Difficulty Remembering	8	133 (45)	10	21 (33)	8	112 (48)
Numbness/Tingling	9	124 (41)	9	22 (35)	9	102 (43)
Constipation	10	118 (40)	8	24 (38)	10	94 (40)
Dyspnea	11	115 (39)	3	41 (65)	12	74 (31)
Cough	12	105 (35)	6	36 (57)	14	69 (29)
Alopecia	13	100 (34)	9	22 (35)	11	78 (33)
Diarrhea	14	93 (31)	9	22 (35)	13	71 (30)
Vomiting	15	45 (15)	11	12 (19)	15	33 (14)
Fever	16	30 (10)	12	9 (14)	16	21 (9)

Presence of Symptoms on All Seven Days

For all persons with cancer, the most frequently reported symptoms present on all seven days prior to the baseline interview were fatigue (47%) followed by dry mouth (27%), insomnia (27%), weakness (24%), alopecia (22%), and cough (21%) (see Table 13). The presence of symptoms occurring on all seven days varied by cancer group (see Table 13). For persons with LC, fatigue (52%), cough (38%), weakness (30%), dyspnea (29%), pain (29%), and dry mouth (29%) were the top ranked symptoms occurring on all seven days prior to the baseline interview. Whereas for persons with OC diagnoses, fatigue (45%), insomnia (29%), dry mouth (27%), weakness (22%), alopecia (21%), and numbness and tingling (20%) were reported as the top ranked symptoms occurring on all seven days prior to the baseline interview.

Table 13

Rank, Frequency, and Percentage of Symptoms Reported by the Total Sample and by Group On All Seven Days Prior to the Baseline Interview

Symptom	Total Sample $N = 298$		Lung Cancer $N = 63$		Other Cancer $N = 235$	
	Rank	*N* (%)	Rank	*N* (%)	Rank	*N* (%)
Fatigue	1	139 (47)	1	33 (52)	1	106 (45)
Insomnia	3	80 (27)	6	11 (18)	2	69 (29)
Lack of Appetite	8	57 (19)	5	15 (24)	7	42 (18)
Weakness	4	71 (24	3	19 (30)	4	52 (22)
Dry Mouth	2	81 (27)	4	18 (29)	3	63 (27)
Pain	7	59 (20)	4	18 (29)	8	41 (17)
Nausea	12	23 (8)	8	8 (13)	11	15 (6)
Difficulty Remembering	10	41 (14)	10	4 (6)	9	37 (16)
Numbness/Tingling	9	56 (19)	7	10 (16)	6	46 (20)
Constipation	13	14 (5)	9	5 (8)	13	9 (4)
Dyspnea	11	36 (12)	4	18 (29)	10	18 (8)
Cough	6	61 (21)	2	24 (38)	9	37 (16)
Alopecia	5	65 (22)	5	15 (24)	5	50 (21)
Diarrhea	13	14 (5)	11	1 (1.6)	12	13 (5)
Vomiting	14	2 (.7)	11	1 (1.6)	14	2 (.9)
Fever	15	1 (.3)	11	1 (1.6)	15	1 (.4)

Symptom Severity

Out of a total of 16 symptoms, alopecia was the most severe ($M = 5.77$; $SD = 3.24$) reported symptom by 32% of all persons with cancer (see Table 14). After alopecia, insomnia ($M = 5.40$; $SD = 2.63$), vomiting ($M = 5.29$; $SD = 2.97$), constipation ($M = 5.26$; $SD = 2.81$), and fatigue ($M = 5.23$; $SD = 2.33$) were the next most severe symptoms reported in persons with cancer.

Mean Symptom Severity Scores

The range of symptom severity scores varied by cancer diagnosis (see Table 14). For persons with OC, the most severe symptom was alopecia ($M = 5.67$; $SD = 3.23$), and the least severe symptom was cough ($M = 3.61$; $SD = 2.49$). However, the range of the symptom severity scores ran higher for persons with LC, with constipation being the most severe symptom ($M = 6.50$; $SD = 2.67$), and difficulty remembering things being the least severe symptom ($M = 4.05$; $SD = 2.42$). Consequently, the total symptom severity score for persons with LC was significantly worse ($M = 4.99$; $SD = 1.43$) as compared to persons with OC ($M = 4.54$; $SD = 1.60$) ($t = -1.99$; $df = 294$; $p = .047$).

Weighted Mean Symptom Severity Scores

When assessing the rank order of the mean symptom severity report, one needs to take into account the mean was computed based on those that reported the symptom. Therefore, the mean severity calculations did not take into consideration the frequency of occurrence of the symptom relative to the total in the corresponding sample. When the mean symptom severity scores were weighted by frequency of occurrence, fatigue and insomnia were the most severe symptoms in both persons with LC (fatigue $M_W = 5.38$; insomnia $M_W = 3.79$) and OC diagnoses (fatigue $M_W = 5.10$; insomnia $M_W = 4.31$).

This is in contrast to the mean symptom severity calculation in persons with LC where fatigue was rated the 7th and insomnia the 5th most severe symptoms, and in persons with OC fatigue was rated the 4th and insomnia the 2nd most severe symptom. Similar to the mean total symptom severity score, the weighted mean total symptom severity score remained higher for persons with LC (M_W = 5.29) than persons with OC (M_W = 4.67) (see Table 15).

Differences in Symptom Severity

As compared to persons with OC, persons with LC had greater symptom severity in pain (t = -2.403; df = 162; p = .017), dry mouth (t = -2.194; df = .035; p = 58.17) and constipation (t = -2.465; df = 116; p = .015). Persons with LC not only trended towards greater report of frequency of weakness, but also more in the severity of weakness (t = -1.823; df = 178; p = .070) as compared to persons with OC.

Table 14

Rank and Mean Symptom Severity of the Total Sample and by Group

Symptom	Total Sample $N = 298$		Lung Cancer $N = 63$		Other Cancer $N = 235$	
	Rank	*M* (*SD*)	Rank	*M* (*SD*)	Rank	*M* (*SD*)
Alopecia	1	5.77 (3.24)	2	6.20 (3.32)	1	5.66 (3.23)
Insomnia	2	5.54 (2.63)	5	5.56 (2.15)	2	5.53 (2.74)
Vomiting	3	5.29 (2.97)	12	4.83 (3.01)	3	5.46 (2.99)
Constipation	4	5.26 (2.81)	1	6.50 (2.67)	6	4.95 (2.78)
Fatigue	5	5.24 (2.33)	7	5.47 (2.23)	4	5.17 (2.37)
Diarrhea	6	5.10 (2.56)	9	5.27 (2.35)	5	5.04 (2.63)
Lack of Appetite	7	5.04 (2.48)	3	5.61 (2.18)	7	4.91 (2.53)
Weakness	8	4.84 (2.42)	8	5.45 (2.56)	8	4.66 (2.36)
Dry Mouth	9	4.80 (2.60)	4	5.61 (2.63)	9	4.57 (2.55)
Pain	10	4.62 (2.27)	6	5.48 (2.23)	11	4.41 (2.23)
Dyspnea	11	4.59 (2.14)	11	4.95 (1.99)	13	4.39 (2.20)
Nausea	12	4.54 (2.64)	10	5.13 (2.83)	12	4.40 (2.59)
Numbness/Tingling	13	4.44 (2.55)	13	4.50 (2.50)	10	4.43 (2.58)
Fever	14	4.07 (2.32)	14	4.44 (2.92)	14	3.90 (2.05)
Cough	15	3.89 (2.36)	15	4.39 (2.03)	16	3.62 (2.49)
Difficulty Remembering	16	3.71 (2.44)	16	4.05 (2.42)	15	3.65 (2.45)
Total Symptom Severity	--	4.64 (1.58) $N = 296$	--	4.99 (1.43) $N = 63$	--	4.54 (1.60) $N = 233$

Table 15

Rank and Weighted Mean Symptom Severity Score for Persons with Lung Cancer and Other Cancer Diagnoses

Symptom	Lung Cancer $N = 63$		Other Cancer $N = 235$	
	Rank	M_W	Rank	M_W
Alopecia	10	1.97	10	1.83
Insomnia	2	3.79	2	4.31
Vomiting	15	0.92	15	0.77
Constipation	9	2.48	8	1.98
Fatigue	1	5.38	1	5.10
Diarrhea	11	1.84	12	1.48
Lack of Appetite	5	3.21	3	3.09
Weakness	3	3.46	4	2.78
Dry Mouth	4	3.38	5	2.63
Pain	7	2.70	6	2.50
Dyspnea	6	3.14	13	1.35
Nausea	8	2.52	7	2.38
Numbness/Tingling	13	1.57	9	1.89
Fever	16	0.63	16	0.32
Cough	14	1.00	14	1.00
Difficulty Remembering	12	1.62	11	1.62
Total Symptom Severity	---	5.29	---	4.67

Correlations Among Symptoms

Correlations were calculated for both the total CRF severity and the individual symptoms, and the total CRF severity and total symptom severity in the total sample and by group (see Table 16). The total symptom severity associated with each symptom was calculated by summing each subject's response to severity scores for each symptom reported (i.e., a reported symptom is a symptom with a severity score greater than zero) and dividing by the total number of symptoms. For the total sample ($r = .512$), and for persons with LC ($r = .441$) and OC ($r = .530$) diagnoses, the total symptom severity positively significantly correlated with total CRF severity ($p = .000$).

Eleven individual symptoms were also statistically significant in positively correlating with total CRF severity in the total sample and persons with OC diagnoses. Out of the 11 individual symptoms, weakness showed the greatest strength in correlating with total CRF severity for both the total sample ($r = .565$; $p = .000$) and persons with OC ($r = .597$; $p = .000$).

For persons with LC, five individual symptoms, nausea, dyspnea, lack of appetite, dry mouth, and weakness significantly positively correlated with total CRF severity. These five symptoms not only significantly correlated with total CRF severity in persons with LC, but also for persons with OC diagnoses. Further, similar to the total sample and persons with OC diagnoses, weakness showed the most strength of any of the individual symptoms in positively correlating with total CRF severity in persons with LC ($r = .487$; $p = .001$).

Table 16

Correlations Among Total CRF Severity, Individual Symptom Severity, and Total Symptom Severity for the Total Sample and by Cancer Group

	Total Sample	Lung Cancer	Other Cancer
	Total CRF Severity	Total CRF Severity	Total CRF Severity
Pain	.367**	.133	.434**
Nausea	.268**	.363*	.245**
Vomiting	.181	.566	.091
Insomnia	.344**	.271	.358**
Dyspnea	.314**	.318*	.336**
Diarrhea	.219**	.248	.211
Lack of Appetite	.347**	.436**	.325**
Fever	.284	.222	.318
Cough	.188	.230	.185
Dry Mouth	.391**	.441**	.379**
Constipation	.386**	.242	.409**
Difficulty Remembering	.268**	.224	.271**
Numbness/Tingling	.238**	.188	.246*
Weakness	.565**	.487**	.597**
Alopecia	.178	-.159	.251*
Total Symptom Severity	.512**	.441**	.530**

Note. * $p < .05$, ** $p < .01$

Summary of Results for Research Question #3

Data indicate a high number of concurrent symptoms in all persons with cancer with a mean of 7.4 symptoms with no significant differences found between the LC and OC diagnoses groups. Fatigue was the most frequently reported symptom occurring for both persons with LC and OC diagnoses. With no significant differences found between groups, fatigue ranked as the 7th most severe symptom in persons with LC and the 4th most severe symptom for persons with OC diagnoses. However, persons with LC as compared to persons with OC diagnoses had a statistically significant higher total symptom severity score as compared to persons with OC diagnoses. For persons with LC and OC diagnoses, total CRF severity positively significantly correlated with the total symptom severity of the other unpleasant symptoms. Five individual symptoms, nausea, dyspnea, lack of appetite, dry mouth, and weakness significantly positively correlated with total CRF severity for both persons with LC and OC diagnoses, with weakness showing the greatest strength of any individual symptom correlating with total CRF severity.

Research Question #4: Does PSE for fatigue management mediate the relationship between CRF severity and PFS in persons with cancer (LC and OC)?

Mediation was tested using a series of three regression analyses as specified by Baron and Kenny (1986) and Kenny (2005). Further analysis was performed which involved significance testing of the mediation pathway via the Sobel Test (Dudley et al., 2004).

For persons with cancer, results indicated that PSE for fatigue management partially mediated the relationship between CRF and PFS (see Table 17). Significant paths were demonstrated from CRF to PSE for fatigue management (b = -.40; p = .000), from CRF

to PFS (b = -6.06; p = .000), from PSE for fatigue management to PFS while controlling for CRF (b = 1.81; p = .006), and from CRF to PFS while controlling for PSE for fatigue management (b = -5.34; p = .000). Note that the previously direct relationship between CRF and PFS was reduced after PSE for fatigue management was controlled. Results of the Sobel Test indicated that this indirect effect was significant (t = -2.59; p = .009). The results support a partial mediation model accounting for 12% of the total mediated effect.

Table 17

Mediation Analysis for the Total Sample ($N = 298$)

Paths	*b*	*se*	*t*	*p*	R^2	*F*	*df*	*p*
CRF to PSE for Fatigue Management	-.40	.05	-7.32	.000	.15	53.64	1, 296	.000
CRF to PFS	-6.06	.62	-9.81	.000	.25	96.30	1, 296	.000
PSE for Fatigue Management to PFS while Controlling for CRF	1.81	.66	2.77	.006	.27	53.07	2, 295	.000
CRF to PFS while Controlling for PSE for Fatigue Management	-5.34	.66	-8.05	.000	.27	53.07	2, 295	.000
Sobel Test	Partial mediation model accounting for 12% of the total mediated effects ($t = -2.59$; $p = .009$).							

b = Unstandardized regression coefficient.

Research Question #5: Does mediation differ in persons with LC as compared to OC when evaluating PSE for fatigue management as a mediator between the relationship of CRF severity and PFS?

Persons with Other Cancer Diagnoses

Similar to the total sample, the results from the regression analyses for the OC group indicated that PSE for fatigue management partially mediated the relationship between CRF and PFS (see Table 18). Significant paths were demonstrated from CRF to PSE for fatigue management (b = -.43; p = .000), from CRF to PFS (b = -5.93; p = .000), from PSE for fatigue management to PFS while controlling for CRF (b = 1.68; p = .015), and from CRF to PFS while controlling for PSE for fatigue management (b = -5.209; p = .000). The previously direct relationship between CRF and PFS for persons with OC was reduced after PSE for fatigue management was controlled demonstrating partial mediation. The results of the Sobel Test indicated that this indirect effect was significant (t = -2.32; p = .020) supporting a partial mediation model accounting for 12% of the total mediated effect.

Table 18

Mediation Analysis for Persons with Other Cancer Diagnoses ($N = 235$)

Paths	*b*	*se*	*t*	*p*	R^2	*F*	*df*	*p*
CRF to PSE for Fatigue Management	-.43	.06	-7.06	.000	.18	49.78	1, 233	.000
CRF to PFS	-5.93	.64	-9.28	.000	.27	86.04	1, 233	.000
PSE for Fatigue Management to PFS while Controlling for CRF	1.684	.67	2.45	.015	.29	46.96	2, 232	.000
CRF to PFS while Controlling for PSE for Fatigue Management	-5.21	.70	-7.48	.000	.29	46.96	2, 232	.000
Sobel Test	Partial mediation model accounting for 12% of the total mediated effects ($t = -2.32$; $p = .020$).							

b = Unstandardized regression coefficient.

Persons with Lung Cancer

After performing the three regression analyses as specified by Baron and Kenny (1986) and Kenny (2005) for persons with LC, the results indicated that PSE for fatigue management partially mediated the relationship between CRF and PFS (see Table 19). Significant paths were demonstrated from CRF to PSE for fatigue management (b = -.26; p = .033), from CRF to PFS (b = -6.60; p = .000), from PSE for fatigue management to PFS while controlling for CRF (b = 3.70; p = .017), and from CRF to PFS while controlling for PSE for fatigue management (b = -5.62; p = .000). The previously direct relationship between CRF and PFS was reduced after PSE for fatigue management was controlled demonstrating partial mediation. The Sobel Test showed that this indirect effect was not significant (t = -1.63; p = .104). However, the results of the Sobel Test are tenuous since the LC group had a shortfall of the number of cases recommended for calculating this test, 63 persons with LC as opposed to 200 persons. The Sobel Test is calculated from the unstandardized regression coefficients and standard errors of these coefficients from the path evaluating CRF to PSE for fatigue management and the path evaluating PSE to PFS. The observed power to detect an effect within these two paths for the total sample (N = 298) and for the OC group was statistically powerful, with an observed power of 1.0. Conversely, for the LC group (N = 63) the observed power to detect an effect was lower, with the observed power in the path from CRF to PSE for fatigue management .574 and the observed power in the path from PSE to PFS .893.

Summary of Results for Research Question #5

For the LC and OC groups separately, the hypothesis of mediation from CRF to PFS through PSE for fatigue management was tested showing significant support for partial mediation.

Table 19

Mediation Analysis for Persons with Lung Cancer ($N = 63$)

Paths	*b*	*se*	*t*	*p*	R^2	*F*	*df*	*p*
CRF to PSE for Fatigue Management	-.26	.12	-2.182	.033	.07	4.76	1, 61	.033
CRF to PFS	-6.60	1.49	-4.43	.000	.24	19.62	1, 61	.000
PSE for Fatigue Management to PFS while Controlling for CRF	3.70	1.52	2.44	.017	.31	13.60	2, 60	.000
CRF to PFS while Controlling for PSE for Fatigue Management	-5.62	1.49	-3.78	.000	.31	13.60	2, 60	.000
Sobel Test	$t = -1.63; p = .104$							

b = Unstandardized regression coefficient.

Research Question #6: What is the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE to the PFS of persons with cancer (LC and OC)?

Hierarchical multiple regression analysis was performed to examine how most of the variance in PFS can be explained by blocks of independent variables, over and above that explained by an earlier block of independent variables. The theoretical framework for this dissertation project guided the statistical model and the decision-making of when and which independent variables were to be entered into the hierarchical model.

In sequential order, the independent variables were entered in six separate blocks: Block I: Contextual Patient Characteristics [race; marital status; level of education achieved; employment data including whether a person was retired, receiving disability, was on a temporary leave from employment, and whether they had to quit employment; annual combined household income; health insurance data including whether or not a person with cancer had health insurance and if so, who held the policy (patient or spouse), and the type of health insurance policy held (private, Medicare, or Medicaid)]; Block II: Physiological Patient Characteristics [type of cancer; stage of cancer; co-morbid conditions; age; and sex]; Block III: Type of Treatment Requiring Statistical Control [receiving radiation therapy treatment; surgery prior to chemotherapy which includes four groups (yes had surgery; don't know if had surgery; this response choice was not selected; no surgery and this group served as the reference group when the groups were dummy coded, i.e., group left out); surgery during chemotherapy which includes three groups (yes had surgery; this response choice was not selected; no surgery and this group served as the reference group when the groups were dummy coded, i.e., group left out)];

Block IV: PSE for Fatigue Management; Block V: Other Unpleasant Symptoms Total Severity; and Block VI: Total CRF Severity.

Impact of Variables on PFS for Persons with Cancer

The results of hierarchical multiple regression analysis is shown in Table 20. An apriori power analysis was conducted showing that when all 28 predictors were entered into Block VI with a power set at 0.80 and an alpha level at .05, small effects (.09) could be detected in a sample of 298 persons with cancer.

Block I (Contextual Patient Characteristics). The first block of the independent variables, contextual patient characteristics, were entered to create Model 1. These variables explained 10.4% of the variance in PFS of persons with cancer [F (14, 281) = 2.32, p = .005]. Receiving disability was the only contextual patient characteristic that demonstrated a statistically significant relationship with PFS. Consequently, persons receiving disability predicted a lower PFS.

Block II (Physiological Patient Characteristics). When the physiological patient characteristics were entered in the second block, type of cancer and co-morbid conditions demonstrated a statistically significant relationship with PFS, and the percent of explained variance increased by 13.7% [F (5, 276) = 10.03, p = .000] to 24.1% [F (19, 276) = 4.62, p = .000]. None of the contextual patient characteristics made a significant contribution to PFS in this second model. Thus, in Model 2, persons with LC as opposed to OC diagnoses, and persons with greater co-morbid conditions predicted lower PFS.

Block III (Type of Treatment Requiring Statistical Control). Type of cancer and co-morbid conditions remained statistically significant in predicting lower PFS after entry of the third block of variables. There was no statistically significant increase in the percent

of explained variance of PFS by 1.9% [F (6, 270) = 1.12, p = .353] to 26% [F (25, 270) = 3.79, p = 000]. None of the treatment variables requiring statistical control entered in the third block were statistically significant in predicting PFS.

Block IV (PSE for Fatigue Management). Entering PSE for fatigue management in the fourth block resulted in a statistically significant positive relationship with PFS. Also found in the fourth block was a model which predicted lower PFS for persons who had surgery prior to chemotherapy. Type of cancer and co-morbid conditions also remained statistically significant predictors to lower PFS as well. From Model 3 to Model 4 there was a 9.1% [F (1, 269) = 37.64, p = .000] increase in the explained variance of PFS to 35.1% [F (26, 29) = 5.59, p = .000].

Block V (Other Unpleasant Symptoms Total Severity). When the other unpleasant symptoms as measured by their total symptom severity score was added in the fifth block to create Model 5, the variables that were in Model 4 continued to remain statistically significant. Additionally, the results showed that the greater the severity of the other unpleasant symptoms, the lower the PFS. The explained variance in PFS in Model 5 increased by 6.9% [F (1, 268) = 31.88, p = .000] to 42% [F (27, 268) = 7.18, p = .000].

Block VI (Total CRF Severity). The sixth and final model commenced with the addition of total CRF severity and resulted in an increase in the explained variance of PFS by 5.7% [F (1, 267) = 29.04, p = .000] to 47.7% [F (28, 295) = 8.68, p = .000]. Like Models 4 and 5, the following variables continued to remain statistically significant in the sixth and final model: type of cancer, co-morbid conditions, having surgery prior to chemotherapy, PSE for fatigue management, and the total symptom severity of the other unpleasant symptoms.

Summary of the Results for Research Questions #6

Through blockwise, hierarchical multiple regression, similar levels of CRF severity were found to significantly worsen the PFS of persons with LC as compared to OC diagnoses ($t = -3.78$). In addition to type of cancer diagnoses, five other factors in the total sample were identified through blockwise, multiple hierarchical regression as the most important factors accounting for 47.7% of the explained variance in PFS [$F(28, 295) = 8.68$, $p = .000$]. Specifically, higher levels of PSE for fatigue management ($t = 3.55$) were found to be one of the strongest predictors of greater PFS, while lower levels of PFS were predicted by greater total CRF severity ($t = -5.39$), greater number of co-morbid conditions ($t = -4.20$), greater total symptom severity ($t = -2.46$), and having surgery prior to chemotherapy ($t = -2.31$).

Table 20

Results of a Hierarchical Multiple Regression Analysis of the Tested Effects of Selected Variables on Physical Functional Status of Persons with Cancer ($N = 296$)

	t-values from Raw Score Regression Coefficients					
Variables In The Model	Block I	Block II	Block III	Block IV	Block V	Block VI
Race	1.08	.74	.77	1.0	1.51	1.46
Marital status	1.56	1.18	1.20	1.31	1.04	.89
Level of education achieved	1.60	1.60	1.61	1.80	1.74	1.73
Employment-Retired	.49	-.19	-.02	.08	-.17	.06
Employment-Receiving disability	**2.44**	1.25	1.19	1.46	1.27	1.34
Employment-Temporary leave from work	-.40	.30	.11	-.12	-.11	-.06
Employment- Had to quit work	.71	1.11	1.10	1.15	1.15	1.16
Annual combined household income	1.05	.35	.30	.18	.04	.34
Health insurance-Possessed insurance	1.16	.40	.61	.37	-.04	-.06
Health insurance-Patient holds policy	-.04	.26	.40	-.00	.18	.42
Health insurance-Spouse holds policy	-.76	-.29	-.18	-.50	-.26	.09

Table 20 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
Health insurance-Private policy held	1.48	1.08	1.23	.90	.72	.71
Health insurance-Medicare policy held	-.86	.65	.72	.83	.63	.53
Health insurance-Medicaid policy held	1.06	.81	.80	.39	.38	.48
Type of cancer		**-3.10**	**-3.50**	**-4.33**	**-3.82**	**-3.78**
Stage of cancer		-.57	-.31	.07	.29	.71
Co-morbid conditions		**-5.10**	**-4.88**	**-4.61**	**-4.75**	**-4.20**
Age		-.57	-.34	-.59	-.83	-1.06
Sex		-1.88	-1.88	-1.5	-1.73	-1.39
Receiving radiation therapy			-.05	.35	.26	.01
Surgery prior to chemo-Yes received			-1.89	**-2.65**	**-2.78**	**-2.31**
Surgery prior to chemo-Don't know			-.61	-.79	.13	.19
Surgery prior to chemo-Not selected			-.54	-.90	-.84	-1.16
Surgery during chemo-Yes received			.51	.39	.73	.91

Table 20 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
Surgery during chemo-Not selected			-1.10	-.42	-.40	-.15
PSE for fatigue management				**6.14**	**5.63**	**3.55**
Other unpleasant symptoms total severity					**-5.65**	**-2.46**
Total CRF severity						**-5.39**
Cumulative percent of explained variance by R^2	**10.4%**	**24.1%**	**26%**	**35.1%**	**42%**	**47.7%**

Values in bold are significant ($p < .05$).

Research Question #7: Considering the unique contribution of physiological and contextual characteristics, CRF, other unpleasant symptoms, and PSE for fatigue management to PFS, how does having a cancer diagnosis of LC compare with OC diagnoses as a predictor of PFS?

In Research Question #6 it was found that after entering the block of physiological patient characteristics from Model 2 through Model 6 that the type of cancer diagnoses (LC versus OC diagnoses) made a statistically significant contribution to the explained variance of PFS. Specifically, it was found that having LC as compared OC diagnoses predicted lower PFS. As a result of this finding, hierarchical multiple regression analysis was performed separately on groups of cancer patients, those with LC and those with OC diagnoses. The procedures used for hierarchical multiple regression analysis with the total sample was also used for persons with LC and OC diagnoses.

Impact of Variables on PFS of Persons with OC Diagnoses

An apriori power analysis was conducted which revealed that in Block VI small effects (.11) could be detected with a sample size of 235 persons with OC diagnoses, the use of 27 predictors from an alpha level of .05 with power set at .80 (Erdfelder et al., 1996). The results of hierarchical multiple regression analysis is shown in Table 21.

Block I (Contextual Patient Characteristics). Model 1 was not statistically significant with the entry of the first block of variables, the contextual patient characteristics [$F(14, 218) = 1.48, p = .119$].

Block II (Physiological Patient Characteristics). Unlike Model 1, with the addition of the second block of variables, Model 2 was statistically significant to explain 18.5% [$F(18, 214) = 2.70, p = .000$] of the variance in the PFS of persons with OC diagnoses.

Co-morbid condition was the only variable out of the contextual and physiological patient characteristics that demonstrated a statistically significant relationship with PFS. Thus, the greater the number of co-morbid conditions, the lower the PFS of persons with OC diagnoses.

Block III (Type of Treatment Requiring Statistical Control). With the addition of the third block of variables which created Model 3, there was not a statistically significant increase in the explained variance [F (6, 208) = .815, p = .560]. None of the new variables entered, the type of treatment variables requiring statistical control, were statistically significant in predicting PFS. Co-morbid condition sustained statistical significance from Model 2 to Model 3 in accounting for 20.3% of the variance in PFS of persons with OC diagnoses [F (24, 208) = 2.21, p = .002].

Block IV (PSE for Fatigue Management). With the entry of the fourth block, PSE for fatigue management, there was a significant increase by 9.4% [F (1, 207) = 27.84, p = .000] in the explained variance of PFS in persons with OC diagnoses from Model 3. Consequently, Model 4 explained 29.8% [F (25, 207) = 3.51, p = .000] of the variance in PFS in persons with OC diagnoses. Specifically, in Model 4, PFS was found to be lower in persons who had a greater number of co-morbid conditions, and higher in persons with greater PSE for fatigue management.

Block V (Other Unpleasant Symptoms Total Severity). With the addition of the other unpleasant symptoms as measured by the total symptom severity score in the fifth block to create Model 5, the variables that were in Model 4 continued to remain statistically significant. Additionally, the results showed that the greater the severity of the other unpleasant symptoms, the lower the PFS. The explained variance in PFS in Model 5

increased by 7.4% [F (1, 206) = 24.37, p = .000] from Model 4 to 37.2% [F (26, 206) = 4.70, p = .000].

Block VI (Total CRF Severity). In the final model, Model 6, with the addition of the sixth block consisting of the variable total CRF severity, the explained variance of PFS increased by 6.3% [F (1, 205) = 22.71, p = .000] to 43.5% [F (27, 205) = 5.84, p = .000]. Similar to Models 4 and 5, the following variables continued to remain statistically significant in the final model: co-morbid conditions and PSE for fatigue management. The other unpleasant symptoms as measured by the total symptom severity was not statistically significant t = -1.96, p = .051).

Table 21

Results of a Hierarchical Multiple Regression Analysis of the Tested Effects of Selected Variables on Physical Functional Status of Persons with Other Cancer Diagnoses ($N = 235$)

	t-values from Raw Score Regression Coefficients					
Variables In The Model	Block I	Block II	Block III	Block IV	Block V	Block VI
Race	.17	.46	.44	.67	1.22	1.06
Marital status	1.61	1.00	.82	1.10	1.08	.83
Level of education achieved	1.51	1.71	1.76	1.74	1.49	1.46
Employment-Retired	1.32	.38	.58	.69	.37	.51
Employment-Receiving disability	.12	.98	.86	.96	.64	.83
Employment-Temporary leave from work	.62	.81	.70	.75	.70	.78
Employment- Had to quit work	1.50	1.34	1.59	1.58	1.72	1.51
Annual combined household income	.27	.20	.23	-.05	-.08	.21
Health insurance-Possessed insurance	.05	.36	.57	.30	-.18	-.17
Health insurance-Patient holds policy	-.27	.14	.18	-.02	.29	.20
Health insurance-Spouse holds policy	-1.05	-.19	-.16	-.39	-.01	.16

Table 21 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
Health insurance-Private policy held	.22	.36	.60	.15	-.33	-.10
Health insurance-Medicare policy held	.02	1.01	1.23	1.19	.89	.78
Health insurance-Medicaid policy held	.000	.04	.17	-.46	-.70	-.40
Stage of cancer		-.66	-.59	-.03	.22	.73
Co-morbid conditions		**-4.38**	**-4.11**	**-3.82**	**-3.85**	**-3.23**
Age		-.54	-.42	-.64	-.93	-1.14
Sex		-1.38	-1.11	-.76	-1.12	-.85
Receiving radiation therapy			.77	.88	.59	.68
Surgery prior to chemo-Yes received			-.74	-1.43	-1.63	-1.22
Surgery prior to chemo-Don't know			-.35	-.56	.32	.28
Surgery prior to chemo-Not selected			.84	.66	.67	.45
Surgery during chemo-Yes received			.16	.25	.63	.76
Surgery during chemo-Not selected			-1.61	-1.06	-.99	-.70

Table 21 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
PSE for fatigue management				**5.28**	**4.82**	**2.85**
Other unpleasant symptoms total severity					**-4.94**	-1.96
Total CRF severity						**-4.77**
Cumulative percent of explained variance by R^2	8.7%	**18.5%**	**20.3%**	**29.8%**	**37.2%**	**43.5%**

Values in bold are significant ($p < .05$).

Impact of Variables on PFS of Persons with LC

Unlike the hierarchical models produced in the total sample and persons with OC diagnoses, the sample size for persons with LC was substantially smaller. As a result, the apriori power and subsequent ability to detect effects was devalued. With the inclusion of 26 predictors, a power set at .80 and an alpha level at .05, a large effect of .57 can be detected with a sample size of 63 (Erdfelder et al., 1996). Nonetheless, a decision was made to continue with the hierarchical multiple regression modeling analysis knowing that the lower sample size would contribute to a lack of precision. The results of hierarchical multiple regression analysis for persons with LC is shown in Table 22.

Block I - Block III (Contextual and Physiological Patient Characteristics, and Type of Treatment Requiring Statistical Control). The blocks of variables found in Model 1 [$F(13, 49) = 1.28, p = .256$], Model 2 [$F(17, 45) = 1.33, p = .218$], and Model 3 [$F(23, 39) = 1.71, p = .069$] were found to have no overall relationship with the PFS in persons with LC.

Block IV (PSE for Fatigue Management). With the entry of the fourth block, PSE for fatigue management, Model 4 explained 36.3% of the variance in PFS in persons with LC [$F(24, 38) = 2.48, p = .000$]. Specifically, this model predicted lower PFS for persons who were Caucasian as compared to other races; persons who said they had surgery prior to chemotherapy; and, persons who did not report whether or not they had surgery prior to chemotherapy. This model also predicted greater PFS in persons who reported having a private or Medicaid insurance policy; and for those persons who had greater PSE for fatigue management. Unlike the models produced for the total sample and persons with

OC diagnoses, these findings which impact PFS are new with one exception, the influence of PSE for fatigue management.

Block V (Other Unpleasant Symptoms Total Severity). When the other unpleasant symptoms as measured by the total symptom severity score was added in the fifth block to create Model 5, the variables that were in Model 4 continued to remain statistically significant. In Model 5, lower PFS was also predicted if a person had a greater number of co-morbid conditions, was receiving disability, had to quit work, or had a greater total symptom severity score. Similar to the total sample and persons with OC diagnoses, the other unpleasant symptoms experienced by persons with LC were statistically significant in predicting PFS in Model 5. Consequently, the variables in Model 5 account for 48.3% of the variance in PFS in persons with LC [F (25, 37) = 3.31, p = .000].

Block VI (Total CRF Severity). In the final model, after total CRF severity was entered to create Model 6, the following variables continued to remain statistically significant since Block 4 in predicting PFS in persons with LC: race; holding a private or a Medicaid insurance policy; persons who did not report whether or not they had surgery prior to chemotherapy; and PSE for fatigue management. Unlike the total sample, the other unpleasant symptoms (t = -1.69) and total CRF severity (t = -1.87) were not significant variables in predicting PFS in persons with LC. Model 6 accounted for 51.5% of the variance in the prediction of PFS in persons with LC [F (26, 36) = 3.53, p = .000).

Summary of the Results for Research Question #7

Perceived self-efficacy for fatigue management significantly contributed to greater PFS in both persons with LC and OC diagnoses. A greater number of co-morbidities and a greater total severity of the other unpleasant symptoms were found to lower PFS in both

groups, persons with LC and OC diagnoses. Greater cancer-related fatigue severity was found to predict lower PFS only in persons with OC diagnoses. The LC group had race, insurance, and employment related variables identified as predictors of PFS that were unique to this group alone.

Table 22

Results of a Hierarchical Multiple Regression Analysis of the Tested Effects of Selected Variables on Physical Functional Status of Persons with Lung Cancer ($N = 63$)

	t-values from Raw Score Regression Coefficients					
Variables In The Model	Block I	Block II	Block III	Block IV	Block V	Block VI
Race	**2.08**	1.57	1.64	**2.04**	**2.17**	**2.13**
Marital status	.88	.68	1.00	.98	.01	.17
Level of education achieved	-.24	-.17	-.23	.12	.68	.70
Employment-Retired	-.19	-.57	.04	.38	.55	.55
Employment-Receiving disability	**2.12**	1.30	1.59	1.83	**2.07**	1.67
Employment-Temporary leave from work	-1.74	-1.07	-.84	-1.18	-.59	-.68
Employment- Had to quit work	-1.35	-1.20	-1.61	-1.48	**-2.57**	-1.81
Annual combined household income	.34	-.03	.34	.74	.60	.915
Health insurance-Patient holds policy	.14	.43	.16	-.30	-.36	.21
Health insurance-Spouse holds policy	-.60	-.71	-.83	-1.11	-1.70	-1.55
Health insurance-Private policy held	**2.03**	1.74	**2.42**	**2.54**	**3.47**	**2.85**

Table 22 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
Health insurance-Medicare policy held	-.75	-.65	-1.01	-.91	-1.45	-1.44
Health insurance-Medicaid policy held	1.78	1.41	1.78	**2.13**	**2.50**	**2.22**
Stage of cancer		-.58	.63	.35	.48	.18
Co-morbid conditions		-1.80	**-2.26**	-1.80	**-2.03**	-1.72
Age		-.35	-.17	-.01	.14	.09
Sex		-.48	-.14	.12	.17	.44
Receiving radiation therapy			-1.4	-1.12	-1.07	.16
Surgery prior to chemo-Yes received			**-2.17**	**-2.44**	**-2.18**	-1.63
Surgery prior to chemo-Don't know			.61	.83	.79	1.01
Surgery prior to chemo-Not selected			**-2.36**	**-2.89**	**-3.18**	**-3.44**
Surgery during chemo-Yes received			1.00	.43	.24	.08
Surgery during chemo-Not selected			-.10	.37	.22	.08

Table 22 Continued

Variables In The Model	*t*-values from Raw Score Regression Coefficients					
	Block I	Block II	Block III	Block IV	Block V	Block VI
PSE for fatigue management				**3.25**	**3.29**	**2.93**
Other unpleasant symptoms total severity					**-3.12**	-1.69
Total CRF severity						-1.87
Cumulative percent of explained variance via Adjusted R^2	5.6%	8.3%	20.8%	**36.3%**	**48.3%**	**51.5%**

Values in bold are significant ($p < .05$).

Research Question #8: Through the employment of a Path Model, is the PFS of persons with cancer (LC and OC) predicted through physiological and contextual patient characteristics, CRF, other unpleasant symptoms, and PSE for fatigue management?

Testing of the exogenous-endogenous initial model started with 16 exogenous variables for the prediction of total CRF severity. The 16 exogenous variables included physiological patient characteristics (type of cancer; stage of cancer; surgery prior to chemotherapy; surgery during chemotherapy; co-morbid conditions; sex; and age) and contextual patient characteristics (marital status, level of education, employment data including whether a person was retired, receiving disability, and whether they had to quit employment; annual combined household income; and the type of health insurance policy held [private, Medicare, and Medicaid]).

The model was initially tested as conceptually depicted in Figure 2 to examine the overall fit. While a converged solution was obtained, the fit of the model was not acceptable (Satorra-Bentler Scaled Chi-Square 185.5; $p = 0.00$; $df = 50$; RMSEA = .098). Driven by model fitting measures which included evaluation of parameter estimates, modification indexes, goodness-of-fit-tests, and following the theoretical framework of the study, modifications were made to attain a parsimonious final solution.

First, the model was simplified by trimming 13 out of 16 nonsignificant paths one at a time from the exogenous variables to the total CRF severity. This resulted in three significant paths, the effect of age ($t = -2.01$), co-morbid conditions ($t = 3.14$), and sex ($t = 2.42$) on the total CRF severity. Two insignificant paths were retained, the effects of stage of cancer ($t = 1.95$) and having surgery prior to chemotherapy ($t = 1.60$) on the total CRF severity since the elimination of their effects revealed that the fit of the model was

significantly worse without the two paths. Subsequently, the model fit was improved (Satorra-Bentler Scaled Chi-Square = 116.14; $p = 0.00$; $df = 17$; RMSEA = .14; CFI = .76).

Next, the effect of having surgery prior to chemotherapy on the total severity of the other unpleasant symptoms was added based upon model fitting measures, particularly the modification index (5.93). The addition of this effect, having surgery prior to chemotherapy ($t = -2.67$) on the total severity of the other unpleasant symptoms improved model fit (Satorra-Bentler Scaled Chi-Square = 109.50; $p = 0.00$; $df = 16$; RMSEA = .14; CFI = .77).

Furthermore, the initial model depicted the total severity from both CRF and the other unpleasant symptoms as non-recursive. The effect of total CRF severity on the total severity of the other unpleasant symptoms was significant ($t = 2.07$), but the effect of the total severity of the other unpleasant symptoms was not significant ($t = 1.16$). However, the model fitting measures indicated that when eliminating the effect of the other unpleasant symptoms on CRF while retaining the effect of CRF on the other unpleasant symptoms, the model fit was improved (Satorra-Bentler Scaled Chi-Square 109.5; $p = 0.00$; $df = 16$; RMSEA = .14; CFI = .77). Consequently, the non-recursive relationship between total CRF severity and the total severity of the other unpleasant symptoms was modified to a single direct path from total CRF severity to the total severity of the other unpleasant symptoms ($t = 9.69$).

Last, model fitting measures indicated an improved model fit with the addition of three paths. First, the effect of total CRF severity on PFS was added based upon a high level modification index (54.16) which resulted in improvement of the model fit

(Satorra-Bentler Scaled Chi-Square 64.73; $p = 0.00$; $df = 16$; RMSEA = .10; CFI = .88). Adding this path from total CRF severity on PFS significantly contributed to the model ($t = -8.01$). The second path, the effect of the total symptom severity on PFS, was added based upon a high level modification index (6.72). The addition of this path ($t = -2.69$) also improved the model fit (Satorra-Bentler Scaled Chi-Square 58.49; $p = 0.00$; $df = 15$; RMSEA = .10; CFI = .89). The last path, the effect of co-morbid conditions on PFS, was added based upon a high level modification index (40.26). The addition of this significant path ($t = -7.47$) resulted in the final parsimonious model (Satorra-Bentler Scaled Chi-Square 17.76; $p = .22$; $df = 14$; RMSEA = .03; the lower bound 90% CI = 0.00; and CFI = .99) (see Figure 3).

Consequently, the direct paths in the final model demonstrate the following for persons with cancer (LC and OC diagnoses): younger age ($t = -2.18$), greater co-morbid conditions ($t = 3.36$), and being female as compared to male ($t = 2.11$) predicts greater total CRF severity. Having surgery prior to chemotherapy ($t = -2.85$) predicts greater total severity from the other unpleasant symptoms. Greater total CRF severity predicts both greater total severity from the other unpleasant symptoms ($t = 9.69$) and lower PSE for fatigue management ($t = -7.02$). Greater PSE for fatigue management predicts greater PFS ($t = 2.87$). Lastly, lower PFS was predicted by greater number of co-morbid conditions ($t = -7.47$), greater total CRF severity ($t = -5.30$), and greater total severity from the other unpleasant symptoms ($t = -2.71$) (see Figure 3).

Figure 2. Conceptual Model for Path Analysis

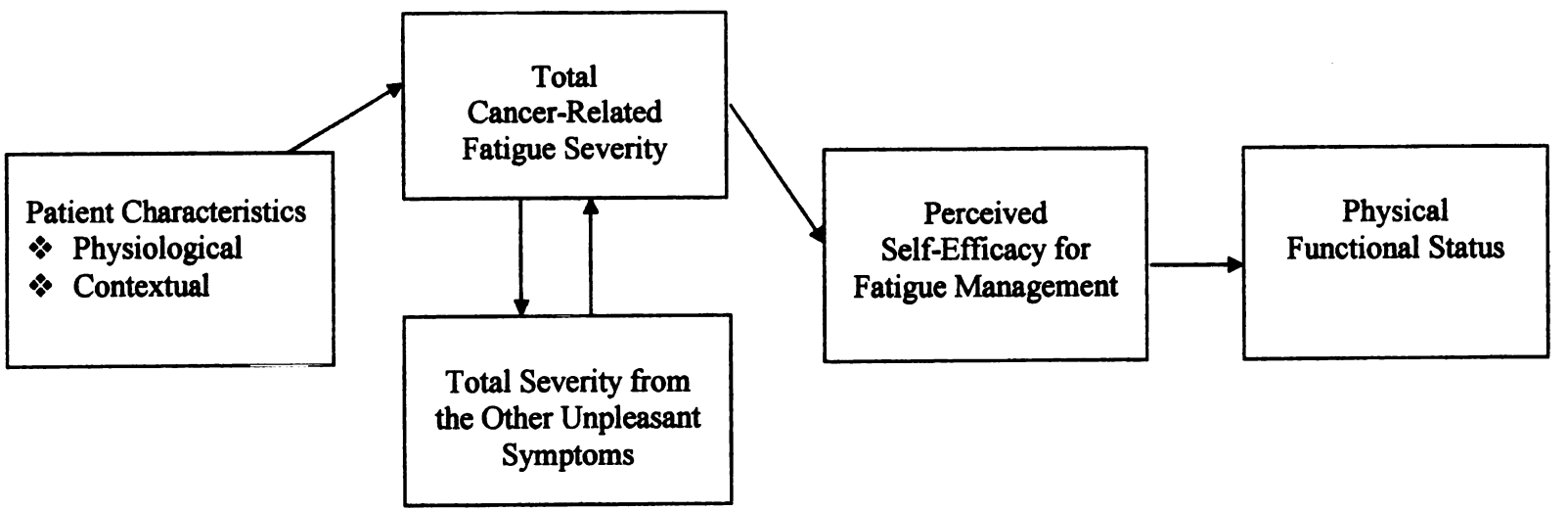
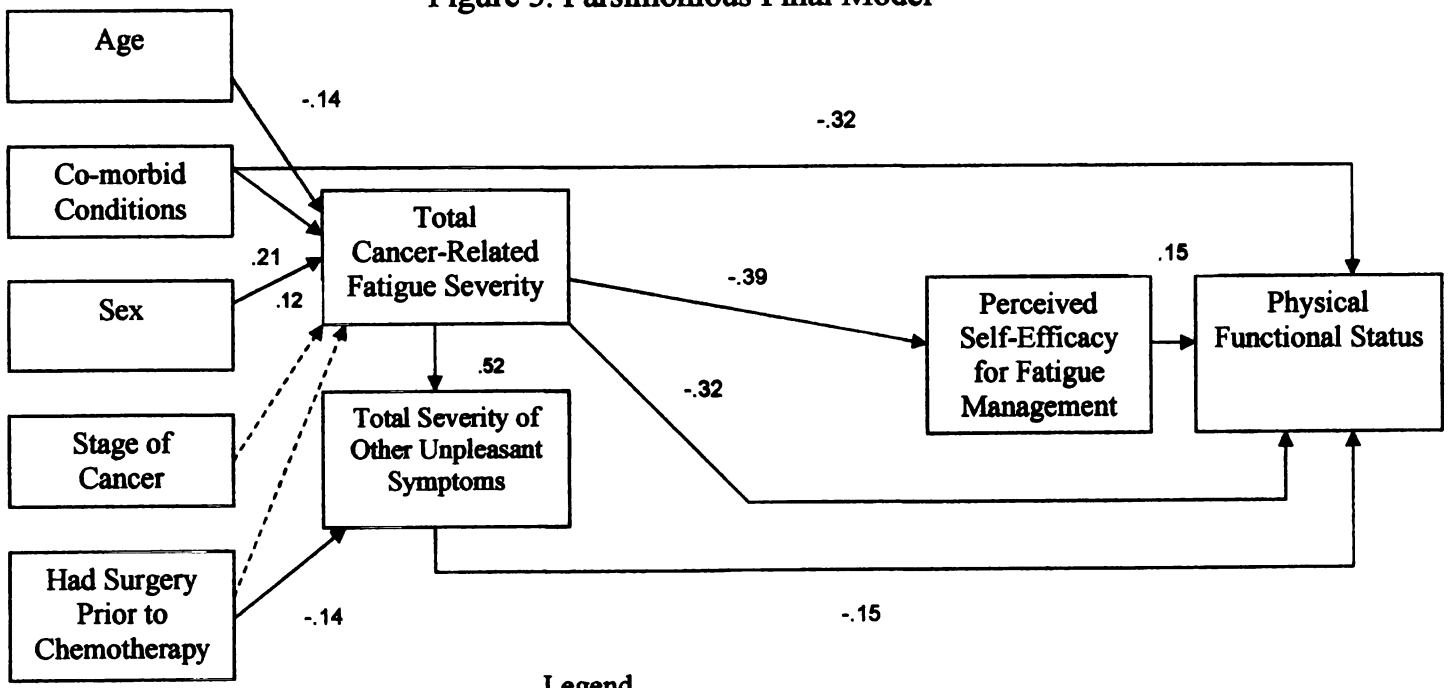


Figure 3. Parsimonious Final Model



Legend

- Solid line means a significant path (t > -/+ 2.0).
- Dashed line means a nonsignificant path (t < 2.0).
- The numerical values represent standardized path coefficients.

- Satorra-Bentler Scaled Chi-Square 17.76; p = .22; *df* = 14; RMSEA = .03; RMSEA lower bound 90% CI = 0.00; and CFI = .99

CHAPTER FIVE

DISCUSSION

This study focused on a person's perceived self-efficacy (PSE) to manage fatigue and analyzed how PSE to manage fatigue impacts the physical functional status (PFS) in persons with cancer, with particular concentration on the lung cancer (LC) population. This study also included an examination of the physiological and contextual characteristics and other unpleasant symptoms of persons with cancer in relation to the phenomenon of the cancer-related fatigue (CRF) experience. The theoretical framework for this study was a synthesis of the Theory of Unpleasant Symptoms with Self-Efficacy Theory and this theoretical framework was used to examine the relationships among the variables. In Chapter Five, the study findings will be presented in relation to the literature as guided by the theoretical framework for this study. This will include discussions on the total sample comprised of all persons with cancer ($N = 298$) and discussions on those in the group with LC ($N = 63$) and those with other cancer (OC) ($N = 235$) diagnoses. A summary of similarities and differences between all three groups are also presented.

Following the theoretical framework, the first set of findings presented will be those related to the relationship between the patient characteristics, other unpleasant symptoms, and PSE for fatigue management to the prediction of cancer-related fatigue (CRF) severity.

Discussion of the Study Findings

Relationship between Patient Characteristics, Other Unpleasant Symptoms, and PSE for Fatigue Management to the Prediction of CRF

Following the theoretical framework, the study began by identifying physiological and contextual patient characteristics that predict CRF.

Persons with Cancer (Total Sample)

In this study, a model was derived which accounted for 37.4% of the explained variance in CRF severity in persons with cancer. This model consisted of four statistically significant predictors which are in order of greatest to least in the prediction of greater total CRF severity: greater total symptom severity of the other unpleasant symptoms, a lower level of PSE for fatigue management, a greater number of co-morbid conditions, and women as compared to men (sex), and one statistically insignificant predictor (i.e., age). Moreover, all predictors taken together as a whole not only predicted CRF severity, but also each predictor individually predicted CRF severity in persons with cancer. The identification of these variables helps to delineate patients who are at risk for the development of CRF.

Total symptom severity of the other unpleasant symptoms. The presence of multiple occurring symptoms is common in persons with cancer. In this study, out of 16 possible symptoms, including fatigue, the total mean number of symptoms reported by persons with cancer at the baseline interview was 7.4, with no significant differences in the mean number of symptoms between LC and OC diagnoses. Hence, in accordance with the Theory of Unpleasant Symptoms (TOUS), symptoms are almost never expressed in isolation. This previous statement is clinically salient since symptoms are likely to

catalyze and reinforce each other worsening the severity of other individual symptoms. Parallel to the TOUS, this study demonstrates that greater total symptom severity from the other unpleasant symptoms is the strongest predictor to greater CRF severity. In this study, the odds of persons with cancer having a total symptom severity score from the other unpleasant symptoms of 6 or greater (scale of 1-10, 10 most severe) were 4.3 times greater for those that had a CRF severity score of 7 or greater versus those that had a CRF severity score of less than 7. Consequently, the higher the total symptom severity score from the other unpleasant symptoms, the greater the likelihood of having increased CRF severity. As a result, symptom management of CRF would be best managed if the patient's other unpleasant symptoms are taken into consideration.

PSE for fatigue management. According to Bandura (1997), persons with high levels of PSE are able to exert control over threats such as unpleasant symptoms like CRF. As described in Chapter 2, investigations have shown the critical role PSE plays in the achievement of symptom management and functional ability for persons with chronic health conditions. Additionally, few studies have been conducted relative to PSE and symptom management in the general cancer population. This study demonstrates that a lower level of PSE for fatigue management is the second strongest predictor to greater CRF in persons with cancer. Bandura states that achieving goals such as CRF management requires an action plan that a person is certain he or she can achieve (1997). In this study, the mean PSE for fatigue management score reported by persons with cancer was 6 on a scale of 0 to 10, with higher scores indicating greater PSE for fatigue management. Moreover, in this study, the odds show that persons with a PSE to manage fatigue of less than 8 are two times greater of having CRF severity of 7-10 (1-10 scale, 10

= most severe) compared with those having a PSE to manage fatigue of 8 or more. Parallel with Bandura, PSE for fatigue management is a person's perception of ability to execute behavior(s) to manage his or her CRF (1997). Bandura advises that a certain threshold of PSE for CRF management is required to attempt a course of action. The stronger the sense of PSE, the greater the perseverance and the higher the likelihood that the chosen activity will be performed successfully (Bandura, 1997). Therefore, according to the findings of this study, if the strength of the PSE for fatigue management is less than 8, action should be taken to increase PSE to 8 or greater and if an action plan is in place, it may need to be adjusted so it is more realistic to achieve success.

Co-morbid conditions. Those persons with two or more co-morbid conditions were found to have nearly twice the likelihood of having a higher level of CRF severity than those with less than two co-morbid conditions. This parallels the work of two groups of researchers who found that in persons with cancer, the number of co-morbid conditions influence CRF (C. Given et al., 2001; Reyes-Gibby, Aday, Anderson, Mendoza, & Cleeland, 2006). Symptoms from co-morbid conditions may develop and subsequently interact and catalyze the effects of a person's symptoms from cancer and cancer treatment. Such a scenario may interfere with a patient's ability to tolerate treatment. Thus, understanding the effect of co-morbid conditions among cancer diagnosis on their ability to achieve symptom management, such as with CRF, is essential to optimize PFS.

Sex. This study found that sex was predictive of greater CRF severity. In fact, when compared with men, women were twice as likely to experience CRF severity at a level of 7 to 10 (on a 1 to 10 scale) as compared with a score ranging from 1 to 6. Remarkably, few studies to date have targeted differences by sex in the symptom experience of

persons with cancer, particularly LC, and even fewer have focused on specific symptoms such as CRF. This is remarkable given the high prevalence and severity of fatigue in the cancer population across the illness trajectory (Hoffman, Given, von Eye, Gift, & Given, in press; Miaskowski, 2004). Differences in the symptom experience have been found with women reporting more symptoms than men (van Wijk & Kolk, 1997). The inclusion of different types of cancer diagnoses in this study makes it difficult to determine what the reasons are for the difference in CRF by sex. Further sex-based research in this area is required.

Persons with OC Diagnoses

For persons with OC diagnoses, a model was derived which accounted for 42.4% to the prediction of CRF severity. This model consisted of four statistically significant predictors which are in the order of greatest to least strength of prediction of CRF: total symptom severity of the other unpleasant symptoms, PSE for fatigue management, stage of cancer, and co-morbid conditions, and one statistically insignificant predictor (i.e., age). Moreover, all predictors taken together not only predicted CRF severity as a whole, but also each predictor individually predicted CRF severity in persons with OC cancer diagnoses. Knowing these predictors provides insight into the symptom assessment process to provide for comprehensive management of CRF.

Similar to the results of the total sample, predictors to CRF severity in persons with OC diagnoses were a greater total symptom severity, a lower level of PSE for fatigue management, and a greater number of co-morbid conditions. Likewise, the strongest predictor to CRF severity for persons with OC diagnoses was the total symptom severity followed by PSE for fatigue management. In contrast with all persons with cancer, stage

of cancer was found to be predictive of CRF severity for persons with OC diagnoses. Thus, parallel to the results for the total sample, the identification of these variables helps to understand which patients may be at greater risk for the development of CRF.

Stage of cancer. Early stage of cancer in persons with OC diagnoses was predictive of greater CRF severity. The odds of having a CRF severity of 7 to 10 as compared to a severity of 1 to 6 were 1.9 times more likely in persons with an early stage rather than late stage cancer diagnosis. Explaining why persons with other cancers in an early stage experienced greater CRF severity is difficult because the contribution of each patient characteristic may vary between patients with different cancer diagnosis and in the individual patients over the cancer disease and treatment trajectory. Both underlying cancer disease and cytotoxic treatment may cause fatigue and are therefore difficult to separate since they coexist. In this study, the majority of persons with an early stage cancer in the OC diagnoses group were those persons with breast cancer (47 out of 66 patients). The other 19 patients with an early stage cancer represented 7 other cancer diagnoses. A reason why there may be greater report of CRF severity in early stage of the OC group is because early stage cancer is comprised with more women and women have been found to be greater symptom reporters than men (van Wijk & Kolk, 1997).

Additionally, in the best of all subset regression, prior to accounting for PSE for fatigue management and the other unpleasant symptoms, younger age of a person with an OC diagnoses was found to significantly predict greater CRF. However, there was no significant difference between age and stage of cancer (age for early stage: $M = 53$, $SD = 11$; age for late stage: $M = 57$, $SD = 12$) found within the entire OC diagnoses group ($t = 1.80$; $df = 233$; $p = .073$). Age was found to differ significantly between those

who had a breast cancer diagnoses ($M = 53$, $SD = 11$) and those who had a diagnosis other than breast cancer ($M = 58$, $SD = 12$) ($t = 2.67$; $df = 233$; $p = .008$). A recent study conducted by Andrykowski, Schmidt, Salsman, Beacham, and Jacobsen (2005) found that younger age was significantly predictive of prevalent CRF in women who were undergoing adjuvant therapy for early-stage breast cancer. Consequently, younger age of a person with a specific type of cancer diagnosis such as breast cancer may be another factor that explains why early stage of cancer is predictive of greater CRF.

The inclusion criteria for this study required subjects to be undergoing chemotherapy treatment. Early stage breast cancer patients who are undergoing chemotherapy consistently report fatigue (Byar et al., 2006; de Jong et al., 2006; Donovan et al., 2004; Hartvig, Aulin, Hugerth, Wallenberg, & Wagenius, 2006). While OC are more advanced in disease at the time of diagnosis, the chemotherapeutic agent used with them may not result in the same high levels of fatigue. This will be further researched. Also, the positive relationship between the total symptom severity of the other unpleasant symptoms and CRF severity found in this study concur with a recent study that the level of CRF is affected by the presence of other unpleasant symptoms while undergoing chemotherapy (Hartvig et al., 2006).

Persons with LC Diagnosis

For persons with LC, a model was derived which accounted for 34.8% to the prediction of CRF severity. This model consisted of four statistically significant predictors which are in the order of greatest to least strength of prediction of CRF severity: total symptom severity of the other unpleasant symptoms, PSE for fatigue management, patient holding the insurance policy, and having surgery prior to

chemotherapy, and one statistically insignificant predictor (sex). All predictors taken together not only predicted CRF severity as a whole, but also each predictor individually predicted CRF severity in persons with LC.

For persons with LC, like those with OC diagnoses and all persons with cancer, having a greater total symptom severity from the other unpleasant symptoms and a lower level of PSE for fatigue management predicted greater CRF severity. Those two variables represented the strongest influence to the prediction of greater CRF severity in all three groups, LC, OC, and the total sample of persons with cancer.

Contrasted with persons with OC diagnoses and all persons with cancer, unique predictors of greater CRF severity in persons with LC was found when the holder of the insurance policy was the patient and having surgery prior to chemotherapy.

Patient holding the insurance policy. There is little known about the health care coverage of cancer patients and spending practices of those with or without health insurance (Thorpe & Howard, 2003). It is known that insurance coverage has been shown to be greatly associated with the receipt of appropriate health care services (Institute of Medicine, 2004). In the current study, greater CRF severity was found when the patient was the holder of the health insurance policy. As discussed in Chapter 2, persons with LC experience multiple occurring severe symptoms and in this study, persons with LC reported 7.71 concurrent symptoms as compared to 7.37 for persons with OC diagnoses, and had a significantly greater total symptom severity score in comparison to persons with OC diagnosis. Evidence exists that despite the availability of clear national and international practice guidelines for common symptoms, patients continue to suffer from unmanaged symptoms (National Institutes of Health, 2004). Thus, this finding suggests

that barriers may exist to the appropriate receipt of management of even one of the most common symptoms like CRF within the health care delivery system when the patient holds the health insurance policy.

Having surgery prior to chemotherapy. Finally, for persons with LC, having surgery prior to chemotherapy in comparison to those who did not have surgery prior to chemotherapy was found to predict greater CRF severity. In this study, the odds of having CRF severity of 7 to 10 as compared to a severity of 1 to 6 were 3.3 times more likely in persons who had surgery prior to chemotherapy relative to persons who did not have surgery prior to chemotherapy. Note that in this secondary analysis the timing of the surgical procedure was before chemotherapy and consent for entry into the study. Cooley et al. (2003) identified in persons with LC that the frequency of fatigue was the second most distressing symptom following pain after surgical treatment alone, and fatigue was the most frequently distressing symptom reported by persons who had combined treatment for LC. The finding in this present study that having a surgical procedure prior to chemotherapy predicts greater CRF severity affirms the work done by Cooley et al. (2003). It is surprising that this effect shows up even though the type of surgery incorporates a wide variety of procedures from minor to major procedures, and the timing of the surgery in relation to the baseline interview data collection used for analyses of this study is unknown in this secondary data analysis (see Limitation Section). Knowledge of the occurrence/timing of treatments is important for nurses in being able to tailor PSE for fatigue management interventions to be initiated prior to surgery and continued over time until the resolution of CRF.

Summary of the Relationship between the Patient Characteristics, Other Unpleasant Symptoms, and PSE for Fatigue Management to the Prediction of CRF

Similarities and differences in the predictors of greater CRF were found among the three groups (total sample, persons with OC, and persons with LC diagnoses). For all three groups, the strongest predictors of CRF severity were greater total severity from the other unpleasant symptoms and lower PSE for fatigue management. A greater number of co-morbid conditions predicted greater CRF severity for both the total sample and persons with OC diagnoses, but not for persons with LC. In OC diagnoses, an early stage diagnosis as compared to a late stage diagnosis was found to be predictive of CRF severity. Whereas, for persons with LC, holding a health insurance policy and having surgery prior to chemotherapy predicted greater CRF severity. Now that the predictors of CRF severity have been examined, understanding the relationships between CRF and the other unpleasant symptoms will provide the fidelity needed to better understand the interrelationships of the symptoms that effect CRF.

The Symptom Experience and Relationship between CRF and the Other Unpleasant Symptoms from Cancer and Cancer Treatment

The analysis of the symptom experience of persons with cancer (total sample), OC, and LC focused on two dimensions of CRF and the other unpleasant symptoms associated with cancer and cancer treatment, frequency and severity.

Symptom Frequency

Data indicate a relatively high number and variety of symptoms in persons with cancer. Of the 16 symptoms assessed, persons with cancer reported a mean of 7.4 symptoms with no significant differences across the groups and this is similar to the

number of co-occurrences reported in the cancer population (Dodd, Miaskowski, & Lee, 2004; Gift et al., 2004). Fatigue was the most frequently reported symptom occurring in the total sample and those with LC and those with OC diagnoses. The mean number of days that fatigue was reported was five days, with 52% of persons with LC reporting its presence and 45% of persons with OC diagnoses reporting its presence of fatigue on all 7 days. Insomnia was the second most frequently reported symptom reported by all groups, 79% for OC and 68% for LC diagnoses. All groups reported weakness, lack of appetite, nausea, dry mouth, and pain nearly 50% of the time. However, for persons with LC, dyspnea was reported by 64% and cough by 57%, and this is in contrast to the other groups. Statistically significant differences were found in the symptom frequency reported by persons with LC and OC diagnoses. Persons with LC experienced a greater number of days with dyspnea and cough, while persons with OC diagnoses reported a greater number of days with difficulty remembering. While some symptoms are common amongst all persons with cancer, it is important to note that the prevalence of some symptoms are unique to a given cancer diagnosis. These differences need to be anticipated and included in the assessment and management when treating patients with different cancer diagnosis.

Symptom Severity

The individual mean symptom severity reports ran higher for persons with LC as compared to OC diagnoses. This is exemplified in the statistically significant difference found in the total symptom severity score where persons with LC had a higher mean score as compared to OC diagnoses. Also, similar to the symptom frequency reports, the mean severity scores varied by cancer diagnosis. Here one can note that the seventh most

severe symptom for persons with LC, fatigue, has a higher reported mean severity score than that for persons with OC diagnoses who ranked fatigue as the fourth most severe symptom. When assessing the rank order of the mean symptom severity report, one needs to take into account the mean was computed based on those that reported the symptom. Therefore, the mean severity calculations did not take into consideration the frequency of occurrence of the symptom relative to the total in the corresponding sample. When mean severity scores were weighted by frequency of occurrence, fatigue and insomnia were the most severe symptoms in both persons with LC (fatigue M_W = 5.38, insomnia M_W = 3.79) and OC diagnoses (fatigue M_W = 5.10, insomnia M_W = 4.31). Lastly, persons with LC as compared to persons with OC diagnoses reported statistically significant greater mean severity scores for pain and dry mouth, and a mean score that was trending toward statistical significance for weakness (t = - 1.82; p = .07). Understanding that CRF is a severe and frequently occurring symptom and that CRF rarely exits as a lone symptom is key to developing future CRF and other symptom management intervention strategies. In addition, while some of the symptom cluster work that has been done thus far has provided some insight into individual cancer diagnoses, many have conducted investigations on a variety of cancer diagnoses as a whole. The differences in frequency and severity of symptom presentation in different cancer diagnoses makes it clear that in order to map the science it is imperative to look at symptom clusters by cancer diagnosis rather than grouping them altogether.

Correlations among CRF Severity and the Other Unpleasant Symptoms Severity for Persons with LC

Since the focus of this study is centered on the symptom experience of persons with LC, this portion of the discussion will provide a more in depth description of the examination of the correlations between CRF and the individual symptoms of persons with LC. In persons with LC, five symptoms were found to correlate positively with CRF including weakness, dyspnea, dry mouth, nausea, and lack of appetite. All five symptoms also positively correlated with CRF in the total sample and persons with OC diagnoses.

The positive relationship between the severity of CRF and weakness is interesting since it had the strongest correlation among all symptoms in all three cancer groups in this study. Fatigue and weakness are enormous challenges for persons with cancer. Although weakness is consistently reported to be a common symptom in cancer, compared to fatigue, weakness has received little attention. There is a scarcity of literature devoted to the symptom of weakness as it is often used synonymously with fatigue. Clinical practice guidelines have been developed for CRF but not for weakness.

Weakness has been described by Nail and Winningham (1995) as a reduction in muscle strength or endurance below a baseline level. Parallel to Nail and Winningham, Brown (1999) depicted weakness as a physical symptom; Bruera and MacDonald defined weakness as difficulty initiating activity (1988); Barnish (1994) stated weakness was physical inability to perform a task; and Dunlop (1989) depicted weakness as a patient no longer physically able to do what they want to do. In this study, CRF and weakness are shown to coexist in persons with cancer as two separate and related symptoms as

evidenced by their moderate rather than strong correlation coefficient. Further study of fatigue and weakness is merited.

Dyspnea is another symptom that has been reported in persons with LC to be a highly prevalent distressing symptom in persons with LC as compared to OC diagnoses (Cooley et al., 2003; Gift et al., 2004; P Hopwood & Stephens, 1995; Okuyama et al., 2001). The severity associated with dyspnea was found to correlate positively with CRF. The current analysis also reveals that persons with LC significantly experienced dyspnea on more days as compared to persons with OC diagnoses. While Sarna (1998) identified fatigue to be the most severely distressing and persistent symptom over time in 48 persons newly diagnosed with LC with most persons receiving chemotherapy treatment, she also reported dyspnea to be a severely distressing symptom in newly diagnosed persons with LC.

Tanaka, Akechi, Okuyama, Nishiwaki, and Uchitomi (2002b) also identified that dyspnea was a highly prevalent symptom with 55% of 157 outpatients with advanced LC reporting dyspnea interfering with physical and psychological activities of daily living. In later studies, the same researchers reported that symptoms of dyspnea and cough were correlated. Sarna and Brecht (1997) found the correlation between dyspnea and cough in 60 women with advanced LC, and Tanaka et al. found the correlation between dyspnea and cough in 171 outpatients with advanced LC (2002a). While this study did not find cough correlated with dyspnea, it is important to acknowledge that both dyspnea and cough occurred more frequently in persons with LC as compared to OC diagnoses. The current study identifies that for persons with LC, CRF and dyspnea are positively correlated. As with the symptom relationship between CRF and weakness, further

investigation is required between CRF and dyspnea since an interaction and reinforcement of the severity of both symptoms is possible and may negatively impact performance outcomes such as optimizing symptom management and PFS.

Within the current study, the severity associated with the symptom of dry mouth was found to positively correlate with CRF. This symptom, having a dry mouth, has been reported as being common and severe in the LC population as well as OC diagnoses (Gift et al., 2004; P Hopwood & Stephens, 1995; Morita, Tsunoda, Inoue, & Chihara, 1999). The current study is the first to report that dry mouth is associated with CRF. It is possible that this finding may be related to the type of chemotherapeutic agent used in persons with LC.

The severity associated with two other symptoms, nausea and lack of appetite, were found to positively correlate with CRF severity and have been reported in the literature to be common and severe symptoms experienced by persons with LC (Gift et al., 2004; P Hopwood & Stephens, 1995; Sarna, 1998; Sarna & Brecht, 1997). In fact, Sarna and Brecht (1997) found through factor analysis that nausea, lack of appetite, and CRF were interrelated as 1 of 4 factors that accounted for 63.1% of the variance in symptom distress. Later, Gift et al. (2003) found in newly diagnosed persons with LC that five symptoms (fatigue, weakness, nausea, lack of appetite, and altered taste) formed a cluster that remained over time. The analysis included 112 persons including both women and men with LC who provided symptom information at the time of diagnosis as well as 3 and 6 months later. In the current study, altered taste was not included in the symptom assessment, but fatigue, weakness, nausea, and lack of appetite were. Thus, it is interesting to compare the similarity of the associations among the symptoms in the

current study with those of the studies conducted by Sarna and Brecht (1997) and Gift et al. (2003). In the current study, CRF is significantly associated with the symptoms of nausea, lack of appetite, and weakness. This similarity holds true for persons with OC diagnoses and the total sample.

Summary of the Symptom Experience and Relationship between CRF and the Other Unpleasant Symptoms from Cancer and Cancer Treatment

To this point in the discussion, a description portraying the CRF phenomenon in persons with LC has been documented. Moreover, greater depth of understanding of this phenomenon in LC patients has been achieved since the CRF experience of persons with LC diagnoses were compared and contrasted to persons with OC. It has been determined that CRF is a symptom of moderate to high severity and high prevalence for both persons with LC and OC diagnoses while receiving chemotherapy.

The CRF phenomenon is also surrounded by other multiple occurring symptoms of which all persons with cancer experienced 7.4 out of 16 possible symptoms concurrently. The total symptom severity from the other unpleasant symptoms was significantly greater for persons with LC as compared to persons with OC diagnoses. Persons with LC reported significantly more days of dyspnea and cough, and more severe pain and dry mouth in comparison to persons with OC diagnoses. The total sample and persons with OC diagnoses had more individual symptoms positively correlate with the severity of CRF as compared to persons with LC. All five symptoms that were positively correlated with the severity of CRF in persons with LC also positively correlated with the severity of CRF in the total sample and persons with OC diagnoses. Lastly, the individual symptoms of weakness, lack of appetite, and nausea were found to correlate positively

with CRF for the total sample and persons with LC and OC diagnoses. These same symptoms were reported in two studies to form a symptom cluster in persons with LC and warrant continued attention as a symptom cluster in all patients with cancer. Having knowledge about the symptom experience and the relationship between CRF and the other unpleasant symptoms is necessary to optimize management of CRF, other unpleasant symptoms, and PFS. Now that the relationships between CRF and the other unpleasant symptoms are better understood, the next item to examine is whether PSE for fatigue management mediates the relationship between CRF severity and PFS.

Relationship between CRF, PSE for Fatigue Management, and PFS

Bandura (1997) has identified PSE as a powerful mediator linked to successful outcome attainment. In this study for persons with cancer (the total sample), and both persons with OC and LC diagnoses, the mediation hypothesis was supported using mediation assessment as prescribed by Baron and Kenny (1986) and Kenny (2005). Greater CRF severity in the context of lower PSE for fatigue management was related to lower PFS. The model also demonstrates a partial mediation which indicates that the severity of CRF directly influences PFS and indirectly influences PFS by its effect on PSE for fatigue management. Thus, although some of the effect of the severity of CRF on PFS clearly passes through PSE for fatigue management, the severity of CRF has a direct effect on PFS as well.

Baron and Kenny (1986) stress that most complex human phenomena, such as the CRF experience, have a variety of causes and it is unrealistic to think that a single mediator, a single cause, would completely explain an independent variable to dependent variable relation. The Sobel Test confirmed that PSE for fatigue management carried

12% of the influence on the relationship between CRF and PFS for persons with cancer and OC diagnoses. In persons with LC, the Sobel Test showed there was no mediating effect by PSE for fatigue management on CRF and PFS. However, the results of the Sobel Test are tenuous for the LC group since the LC group did not meet the recommended number of cases for conducting the test, 63 cases as opposed to 200 cases as recommended by Hoyle and Kenny (1999) and Kenny (2005). Consequently, the results propose that PSE for fatigue management is an important factor to consider in CRF management because of its relationship with PFS for the total sample, and persons with OC and LC diagnoses. The findings lead to potential intervention opportunity to optimize PFS addressing two areas: the CRF and PSE for fatigue management. The concept of enhancing a person's PSE for CRF management provides a means to modify how a person thinks, feels, motivates, and performs in order to strengthen a person's symptom control and PFS. Knowing which components of the theoretical framework, the patient characteristics, CRF, other unpleasant symptoms from cancer and cancer treatment, or PSE for fatigue management, is the final important step in being able to positively impact the PFS of a person with cancer.

Relationship between Patient Characteristics, CRF, other Unpleasant Symptoms, PSE for Fatigue Management, and PFS

Management of CRF and other unpleasant symptoms is a major element to optimizing performance outcomes of the symptom experience.

Persons with Cancer (Total Sample)

Having LC as compared to OC diagnoses, greater co-morbid conditions, having surgery prior to chemotherapy, greater total severity of the other unpleasant symptoms,

and greater CRF severity predicted lower PFS in persons with cancer. In contrast, having greater PSE for fatigue management predicted greater PFS. The addition of the physiological patient characteristics represented the largest increase in the percent of explained variance of PFS with an increase of 13.7%, followed by the total severity of the other unpleasant symptoms (6.9%), PSE for fatigue management (6.3%), and CRF severity (5.7%).

Type of cancer. Similar to this study, past research has demonstrated that in comparison to persons with other types of solid tumors, persons with LC have lower levels of PFS along the illness and treatment trajectory. Kurtz, Kurtz, Stommel, Given, and Given (1997) found among persons 65 years and older with cancer that persons with LC were worse off than persons with OC diagnoses. Similar to the current study, the physical functioning subscale of the Medical Outcomes Study Short Form-36 (SF-36) was used. Kurtz et al. found the mean PFS scores to be 75.4 for prostate cancer, 68.8 for breast cancer, 63.4 for colon cancer, and 43.1 for LC. In another study conducted by Kurtz et al (1999a) on 299 persons recently diagnosed with cancer they reported similar results in persons with LC in physical functioning. Corresponding PFS scores from the physical functioning subscale of the SF-36 were 74.8 for breast cancer, 71.5 for colon cancer, and 46 for LC. Further, Given et al. (2001) found that among persons with breast, colon, prostate, and lung cancer 65 years and older, persons with LC were significantly more likely to report lower levels of PFS immediately prior to diagnosis with a continued decline noted 6 to 8 weeks after diagnosis. Prior to diagnosis, the mean PFS score for persons with prostate cancer was 88, colon cancer was 85, breast cancer was 80, and LC was 44. However, PFS declined 6 to 8 weeks after diagnosis within these groups with

mean PFS scores falling to 76 for prostate cancer, 68 for breast cancer, 61 for colon cancer, and 44 for LC.

A recent study reported on by Doorenbos et al. (2006) showed that for 237 persons with solid tumors, PFS varied according to cancer site. Specifically, women with breast cancer had an average score of 73 on the SF-36 physical functioning subscale compared to an average PFS score of 55 for women with LC. This is similar to the findings in our current study in which we found significant difference in the mean PFS in persons with LC (M = 44.3) as compared to persons with OC (M = 61.8) diagnoses (t = 4.70; p = .000).

These studies which span time over the past ten years indicate several salient points. First, the PFS for persons with LC are poor and have not improved over the course of these studies. Similar to the previous studies, persons with LC (M = 44) in this current study demonstrated lower PFS scores when compared to persons with OC diagnoses (M = 58.1) (t = 4.70; p = .000). Ware et al. (1993) has also reported on PFS norms for specific medical conditions using the SF-36 physical functioning subscale. For those with a recent acute myocardial infarction the median was 75, 61 for chronic obstructive pulmonary disease with hypertension, 50 for diabetes type II, and 50 for congestive heart failure. Hence, persons with LC in the current study also demonstrate lower PFS scores (Median = 40) in comparison to other serious medical conditions. Consequently, the PFS of persons with LC is worse in comparison to OC diagnoses and other medical conditions. Further, the PFS of persons with LC has not improved over the past ten years. Since PSE for fatigue management has been found to mediate the relationship between CRF severity and PFS in persons with cancer, nursing interventions developed to

maximize PSE to manage CRF to optimize CRF control may contribute to improved PFS in persons with LC.

Co-morbid conditions. In this study, a greater number of co-morbid conditions were identified as another significant predictor of lower level of PFS in persons with cancer. Persons with LC (M = 2.8) reported significantly more co-morbid conditions as compared to persons with OC diagnoses (M = 1.5) (t = -4.5; df = 298; p = .000). This compares closely with four previous studies which show within varied cancer populations consisting of persons with solid tumors (including LC) that patients with greater co-morbid conditions score lower in PFS (B. Given et al., 2001; C Given et al., 2000; Kurtz et al., 1997, , 1999a). B. Given et al. (2001) specifically reported that in persons with cancer, "compared to patients having no co-morbid conditions, those with two, three, or more have 2 and 4 times greater odds of lower physical functioning." In contrast, two studies consisting of only persons with LC found that the number of co-morbid conditions did not predict loss of PFS (Kurtz, Kurtz, Stommel, Given, & Given, 1999b; Kurtz et al., 2000). Hence, relationships between co-morbid conditions and PFS have produced different results perhaps because of different methods used in analyses (e.g., examining the predictors to improved PFS as compared to predictors of loss of PFS). However, the methods used in the current study are parallel with that of the first four reports examining the number of co-morbid conditions as a predictor to PFS.

Surgery prior to chemotherapy. The current study also identified that having surgery prior to chemotherapy (time prior to and type of surgery is not known for this current study) predicted lower PFS. Cancer treatment is normally characterized by multiple combinations of concurrent interventions and in so doing makes it difficult to understand

how each intervention purely in and of itself contributes negatively or positively to performance outcomes. For example, in a study conducted by Kurtz et al. (1997) within a varied cancer population of solid tumor composition (including LC) who were 65 years or older, the researchers examined the effects of various treatment modalities (surgery, radiation therapy, surgery and radiation therapy, and neither) and identified that surgery was the most debilitating treatment modality for all patients showing significant differences for PFS and physical role limitations. The researchers noted that while a number of patients (16.7%) were also undergoing chemotherapy in conjunction with either surgery or radiation, the patients who only had surgery had less recovery time than those who had surgery in combination with radiation therapy.

In a study conducted by B. Given et al. (2001) which included patients with solid tumors (including LC) who were 65 years of age and older with a new cancer diagnosis, more compromise in PFS was found when undergoing surgical procedures alone or in combination with the beginning of chemotherapy or radiation therapy. B. Given and colleagues also noted that "when compared with those receiving surgery, LC patients who received chemotherapy or radiation therapy without surgery were significantly less likely to be in the lower physical functioning groups." In addition, C. Given et al. (2000) found for 907 patients age 65 or older with a new diagnosis of breast, colon, prostate, or lung cancer that surgery had a "time-bounded effect" in that "patients interviewed within 40 days of surgery were more compromised, but once beyond 40 days, they improved to a level that either equaled or exceeded those who did not have surgery." Consequently, the finding in this study is relevant to previous studies in that surgery was found to impact the PFS of persons with cancer. This is important to note that this positive finding

occurred in this secondary data analysis even though the secondary data analysis design does not include information regarding exactly when the surgery occurred except that it occurred before receiving chemotherapy. Also, the surgery varied from minor to major procedures.

PSE for fatigue management. This finding from the current study is important demonstrating that greater PSE for fatigue management predicts greater PFS. As emphasized in the review of the literature, very few studies have been conducted relative to symptom management in the general cancer population and only one small study has been done concentrating solely on PSE in persons with LC (Porter et al., 2002). Moreover, no studies have been found in the literature on the role PSE plays in the management of CRF and other associated symptoms to achieve optimal functional status for the lung cancer population. Accumulating evidence demonstrates that PSE is critical to positively affecting symptom management and functional ability in persons living with chronic health conditions. This current study is unique in that it focuses on PSE for fatigue management and persons with LC.

Total symptom severity of the other unpleasant symptoms. In the current study, greater total symptom severity from the other unpleasant symptoms predicted lower PFS. This finding supports the finding of previous research focused on persons with solid tumor cancers (Dodd et al., 2001; Kurtz et al., 1999b, , 2000; Kurtz, Kurtz, Stommel, Given, & Given, 2001; Sarna, 1993a). C. Given et al. (2000) found in 907 persons aged 65 years or greater who were newly diagnosed with breast, colon, prostate, or lung cancer that symptoms had an effect that was independent of cancer treatment (surgery, radiation therapy, and chemotherapy) such that each additional symptom experienced resulted in

further PFS decline. In a recent secondary analysis of three prospective studies conducted by Doorenbos, Given, Given, and Verbitsky (2006b), increased dependencies in physical functioning were found to be associated with an increased symptom experience. They also reported that persons with LC experienced more symptoms in their last year of life than those with other solid tumor cancers. Therefore, the finding in the current study that increased symptom severity predicts lower PFS is consistent with prior research that has documented this relationship for over a decade.

Cancer-related fatigue severity. In the current study, greater CRF severity was found to be predictive of lower PFS in persons with cancer, which is consistent with prior findings of this phenomenon. However, there is limited research describing the adverse impact of CRF on the PFS of persons in the general cancer population and even more so for the LC population. The finding that greater CRF severity predicts lower PFS is important since CRF is documented as a prevalent and severe symptom among persons with cancer, and particularly for persons with LC.

Persons with OC Diagnoses

All four significant predictors to PFS in persons with cancer (total sample) were also the most significant predictors for persons with OC diagnoses: co-morbid conditions, PSE for fatigue management, total symptom severity from the other unpleasant symptoms, and CRF severity. The addition of the physiological patient characteristics (i.e., co-morbid conditions) represented the largest increase in the percent of explained variance of PFS increasing it by 18.5%, followed by PSE for fatigue management (9.5%), the total severity of the other unpleasant symptoms (7.4%), and CRF severity (6.3%).

Persons with LC Diagnosis

Similar to the total sample and persons with OC diagnoses, PSE for fatigue management, co-morbid conditions, and other unpleasant symptoms were significant predictors to PFS of persons with LC. Also, having surgery prior to chemotherapy was predictive in persons with LC as well as the total sample but not persons with OC diagnoses. Further study of this variable is merited since in this secondary data analysis not all information surrounding this variable is known as discussed previously. Monitoring a patient's fatigue and PFS level after surgery would be key to astute clinical assessment. A discussion regarding these predictor variables occurred in the total sample section as it was important to point out differences if available via the literature among the persons who comprised the total sample (i.e., persons with LC and OC diagnoses). However, it is interesting to note that not until PSE for fatigue management was entered into the fourth block did the model become statistically significant accounting for 36.3% of the variance in PFS of persons with LC. Entering the other unpleasant symptoms from cancer and cancer treatment into the fifth block represented the second largest increase (12%) in the percent of explained variance of PFS. The addition of CRF severity in the sixth block increased the explained variance of PFS by 3.2%, and CRF severity trended towards statistical significance (t = -1.87; p = .07). The trend in statistical significance of CRF severity was in contrast to the findings of the total sample and persons with OC diagnoses. However, as discussed previously in the results section, power to detect effects was limited by sample size and the number of predictors in order to gain beginning information for future research. In addition, issues of multicollinearity are more likely when samples are small and the numbers of predictors are high, thus, the

presence of other predictors can change the parameter estimate for a given predictor, such as CRF (von Eye & Schuster, 1998). Replication of this analysis with a larger sample size of persons with LC is needed to substantiate the findings.

Nonetheless, significant predictors of PFS in persons with LC not found to be predictive of PFS in the total sample or in persons with OC diagnoses were: insurance and employment related variables, and race. Specifically, the following predicted greater PFS in persons with LC: holding a private insurance policy as compared to not holding a private insurance policy; and holding a Medicaid policy as compared to not holding a Medicaid policy. Lower PFS in persons with LC was found to be predicted by being Caucasian as compared to being non-Caucasian; and receiving disability or having to quit work. Next, a discussion will ensue to highlight these significant predictors that were found to be unique to persons with LC in the prediction of PFS.

There is limited published research identifying the contextual variables that contributes to management of CRF, other unpleasant symptoms, and PFS in persons with cancer, particularly LC (Montazeri et al., 1998). This research identifies variables that may serve as potential risk factors to lower PFS. In this study, being Caucasian as compared to being non-Caucasian predicted lower PFS. The findings for this study show that persons with LC who were Caucasian were slightly younger (M = 62, SD = 10) and had lower PFS scores (M = 43; SD = 26.3) as compared to persons who were non-Caucasian (age: M = 66, SD = 12.6; PFS score: M = 60, SD = 31.9). The sample size was unequal between the Caucasian (n = 59) and non-Caucasian (n = 4) groups meriting further study with a different sample and with a larger non-Caucasian representation.

Likewise, little research has been conducted regarding health-related quality of life outcomes and the relationship with the health insurance status of persons with cancer, particularly LC. The findings of this study showed that possessing a private insurance policy or Medicaid in comparison to not possessing either policy predicts greater PFS in persons with LC, and this parallels the published literature. For example, the Institute of Medicine states that uninsured cancer patients fare poorly and die sooner, on average, than do persons with insurance, mostly because of a delay in diagnosis (Institute of Medicine, 2002). Also, Bradley, Given, and Roberts (2003) found that adults with either cervical, colorectal, or lung cancer who were younger than age 65 who enrolled in Medicaid the same month or after a diagnosis of cancer were approximately 2 to 3 times more likely to have late stage disease than adults enrolled in Medicaid before diagnosis. Thus, possessing a health insurance policy may provide for a better outcome than not holding a health insurance policy.

One study was identified that quantified the relationship between perceived financial difficulties with quality of life in patients with advanced cancer. Gupta, Lis, and Grutsch (2007) found in 954 persons with advanced cancer that perceived financial difficulty predicted lower health and physical functioning. While the current study did not identify the perceived financial difficulty of persons with LC, receiving disability or having to quit work may serve as probable proxies to financial difficulty making the findings in this current study consistent with Gupta and colleagues.

Summary of the Relationship between the Patient Characteristics, CRF, Other Unpleasant Symptoms, PSE for Fatigue Management, and PFS

For the total sample, PFS was found to be predicted by type of cancer diagnosis, LC or OC diagnoses. Additionally, all predictors (co-morbid conditions, surgery prior to chemotherapy, PSE for fatigue management, total symptom severity of the other unpleasant symptoms, and CRF severity) to PFS in the total sample were predictors in the OC diagnoses group. For persons with LC, all but CRF severity were found to predict PFS. The LC group had race and insurance and employment related variables identified as predictors of PFS that were unique to this group alone.

Relationship among the Patient Characteristics, CRF, Other Unpleasant Symptoms, PSE for Fatigue Management, and CRF Severity

An examination of the relationships among the components of the theoretical framework via path analysis revealed several findings in persons with cancer. Patient characteristics significantly related directly to three different criterion variables. First, greater CRF severity was predicted by lower age, greater number of co-morbid conditions, and women as compared to men. The findings that greater co-morbid conditions and women as compared to men predicted CRF severity was consistent with regression analysis done to identify predictors to CRF severity as reported earlier in this study.

The second criterion variable impacted by patient characteristics was the total symptom severity of the other unpleasant symptoms. This was a new finding relative to the prior analyses conducted in that greater total symptom severity of the other unpleasant symptoms was predicted by having surgery prior to chemotherapy in

comparison to those who did not have surgery prior to chemotherapy (time prior to and type of surgery is not known for this current study). Both Cooley et al. (2002) and Given et al. (2000) have reported that in persons with cancer, patterns of symptom distress varied among cancer treatment, including surgery. Given and colleagues (2000) found that symptoms "did not simply mediate between treatments and patient functioning but produced a significant effect that was independent of surgery, radiation, and chemotherapy, and each additional symptom was associated with a decline in physical functioning." The results from the current path analysis emulate the findings from Given and colleagues: total symptom severity was both heightened from the direct influence of the severity of another symptom, CRF, and as a result of undergoing surgery prior to chemotherapy.

The last criterion variable identified to be influenced by the patient characteristics was the PFS of persons with cancer. Specifically, lower PFS was predicted by greater numbers of co-morbid conditions and this finding is supported via the hierarchical multiple regression analysis described previously in this study.

The symptoms in the theoretical framework, CRF severity and the total symptom severity from the other unpleasant symptoms demonstrated interesting relationships with each other and other components of the model. First, CRF severity indirectly and directly impacted PFS in persons with cancer. The indirect path is an exciting and unique finding to this study. Here the indirect path shows that PSE for fatigue management served as a mediator between CRF severity and PFS in persons with cancer. Specifically, greater CRF severity predicted lower PSE for fatigue management, and greater PSE for fatigue management predicts greater PFS. Also, greater CRF severity was found to directly

predict lowered PFS in persons with cancer. As previously mentioned, CRF severity was identified to directly impact the total symptom severity of the other unpleasant symptoms from cancer and cancer treatment.

Parallel to the TOUS, symptoms interact and create a catalyzing effect having a resultant effect on critical patient outcomes (1997). Given et al. (2001) found that in cancer patients who experienced the symptom of fatigue that 4.5 other symptoms were reported. This current study is consistent with the work of Given et al. in that CRF severity drives greater levels of total symptom severity from the other unpleasant symptoms which leads to lower PFS in persons with cancer. In summary, a model produced via path analysis provided an overall synthesis of the analyses conducted in the current study. The application of path analysis, a rubric part of the structural equation modeling framework (Raykov & Marcoulides, 2006), is important in behavioral oncology since in this current study it helped to unravel theoretical predictions of directional relationships (Schnoll, Fang, & Manne, 2004). This current study employed a cross-sectional design which provides a single view of the relations among the manifest constructs. A cross-sectional design is limited in the sense that simultaneous measurement of constructs often takes time to develop to really understand how they operate. However, "data can never confirm a model; they can only fail to disconfirm it" (Maruyama, 1998). Thus, replication of this study would determine whether failure to reject is plausible beyond the data set for which a model initially was fitted and to uncover any alternative explanations for any finding (Maruyama, 1998). Consequently, the identification of the model via path analysis extends the understanding of how

variables in the theoretical framework directionally relate to each other to explain the CRF phenomenon in persons with cancer, particularly those persons with LC.

Strengths and Limitations

Strengths

This is the first known study in the LC population to demonstrate the beneficial effect that PSE has on symptom management and PFS. In this study, PSE for fatigue management has been found to be both influential in directly influencing CRF severity and mediating the relationship between CRF severity and PFS for persons with LC as well as OC diagnoses. Cancer-related fatigue has been documented as a prevalent and severe symptom that negatively impacts persons with cancer. Investigations that span the course of the past ten years show that CRF has a significant effect on PFS of persons with cancer throughout their illness and treatment trajectory without any guarantee that patients will resume full functioning when treatment is complete. Moreover, past investigations show that there has been little if any improvement in the PFS of persons with cancer, particularly those diagnosed with LC.

This current study is consistent with prior research in that CRF is a prevalent symptom which adversely impacts the PFS of persons with cancer, particularly for those diagnosed with LC. The gaps in knowledge contributing to the continued prevalence, severity, and adverse impact that CRF has on persons with cancer may represent the paucity of work done to identify underlying factors and mechanisms responsible for CRF production. Another strength of the current study provides support for future intervention studies to increase PSE to achieve optimal symptom management and functioning in persons with LC and OC diagnoses.

A second strength of the current study is that unique physiological and contextual patient characteristics were identified as important predictors of CRF severity and PFS in persons with LC. Unique patient characteristics identified to the prediction of CRF severity include the patient holding the insurance policy and the patient having surgery prior to chemotherapy (see Limitation Section). The unique patient characteristics identified to predict PFS in persons with LC include race, holding a private or Medicaid health insurance policy, receiving disability, and having to quit employment. In addition, factors were identified not only to be important in optimizing CRF in persons with LC but also in persons with OC diagnoses. For example, the severity of CRF has been found to increase the severity of the other unpleasant symptoms from cancer and cancer treatment which negatively impacts the PFS of persons with both LC and OC diagnoses. Moreover, the study design itself was a third strength since the design included persons with LC and OC diagnoses which gave a comparative basis to give added support to the findings of the study. In addition, while the focus of this study was centered on persons with LC, the results of the findings can be generalized to persons with OC diagnoses. Specifically, since PSE is an important factor in optimizing management of CRF for greater PFS, PSE could also be effective in optimizing other unpleasant symptoms of cancer and cancer treatment to more comprehensively impact symptom management and PFS in all persons with cancer. Lastly, the study employed a cross-sectional design and the measurement of the data to analyze the research questions within this design was bounded by all persons diagnosed with the disease of cancer undergoing chemotherapy with at least two cycles remaining at the time of enrollment.

Limitations

This study extends the science by providing data that currently were not available showing a relationship between CRF, PSE for fatigue management, and PFS in persons with cancer, particularly for persons with LC. However, the findings of the study should be considered in context with the study limitations. It is important to note that the data were obtained from two studies, one that was derived from the FHCC study whose inclusion criteria required that persons with a cancer diagnosis must exhibit either a high level pain or fatigue to gain entry into the study. The data were also derived from the ATSM study whose inclusion criteria required that persons with cancer diagnosis exhibit a symptom severity threshold of 2 out of 10 for any symptom. Hence, the presence of fatigue in this study is biased by the inclusion criteria for one study that requires presence of either high pain or fatigue and the other by the presence of one symptom with fatigue being the most prevalent symptom in the cancer population. Equally important to acknowledge is that CRF is an underreported and underdiagnosed universal symptom of cancer and cancer treatment (National Comprehensive Cancer Network, 2006) and thus would be a likely symptom to be reported.

The focus of this study is centered on persons with LC. The data from this study originates from the FHCC and ATSM studies and uses both persons with LC (N = 63) and OC diagnoses (N = 235) which consists of persons with breast cancer (n = 105), colon cancer (n = 44), and an array of other types of cancer diagnoses (n = 86) for secondary data analysis. However, in this study, persons with LC not only represent a smaller proportion of the sample size as compared with persons of other cancer diagnoses, but were also less representative of the worldwide cancer population in terms

of incidence and mortality. Notwithstanding the smaller proportion of persons with LC in comparison to persons with OC diagnoses in this study, results indicate significant relationships between CRF, PSE for fatigue management, and PFS for persons with LC. Similarly, the results also reveal significant relationships among CRF, PSE for fatigue management, and PFS for persons with OC diagnoses.

Laboratory values were not analyzed in this study as most of the laboratory value data were not collected. The data for this study comes from a de-identified dataset which excludes all information that could potentially lead to subject identification. Consequently, references to all dates have been excluded from this dataset. The exact date of the onset of administration of chemotherapy as well as the exact date of a surgical procedure has not been included in this dataset as part of the de-identification protocol. As defined in the Methods Section of this study, the variable "Surgery Prior" is defined as surgery "prior to chemotherapy and prior to consent." Also defined in the Methods Section of this study, the variable "Surgery During" is defined as surgery "during chemotherapy and the audit period which is from consent to the last interview." The variables "Surgery Prior" and "Surgery During" refer to a wide variety of procedures from minor to major procedures which may or may not be related to cancer treatment, and the timing of the surgery in relation to the baseline interview data collection used for analyses of this study is unknown in this secondary data analysis.

Race was another variable included in the dataset and there were more persons who were Caucasian (87%) as compared to non-Caucasian (13%). However, this was expected and exceeded the anticipated accrual of 8% to 10% non-Caucasian that were expected to be found in the study sites.

The study only used variables in the original FHCC and ATSM randomized control trial. As a result, 2 of the 4 symptom dimensions (i.e., frequency and severity) were assessed. The distress from a symptom, the degree or amount to which a person is bothered by a symptom and quality descriptors of the symptoms are not known.

The current study focused on the current physical symptom experience and not psychological symptoms. Future study incorporating psychological symptoms is merited.

Since persons with LC represented a smaller group ($N = 63$) as compared to the total sample ($N = 298$) and persons with OC diagnoses ($N = 235$), power to detect effects was limited by sample size and the number of predictors. In addition, issues of multicollinearity are by nature more likely when samples are small and the numbers of predictors are high. However, analysis with persons with LC as a group proceeded since information gleaned would provide beneficial beginning information for future research.

The study focused on baseline measurement from the parent studies prior to the beginning of the intervention. Analysis of longitudinal data is planned for the future.

Implications of the Study

This study has implications for clinical practice and research relative to relationships among the components of the theoretical framework that guides this study. Some findings have more immediate clinical applicability and others require more inquiry that necessitates further research.

Significance for Clinical Practice

Relationships between the Patient Characteristics, CRF, other Unpleasant Symptoms, and PFS

This study identified patient characteristics that may be labeled as risk factors to CRF and other unpleasant symptoms leading to worsening PFS that are common among persons with cancer, and patient characteristics that are unique to LC and OC diagnoses. Knowledge of which patient characteristics predict CRF, other unpleasant symptoms, and PFS provides a risk profile to pre-empt the development of higher levels of CRF and other unpleasant symptoms and worsening of PFS. This study identified that assessing patient characteristics is important to develop an individualized plan of care which utilizes PSE enhancing interventions.

Symptoms (CRF and Other Unpleasant Symptoms from Cancer and Cancer Treatment)

The findings from this study stress the need for nurses to incorporate assessment of CRF and other multiple occurring symptoms into everyday practice to optimize symptom management and the PFS of all persons with cancer. This is especially important for persons with LC since their CRF was pervasive and adversely impacted their PFS, and their total severity from the other unpleasant symptoms was greater in comparison to persons with OC diagnoses. While it is important to have knowledge about the frequency of occurrence and severity of symptoms, having additional information such as the distress evoked by the symptom and its interference in their PFS would help the patient and nurse prioritize which symptoms require attention first. Additional information about the distress of the symptom was not a part of this study since this study was a secondary data analysis. This is necessary to achieving goals of a symptom action plan that is built

in partnership with the patient and is specifically related to doable, valued symptom management activity. Hence, incorporating the assessment of CRF and other multiple occurring symptoms into everyday practice provides for real time symptom management action utilized to optimize symptom status and PFS.

In designing a symptom assessment tool that would reduce the degree of respondent burden while capturing key symptom dimension information to optimize clinical outcomes would require including those key symptoms which are prevalent and severe as identified over time in studies for persons with LC and OC diagnoses. In this study, for persons with LC and OC diagnoses, fatigue, insomnia, weakness, dry mouth, anorexia, and nausea were identified as the most common and severe symptoms when weighted by frequency of occurrence. This finding has been shown to be consistent with previous studies identifying common and severe symptoms in persons with LC and OC diagnoses. Consequently, incorporating symptoms in a cancer assessment tool that are found to be a common concern for all persons and then tailoring the tool with site specific symptoms would facilitate the nurse's ability to target key symptoms for each major cancer diagnosis. As identified in this study, site specific symptoms for nurses to address for persons with LC would be dyspnea, cough, and dry mouth which were different form those identified for OC diagnoses.

Multiple concurrent symptom management means that nurses need to assess and manage symptoms with an anticipatory approach. Nurses need to assess and manage not only one symptom, but multiple symptoms. This study identified several severe symptoms that were correlated with CRF severity. The severity of CRF in this study was shown to be the driver for increasing the total symptom severity of the other unpleasant

symptoms of cancer and cancer treatment. This means that nurses need to establish a pre-emptive plan to equip the patient with the ability to prevent and address symptoms at their onset. Pre-emptive planning begins with the initial assessment of the symptom experience with nurses evaluating for the presence of multiple symptoms rather than symptoms in isolation. Persons living with cancer have expressed the expectation of being a partner in the management of their cancer. However, nurses must understand that persons living with cancer and receiving treatment are faced with new challenges that are not part of their current repertoire of knowledge, skill, and efficacy for symptom management. As indicated by the National Institutes of Health, there is a lack of awareness by health care providers of a person's symptom experience. In addition, many patients do not independently report their symptoms for reasons such as a belief that their symptoms are an inevitable part of their cancer, belief that nothing can be done, and fear that reporting symptoms will distract health care providers from cancer treatment (National Institutes of Health, 2004). Therefore, nurses must take the lead and cultivate an environment of partnership with and empowerment of the patient in the assessment and management of multiple concurrent symptoms.

An anticipatory approach starts with the initial assessment of the symptom experience and continues on a regular ongoing basis with reassessment, intervention, and evaluation. Knowing that CRF is a prevalent severe symptom associated with other unpleasant symptoms of cancer and cancer treatment, nurses can tailor prevention and intervention strategies to address these symptoms to optimize CRF and other unpleasant symptom management. Since CRF may be linked together with the other unpleasant symptoms, a single strategy may be prescribed by nurses to culminate relief for all of the symptoms.

Given the significant impact of CRF and other unpleasant symptoms predicting an adverse effect on PFS in persons with LC and OC diagnoses in this study, the nurses' role in symptom management cannot be underscored and becomes key to alleviate the burden experienced by patients and their families.

CRF, PSE for Fatigue Management, and PFS.

The findings from this study demonstrate a partial mediation by PSE for fatigue management between CRF severity and PFS which indicates that the severity of CRF directly influences PFS and indirectly influences PFS by its effect on PSE for fatigue management for persons with LC and OC diagnoses. Further research is required to isolate under what conditions symptom control and PFS can be optimized for persons with LC and OC diagnoses. However, the findings reveal that in order to optimize PFS for persons with LC and OC diagnoses, both CRF and PSE for fatigue management should be included in the treatment plan. Consequently, nurses can provide for symptom control and optimize PFS using two concurrent strategies. First, nurses should attempt to identify any cause for CRF and partner with the patient to correct it. However, in many persons with cancer, no cause for fatigue can be easily discerned. Consequently, nurses should implement best known clinical practice standards to prevent and manage CRF if it should occur thereby providing for symptom control and optimizing PFS. Second, nurses can assess the patient's characteristics and any other unpleasant symptoms and in partnership with the patient implement PSE for fatigue management strategies to help prevent the onset or alleviate CRF.

Perceived self-efficacy beliefs are developed and altered through four sources of information. These sources of information are precursors to PSE and form the basis of

PSE for enhancing interventions. The nurse in partnership with the patient can implement any one or a combination of PSE for fatigue management interventions which include direct mastery experiences, vicarious experiences, use of social/verbal persuasion, and interpreting inferences from physiological and psychological states indicative of personal strengths and vulnerabilities to reach goals. Note that PSE is enhanced by these four sources of information and the literature indicates that persons with cancer view information as crucial to promote a sense of control, decrease emotional distress, support effective self-management, and eliminate disruptions of daily activities (Balmer, 2005; Barnett, 2005). In a recent study, persons with cancer reported that the most distressing symptoms were those that they were least prepared to handle (Skalla, Bakitas, Furstenberg, Ahles, & Henderson, 2004). Moreover, these persons stated that they wanted as much information as possible about cancer, its treatment, and the potential symptoms and interventions to manage those symptoms. Consequently, through the use of PSE enhancing fatigue management interventions, nurses can equip the patient with the information vital to provide for managing CRF and optimizing PFS.

Significance for Further Research

Relationships between the Patient Characteristics and CRF

Many predictors to greater levels of CRF severity were found among the total sample and persons with LC and OC diagnoses. Some of the findings elicit further inquiry to understand the relationship between certain patient characteristics and their predictability value for CRF. Further work needs to be done to understand the underlying basis for why CRF is experienced greater in women as compared to men among persons with LC and OC diagnoses. Although CRF is a highly prevalent and severe symptom in the cancer

population, there are very few studies that evaluate gender differences in CRF, and there are no known studies exploring for sex-specific interventions to treat CRF.

A greater number of co-morbid conditions were found to predict greater CRF in the total sample and for persons with OC diagnoses but not for persons with a LC diagnosis. This is consistent with prior research. Understanding which co-morbid conditions and for which cancer diagnoses generates higher levels of CRF would inform nurses which patients are at greater risk for CRF. Exploring to see which specific co-morbid conditions predict CRF as opposed to the number of co-morbid conditions would be important in persons with LC, particularly exploring pulmonary-related co-morbid conditions.

Likewise, additional research is necessary to explain why persons with an early stage cancer in comparison to a late stage cancer experience greater fatigue among the group with OC diagnoses. Knowing that most persons within the OC diagnoses group were women with breast cancer would be a starting point to better understand why stage of disease may make a difference and if discovered, design interventions to promote CRF control.

Relative to age, the findings of the current study are consistent with Degner and Sloan (1995) who found that younger age related to higher levels of symptom distress in newly diagnosed ambulatory cancer patients. The researcher of the current study as well as Degner and Sloan noted that this finding was not in the hypothesized direction. More analysis needs to explore what factors and under what conditions may lead to greater fatigue in younger versus older persons with cancer.

Relationships between Patient Characteristics and PFS.

Cancer and its treatment results in financial burden for patients and their families, especially when the disease is advanced, particularly for persons with LC. Persons with cancer assume great responsibility not only for the direct financial cost of medical expenditures, but also for indirect financial costs which are brought about by cancer and cancer treatment such as the wages lost due to the reduction or loss of employment. The findings of the current study are similar to reports demonstrating that the adverse impact of the disease and treatment make it difficult to maintain employment (Kim, 2007; President's Cancer Panel, 2004). In the current study it was found that receiving disability and having to quit work predicts lower PFS for persons with LC. This finding cannot be directly tied with whether or not the change in employment status was related to the disease of LC, but the data were collected at the baseline interview when the subjects had active cancer disease. Subsequently, further research is necessary to understand how the direct and indirect financial costs influence the cancer care and health-related quality of life issues (i.e., symptoms status, functional status, and survival) for persons with LC.

The current study also reported that persons who possessed private health and Medicaid insurance policies predicted greater PFS in persons with LC. This finding is consistent with previous literature describing those patients without insurance have greater risk for later stage of cancer at diagnosis and have decreased survival time. Although health insurance is helpful, many Americans are underinsured and find that insurance is not sufficient to cover the additional costs of cancer care (DeNavas-Walt, Proctor, & Lee, 2004). Further research is necessary to understand the impact that health insurance has on health-related quality of life indicators (i.e., symptom status, functional

status, and survival). This research is essential since literature describes how patients make decisions to forego aspects of cancer care due to the high expense despite the fact that the treatment would extend survival (Kim, 2007; Wei, Reeves, Gadgeel, Abrams, & Peters, 2003). To this end, research should also describe how the cost of cancer care influences the decisions persons with LC make in regard to cancer treatment and care. This information would inform health policy decision-making at a minimum for ensuring that persons with LC have access to appropriate receipt of cancer treatment and management of the adverse effects associated with cancer and cancer treatment such as with unrelieved symptoms and low PFS.

Symptoms (CRF and Other Unpleasant Symptoms from Cancer and Cancer Treatment)

The CRF experience in persons with LC and OC diagnoses encompasses multi-symptom relationships. Since CRF was identified as an antecedent to the total symptom severity in persons with cancer, further research is needed to identify the temporal pattern of CRF to other specific unpleasant symptoms. In the current study, CRF is significantly associated with the symptoms of nausea, lack of appetite, weakness, dyspnea, and dry mouth in the total sample as well as in persons with LC and OC diagnoses. Along with pain and insomnia, the former symptoms were identified as the most common and severe symptoms in the current study when weighted by frequency of occurrence, which is consistent with past research. Hence, these potential other unpleasant symptoms can serve as a starting point to better understand how they are affected by CRF both individually and collectively as a potential cluster. Investigation should include determining: 1) the pattern of the relationships among CRF to the other unpleasant symptoms; 2) the relationships among the other unpleasant symptoms when the severity

of CRF is low and high; 3) patient characteristics that influence the interrelationships among CRF and the other unpleasant symptoms; 4) and determining whether or not PFS is changed given the symptom relationships.

Further study is also needed to investigate whether a symptom cluster exists among the symptoms of CRF, nausea, lack of appetite, and weakness in persons with LC and OC diagnoses. This builds upon the work of Gift et al.(2003) and Sarna and Brecht (1997) since both persons with LC and OC diagnoses in the current study showed that CRF was significantly associated with the symptoms of nausea, lack of appetite, and weakness.

This study examined the physical symptoms of cancer and cancer treatment in persons with LC and OC diagnoses. In addition to the physical symptoms, persons with cancer experience significant psychological symptoms, particularly anxiety and depressive symptoms. It is well documented that anxiety and depressive symptoms are prevalent throughout the cancer trajectory (P. Hopwood & Stephens, 2000; National Institutes of Health, 2003; Smith, Gomm, & Dickens, 2003; Stark et al., 2002). Future research should investigate if and how the physical symptom relationships contribute to the development and severity of common psychological symptoms (e.g., depression and anxiety) in persons with LC and OC diagnoses. Similarly, examination should occur to understand if and how the psychological symptoms are also interrelated in the presence of physical symptoms.

To this end, knowing the interdependencies of the physical and psychological symptoms we can identify which key symptoms trigger or catalyze other symptoms and allowing intervention to address these symptoms to optimize symptom management and PFS. Using a homogenous sample in regard to diagnosis and treatments may be more

advantageous since the symptom profiles may be quite different based upon these factors. However, since CRF and the other unpleasant symptoms were common among both groups of patients, LC and OC diagnoses, extending the investigation of multi-symptom relationships may provide greater benefit for the cancer population as a whole. The end goal would be to expose the causal pattern of multi-symptom relationships among CRF and other unpleasant symptoms and their effect on PFS via longitudinal study across the illness and treatment trajectory. This would serve as a platform for the testing of interventions for the control of CRF and other unpleasant symptoms and optimization of PFS.

CRF, PSE for Fatigue Management, and PFS.

The results of the mediation analysis indicate that CRF severity directly influences PFS and indirectly influences PFS through its effect on PSE for fatigue management. As a result, the findings from this analysis lead to potential intervention opportunities to optimize symptom control and PFS by addressing two areas together in a model for PSE for fatigue management and optimized PFS in persons with LC: CRF severity and PSE for fatigue management.

First, research is needed to address CRF severity directly through the use of an exercise program tailored to meet the needs of persons with LC. Although most studies have included persons with breast cancer and varied cancer diagnoses in the management of CRF, exercise is the intervention with the most supporting evidence of effectiveness (Ahlberg et al., 2003; Dimeo, Thomas, Raabe-Menssen, Propper, & Mathias, 2004; Headley, Ownby, & John, 2004; V Mock et al., 2005; Stricker et al., 2004). Next, testing is required for the effectiveness of various PSE for management of CRF enhancing

interventions to alleviate CRF and improve PFS. Additionally, path analysis revealed that CRF severity impacts PFS indirectly as a driver of the total severity of the other unpleasant symptoms. Consequently, as discussed earlier, multi-symptom relationships stemming from CRF would require further investigation to provide a comprehensive approach to symptom management and optimization of PFS in persons with LC.

Finally, mediation analysis revealed that PSE for fatigue management was not only effective for persons with LC but also for OC diagnoses. The analyses also demonstrated that there are similarly shared symptom experiences among persons with both LC and OC diagnoses. As a result, further research could focus not only on PSE for CRF management but PSE for other unpleasant symptom management. Likewise, this model would be applicable for persons with OC diagnoses. However, note that interventions such as exercise would need to be tailored given the cancer diagnoses and other patient characteristics to ensure a safe and effective intervention.

Closing

Cancer-related fatigue is a prevalent and distressing symptom in the cancer population and especially for the LC population. It is accompanied by many other symptoms that negatively impact PFS. A contributing factor to CRF and other unpleasant symptom management is a person's PSE. Except for this study, there has been no research identified examining the relationships between CRF, PSE, and PFS in the LC population. This investigation examined CRF in persons with LC and how the person's PSE for fatigue management impacts their perception of their CRF and PFS. The importance of optimizing symptom management for persons with LC cannot be underestimated.

This study is unique in that it focused on persons with LC in comparison to persons with OC diagnoses and explored specific patient characteristics that predict higher levels of CRF. Moreover, this research measured a person's PSE and whether PSE related to their CRF and their PFS. This is also the first identified study in the LC population that demonstrates the beneficial effect that PSE has on symptoms and PFS. In this study, PSE for fatigue management has been found to be both influential in directly influencing CRF severity and mediating the relationship between CRF and PFS for persons with LC and OC diagnoses. Further, this study affirms prior research that CRF is a prevalent symptom that adversely impacts the PFS of persons with cancer. However, similar levels of CRF were found to relate to worse PFS in persons with LC as compared to OC diagnoses. Similarly, the total severity of the other unpleasant symptoms was reported to be significantly greater in persons with LC as compared to OC diagnoses. This study also found CRF severity directly increased the total severity of the other unpleasant symptoms which negatively impacted PFS. Moreover, this study identified unique physiological and contextual patient characteristics responsible for predicting CRF severity and PFS in persons with LC and OC diagnoses.

One of the most important findings of this study for future research and clinical practice was that PSE for fatigue management was found to be a mediator between CRF and PFS for both persons with LC and OC diagnoses. In this study, mediation modeling demonstrates that the relationship between CRF and PFS in persons with cancer was partially attributable to the mediating variable PSE for fatigue management. Knowing that PSE for fatigue management functions as a mediator between CRF and PFS in persons with cancer provides the foundation for nurses together in research and clinical

practice to design powerful efficacy enhancing interventions for symptom management and optimal PFS.

APPENDICES

APPENDIX A

FAMILY HOME CARE FOR CANCER:
A COMMUNITY-BASED MODEL

EXECUTIVE SUMMARY
GRANT # R01 CA-79280

Background

Pain and fatigue are reported by 70% of patients with advanced cancer undergoing radiation or chemotherapy. In a randomized clinical trial, this research team found that patients who reported both pain and fatigue had lower physical function and reported twice as many other symptoms as patients with either pain or fatigue alone. Pain and fatigue are associated with increased depression, which in turn leads to higher levels of pain and fatigue. Better management of pain and fatigue can break this cycle by decreasing the number of other symptoms, and improving the quality of life of family members who care for the patient. As patient symptoms and functioning improve, family members develop a more positive reaction to the care situation.

Goal

The primary goal of this research is to test a symptom management intervention, delivered by nurses with special training, using a stepped-care approach targeted toward pain and fatigue, followed by fifteen other prevalent cancer symptoms. Second goals are to improve physical and social functioning, lower emotional distress, and improve communication with family caregivers and providers. The intervention will engage patients and their family caregiver in symptom management, and assist them to reduce their levels of depression and burden.

This research is funded through a grant from the National Cancer Institute, and builds upon the Family Care Research Team's program of supportive cancer-care research.

Specific Aims

Patients with active disease who are undergoing chemotherapy and who, during a twice weekly, 6-week contact telephone screening, report pain and fatigue of a 2 or higher on a 10-point scale, or who report pain or fatigue at 3 or higher will be assigned randomly to an 8-week, 6-contact attention self-management intervention (control), or to an 8-week, 6-contact experimental intervention. The hypothesized outcomes are:

1) lower reported severity of symptoms – primary patient outcome
2) reduced deterioration in physical role impact and social functioning, emotional distress, levels of communication with caregiver about care and communication, and satisfaction with provider are – secondary patient outcomes

3) greater involvement in symptoms management, increased mastery of the caregiving process, reduced levels of depression and burden – caregiver outcomes

Sample and Eligibility

This randomized clinical trial will recruit 350 caregiver-patient dyads. Cancer patients with active disease, who are over the age of 21, undergoing chemotherapy for solid tumors, will be approached for participation. Patients must be cognitively intact, English speaking, able to complete telephone interviews, and be willing to participate in the screening, intervention, and an audit of their medical records. Patients under the care of a psychologist or psychiatrist with diagnosed emotional or psychological disorders will be excluded.

The Specialized Care Intervention

Once the patient and caregiver dyads are enrolled, the patient will complete twice weekly automated telephone calls, for up to 6 weeks, assessing symptoms until a threshold (2 out of 10) for both pain and fatigue is reached or a "3" on either pain or fatigue. Patients reaching the threshold will be contacted by telephone to complete the intake interview, and will be assigned randomly to either the experimental group or the attention self-management (control) group. If, after 6 weeks, patients do not reach threshold, they will be sent a letter thanking them for participating.

Patients and family caregivers who are randomized into the experimental group will receive an 8-week, 6-contact stepped-approach cognitive behavioral intervention targeted toward pain and fatigue and implemented by a nurse who specializes in cancer care. The Patient Intervention for Management of Symptoms and Support (PIMSS) will assist patients with active disease acquire skills, initiate behaviors, address emotions, and involve their family caregivers in managing pain, fatigue, and other commonly occurring cancer symptoms, including constipation, dyspnea, anorexia, inability to concentrate, dry mouth, nausea, cough, emotional distress, and insomnia. Patients' caregivers will be contacted three times to assist them to better manage their patients' problems. Problem-solving and self-care management interventions are targeted toward those who report higher severity of pain and fatigue, this intervention assists patients and family caregivers in developing a repertoire of strategies for communicating, obtaining support, acquiring information, carrying out self-care behaviors, and coping with emotional distress.

Once a plan of care has been established at the first visit, during subsequent contacts the nurse will evaluate the success of each strategy directed toward a specific problem, following the problem-solving approach of identifying with the patient interventions that were successful or unsuccessful. This evaluation is facilitated by computer software that takes the nurse to specific problem screens, where the patient reassesses the severity and intensity of symptoms, function and emotional distress in conjunction with strategies previously recommended at prior contacts. Based on the patient's evaluation of the strategy, the nurse and patient together determine if the behavioral strategy will be kept, changed or deleted. All patients in this arm receive a symptom management toolkit.

In the attention self-management arm, a trained non-nurse intervener will provide a self-management intervention covering the same number of contacts for both patients and their caregivers. However, so that separate interventions are assured, these interveners

will not be trained in oncology. Each patient, regardless of intervention group, will receive a toolkit of written suggestions, which address common concerns of cancer patients. In the attention self-management intervention, patients will be referred to the toolkit and will need to apply strategies on their own.

The patient's medical record will also be reviewed to identify variables that may affect the patient's level of pain and fatigue, such as diagnostic information, ongoing treatment information, site of cancer recurrence, complication and/or metastases, co-morbidity, hospital service usage and charges, dose and date of chemotherapy, dose and date of symptom management and supplements, and chemotherapy doses and charges.

Outcomes

This study tests a stepped-approach intervention to determine if it improves symptom outcomes, especially pain and fatigue. Secondary outcomes addressed by the intervention are physical role impact, social functioning, and emotional distress. These outcomes can have significant impact on patients and family caregivers' well-being as patients undergo chemotherapy. The shorter, more intense intervention corresponds to changes in the clinical management of cancer patients with more intense, shorter chemotherapy treatments; therefore, this intervention will be more easily translatable to the clinical setting.

APPENDIX A

AUTOMATED TELEPHONE MONITORING FOR SYMPTOM MANAGEMENT

EXECUTIVE SUMMARY
GRANT # R01 CA-30724

Overview

Prevalent symptoms among patients undergoing chemotherapy include: pain, fatigue, dry mouth, constipation, anorexia, nausea, sleep disturbance, shortness of breath or difficulty breathing, as well as psychological symptoms such as depression and anxiety. A survey of 1000 patients with cancer indicated that close to a quarter reported 10-12 symptoms. Given the impact of symptoms upon physical function, work, emotional distress, and hospitalizations, it is critical that strategies be developed and tested to improve symptom management.

This trial of a behavioural intervention for symptom management is significant because: 1) it contrasts a proactive approach, individualized to patients' symptom management needs, with a more conventional model that places responsibility on the patient for symptom management; 2) it controls for the method of delivery and the use of printed material; 3) it targets prevalent symptoms known to affect cancer patients undergoing chemotherapy; 4) it examines the relative effects of each arm, in terms of symptom severity (primary outcome), impact on patients' physical and social roles, and emotional distress; and 5) it explores these outcomes in terms of their impact on the use of services and costs of care.

Goal

The goal of this randomized trial is to determine if a nurse delivered Patient Assisted Management of Symptoms (PAMS) intervention individualized to patients' needs for symptom management, delivered by telephone, when compared to Telephone Information and Monitoring of Symptoms (TIMS) where symptoms are only monitored by telephone, with references to the symptom management toolkit will reduce symptom severity, improve physical function, and other outcomes.

Specific Aims

Patients receiving conventional care while undergoing a course of chemotherapy, and who are receiving twice weekly telephone calls for six weeks, and who have one or more symptoms, which reach or exceed a pre-established level of severity, will be interviewed and assigned randomly to one of two groups. These groups will be assessed at intake, 10, and 16 weeks in order to determine if, compared to the TIMS with encouragement to use their symptom management guide, the PAMS individualized to patient needs will result in:

1) lower reported severity of symptoms - primary outcome
2) reduced impact of physical role performance, improved social functioning, and reduced emotional distress - secondary outcomes
3) improved levels of communication between patients and providers
4) improved patient satisfaction with care
5) fewer hospitalizations and visits to emergency departments - exploratory outcome
6) lower cost-per-unit of symptom severity - exploratory outcome

Sample and Eligibility

This randomized clinical trial will recruit 350 cancer patients over the age of 21, and undergoing chemotherapy for solid tumors. Patients must agree to participate in the telephone screening, interviews, the intervention, and an audit of their medical record. Patients must be cognitively intact, English speaking, and able to participate in telephone interviews. Patients under the care of a psychologist or psychiatrist with diagnosed emotional or psychological disorders will be excluded.

Intervention

Patients who consent to the study will be entered into the Automated Telephone Symptom Monitoring (ATSM) system to receive 12 monitoring telephone calls over 6 consecutive weeks. Patients will be told that their oncologist will be notified if any of their symptoms reach a level requiring urgent attention. Patients who reach or exceed threshold of 2 or higher for a severity rating for one or more symptoms at any one of the calls will be contacted by phone to complete the intake interview. If, after 12 calls, patients do not reach threshold, they will be sent a letter thanking them for participating.

Once the interview is completed, patients will be assigned randomly to either the PAMS or the TIMS (see Figure 1). At weeks 10 and 16, patients will complete outcome interviews. Following the 16-week interview, each patient's medical record will be audited to obtain treatments, complications, stage and cost and charge data.

Patients in the PAMS arm will receive 6 weekly calls from a nurse with special training, who will assess all symptoms at each contact, individualized interventions using a problem-solving, stepped approach for all symptoms with a 2 or greater severity, review existing strategies to determine if patients were able to implement each strategy from the prior week, and revise and adapt interventions following the symptom management protocol that is guided by computer software. Patients will be referred to a Symptom Management Toolkit (SMT) for additional assistance managing each symptom.

Patients in the TIMS arm will continue to receive automated telephone calls for 6 of the 8 consecutive weeks with instructions to refer to specific pages of the SMT for assistance with managing each symptom. During the study, any patient who scores a 7 or higher on key symptoms will be referred to their oncologist for immediate attention, except for pain, which will be referred at a 5 or higher. This strategy assures that the most severe symptoms, which are less likely to be amenable to behavioral interventions, are referred to patients' medical oncologists.

Outcomes

This study compares an individualized intervention delivered by a trained nurse via telephone with an automated telephone intervention with respect to reducing symptom severity and secondary outcomes related to improving the quality of life among cancer patients undergoing chemotherapy.

APPENDIX B

Collaborating Sites for the FHCC and ATSM Studies

Collaborating Sites
1. Northern Indiana Cancer Research Consortium, Southbend, IN
2. Rose Cancer Center at Beaumont Hospital, Royal Oak, MI
3. Cancer Center at St. Joseph Mercy Oakland Medical Center, Pontiac, MI
4. Cancer Center at St. Mary's Mercy Medical Center, Grand Rapids, MI
5. Indiana University Cancer Center, Indianapolis, IN
6. Yale Cancer Center at Yale-New Haven Hospital, New Haven, CT
7. Cancer Center at Holy Cross Hospital, Silver Spring, MD

APPENDIX C

Summary of Measures for Research

Research Questions	Variable of Interest, Scale of Variable, & Description of Instrument	Scoring Information
#1 - #2 #6 - #8	Physiological and Contextual Patient Characteristics: • Type and Stage of Cancer (Ca) • Treatment variables (Ca) • Co-morbid conditions (CO) • Sex (Ca) • Age (CO) • Laboratory values (Ca) • Race (Ca) • Marital status (Ca) • Level of education (Ca) • Employment data (Ca) • Health insurance data (Ca) • Variables derived from the Demographic Questionnaire and Medical Records Chart Abstraction Form	• Scoring is either a Categorical (Ca) or Continuous (CO) variable. • Co-morbid Conditions is the average number of co-morbid conditions within the sample of persons with cancer. • Absolute Neutrophil Count and Hemoglobin Level were to be scored according to National Cancer Institute Toxicity Criteria, but data were not collected.
#1 - #8	Symptom(s): Cancer-Related Fatigue (CO) • The Brief Fatigue Inventory, which includes 2 of the 9 items for the study measuring the patient's current (now) and worst severity of CRF within the past 7 days.	• Fatigue Frequency is 0-7 (days). • Total CRF Severity score will be calculated by summing each subject's response to severity scores for each of the two CRF severity items from the BFI (current and worst CRF severity) and dividing by two to standardize the score on an 11-point scale.

Research Questions	Variable of Interest, Scale of Variable, & Description of Instrument	Scoring Information
#1 - #3 #6 - #8	Symptom(s): Other Unpleasant Symptoms (CO) • The Symptom Experience Inventory, consisting of 32 items (frequency and severity).	• Symptom Frequency is 0-7 (days). • Individual Symptom Severity is 0-10, with 0 being "symptom not present" and 10 being "worst it can be". • Total Symptom Severity is calculated by summing each subject's response to severity scores for each symptom reported (i.e., a reported symptom is a symptom with a severity score greater than zero) and dividing by the total number of symptoms reported to standardize the score on an 11-point scale.
#1 - #2 #4 - #8	Perceived Self-Efficacy for Fatigue Management: (CO) • Self-Efficacy for Fatigue in Patients with Cancer Scale, consisting of 6 items.	• Degree of Fatigue Self-Efficacy is 0-10, with 0 being "very uncertain" and 10 "very certain". Calculated by summing the responses for each item and dividing that sum by six, the number of items in the scale.
#4 - #8	Performance Outcomes (Functional Status): (CO) • From the Medical Outcomes Short Form-36 (SF-36): 1. Physical Functional Status Subscale/10 items	• The subscale score of the SF-36 are linearly transformed to range from 0 to 100, with higher scores representing better levels of functional status. • The SF-36 Health Survey Manual and Interpretation Guide will be used for scoring.

Legend: (Ca) = Categorical Variable; (CO) = Continuous Variable

APPENDIX D

Symptom(s): Items from the Brief Fatigue Inventory

1) Please rate your fatigue (weariness, tiredness) by telling me the one number that best describes your fatigue *currently* (now)?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

2) Please rate your fatigue (weariness, tiredness) by telling me the one number that best describes your fatigue at its *worst* in the past 7 days.

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

APPENDIX E

Symptom(s): The Symptom Experience Inventory

1) During the past 7 days, on how many days did you experience pain?
   a) 0 day
   b) 1 day
   c) 2 days
   d) 3 days
   e) 4 days
   f) 5 days
   g) 6 days
   h) 7 days

2) On a scale of 0 = not present to 10 = the worst it could be, how severe is pain?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

3) During the past 7 days, on how many days did you experience shortness of breath (difficulty breathing)?
   a) 0 day
   b) 1 day
   c) 2 days
   d) 3 days
   e) 4 days
   f) 5 days
   g) 6 days
   h) 7 days

4) On a scale of 0 = not present to 10 = the worst it could be, how severe is shortness of breath (difficulty breathing)?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

5) During the past 7 days, on how many days did you experience disturbed sleep (insomnia)?
   a) 0 day
   b) 1 day
   c) 2 days
   d) 3 days
   e) 4 days
   f) 5 days
   g) 6 days
   h) 7 days

6) On a scale of 0 = not present to 10 = the worst it could be, how severe is disturbed sleep (insomnia)?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

7) During the past 7 days, on how many days did you experience nausea?
   a) 0 day
   b) 1 day
   c) 2 days
   d) 3 days
   e) 4 days
   f) 5 days
   g) 6 days
   h) 7 days

8) On a scale of 0 = not present to 10 = the worst it could be, how severe is nausea?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

9) During the past 7 days, on how many days did you experience difficulty remembering things?
   a) 0 day
   b) 1 day
   c) 2 days
   d) 3 days
   e) 4 days
   f) 5 days
   g) 6 days
   h) 7 days

10) On a scale of 0 = not present to 10 = the worst it could be, how severe is remembering things?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

11) During the past 7 days, on how many days did you experience lack of appetite?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

12) On a scale of 0 = not present to 10 = the worst it could be, how severe is lack of appetite?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

13) During the past 7 days, on how many days did you experience dry mouth?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

14) On a scale of 0 = not present to 10 = the worst it could be, how severe is dry mouth?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

15) During the past 7 days, on how many days did you experience vomiting?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

16) On a scale of 0 = not present to 10 = the worst it could be, how severe is vomiting?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

17) During the past 7 days, on how many days did you experience numbness or tingling?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

18) On a scale of 0 = not present to 10 = the worst it could be, how severe is numbness or tingling?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

19) During the past 7 days, on how many days did you experience diarrhea?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

20) On a scale of 0 = not present to 10 = the worst it could be, how severe is diarrhea?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

21) During the past 7 days, on how many days did you experience fever?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

22) On a scale of 0 = not present to 10 = the worst it could be, how severe is fever?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

23) During the past 7 days, on how many days did you experience cough?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

24) On a scale of 0 = not present to 10 = the worst it could be, how severe is cough?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

25) During the past 7 days, on how many days did you experience constipation?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

26) On a scale of 0 = not present to 10 = the worst it could be, how severe is constipation?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

27) During the past 7 days, on how many days did you experience fatigue?
a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

28) On a scale of 0 = not present to 10 = the worst it could be, how severe is fatigue?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

29) During the past 7 days, on how many days did you experience hair loss (alopecia)?

a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

30) On a scale of 0 = not present to 10 = the worst it could be, how severe is hair loss (alopecia)?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

31) During the past 7 days, on how many days did you experience weakness?

a) 0 day
b) 1 day
c) 2 days
d) 3 days
e) 4 days
f) 5 days
g) 6 days
h) 7 days

32) On a scale of 0 = not present to 10 = the worst it could be, how severe is weakness?

0	1	2	3	4	5	6	7	8	9	10
Not present										The worst it could be

APPENDIX F

Perceived Self-Efficacy:
Self-Efficacy for Fatigue in Patients with Cancer Scale

In the following questions, we would like to know how your fatigue from cancer affects you. For each of the following questions, let us know how certain you are in performing the activities as of now without assistive devices not previously used before cancer or help from another person. Please consider what you routinely can do, not what would require a single extraordinary effort.

Please rate your degree of certainty in performing the tasks from 0 (very uncertain) to 10 (very certain).

1. How certain are you that you can control your fatigue?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

2. How certain are you that you can regulate your activity so as to be active without aggravating your fatigue?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

3. How certain are you that you can do something to help yourself feel better if you are feeling fatigued?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

4. As compared to other people with cancer like yours, how certain are you that you can manage fatigue during your daily activities?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

5. How certain are you that you can manage your fatigue so that you can do the things you enjoy doing?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

6. How certain are you that you can deal with the frustration of fatigue?

0	1	2	3	4	5	6	7	8	9	10
Very uncertain										Very certain

APPENDIX G

Performance Outcomes (Functional Status):
Medical Outcomes Study Short Form-36 (SF-36):
Physical Functional Status Subscale

The following questions are about the activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

1) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

2) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

3) Lifting or carrying groceries?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

4) Climbing several flights of stairs?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

5) Climbing one flight of stairs?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

6) Bending, kneeling, or stooping?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

7) Walking more than a mile?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

8) Walking several blocks?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

9) Walking one block?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

10) Bathing or dressing yourself?
   a) Yes, limited a lot
   b) Yes, limited a little
   c) No, not limited at all

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