

FAMILY CAREGIVER QUALITY OF LIFE IN A PEDIATRIC ONCOLOGY SETTING

By

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This dissertation is dedicated to my beautiful daughter, Olivia Grace, and my loving wife, Brooke, who I love now, forever, always.

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FAMILY CAREGIVER QUALITY OF LIFE IN A PEDIATRIC ONCOLOGY SETTING

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Research in the field of family caregiver quality of life (QOL) is growing but few studies have addressed family caregivers of children with cancer and few have been guided by a theoretical framework.

This research looked to examine what factors may influence QOL of family caregivers of children with cancer. Specific focus was placed on how demands of caregiving, hassles of patient medication administration and the appraisal of caregiving stress affect the family caregiver's QOL. The variables tested in the study were driven by a cognitive appraisal model of stress.

Family caregivers filled out questionnaires that included subscales from (1) the Caregiver Quality of Life Index – Cancer, (2) the Care of My Child With Cancer (demands), (3) the Family Caregiver Medication Administration Hassles Scale (hassles) and (4) the Appraisal of Caregiving Scale (stress). Demographics were also collected on the caregivers, the patients and the patient's disease state. The response rate was 90.91% (50 out of 55 who were told about the study).

A 3-step multistage path analysis determined the path coefficients for the final model. The first regression showed that demands and hassles accounted for 51% of the variance in stress.

The second regression showed demands and hassles accounted for 47% of the variance in family caregiver QOL. The final regression showed demands, hassles and stress accounted for 71% of the variance in family caregiver QOL with demands and stress each contributing significantly.

The final model was partially mediated. Hassles effect on QOL was fully mediated through stress. Demands had some mediation through stress along with a direct effect on QOL. Stress had a direct effect on QOL.

Hassles have a negative influence on QOL mediated through the caregiver's stress appraisal. Demands of caregiving and stress were both found to have direct negative impacts on QOL. This questionnaire can be used to help health care professionals identify areas of stress impacting the family caregivers. It will then allow for focused education or support that may be needed to help the family caregivers reduce their stress and make them an integral part of the patient's health care team.

## CHAPTER 1 INTRODUCTION

### **Problem Statement**

One of the most significant shifts in health care in recent years has been the migration of care from the hospital setting to the home or ambulatory setting. A number of factors have contributed to this shift, including pressures by managed health care organizations to limit hospital days as well as improved treatment options that no longer require in-patient stays. With this shift out of the hospital and into the home or outpatient setting there generally comes a transfer of care for the patient from trained professionals to the family or guardian(s) of the patient, with one or more individuals taking on the role of the patient's primary family caregiver. This transfer of care can often have a profound effect on a number of aspects of the family caregiver's life including their overall quality of life.

Research is growing in the field of family caregiver quality of life, but few studies have addressed the effects of caregiving on family caregivers of children with cancer. The majority of studies have included adult patient populations with a major focus on Alzheimer and dementia patients. A theoretical foundation to help bring together the constructs of the study into a meaningful conceptual framework has guided even fewer studies. This project looked at the quality of life of family caregivers of children with cancer and used a cognitive appraisal model of stress to identify how antecedent and mediating variables combine to affect the family caregiver's quality of life.

### **Background**

#### **Shifts in Health Care**

The shift in the care of patients from the hospital to the home has forced family caregivers to face tasks that many are ill prepared to handle. Arno, Levine and Memmott (1999) noted that

not only are caregivers unprepared for their new roles but most are never “offered appropriate follow-up services, reevaluation of care arrangements or referrals to community services.”

The roles of the family caregiver can include symptom management, administration of medications, equipment management, assistance with activities of daily living and acting as a patient advocate to name just a few (Laizner, Yost, Barq & McCorkle, 1993; Schoenfelder, Swanson, Specht, Maas & Johnson, 2000; Given, Given & Kozachik, 2001; Aranda & Hayman-White, 2001; Haley, 2003; Glajchen, 2004). Tasks undertaken by family caregivers can be identified as either direct care or indirect care. Direct care encompasses tasks that are carried out with the patient directly while indirect care tasks are done on behalf of the patient by the family caregiver, such as paying bills (Given et al., 2001). The role of the family caregiver changes as the condition and treatment strategies of the patient change.

Family caregivers, along with assuming their new roles and undertaking these new tasks, must also deal with their usual daily life responsibilities as well. This collision of caregiving roles and daily life responsibilities can often have a detrimental effect on the family caregivers, affecting their quality of life including their physical, social, financial and psychological well-being (Edwards & Ung, 2002).

### **Value of Caregiving**

Aside from the assistance that family caregivers offer to the patient they also bring relief to the health care system in terms of the freeing up of provider time and financial constraints on the health care system that often accompany the treatment of chronic conditions. Neglecting the needs of the family caregiver and ignoring their quality of life ultimately affects the caregiver, the patient and the health care system. Because of this, treatment strategies need to address not only the concerns of the patient but those of the family caregiver as well. The World Health Organization has noted in their work on palliative care of cancer patients that psychological

support should be provided to both the patient and the family (World Health Organization [WHO], 1990).

The financial impact that family caregivers have on the medical field is difficult to assess. Arno and colleagues (1999) and Arno during a lecture on the economic value of informal caregivers (2002) attempted to place a dollar figure on the value of informal caregiving. Mid-range estimates suggested that there were approximately 27.3 million family caregivers (providing assistance to adult patients) in the United States during the time of their analysis. Based on their calculations, they estimated that family caregivers provided the health care field with \$257 million in “free” health care services. This was well above the estimates for professional care provided in the home setting (\$32 million) or in nursing home environments (\$92 million). While these figures represent family caregivers of adult patients, the impact of family caregivers of children with chronic conditions can be assumed to be as significant if not greater since children will often require more around the clock care compared to adult patients.

### **Pediatric Cancer Impact**

Children (those under the age of 20) account for approximately 30% of the population in the United States (Ries, Percy & Bunin, 1999). When it comes to children, cancer is the leading disease in terms of mortality rates. In children aged 1 to 14, cancer is the second leading cause of death behind accidents (American Cancer Society, 2002).

Projections for 2007 suggest that approximately 10,000 children under age 15 will be diagnosed with cancer. Of those diagnosed nearly 80 percent will become long-term survivors of 5 years or more. This number has risen dramatically since before the 1970s when the 5 year survival rate was below 50% (American Cancer Society, 2007).

The majority of cancers found in children are a form of leukemia. Other cancers that children face include; brain tumors and neuroblastomas, bone cancers, lymphomas and kidney

and liver cancers. While adult cancers have been attributed mostly to lifestyle factors, little is known about the cause of children cancers.

The incidence for genders is fairly similar when looking at all cancers for children. Data indicate that one in every 300 boys will develop cancer while girls have an incidence rate of one in 333. When broken down by ethnic groups, the rates for white children are higher than all other races (Ries et al., 1999).

The importance of the role that family caregivers provide to the health care community and their impact on the care of the patient is undeniable. While the number of children afflicted with cancer is low compared to disease states affecting adults, the need remains to provide them the best care possible, including care by parents and other family members. A desire to understand the needs of children with cancer and their family caregivers provided the catalyst for the development and execution of this study.

### **Significance of the Study**

There are a number of reasons why this study is needed and what contributions it will bring to the family caregiving and pediatric oncology communities. The first of these is to give the family caregivers of children with cancer a voice regarding what impact the fight for their child's health is having on their lives both physically and mentally. Research has shown how family caregivers of adults with Alzheimer's, dementia and other disease states are impacted by their roles; but there is little literature to paint the same picture for family caregivers of children, specifically those family caregivers of children with cancer. This study will begin to bring to the forefront the types of activities family caregivers handle and struggle with by understanding the demands and hassles these caregivers face and how these impact the daily stress in their lives and their quality of life.

Secondly this study provides a theoretically based look at the impact that caregiving has on family caregivers who have not been studied by previous research. While a cognitive appraisal of stress model has been tested in adult patient populations, it has not been utilized in a pediatric setting.

Thirdly this study adds a component that has not been well studied in family caregivers – the stress involved in managing medication therapy of the patient. The review of literature found that none of the studies identified contained a measure of medication administration hassles included in this study, as a predictor of family caregiver quality of life.

### **Research Objectives**

This research examined the quality of life of family caregivers of children diagnosed with cancer. To better understand the quality of life of family caregivers of children with cancer and how their quality of life is influenced by various stressors, we established two primary objectives for this study. The first objective was to establish the validity and reliability of a quality of life instrument for use in a population of family caregivers of children with cancer. The second objective was to test a cognitive appraisal model of stress in the same population in order to identify factors that influence family caregiver quality of life. Specific focus will be on how demands of caregiving, hassles of medication administration and the appraisal of stress related to caregiving affect the family caregiver's quality of life.

## CHAPTER 2 THEORETICAL FRAMEWORK

### **Introduction**

The purpose of this chapter is to establish the theoretical framework used to better understand how the quality of life of family caregivers of children with cancer is influenced by selected factors. The first part of the chapter looks at how models of cognitive appraisal of stress have evolved over the years. The next section will be a review of studies that have used models of cognitive appraisal of stress as their foundation. The third section of the chapter will provide in detail the model that was used in this study and the specific variables that were included in the model for measurement purposes. After describing the model used in this study, the final section outlines the five research questions that were established in order to meet the two objectives of this study which were 1) to validate an instrument to measure the quality of life of family caregivers of children with cancer and 2) to identify factors that predict a caregiver's overall quality of life based on a cognitive appraisal model of stress.

### **Cognitive Appraisal Model of Stress**

The conceptual framework for this study was a cognitive appraisal model of stress. Origins of the model come from the combined works of Lazarus (1966), Lazarus and Folkman (1984), Lazarus (2000), Scott, Oberst and Dropkin (1980) and finally the model proposed by Carey, Oberst, McCubbin and Hughes (1991). The various formulations of the Lazarus model posit that individuals (in the case of this study family caregivers) are constantly evaluating relationships with the environment with respect to implications for personal well-being (Lazarus, 2000). This evaluative process is the "cognitive appraisal" component of the model and it allows individuals to ascertain how well they have responded to environmental events, such as a cancer

diagnosis. The cognitive appraisal process is continuous and leads to an individual's psychological or physiological response to the environmental event.

### **Lazarus and Folkman Appraisal Model of Stress**

The initial model developed by Lazarus (1966) and then revised by Lazarus and Folkman (1984) identified a set of antecedent variables that influence a person's appraisal of a given situation or event. These antecedent (or causal) variables were broken into two main sets; environmental and personal variables. Person variables are tied to an individual's values, their commitments and beliefs and what Lazarus and Folkman called an existential sense of control. Environmental variables focus on demands (situational), constraints, resources, ambiguity of harm and imminence of harm. Together the effects of these person and environment variables have an influence on how an individual appraises an event or situation.

Lazarus and Folkman identified appraisal as operating in a mediating fashion between the person/environment factors and the immediate and long-term effects that individual's experience. Lazarus defined appraisal as the evaluative product of appraising which itself was defined as the act of making an evaluation (2000). In their initial work Lazarus and Folkman (1984) separated appraisals into primary and secondary appraisals.

Primary appraising answers the question of "what does this mean to me?" Each person reacts differently to a particular situation and must decide whether or not it is necessary for them to react or respond to that situation or event. Lazarus identified that in order for a person to decide whether what is happening to them is relevant or not they weigh it against their values, goal commitments, beliefs about self and world and situational intentions (2000). Of these values, beliefs, commitments and intentions, Lazarus saw goal commitments as the most influential. He noted that if "there is no goal commitment, there is nothing of adaptational importance at stake in an encounter to arouse emotions" (2000).

The idea of goal commitments is a relevant concept that has significant meaning to family caregivers of pediatric patients fighting cancer or any other chronic condition. Lazarus viewed goal commitments as the inner drive of a person to work hard at achieving a goal no matter the obstacles or adversity that individual faced. This view of goal commitments, as doing whatever it takes, goes hand in hand with a parent's need to protect their child or help them when in need, no matter the cost, both personally and financially.

While primary appraising answers the question of "what does this mean to me", secondary appraising asks the questions of "Do I need to respond to this situation and if so what can be done?" This component of the cognitive appraisal model of stress is focused on what can be done to handle what Lazarus called a "troubled person-environment relationship" (2000). Individuals must decide what coping options are available to them and at the same time also decide whether or not those options can be acted upon or whether there are social and/or intrapsychic constraints in place that do not allow the individual to react to the situation/event.

In his writings Lazarus was clear to point out that the designations of "primary" and "secondary" do not signify a level of increased importance between the two types of appraising. Thus primary does not signify that it is more important than secondary. Together the two types of appraising allow for a complete understanding of the situation that will allow for the individual to cope with the situation in the most efficient manner possible. Lazarus spoke of an "active interplay" between the two appraisals.

The appraising process that individuals go through leads to a reaction to, or appraisal of, the situation. Lazarus distinguished between appraising, which is the process of making an evaluation of an event/situation, and appraisal which is the resulting reaction born from the

appraising process. In terms of appraisals there are three main classifications: benign, beneficial and stressful.

Benign appraisals have no impact on the individual as the event is viewed as neither positive nor negative. A positive reaction leads to a beneficial appraisal of the situation/event. Finally the reaction can be viewed in a negative connotation leading to what is termed a stressful appraisal. A stressful appraisal can itself fall into one of three classifications. The classifications are (1) harm or loss, (2) threat and (3) challenge. Harm or loss corresponds to damage that has already been done. Threats signify that damage may occur but at the present it has not. Finally, challenges are obstacles or events that may be difficult to overcome but are not immediately viewed as impossible to surmount.

### **Modified Model of Stress**

Following in the footsteps of Lazarus and other stress and coping researchers Scott, Oberst and Dropkin (1980) developed their own cognitive appraisal model of stress. Their goal was to develop a theoretical framework to be used for studies within an acute care cancer center focused on both patients and caregivers (Scott et al., 1980). The model has similar components to that of the models by Lazarus (1966) and Lazarus and Folkman (1984) but has some major differences as well.

One of the most important components of the Scott, Oberst, Dropkin (SOD) model that ties it to that of Lazarus and Folkman's work is the underlying assumption that the entire process of stress-coping is an ever-changing process that is continually adjusting to the event or situation based on the individual's appraising and coping. Backer et al (2000) point out additional similarities between the two theories and the major assumptions inferred by the researchers. They note that the works of Lazarus and Folkman and that of Scott et al. infer that the experience of stress is the result of a cognitive process and that this cognitive process leads to an assessment

that the demands of a given situation or event exceed current resources available to the individual and therefore produce stress.

A major difference in the models that Backer and colleagues (2000) identified has to do with an individual's perception of anxiety. They point out that in the eyes of SOD model, anxiety is initially experienced by every individual and then transformed into more specific emotions following the appraisal of the situation/event while Lazarus and Folkman felt that anxiety was just one of many emotions that individuals experienced after the appraisal process. To Lazarus and Folkman anxiety may or may not occur while Scott and colleagues felt everyone experiences anxiety when under stress.

Along with these similarities and differences in the major assumptions of both of these theoretical models there are also differences in the components included in the SOD model and some of the definitions of variables that are found in the SOD model and the model developed by Lazarus and Folkman.

As described above the major components of the Lazarus and Folkman model of stress-coping include an initial event or situation, person and environmental variables, primary and secondary appraising, coping and then finally an immediate or long term effect. In their work, Scott, Oberst and Dropkin had most of these variables within their model but the model was later expanded. Oberst and team (1991) included a "self care burden" variable for patients while Carey and colleagues (1991) added a "caregiver burden" variable for caregivers. Even though many of the variables appear to be similar in the separate models, definitions have some variability

Like the Lazarus and Folkman model, the SOD model begins with the occurrence of an event or situation that an individual must react to or appraise to determine its relevance and need

for response by the individual. The appraising process is influenced by what Oberst et al. (1991) identified as three initial antecedent categories. These three categories encompassed illness factors, personal factors and resources (Lazarus and Folkman had only “personal” and “environmental” categories).

In the study by Oberst, Hughes, Chang and McCubbin (1991), they identified illness factors as those tied specifically to the disease, including how distressing the patient felt the symptoms were, how dependent the patients felt, the perceived level of seriousness of the disease and the length of time the patient had been ill. Personal factors identify demographics of the patients including such measures as their age, education and gender. The final category of resources was comprised of socioeconomic status of the patient and the level of family hardiness. Family hardiness was conceptualized as “the family’s internal strengths and durability” (1991).

Lazarus and Folkman showed the initial antecedent variables in their model directly impacting the appraising process while in the SOD model that Oberst and colleagues used in their 1991 work they added a mediating factor between the initial antecedent variables and the appraising process. This new variable was identified as self-care burden and was defined as the product of both self care demands, that is demands related to taking care of oneself, and the difficulty associated with dealing with these demands.

The next component of the SOD model is the appraising process itself. Like Lazarus and Folkman, the work of Scott, Oberst and Dropkin subdivided appraising into primary and secondary forms. Scott and colleagues however had a different concept for how primary and secondary appraising were defined. They also believed that coping was a part of the appraising process rather than a separate variable as Lazarus and Folkman conceptualized it.

Primary appraising focuses on the evaluation of the stressor itself and its personal meaning to the individual. The primary appraising process results in one of three appraisals of stress. These results are identical to the ones outlined by Lazarus and Folkman: 1) irrelevant/benign (that is having no impact on the individual), 2) positive (beneficial to the individual) and 3) stressful (having a possible negative impact on the individual). Primary appraisals resulting in a stressful perception of the stressor can be further broken down into harm or loss, threats or challenges. These categories follow the Lazarus and Folkman model.

While primary appraising in the SOD model is similar to that of Lazarus and Folkman's work, secondary appraising is different. Scott and colleagues identified secondary appraising as focusing on the "initial coping strategies and their effectiveness in neutralizing the stress situation" (1980). While Lazarus and Folkman saw secondary appraising as asking the question "what can be done?", Scott, Oberst and Dropkin saw the question being asked during secondary appraising as "how well did this coping strategy work and what if anything needs to be done next to alleviate the stress?"

The outcome of the model is an adaptation of the individual to the stressor. Scott and colleagues saw three potential outcomes to the entire stress-coping process - a fluctuation of emotion, a fluctuation of endocrine profile or a behavioral response. They also noted "the ultimate adaptation is unique for each individual and occurs within a range of effectiveness from maintenance of ideal integrity to death" (1980).

### **Cognitive Appraisal of Stress Research**

A number of researchers have conducted studies using models based on the work of Lazarus and Folkman and their stress model. Northouse and colleagues conducted a study based on this model with a focus on both cancer patient quality of life and caregiver quality of life (2002). Additionally there have been a number of studies that have based their theoretical

framework on the works of both Lazarus and Folkman and Scott, Oberst and Dropkin that have focused on either caregivers alone or patients and caregivers within the same study (Carey et al., 1991; Northouse, Mood, Templin, Mellon, & George, 2000; Northouse, Templin, & Mood, 2001).

In a study based on the theoretical work of Lazarus and Folkman, Northouse and colleagues (2002) looked at the quality of life of women with recurrent breast cancer and also the quality of life of their family caregivers. In the study a total of 189 women and their caregivers completed a battery of instruments.

The antecedent variables included person factors (demographics, self-efficacy and current concerns), social factors (family hardiness and social support) and illness-related factors (symptom distress, stage of disease and disease-free interval). Appraisal was the mediating factor in the study and included measures of appraisal of illness/caregiving, uncertainty and hopelessness. The outcome variable was the quality of life of both the patient and the caregiver. In a slight change from Lazarus and Folkman's original model, Northouse predicted that the illness-related factors "would have a direct effect on each person's QOL and an indirect effect on their quality of life through the appraisal variables" (2002).

In this study the models accounted for 80.6% of the patient's mental health quality of life and 81.2% of the caregiver's mental health. Looking at physical quality of life the model accounted for 71.5% in the patient population and 71.7% in the caregiver population. Focusing specifically on caregiver QOL, the results of the study showed that personal factors (family member's education, caregiving efficacy and current concerns) had a significant direct effect on at least two of the appraisal variables, while caregiver efficacy and current concerns had a direct effect on all three appraisal variables. Each of these factors also had a significant indirect effect

on mental QOL. Only caregiving efficacy had an indirect effect on physical QOL while current concerns had a significant direct effect on physical QOL.

Of the social factors measured, only the caregiver's assessment of family hardiness showed any significant results, having a direct effect on caregiver hopelessness and uncertainty along with direct and indirect effects on both mental and physical QOL. Illness-related factors did not have a significant impact on the mediating factors (only caregiver symptoms and patient symptoms significantly predicted negative appraisal of caregiving). Of the effects of the illness-related factors on caregiver QOL, only caregiver symptoms had a significant predictive effect with both a direct and indirect effect on mental QOL and a direct effect on physical QOL.

Carey, Oberst, McCubbin and Hughes (1991) conducted research that combined the models of Lazarus and Folkman and that of SOD. This study looked at caregivers of patients receiving chemotherapy to explore what variables were predictive of caregiver mood.

Unlike the Northouse model discussed above which only had exogenous antecedent factors, two sets of antecedent factors (exogenous and endogenous) were included in this model. The exogenous factors in this model included patient/illness characteristics (seriousness of the disease, length of the illness, dependency of the patient and symptom control), caregiver characteristics (age, education, gender and health) and resources (socioeconomic and family hardiness). The endogenous antecedent factor included in the study was caregiving burden, which included measures of demand and difficulty of the caregiving role.

The mediating factor was again appraisal, this time measured on five levels including harm/loss, threat, challenge, benefit and benign. For analysis purposes harm/loss and threat were grouped together as negative appraisal because of high multicollinearity. The outcome factor was caregiver mood with only total mood disturbance included in the final study analysis.

Included in the study were 49 family caregivers caring for cancer patients currently receiving outpatient chemotherapy. Results of the analysis show that 47% of variance of caregiver burden was related to patient dependency. None of the other exogenous antecedent variables predicted caregiving burden.

Negative appraisal was directly influenced by the health of the caregiver (those with worse health had a more negative appraisal of caregiving), family hardiness (higher levels of family hardiness likely leads to fewer reports of negative appraisal of caregiving) and caregiving burden (those who perceived caregiving to be a burden were also likely to appraise caregiving as being a negative stressor). Patient dependency did not have a direct influence on negative appraisal of caregiving but because of its direct effect on caregiver burden it did have an indirect effect, accounting for 50% of the variance in negative appraisal.

Finally, stepwise regression analysis showed that 49% of the variance in mood dysfunction was accounted for by negative appraisal and age of the caregiver. Younger caregivers were more likely to experience higher levels of mood disturbance as compared to older caregivers. Additionally, those who had a negative perception of their caregiving role also were more likely to have greater levels of mood disturbance. The fact that negative appraisal was one of only two variables with a direct effect on caregiver mood helped to support the model that identifies appraisal as a mediating factor between the outcome variable and the two sets of antecedent variables.

Northouse and colleagues conducted two studies (2000 & 2001) focused on caregivers that used a model from the combined works of Lazarus and Folkman and Scott, Oberst and Dropkin. The first study looked at how well both patients and caregivers adjusted to a diagnosis of colon cancer. A total of 112 subjects participated in the study with 56 patients and 56 spouses.

Surveys were filled out during three different time frames (one week following diagnosis, 60 days post surgery and one year post surgery). In this study the model predicted that adjustment to the disease would be influenced by person, social and illness-related factors and that the effects of these three factors would be mediated by an individual's appraisal of the situation.

Person factors included variables measuring demographics, role of the participant (either patient or caregiver) and concurrent stress (the degree of stress in a variety of areas). Social factors included measures of family functioning, social support and marital satisfaction. The final antecedent factor was illness-related factors, which identified whether or not the patient had received a colostomy or not. The assessment of appraisal involved two separate variables: uncertainty about the nature and course of the illness and hopelessness about the future. The outcome factor in this study was psychological adjustment and consisted of measures of level of emotional distress and number of role adjustment problems.

Results of surveys completed one year after surgery supported the predicted model. Caregiver uncertainty had a direct effect on the caregiver's role adjustment problems at one year post-surgery. Uncertainty also acted as predicted, mediating the effects of caregiver age, caregiver concurrent levels of stress and the presence of a colostomy. Certain predicted antecedent variables were found to have direct effects on role adjustment rather than predicted indirect effects. Specifically caregiver marital satisfaction and presence of a colostomy both had direct effects (as previously noted colostomy also had a significant indirect effect) on caregiver role adjustment when it was expected that their effects would only be indirect.

Caregiver's age and concurrent stress both had direct effects on caregiver hopelessness but these effects did not carry on to role adjustment, as the direct effect of hopelessness was not found to be significant. The final predictive variable was caregiver role problems assessed at

time one. These had a direct effect on role adjustment at time two. Overall the model accounted for 64% of the caregiver's role adjustment.

The second study by Northouse and colleagues (2001) again looked at couples. The specific focus was couples' adjustment to breast cancer during the first year following diagnosis. Subjects in the study were 131 couples with 58 having a breast cancer diagnosis and 73 having a benign diagnosis. Data were collected from participants at 1 week, 60 days and 1 year after diagnosis. The focus of this review will be on both the husband's adjustment to the diagnosis and emotional distress at one year post-diagnosis.

The model used in the 2001 study was similar to the 2000 study previously discussed regarding three major components making up the model: antecedents, mediators and outcomes. Antecedent factors again included person, social and illness-related factors. The mediating factor was appraisal of the stressor and the outcome was adjustment to the diagnosis.

Person factors measured were demographics of the subjects and concurrent stress (impact of other stressors the subject is currently facing while also facing the cancer diagnosis). The variable included within the social factor was marital satisfaction. The illness-related factor was defined as severity of the illness. Severity was classified as benign, malignant with no lymph node involvement and malignant with lymph node involvement.

Appraisal of the diagnosis was measured by two variables, hopelessness and uncertainty. The final outcome of adjustment was also measured using two variables. The variables were measures of emotional distress and role problems. Because this model was longitudinal Northouse and colleagues also included in their model the measure of adjustment at baseline (one week post-diagnosis) as a predictor of adjustment at one year post-diagnosis.

Following other stress models, Northouse and colleagues predicted that the three antecedent factors would have an indirect effect on adjustment. The effect of these factors would be mediated through the appraisal factor, which would have a direct influence on adjustment to the diagnosis. The model in this study contained two changes that were not included in the Northouse model discussed above. The first change saw one of the antecedent factors (illness-related) hypothesized to have not only an indirect effect on the outcome but also a direct effect on adjustment to the diagnosis. Because of the longitudinal nature of the study they also predicted that baseline adjustment (measure one week post-diagnosis) would have a direct effect on how adjustment to the diagnosis was perceived at the final survey time. The model also suggested an interaction between the patients' perception of adjustment and the perception of the husband.

In their analysis, Northouse and colleagues ran two separate models, one for each of the outcome variables measured. The first model looked at how role adjustment problems were predicted by the model. Overall, the significant variables accounted for 59% of the variance in the husbands' role adjustment problems one year after diagnosis. As predicted, uncertainty, baseline role problems, illness severity and the patients' role problems all had direct effects on the husbands' role adjustment problems at one year post-diagnosis. Additional variables that had not been predicted to have direct effects were identified from the analysis and included concurrent stress and marital satisfaction. These variables were only predicted to have indirect effects through either uncertainty and/or hopelessness. Two factors did have indirect effects; education and marital satisfaction and both had their effects mediated through uncertainty. Both concurrent stress and marital satisfaction were significantly related to hopelessness, but

hopelessness failed to significantly predict role adjustment problems and therefore did not act as a mediating factor as predicted.

The second model that Northouse and colleagues ran considered the husbands' emotional distress one year after diagnosis as the outcome variable. As predicted, direct effects on emotional distress were found for husbands' baseline emotional distress, hopelessness and the patients' emotional stress one year after diagnosis. An indirect effect was found for husbands' baseline emotional distress with hopelessness acting as the mediating variable. Husbands' education level and concurrent stress were significantly related to uncertainty but as with hopelessness, uncertainty failed to significantly predict role adjustment problems and therefore did not act as a mediating factor.

All the studies reviewed that used models based on the concept of cognitive appraisal suggested that there was always some mediation between the measured antecedent variables and the appraisal component of the model leading to the emotional outcome of the participants. While no models showed full mediation of the antecedents through the appraisal component, they all suggested that a large portion of the variance in the emotional outcomes were attributed to the appraisal component. The next section of this chapter will explore the model proposed for this study and will identify how the variables chosen to measure fit into the concept of a cognitive appraisal of stress model.

### **Cognitive Appraisal of Stress in Caregivers of Pediatric Oncology Patients**

The model used in this study contains elements of the models put forth by Lazarus and Folkman (1984), Scott, Oberst and Dropkin (1980) and Carey, Oberst, McCubbin and Hughes (1991). The complete model is presented in figure 2-1.

In any cognitive appraisal model of stress there is an initial event or situation that initiates the stress appraisal process. The focus stimulus for this project was the diagnosis of cancer in

pediatric patients. Family caregivers of these children were the population of interest that were surveyed to see what factors influence their appraisal of their caregiving role and how their quality of life is affected by their role as a caregiver.

Like the modified SOD model introduced by Carey and colleagues (1991), this model has two sets of antecedent variables. The first variable set is exogenous variables while the second set is endogenous in nature. The exogenous set of antecedent variables (Fig 2-2) fell into the two main categories: environmental and personal. Environmental variables in this study were those that were tied specifically to the disease itself. Measures included the time since the patient was last diagnosed and the number of medications the patient was currently taking. The personal variables were classified as either caregiver variables or patient specific variables. Measures related to the patient were gender and age. Caregiver variables included gender, age, marital status, employment status, ethnicity, education level, relationship to the patient, SES, presence of social support, employment status and source of medical expense coverage.

The next step in the model involved the endogenous variables that were first included in the work of Oberst and colleagues (1991). The current model considers caregiver burden including medication hassles along with more general caregiving demands (Fig 2-3). Demands will focus on both the intensity and time devoted to caregiving while the medication hassles measurement will look at the intensity of the hassles associated with management of a patient's medication regimen.

Appraisal of stress was included in this model in the role of a mediating factor between the already discussed exogenous and endogenous antecedent variables and the outcome of interest, caregiver quality of life (fig 2-4). In this study, appraisal as stressful was the focus of analysis.

In particular, level of appraisal of stress as a threat was examined using an established instrument assessing caregiver stress.

The final outcome variable in the model is quality of life. Quality of life is a multidimensional measure that encompasses a number of concepts including physical functioning, emotional functioning, family functioning and social functioning. The complete model is included in Figure 2-1 below.

### **Research Questions**

The objectives of this study were to (1) validate a quality of life instrument for use in a population of caregivers of children with cancer and (2) to test a cognitive appraisal model of stress in the same population to identify factors that influence caregiver quality of life with specific focus on demands and hassles and the appraisal of stress related to caregiving. The following research questions were established for the purpose of meeting the above objectives. Question 1 focuses on Objective 1, while questions 2 through 7 are focused on Objective 2.

1. Is the Caregiver Quality of Life Index – Cancer Scale a reliable and valid instrument to use to measure quality of life in a population of caregivers of children with cancer?
2. Will the exogenous antecedent variables in the model being tested (patient characteristics, caregiver characteristics and illness characteristics) predict the demands placed on the caregiver?
3. Will the exogenous antecedent variables in the model being tested predict the caregiver's assessment of hassles related to medication administration?
4. Will the exogenous antecedent variables and endogenous antecedent variables (demands and medication administration hassles) predict the caregiver's stress appraisal?
5. Will the exogenous antecedent variables and endogenous antecedent variables (demands and medication administration hassles) predict the caregiver's quality of life?
6. Will the exogenous antecedent variables and endogenous antecedent variables and caregiver's stress appraisal predict the caregiver's quality of life?

7. Will the final model be a fully mediated model with only stress appraisal having a direct effect on CQOL or will it be a partially mediated model with some other variables aside from stress appraisal having a direct effect?

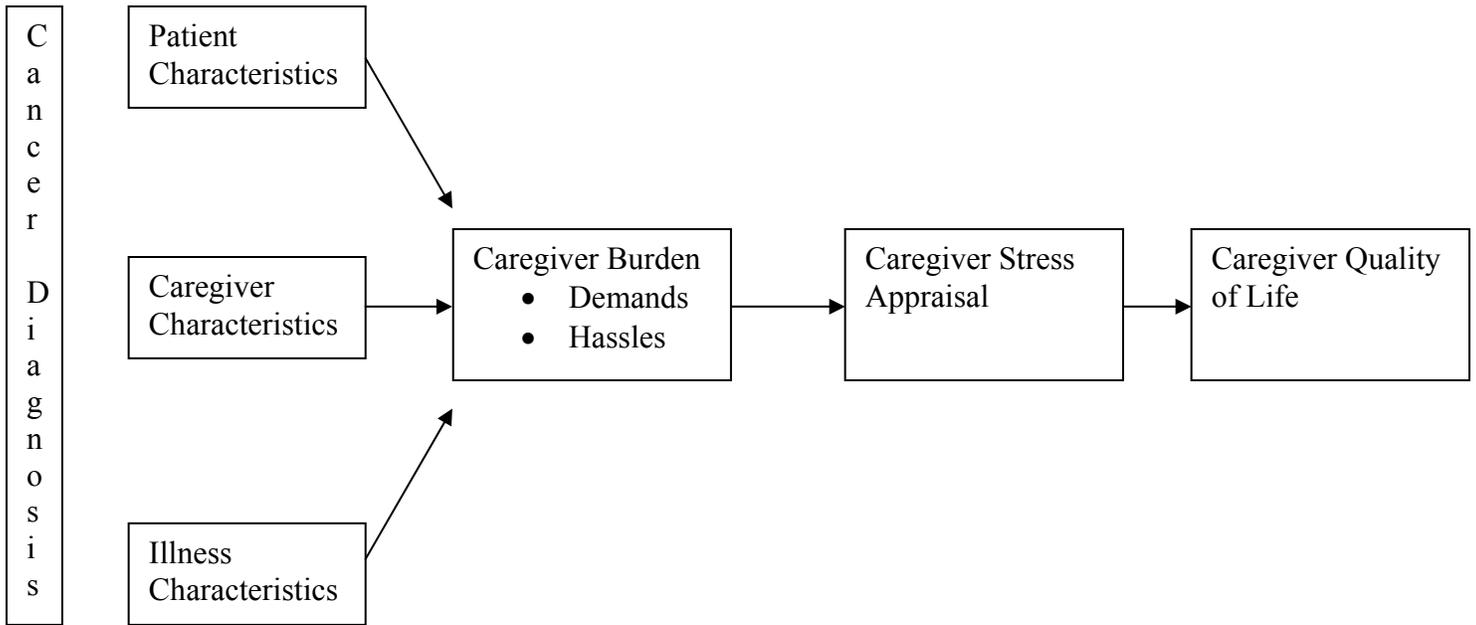


Figure 2-1. Cognitive appraisal model of stress for caregivers of pediatric oncology patients

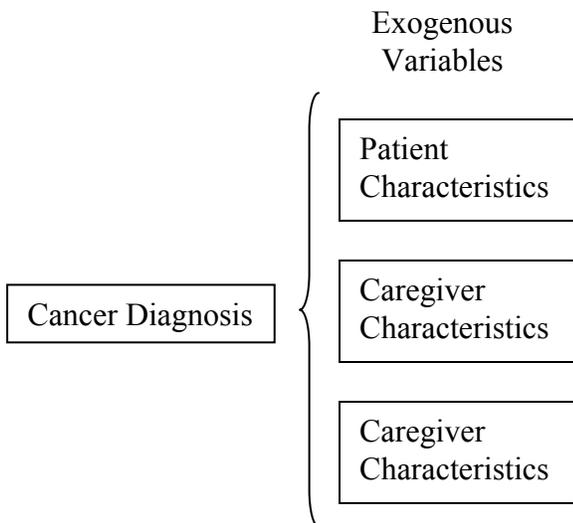


Figure 2-2. Exogenous antecedent variables in the model

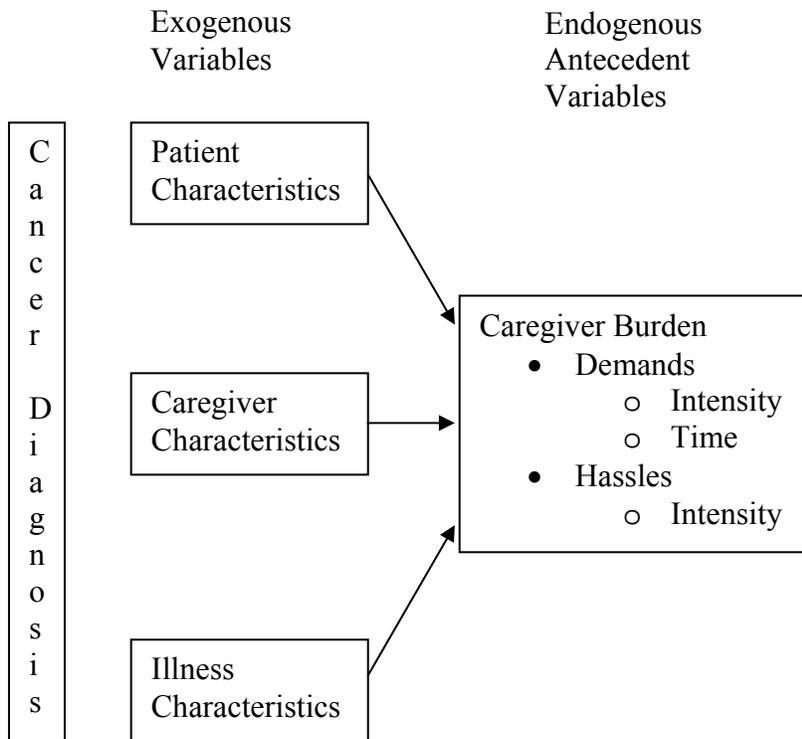


Figure 2-3. Endogenous antecedent variables added to the model.

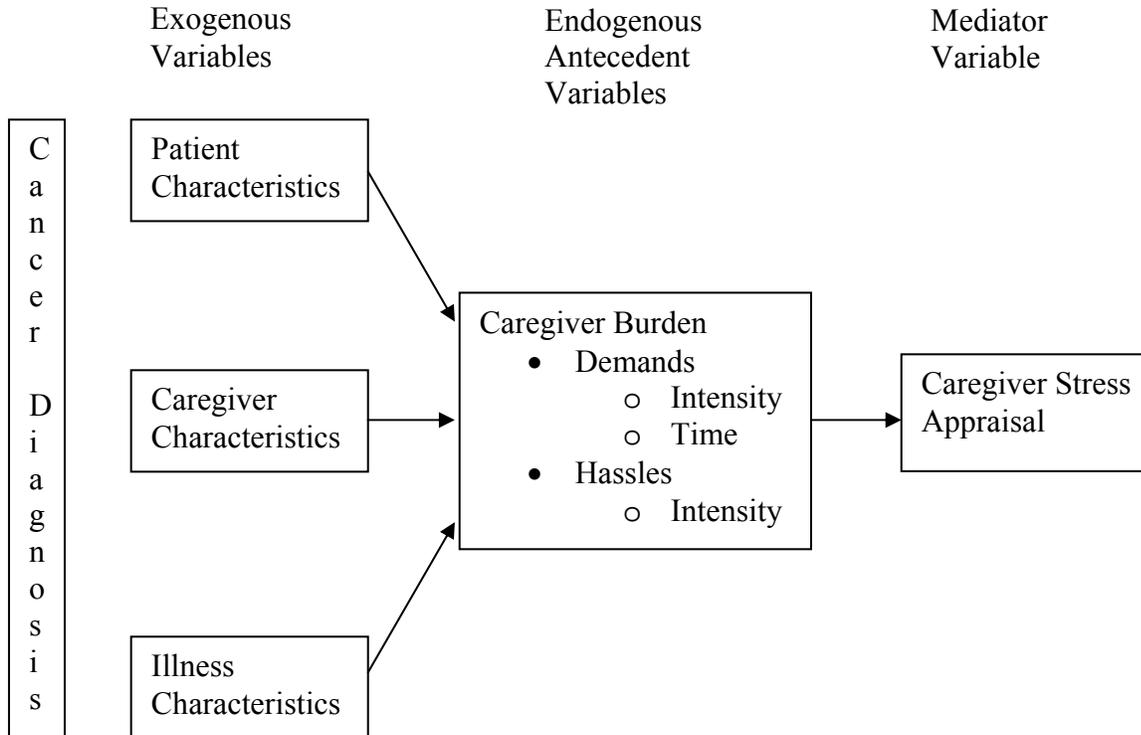


Figure 2-4. Mediator variable (caregiver appraisal) added to the model

## CHAPTER 3 LITERATURE REVIEW

The focus of this chapter is to provide insight into what type of research has been done to date with regards to caregiver quality of life. To keep in line with the current research project the studies reviewed are all studies that include cancer as the primary or one of the primary disease states. Areas that will be addressed will be the type of instruments that have been used to study caregiver quality of life (QOL), the type of caregiver populations that have been studied, the theoretical frameworks that have guided these studies, the findings of the studies with regard to caregiver QOL and the limitations of past research. Finally the chapter will conclude with a discussion of how the current project builds on the studies that have already been conducted.

### **Cancer Caregiver Quality of Life Research**

The author performed a literature search of the PubMed, CINAHL and ISI Web of Science electronic databases using key words: *caregiver, caregiving, quality of life, cancer, child, pediatric(s) and parent*. Inclusion criteria for articles were that they had to be in English, a primary measure of the study had to be caregiver quality of life, the caregivers were to be unpaid family caregivers and not paid professionals, data analysis had to look at identifying factors related to QOL. Patients being cared for by the caregivers had to have a diagnosis of cancer. Along with the database search, reference lists for identified articles were culled as well for additional studies not identified in the database searches.

The literature search netted a total of 26 usable articles that met the inclusion criteria. Sixteen of the articles were based in North America, while the other ten articles came from countries outside North America. Articles were published as recently as 2007 and dated back to 1994. The fact that all the studies were conducted within the past 13 years coincides with that fact that caregiver quality of life research is a fairly young field of research that is primed for

great expansion over the next few years. It is also a topic that crosses over numerous health care fields as studies were conducted in disciplines including nursing, psychology, and medicine.

Table 3-1 contains a summary of the articles included in this review along with some of the facts regarding each of the studies.

### **Quality of Life**

When it comes to the study of quality of life, a review of literature focused on either patients or caregivers will show that in most respects there is little agreement as to an explicit definition of quality of life (Le et al., 2003). What is consistent is an understanding that quality of life itself is a multidimensional concept that can include a range of domains. Domains often included are physical, social and psychological domains. Other domains that have been included but are not seen as often in studies include financial, spiritual, anxiety, burden, family functioning and depression (Edwards & Ung, 2002).

The lack of a consistent and agreed upon definition of quality of life is clear in the 26 articles that were reviewed here. In all, only four out of the 26 articles clearly defined quality of life outright while others simply hinted at the concept of what it was they were measuring. The four studies found to define quality of life all used a different definition to identify what ultimately is assumed to be the same concept. Wagner and colleagues (2006) saw QOL as “a multi-dimensional construct measuring overall enjoyment of life”, while Yamazaki and colleagues (2005) viewed QOL as “perceived health status and daily functioning associated with changes in health status, including physical and mental health and role and social functioning.” Witt Sherman and colleagues (2006) combined several concepts to come up with their perception of QOL that is “the impact of sickness and health care on a person’s daily activities and sense of well-being, and is related to an individual’s ability to cope, which is highly individualized.” The fourth article found to clearly define QOL relied on what would be viewed as the most accepted

definition as it is the definition designated by the World Health Organization Quality of Life Group (WHOQOL). Chien and colleagues (2003) conceptualized QOL as “individuals’ perceptions of their position in life within the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”

### **Measuring Quality of Life**

Tied into the fact that there is little agreement as to how researchers define quality of life, there is also little agreement as to how QOL should be measured. Of the 26 articles reviewed there were at least 15 different instruments used to measure caregiver QOL with some studies using more than one instrument to measure QOL. The instruments identified were classified into one of three measurement categories: global, generic and disease specific.

#### **Global instruments**

Global instruments are single item instruments (generally a visual analogue scale) that measure QOL across any population. They leave it up to the individual to conceptualize what they consider QOL to be. Because of this individual assignment of QOL these instruments are difficult to use to compare QOL scores across different populations. Global instruments were the sole means of QOL measurement in four of the 26 studies reviewed. Hagedoorn and team (2000) had caregivers rate their QOL on a scale of 0 to 10 with higher scores indicative of the best imaginable life. The other three global instruments were all 100mm visual analog based instruments (Nijboer, Triemstra, Tempelaar, Sanderman, & van den Bos, 1999; Iconomou, Viha, Kalofonos, & Kardamakis, 2001; Clark et al., 2006).

#### **Generic instruments**

Generic instruments are multiple item instruments or multiple instruments that measure multiple concepts of quality of life. Just over half (15) of the studies reviewed here used some type of generic instrument to measure quality of life. The most prevalent generic instrument

used in these studies was the Medical Outcomes Study Short Form 36 (MOS SF-36). This instrument has been validated in numerous populations and countries so it allows for some comparison of scores across studies.

The MOS SF-36 consists of 36 items that fall into eight multi-item scales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health). The eight subscales are clustered into two summary measures of physical health and mental health. Studies reviewed here based their results on the two summary scores only (Kershaw, Northouse, Kritpracha, Schafenacker, & Mood, 2004; Northouse et al., 2002; Weitzner, Jacobsen, Wagner, Friedland, & Cox, 1999; Kim, Baker, & Spillers, 2007) or on the scale score and summary scores (Wagner et al., 2006; Yamazaki et al., 2005; Boyle et al., 2000; Tuinman, Fler, Hoekstra, Sleijfer, & Hoekstra-Weebers, 2004). Other generic instruments used in the studies reviewed included the Quality of Life Index (Gaston-Johansson, Lachica, Fall-Dickson, & Kennedy, 2004), the Profile of Mood States-Short Form and Caregiver Strain Index (Campbell et al., 2004; Kim et al., 2007), Assessment of Quality of Life at the End of Life (Axelsson & Sjoden, 1998), World Health Organization Questionnaire on Quality of Life: BREF-Taiwan Version (Chien et al., 2003 and Chang, Tsai, Chang, & Tsao, 2007), the Quality of Life-Family (Borneman et al., 2003), the Mental Health Inventory-17 (Kornblith et al., 2001), the Quality of Life Scale (Family Version) (Witt Sherman et al., 2006) and the Functional Assessment of Chronic Illness Therapy-Spirituality (Kim et al., 2007). That is seven additional studies using eight different generic instruments to measure what is conceptually the same outcome.

### **Disease-Specific instruments**

Disease-specific quality of life instruments are similar to generic instruments in that they are multi-item instruments that measure multiple concepts. They can either provide overall

quality of life scores or a combination of subscale scores and overall scores. Unlike generic instruments that are viable across multiple populations, disease-specific instruments, as their name implies, are designed to measure quality of life within a specific disease state. The items of measurement have been developed with specific activities and outcomes associated specifically with a given disease state. The instruments can be focused even more specifically on populations within disease states, like patients or caregivers. Nine of the studies reviewed used some type of cancer-specific instrument to measure quality of life. Five of the nine studies used the Caregiver Quality of Life Index – Cancer (CQOLC) or a language-adapted version of the instrument. The CQOLC is the same instrument used in this study so it is discussed in more detail in the Methods chapter.

The other four instruments included the Functional Assessment of Cancer Therapy (Northouse et al., 2002), the Cancer Caregiver Quality of Life Index Chinese Version (Chen et al., 2004), the Functional Assessment of Cancer Therapy-BMT (Boyle et al., 2000) and the EORTC Prostate Cancer Quality of Life Questionnaire (Kornblith et al., 1994).

### **Additional Study Characteristics**

Twenty four of the studies reviewed included caregivers of adult cancer patients while only two were found that looked at the caregivers of children with cancer. Convenience samples were used in 20 of the studies while six studies used longitudinal study techniques to track quality of life over an extended period. Twenty one studies identified what the types of cancer the patients had while five did not. Of the 21 studies, the majority focused on breast or prostate cancer while the others focused on other specific cancer types or included patients covering a wide range of cancer types. Sample sizes ranged from 20 to 270 across the studies and nine studies compared the caregiver results to the patients, healthy matched subjects or other caregivers. Looking at whether or not the study was guided by a theoretical foundation, ten studies identified some

theoretical model as their basis while the remaining 16 did not. Caregivers in the studies included spouses/partners only in seven studies and a combination of individuals in the other 19 studies including children, parents, siblings, family friends, in-laws or other relative.

### **Factors Associated with Caregiver Quality of Life**

Current research in caregiver quality of life has identified a number of factors that are associated with or predictive of caregiver quality of life. In an effort to organize the findings of the studies identified for this review and to keep in line with the theoretical framework used in this current study, factors that were found to be significantly associated with caregiver quality of life in the reviewed studies were organized into one of three categories: patient factors, disease-related factors and caregiver factors.

#### **Patient characteristics**

Patient factors were those related specifically to the patient. Factors ranged from general demographic information like age and gender to factors such as performance status and activities of daily living.

The impact that cancer had on a patient was measured in a number of studies. Impact was measured by the patient's ability to perform overall activities of daily living (Wagner et al., 2006), to perform specific daily activities (Axelsson & Sjoden, 1998) and as a measure of the patient's overall physical status and ambulatory ability (Weitzner & McMillan, 1999; Weitzner et al. 1999a; Weitzner et al., 1999b). Of the items related to the patient's ability to lead a "normal" life, all but one study identified a negative relationship between these patient measures and caregiver QOL, which suggests that as the patient physically deteriorates and becomes more reliant on others to function physically the caregiver's quality of life declines. While two of Weitzner's studies (Weitzner et al. 1999a and Weitzner et al., 1999b) showed a negative

relationship between physical status of the patient and caregiver QOL, Weitzner & McMillan (1999) identified a slightly positive relationship.

Patient gender was identified in only one study as having a significant relationship to QOL. In this case Chien and colleagues (2003) identified that caregivers of females reported a significantly lower measure of social relationships (one of four QOL domains measured) than caregivers of male patients. Patient depression was another factor identified as negatively influencing caregiver QOL (Nijboer et al., 1999). Finally personal factors related to patients were identified by Kornblith and colleagues (1994) as having an influence on caregiver QOL. Four factors identified as having a negative impact on caregiver QOL were patient pain level, frequent urination by the patient, decreased sexual interest and patient lack of energy. As these factors all increased for the patient (that is they got worse) the caregivers saw a negative impact in certain factors related to their QOL. Clark and colleagues (2006) looked at what effect an intervention to improve the patient's overall quality of life would have on the caregiver's quality of life. In the end they saw no effect when comparing longitudinal results for caregivers of patients who had received the intervention and caregivers of patients who received standard care.

### **Disease related factors**

A handful of the studies reviewed identified disease specific factors as potential predictors of caregiver QOL. Disease related factors were those tied specifically to the disease and included factors ranging from disease type to time since diagnosis and stage of the disease. Reviewing the results of the studies showed that when disease specific factors were measured they often had no effect on caregiver QOL (Wagner et al., 2006; Kershaw et al., 2004; Iconomu et al., 2001; Northouse et al., 2002).

One study (Chien et al., 2003) identified two disease-specific factors as having an influence on caregiver QOL. The time since diagnosis had a negative impact (as time since

diagnosis increased caregiver QOL decreased). Treatment stage of the child also had an impact with parents of deceased children reporting the lowest QOL scores, while parents of children who were just under surveillance reporting the highest QOL. Caregivers of children who had relapsed reported scores that fell between the other two stages discussed.

Disease site was also found to have an influence on reported caregiver QOL scores (Weitzner et al., 1999b). The site of cancer diagnosis (lung, breast or prostate in this study) suggested that caregivers of patients with certain types of cancer were impacted more than caregivers of patients with other types of cancer. Caregivers of patients with lung cancer reported lower QOL scores than caregivers of patients with prostate cancer and caregivers of breast cancer patients had higher assessments of their QOL compared to caregivers of patients with prostate cancer.

### **Caregiver characteristics**

The final breakdown of categories from the reviewed studies included factors that were associated with the caregivers themselves. Caregiver characteristics included factors that ranged from basic demographics to factors related to their caregiving roles such as level of self-efficacy and symptom management. The coping skills of the caregiver (both emotion-focused and problem-focused) were shown to have a negative relationship with caregiver quality of life while the presence of social support was found to have a positive impact on caregiver QOL (Wagner et al., 2006). Social support was found to be positively related to caregiver QOL in other studies as well (Northouse et al., 2002; Yamazaki et al., 2005; and Chang et al., 2007). Kim and colleagues (2007) found that caregiver's self-esteem had positive effects on three of four quality of life dimensions that they measured (it had no effect on the fourth dimension). Other factors that were found to be positively related to caregiver quality of life included caregiver age, caregiver efficacy, family hardiness, higher education level, higher self-reported health status, relationship

with the patient, employment status, caregiver income level, quality of the relationship with the patient, self-esteem, marital status and county of residence population (Kershaw et al., 2004; Northouse et al., 2002; Chien et al., 2003; Weitzner et al., 1999b; Nijboer et al., 1999; Meyers & Gray, 2001; Witt Sherman et al., 2006).

Along with coping skills having a negative impact on caregiver QOL, others factors were also identified as having a similar effect. Demographic factors that lowered caregiver QOL included age and education level (Kershaw et al., 2004; Campbell et al., 2004) along with relationship to the patient, with spouses and partners reporting lower QOL compared to other caregivers (Witt Sherman et al., 2006). Looking beyond simple demographics, caregiver quality of life was negatively influenced by fatigue, depression, anxiety, burden of care, coping strategy, impact of caregiving on life, negative appraisal of caregiving, feelings of hopelessness, health status and caregiving stress (Gaston-Johansson et al., 2004; Kershaw et al., 2004; Iconomou et al., 2001; Northouse et al., 2002; Chien et al., 2003; Nijboer et al., 1999; Kim et al., 2007). Chang and colleagues (2007) looked at what effects sleep quality had on the caregiver QOL and identified a number of factors that had negative effects on QOL assessment including, daytime dysfunction, sleep disturbance and subjective sleep quality

Individual components of QOL itself also had effects on other QOL domains and overall quality of life. Nijboer and colleagues (1999) found that caregivers with high levels of quality of life at baseline reported higher QOL at 6 months. Higher mental health was found in multiple articles to be positively related to caregiver QOL (Weitzner et al., 1999a; Rhee et al., 2005).

### **Limitations in the Current Research**

One of the most significant limitations discussed earlier is the lack of a consensus on what makes up quality of life. A total of 26 articles were reviewed and only four had a clear definition of quality of life. This lack of a consensus leads to two other issues. The first is the wide-

ranging types of instruments used to measure quality of life. Instruments were found to be global, generic or disease specific. The second other issue that is spawned from the lack of a consensus for defining QOL is that the use of so many different types of instruments leads to the inability to be able to compare results across different studies and therefore different populations.

Another fault found in many of these studies and in most psychological studies, for that matter, is that the participants are drawn from convenience samples and there is little longitudinal work done to look at the true impact of caregiving. Cancer is a chronic disease that generally requires long term care by the caregiver. Studies that are only taking a snapshot of the caregivers live face the possibility of not capturing a true picture of what impact the disease is actually having on the caregiver.

While the researchers of these reviewed studies looked at a number of factors that influence caregiver quality of life, none of the studies here looked at the impact that the administration of the patient's medication had on the caregiver's QOL. Proper pain control depends on proper medication dosing which often becomes the responsibility of the caregiver.

A final limitation of the studies reviewed centers on the minimal focus on caregivers of children with cancer. Two of the 26 articles had a pediatric focus, while the others were all focused on caregivers of adult patients (at least 18 years of age). While the number of pediatric incidences of cancer is below that of adult cases, the fact remains that family caregivers of pediatric patients face many of the same difficulties as family caregivers of adult patients. However, caregivers of pediatric patients also face many different obstacles, that are not experienced by caregivers of adult patients and it is imperative that health care professionals understand these challenges.

## **Caregiver Quality of Life in a Pediatric Oncology Setting**

The current research project set out to address many of the limitations identified from the current literature on the quality of life of caregivers of patients with cancer. The focus population was caregivers of children with cancer, which to this point has been mostly ignored in current quality of life research. This study was driven by a cognitive appraisal of stress model, which was outlined in detail in chapter 2. This model helped to establish both the factors that were measured and the statistical techniques that were used to analyze the data collected. While some of the factors that were tested in this project have been incorporated into previous studies, newer variables were also added including a measure of the impact of medication administration. While this project was not able to address all of the limitations that have been found in the current caregiver quality of life issue, it did address many of them. An effort was made to further identify how family caregivers are impacted by their roles and to remind health care professionals of the impact that a disease like cancer has on not only the patient but also their loved ones who play a major, but often ignored role in the health care process.

Table 3-1. Studies of quality of life of caregivers of cancer patients

Title	Authors	Year	Design	QOL Instrument	Type of QOL Instrument	Sample (Spouse, parent, family, other)	Patients (adults or Children)	Definintion of QOL (yes/no)
Quality of Life of Husbands of Women with Breast Cancer	Christina D Wagner, et al.	2006	Cross-sectional	Medical Outcomes Short-Form (SF-36)	generic	husbands	Adult	Yes
Psychological distress, fatigue, burden of care and QOL in primary caregivers of patients with breast cancer undergoing autologous bone marrow transplantation	Fannie Gaston-Johansson, et al.	2004	Cross-Sectional Convenience Sample	Quality of Life Index	Generic	Majority were husbands (90%), others not specifically identified	Adult	No (conceptualized as 4 domains - health & functioning, socioeconomic, psychological/spritual, family)
Coping strategies and QOL in women with advanced breast cancer and their family caregivers	Trace Kershaw, et al.	2004	Cross-sectional convenience samples	Medical Outcomes Short-Form 36 (SF-36)	Generic	Husbands, sisters, daughters, sons and relatives/friends	Adult	no
Prostate Cancer in African Americans: Relationship of patient and partner self-efficacy to QOL	Lisa C Campbell, et al.	2004	Cross-Sectional Convenience sample	Profile of Mood States-Short Form (POMS-SF) and Caregiver Strain Index	Generic and Generic	Partners of prostate cancer patients (adults)	Adult	no
Couples dealing with cancer: role and gender differences regarding psychological distress and QOL	Mariet Hagedoorn, et al.	2000	Cross Sectional Convenience Sample	Quality of life ladder scale	Global	partners of cancer patients.	Adult	NO
Quality of life of cancer patients and their spouses in palliative home care	Bertil Axelsson and Per-Olow Sjoden	1998	Longitudinal	modified Assessment of quality of life at the end of life (AQEL)	Generic	partners of cancer patients	Adult	No
Impact of Cancer on primary caregivers of patients receiving radiation therapy	Gregoris Iconomou, et al.	2001	Cross-sectional convenience sample	100mm visual analogue scale	Global	spouse (54.5% female)	Adult	No

Table 3-1. Continued

Title	Authors	Year	Design	QOL Instrument	Type of QOL Instrument	Sample (Spouse, parent, family, other)	Patients (adults or Children)	Definiton of QOL (yes/no)
The caregiver quality of life index-cancer (CQOLC) Scale: revalidation in a home hospice setting	Michael A Weitzner, Susan C McMillan	1999	Cross-sectional convenience sample	Caregiver Quality of life Index-cancer Scale (CQOLC)	Disease Specific	family caregivers of adult cancer patients in a hospice setting (spouse, mother, daughter, son, sibling and other)	Adult	No
The caregiver quality of life index- cancer (CQOLC) scale: development and validation of an instrument to measure quality of life of the family caregiver of patients with cancer	Michael A Weitzner, et al.	1999	Cross-Sectional, convenience sample	CQOLC	Disease specific	Spouse, mother, daughter, son sister and other	Adult	no
Korean Version of the Caregiver Quality of life index-cancer(CQOLC-K)	Young Sun Rhee, et al.	2005	Cross Sectional, Convenience Sample	Caregiver Quality of Life Index - Cancer (QOLC-K)	Disease Specific	Spouse, child, parent and other	Adult	no
Quality of life of women with recurrent breast cancer and their family members	Laurel L Northouse, et al.	2002	cross-sectional, convenience sample	Functional Assessment of Cancer Therapy (FACT-G) and the SF-36	FACT-G = disease specific, SF-36 = generic	Husband, children, sister or other friend relative	adult	no
Health-related Quality of Life of Mothers of Children with Leukemia in Japan	Shin Yamazaki, et al.	2005	Cross-Sectional, Convenience Sample	Short-Form 36 (SF-36)	Generic	Mothers of leukemia patients	Children	Yes
Quality of Life Among Primary Caregivers of Taiwanese Children with Brain Tumor	Li-Yin Chien, et al.	2003	Combination of randomly selected strata and a convenience sample	World Health Organization Questionnaire on Quality of Life: BREF-Taiwan Version (WHOQOL-BREF-TAIWAN)	Generic	Caregivers (mothers, fathers and grandmother) of children with brain tumor	Children	yes

Table 3-1. Continued

Title	Authors	Year	Design	QOL Instrument	Type of QOL Instrument	Sample (Spouse, parent, family, other)	Patients (adults or Children)	Definintion of QOL (yes/no)
Family Caregiver Quality of Life: Differences Between Curative and Palliative Cancer Treatment Settings	Michael A Weitzner, Susan C McMillan, Paul B Jacobsen	1999	Cross-sectional, convenience sample	Caregiver Quality of Life Index-Cancer and SF-36 overall physical health scores	Disease Specific and generic	Spouse, child, other	Adults	no
Determinants of Caregiving Experiences and Mental Health of Partners of Cancer Patients	Chris Nijboer, et al	1999	Longitudinal Study	one-item linear visual analogue self-assessment scale	Global	Partner of patient (spouse, lover, etc)	Adults	no
Impact of Cancer patient's quality of life on that of spouse caregivers.	Mei-Ling Chen, et al.	2004	Cross-sectional, convenience sample	Caregiver Quality of Life Index (chinese Version)	disease Specific	Partners, children, other	Adult	No
Concerns of family caregivers of patients with cancer facing palliative surgery for advanced malignancies	Tami Borneman, et al.	2003	Longitudinal	Quality of Life- Family (QOL-F)	Generic	Spouse, child, parent and other	Adults (18 and older)	no
Caregiver Quality of Life after autologous bone marrow transplantation	Deborah Boyle, et al.	2000	Cross-Sectional, Convenience Sample	SF-36 and Functional Assessment of Cancer Treatment-BMT (FACT-BMT)	Generic and disease specific	Spouse, parents, friends and other	Adults (older then 19)	No
The Relationships between family primary caregiver characteristics and satisfaction with hospice care, quality of life an burden	Judy L Meyers, Louis N Gray	2001	Cross-Sectional, Convenience Sample	Caregiver Quality of Life Index-Cancer (CQOL-C)	Disease Specific	Spouse, child, in-law, other	Adults	No
Quality of life of patients with prostate cancer and their spouses	Alice B Kornblith, et al.	1994	Cross-Sectional, Convenience Sample	EORTC Prostate Cancer Quality of Life Questionnaire	Disease Specific	spouses/partners	Adults over 50	No

Table 3-1. Continued

Title	Authors	Year	Design	QOL Instrument	Type of QOL Instrument	Sample (Spouse, parent, family, other)	Patients (adults or Children)	Definition of QOL (yes/no)
Quality of life and stress response symptoms in long-term and recent spouses of testicular cancer survivors	Marrit A Tuinman, et al.	2004	Cross-Sectional, Convenience Sample	RAND-36 (Dutch version of the SF-36)	Generic	spouses during diagnosis and treatment and spouses after treatment	Adults over 20	No
The impact of docetaxel, estramustine and low dose hydrocortisone on the quality of life of men with hormone refractory prostate cancer and their partners: a feasibility study	AB Kornblith, et al.	2001	Longitudinal	Mental Health Inventory-17	generic	Spouse, siblings, children and friend	Adults	No
Quality of life of patients with advanced cancer and acquired immune deficiency syndrome and their family caregivers	Debroah Witt Sherman, et al.	2006	Longitudinal	Quality of Life Scale (Family Version)	generic	Spouse, siblings, children, relative, partner and other	Adults	Yes
Quality of life of caregivers of patients with advanced-stage cancer	Matthew Clark, et al.	2006	Longitudinal	Longitudinal Analog Self-Assessment Item	Global	Spouse, siblings, children, parent, and significant other	Adults	No
Quality of sleep and quality of life in caregivers of breast cancer patient	Edward Wei-Chung Chang, et al.	2007	Cross-Sectional, Convenience Sample	World Health Organization Questionnaire on Quality of Life: BREF-Taiwan Version (WHOQOL-BREF-TAIWAN)	Generic	Spouse, or children	Adults	No
Cancer Caregivers' Quality of life: effects of gender, relationship, and appraisal	Youngmee Kim, et al	2007	Cross-Sectional, Convenience Sample	Profile of Mood States-Short Form (POMS-SF), Short-Form 36 (SF-36) and Functional Assessment of Chronic Illness Therapy-Spirituality (FA-CIT-SP)	Generic	Spouse, children and other	Adults	No

## CHAPTER 4 METHODOLOGY

### **Introduction**

This chapter discusses the process that was used for establishing reliability and validity of the Caregiver Quality of Life Index – Cancer Scale (CQOLC) in a pediatric oncology setting, describes the dependent and independent variables and their corresponding measurement instruments and lists inclusion criteria for subjects. The chapter then moves on to identifying the data analysis strategies and concludes with the list of the study hypotheses.

### **Caregiver Quality of Life Index – Cancer**

The first goal of this study was to establish validity and reliability of using the CQOLC to measure quality of life of family caregivers who are caring for children with cancer. There are currently a number of generic instruments available to measure quality of life of family caregivers but to date there is no disease specific instrument focused on family caregivers of children with cancer. A review of literature by Edwards and Ung (2002) identified four instruments that had been used to measure family caregiver quality of life specifically designed for those in a cancer setting, one of which was the CQOLC. All four instruments had been used to look at family caregivers of adult cancer patients (patients over the age of 18).

The CQOLC is a 35-item instrument that uses a 5-point Likert-type scale to assess the quality of life of family caregivers of cancer patients. The instrument has a maximum score of 140 with higher scores representing a higher quality of life. Development of the instrument occurred over three phases that included patient, family caregiver and expert interviews, pilot testing and extensive psychometric testing to establish reliability and validity of the instrument (Weitzner et al., 1999a). The instrument, like most quality of life instruments, is

multidimensional with items measuring physical, emotional, family and social functioning as well as spirituality and financial issues (Boling, Macrina, & Clancy, 2003)

Psychometric testing was conducted using a sample of 263 family caregivers of adult cancer patients diagnosed with lung, breast or prostate cancer currently receiving active/curative care. Testing showed that the instrument had an internal consistency of  $\alpha = 0.91$  and test-retest reliability correlation coefficient of 0.95. Convergent reliability testing results ranged from  $r=0.49$  to  $r=0.65$  when correlation coefficients were examined between the CQOLC and the mental composite score (MCS) of the SF-36 and the subscale scores that make-up the MCS. Additional convergent reliability was established by looking at the correlations between the Beck Depression Inventory (BDI) and the CQOLC and also the State Trait Anxiety Inventory (STAI). These tests resulted in high correlations of  $-0.50$  and  $-0.52$  respectively. This indicated that lower anxiety and depression scores were associated with more positive quality of life. Weitzner and colleagues also looked at how well the CQOLC correlated to family caregiver burden using the Caregiver Burden Scale (CBS). Results showed as expected a highly significant correlation of  $-0.65$ . Discriminant validity was established by looking at the correlations between the CQOLC and the physical composite score (PCS) of the SF-36, the subscale scores of the PCS, scores from the Multidimensional Scale of Perceived Social Support (MSPSS) and finally scores from the Marlowe-Crowne Social Desirability Scale (MCSDS). Results showed that low significant correlations were found between the CQOLC and the subscales of the PCS, and the MSPSS score (range =  $0.20-0.37$ ). Results were not significant when looking at the correlation between CQOLC and the PCS score and the results of the MCSDS (Weitzner et al., 1999a).

Weitzner and McMillan (1999b) followed up the initial development and validation study of the CQOLC with a study that validated the instrument within a population of family

caregivers of cancer patients in a home hospice setting. Convergent validity was established in a similar fashion by looking at correlations between the CQOLC and MCS score and the subscale scores of the MCS of the SF-36. As before correlations were high and significant (range = 0.48-0.67). CQOLC scores were also compared to the total score and subscale scores of the Caregiver Quality of Life Index (CQLI). Results showed low to moderate correlation results (range = 0.27-0.48). Comparing scores between the CQOLC and the CQLI identified that while the two instruments were related they do not necessarily measure the same elements allowing the CQOLC to stand-alone as an independent measure of family caregiver quality of life.

Along with the two studies that Weitzner and colleagues (1999a,b) and Weitzner and McMillan (1999) conducted, the CQOLC has been revalidated in another disease state - Cystic Fibrosis (Boling et al., 2003) and another language – Korean (Rhee et al., 2005). Like the two Weitzner studies, these two revalidation studies followed the same procedures for establishing validity by looking at the strength and significance of correlations between scores on the modified CQOLC and the composite and subscale scores of the SF-36. Both studies also looked at the relationship between the modified CQOLC and the BDI. Results were similar in both studies with moderate to high correlations found between the modified CQOLC and the mental/emotional measures (MCS and corresponding subscales and the BDI) and low correlations to physical measures (PCS and corresponding subscales).

In an effort to reduce any burden on the family caregivers that chose to participate in this study, only subscales of each of the instruments were used in this study. To measure family caregiver quality of life, we chose to focus on the burden and financial concerns subscales. The burden subscale items were chosen because of their focus on the emotional impact of the caregiving role on the family caregiver and the family unit of the caregiver. The financial

subscale items were selected to help us better understand the financial impact that the caregiving role was having on the family caregiver and their family, given the amount of time that often is devoted to the care of a child being treated for cancer, and the fact that it often limits the employment of one or both parents. All items for each subscale were used to keep them as the original author intended. The total number of items from these two scales that were used in this study was 13. Appendix A contains a complete copy of the questionnaire packet that the caregivers filled out. Section 1 contains the 13 items that were used to measure family caregiver quality of life. The burden subscale items were 1, 2, 3, 4, 5, 7, 8, 9, 10 and 11. The financial concerns subscale included items 6, 12 and 13.

Validation of the CQOLC in a pediatric oncology population occurred in a two-phase process. The first phase of the instrument validation involved the convening of an expert panel to review the instrument for content validity. The panel was made up of members of the Hematology/Oncology Division in the Department of Pediatrics at the University of Florida. In order to establish content validity of the instrument the role of the panel was to review the CQOLC to assess the clarity and relevance of the items to the target population of family caregivers of children with cancer. Content validation allows for the assessment of whether the items adequately represent a performance domain or construct of specific interest (Crocker & Algina, 1986). The panel also determined if any items should be removed or modified. Before presenting the instrument to the panel minor grammatical changes were made to the instrument to make the wording relevant to family caregivers of children with cancer. Table 4-1 shows the four items, used in this study, that were changed along with the original items as they appear in the original version of the CQOLC.

Along with the review and modification of items the expert panel was also asked to advise on the actual administration of the instrument. They looked at response options for the family caregivers, time specification for recall (only back 7 days), administration strategy (interview or self-completion), time to complete, readability of the instrument (including order of the items) and scoring for possible changes that need to be made to accommodate the target population.

The only recommendation by the panel was to change the order of the items as they were originally presented to them. This change meant removing the item “I am frightened my child/infant will die” as the first item the caregivers would see and moving it to later in the survey. The panel did not feel comfortable with asking the caregivers to think about the potential death of their child as the first item they would complete related to this study.

The second phase of the validation process was to establish reliability and validity estimates for the CQOLC within a population of family caregivers of children with cancer. Family caregivers were recruited from the pediatric oncology department of the University of Florida Shands Cancer Center (UFSCC) located in Gainesville, Florida. The clinic is in operation five days per week and sees approximately 15 patients a day. Eighty to ninety new patients a year seek treatment.

Reliability was established by measuring the internal consistency reliability of the overall instrument along with the two subscales as well. Internal consistency is a reflection of “the extent to which items measure various aspects of the same characteristic and nothing else” (Portney & Watkins, 2000). Cronbach’s coefficient alpha ( $\alpha$ ) was used as the measure of internal consistency, which ranges from 0.00 to 1.00. Higher levels of  $\alpha$  are expected to be found for instruments that show high internal consistency with acceptable levels above 0.70.

Convergent validity was established by looking at how well the family caregiver's quality of life, as measured by the modified CQOLC, correlated with the measures for demands, medication administration hassles and appraisal of stress. To establish the presence of convergent validity, Pearson's correlations were expected to be high between the scores on the CQOLC and the scores for demands, hassles and stress appraisal.

### **Family Caregiver Quality of Life**

The second objective of this project was to study how the quality of life of family caregivers of children with cancer is influenced by factors associated with a cognitive appraisal model of stress. Primary factors of interest included measures of family caregiver burden (the demands of family caregiving and the level of hassles associated with medication management of a child with cancer) and the family caregiver's appraisal of stress associated with caregiving. Secondary variables of interest in terms of their role in predicting family caregiver quality of life were sociodemographic variables tied to patient characteristics (age and gender), family caregiver characteristics (age, gender, level of social support, marital status, employment status, ethnicity, education level, relationship to the patient, household income and medical expense coverage) and illness characteristics (time since diagnosis/re-diagnosis and number of current medications).

Instruments used to meet this objective included the CQOLC, the Care of My Child with Cancer (CMCC), the Family Caregiver Medications Administration Hassles Scale (FCMAHS) and the Appraisal of Caregiving Scale (ACS) along with questions used to collect demographic information.

### **The Care of My Child With Cancer**

The Care of My Child with Cancer (Keegan Wells et al., 2002) was used to measure caregiving demands. The instrument consists of 28 items with which family caregivers identify

both the time spent in caregiving activities, and the difficulty/effort associated with these various caregiving activities. Items are scored on a 5-point Likert-type scale with time broken down as none, <1 hour/week, 1-2 hours/week, 2-5 hours/week and >5 hours/week. Effort/difficulty is also scored on a 5-point Likert-type scale including none, a small amount, moderate, quite a lot and a great deal as the response choices. Individual demand scores are calculated by taking the square root of the product of reported time score and effort score for each item and then summing the scores for all the items. Overall scores are a sum of the individual calculated demand scores with a total range of 28 to 140. Higher scores estimate higher levels of demand associated with caregiving.

Items for the instrument were developed through a two-step process including a review of literature and feedback from pediatric oncology nurses. An expert panel was formed of eight leading pediatric oncology nurses to assist in the initial formation of items. The panel was used to establish content validity of the instrument. The instrument was validated by a sample of 158 primary family caregivers (153 provided complete usable data) of children being treated at one of nine participating Pediatric Oncology Group institutions. Internal consistency was established through the calculation of Cronbach's alpha, which was 0.93. Test-retest reliability was reported using Pearson's product-moment coefficient. A value of 0.90 was calculated following a retest interval of 3 to 7 days (Keegan Wells et al., 2002).

As described earlier, there was a concerted effort to reduce the amount of burden placed on caregivers who agreed to participate in this study. For measurement of the demands of caregiving a 13 item subscale identified in the initial development of the instrument was used rather than using the entire instrument. Like the burden subscale used from the CQOLC, the items in the demands of caregiving subscale that was used were focused primarily on the

emotional impact of the family caregiver and that of the caregiver's immediate family. The items used can be found in the complete questionnaire included as appendix A. The 13 demands items are all in section 3 of the questionnaire.

### **The Family Caregiver Medication Administration Hassles Scale**

The Family Caregiver Medication Administration Hassles Scale (Travis, Bernard, McAuley, Thornton, & Kole, 2003) is a multidimensional measure of the hassles family caregivers face when dealing with medication administration. The FCMAHS was used to measure the second component of family caregiver burden being measured, which was family caregivers' assessment of how much of a hassle it was to be responsible for administering patients' medication.

The complete instrument consists of 24 items that make up four subscales (information seeking/information sharing, safety issues, scheduling logistics and polypharmacy). The items within the four subscales address areas of caregiving that are specifically tied to medications use and that cover responsibilities that fall within the role of the family caregiver. Along with the four subscale scores the instrument also allows for an overall score of medication administration hassles. The overall score will be used in the analysis phase for this project.

Items are scored on a 6-point Likert-type scale (0=no hassles – 5=worst of all hassles) and the instrument has a maximum score of 120 for the overall hassle rating. Higher scores represent higher hassle assessment for medication administration. A three-phased approach was used to develop and validate the instrument including instrument development, pilot testing and field testing/instrument evaluation.

A total of 158 family caregivers providing medication administration support to chronically ill adult patients were recruited to help with psychometric testing of the FCMAHS. Internal consistency reliabilities for the four subscales ranged from  $\alpha=0.80$  to  $\alpha=0.92$ . An

overall internal consistency reliability score of  $\alpha=0.95$  was also calculated. Two-week test-retest reliabilities were calculated for each of the subscales with scores ranging from 0.78 to 0.85. The overall instrument test-retest reliability was 0.84. Construct validity was also analyzed by examining correlations of the total scale score and subscale scores with scores on the Medication Complexity Index (MCI) and the Modified Caregiver Strain Index (MCSI). Subscale scores significantly correlated with the MCI and MCSI and ranged from  $r=0.19$  to  $r=0.29$  and  $r=0.34$  to  $r=0.40$  respectively. Overall scale scores were significantly related to the MCI ( $r=0.19$ ) and the MCSI ( $r=0.44$ ) as well suggesting modest construct validity (Travis et al., 2003).

For this study only items from the safety issues subscale were used. The items used can be found in the complete questionnaire included as appendix A. The five medication administration hassles items are all in Section 4 of the questionnaire.

### **Appraisal of Caregiving Scale**

Family caregiver appraisal of stress was measured using the Appraisal of Caregiving Scale (Oberst 1991). The current version of the instrument consists of 27 items that look at family caregiver appraisal responses to five situations associated with caring for a sick family member. The situations covered include: 1) caregiving tasks and responsibilities, 2) relationships and interpersonal support, 3) lifestyle, 4) emotional and physical health and 5) overall personal impact. Two types of stressful appraisal (threat and general stressfulness) and one type of positive appraisal (benefit) are measured by the instrument making up three subscales. Family caregivers respond to each of the 27 items using a 5-point Likert-type scale with choices ranging from “very false” (1) to “very true” (5). Scores are calculated for each of the three types of appraisal measure. There is no overall score of appraisal.

The threat appraisal subscale consists of 13 items with scores ranging from a low of 13 to a high of 65. The general stressfulness subscale is made up of eight items with scores ranging from 8 to 40. All items in this subscale are reverse scored. The final subscale of benefit appraisal is made up of six items with scores ranging from 6 to 30. For all of the subscales, higher scores correspond to higher levels of appraisal for the given subscale, that is, greater levels of threat appraisal, higher levels of general stressfulness and higher benefit appraisal.

Instrument validation was established using an aggregated sample of 240 family caregivers. Validation was established using construct validity and internal consistency. Construct validity of the ACS subscales was established by testing theoretically generated hypotheses about the correlation between the two stressful appraisal subscale scores and a number of family caregiver and illness/caregiving situation antecedents. Negative and significant relationships were found between threat appraisal and family hardiness ( $r=-0.36$ ), economic status ( $r=-0.20$ ) and family caregiver health ( $r=-0.29$ ). Results were as hypothesized with threat appraisal decreasing as family hardiness, economic status and family caregiver health improved. General stressfulness was significantly correlated only to family hardiness ( $r=-0.36$ ). Four additional antecedents tested for significant relationship with threat and general stressfulness appraisal were caregiving demands, caregiving difficulty, seriousness of illness and patient dependency. Positive and significant relationships were found between all four antecedent variables and both threat appraisal ( $r$  range = 0.13 to 0.58) and general stressfulness ( $r$  range = 0.20 to 0.35). The results supported the proposed theories that as family caregiver demands, family caregiving difficulty, seriousness of illness and patient dependency get worse, the levels of negative stress increase (Oberst, 1991).

Correlations between benefit appraisal and the same seven antecedent variables discussed above were also calculated. In looking at these correlations there was no initial hypothesized expectations before testing the relationships. Results showed that benefit appraisal was significantly correlated only to family hardiness ( $r=0.25$ ), suggesting that as family hardiness improves caregiving is viewed as more beneficial (Oberst, 1991).

Reliability of the ACS was established by calculating internal consistency (Cronbach's alpha) for each of the three subscales of the instrument. The threat appraisal subscale had a Cronbach's alpha of 0.90. General stressfulness appraisal subscale had a calculated Cronbach's alpha of 0.73. The benefit appraisal subscale had an internal consistency value of 0.74 (Oberst, 1991).

The focus of this study was solely on the negative effects of caregiving. Because of this specific focus, only the items from the threat appraisal subscale were used to measure appraisal of stress. For a complete review of the 13 items used in the study, the complete questionnaire can be found in Appendix A. The items for stress appraisal make up Section 5 of the questionnaire.

### **Study Constructs – Dependent and Independent Variables**

Listed in Table 4-2 below are the variables that were collected in the study along with their operationalization and a source for the data. The purpose of measuring the endogenous antecedent variables, the mediating variable and the outcome variable are discussed in more detail below.

#### **Family Caregiver Burden**

Family caregiver burden is a multidimensional measure of the impact that providing caregiving has on the family caregiver. Given and colleagues (2001) identified burden as a “multidimensional biopsychosocial reaction resulting from an imbalance of care demands

relative to family caregivers' personal time, social roles, physical and emotional states, financial resources and formal care resources given the other multiple roles they fulfill.” For this study burden was looked at via two different aspects, family caregiver overall demands and family caregiver hassles associated with medication administration management.

### **Family caregiver demands**

Demands of caregiving reflect the amount of difficulty and time that family caregivers must devote to taking care of their child with cancer. Tasks fall within a number of categories and require different levels of commitment from the family caregiver. Demands will be measured using The Care of My Child With Cancer instrument. Included in the instrument are demands related to physical care, emotional care, finances, family/interpersonal relationships and communication.

### **Medication administration hassles**

Hassles reflect what are considered minor events that individuals appraise as threatening to their well-being (Lazarus & Folkman, 1984). Individually the threat associated with hassles is considered fairly weak. However as hassles begin to accumulate over time their impact becomes more significant and their effects on an individual become more noticeable. Medication hassles were identified by Travis and colleagues as “minor daily irritants that family caregivers experience when they assist a dependent family member with medication regimens” (2003). The Family Caregiver Medication Administration Hassles Scale was used to quantify the overall measure of daily hassles in family caregiving related to medication administration in this study.

### **Stress Appraisal**

Oberst defined appraisal as “the evaluation of potentially stressful person-environment encounter in terms of its personal meaning or significance to well-being” (Oberst, 1991). These potentially stressful events can be evaluated by family caregivers into one of three categories: (1)

benign – no impact on well-being, (2) beneficial – enhancing well-being and (3) stressful-negative impact on well-being. Stressful appraisal can then be classified as a (1) harm/loss – damage has already been done, (2) threat – potential for damage or harm and (3) challenge – potential for gain or growth. The focus in this study will be solely on threat appraisal associated with caregiving for a patient with cancer. Threat appraisal will be measured using the threat appraisal subscale items of the Appraisal of Caregiving Scale.

### **Family Caregiver Quality of Life**

The outcome variable for this project is the family caregiver’s self-reported quality of life. Measurement of this outcome involved using two of the subscales of the Caregiver Quality of Life Index –Cancer Scale as described in detail above.

### **Subjects**

To be included in this study, participants had to identify themselves as the primary family caregiver for a child with cancer. A primary family caregiver, as defined for this study, is an individual who is responsible for assisting the patient the majority of the time in handling both their physical and emotional needs related to their illness. Along with being the primary family caregiver the participant had to also meet the following inclusion criteria: 1) be the parent or legal guardian of the pediatric (under 21 years of age) oncology patient, 2) be at least 18 years of age, and 3) be proficient in English for both reading and speaking.

### **Procedures**

Following check-in at the pediatric cancer center infusion room, the primary investigator approached family caregivers to explain the purpose of the study. Family caregivers that met the inclusion criteria and elected to participate in the study completed a consent form and were then given a questionnaire packet to complete. A copy of the consent form is in Appendix B while the questionnaire can be found in Appendix A. Family caregivers were asked to complete the

packets while in the clinic during the patient's appointment. It was not uncommon for the patient's infusion session to last for many hours. All caregivers that participated in the study by completing a questionnaire in full were given a Publix \$20 gift card as a sign of thanks.

If more than one caregiver was present and identified themselves as sharing in the caregiving responsibilities, then both family caregivers were allowed to participate and were included in the study sample. Each family caregiver filled out their own survey.

Questionnaire packets were manually, numerically stamped with random numbers allowing all item results, could be combined later on should they become separated. It also helped to identify which consent form went with which questionnaire. A list identifying family caregiver to questionnaire packet was kept in a separate computer database that was password protected. Only the primary investigator had access to the list.

Data from the survey were all entered into a Microsoft Excel spreadsheet that was password protected and then stored on a networked computer within the University Of Florida College Of Pharmacy. This spreadsheet had a separate login that only the primary investigator had access to.

### **Statistical Analysis**

Basic descriptive statistics were run for all variables to establish means and standard deviations for variables measured on continuous scales and frequencies for categorically measured variables. The focus then shifted to establishing reliability and validity of the CQOLC for use in a pediatric oncology setting to go along with the content validation already carried out. Following the tests for validity and reliability the focus of the statistical analyses then shifts to looking at how the data fit the proposed model of family caregiver quality of life through a path analysis procedure based on the works of Baron and Kenny (1986).

### **Internal Consistency Reliability**

To meet objective one of this study, we first established the internal consistency reliability score for the overall score of the CQOLC. The reliabilities of the two subscales of the instrument were also established. We also ran item-total statistics to determine if the instrument would perform better by removing items identified in the analysis that were potentially reducing the overall reliability.

### **Convergent Validity**

The second step to confirm the validity of the instrument was to run convergent validity tests to see how well the CQOLC correlated with the other three main instruments used to measure caregiving demands (CMCC), medication administration hassles (FCMAHS) and stress appraisal (ACS). Pearson's correlations were run during this phase of the validation process to look for convergence.

### **Path Analysis and Mediation Testing**

Meeting objective two of this study was a four step process that occurred in two separate phases.

#### **Tests of association**

The first phase of this process involved establishing the relationships between each of the demographic variables (for patients, caregiver and the disease) and the family caregiver quality of life assessment via either point bi-serial correlations or Pearson correlations for most of the analyses. Analysis of variance was used to look for relationships between family caregiver QOL and education level, income and ethnicity. This was done since these three variables were all measured using multiple categories rather than two. This phase was done to identify which of the demographic variables were significantly related to family caregiver quality of life in an

effort not to flood the path analysis regressions with variables that were not related to the outcome.

Only variables that were significant were to be included in the final steps of the process. As outlined in the next chapter none of the variables were significantly related to family caregiver QOL and therefore were not included in any further analysis.

### **Path analysis**

The second phase of the process to meet objective two involved a three-step multistage regression analysis based on the work of Baron and Kenny (1986). These regressions served two main functions. The first was to determine the path coefficients for the final model enabling us to show how each of the variables influenced family caregiver QOL. The second purpose for these regressions was to determine whether or not the model was a fully mediated model with the effects of demands and hassles on family caregiver QOL passing through stress appraisal. All data analyses were conducted using SPSS version 15.0 for Windows (6 Sep 2006). Attempting to establish that the model was fully mediated the following hypotheses were tested:

H1. Regressing stress appraisal on both caregiving demands and medication administration hassles will result in both demands and hassles contributing significantly to stress appraisal.

H2. Regressing family caregiver quality of life on both caregiving demands and medication administration hassles will result in both demands and hassles contributing significantly to family caregiver quality of life.

H3. Regressing family caregiver quality of life on caregiving demands, medication administration hassles and stress appraisal will result in only stress appraisal contributing significantly to family caregiver quality of life.

The first regression equation run was to test Hypothesis 1 that demands of caregiving ( $X_1$ ) and hassles of medication administration ( $X_2$ ) which were the independent variables had a significant effect on stress appraisal ( $Y_1$ ), the mediator variable:

$$E(Y_1) = \beta_1 X_1 + \beta_2 X_2$$

The second regression, which tested Hypothesis 2, looked at whether or not demands of caregiving ( $X_1$ ) and hassles of medication administration ( $X_2$ ) had a significant effect on family caregiver quality of life ( $Y_2$ ), the dependant variable:

$$E(Y_2) = \beta_1X_1 + \beta_2X_2$$

The final regression that tested Hypothesis 3 looked at the effects of demands of caregiving ( $X_1$ ), hassles of medication administration ( $X_2$ ) and stress appraisal ( $X_3$ ) on family caregiver quality of life ( $Y_2$ ):

$$E(Y_2) = \beta_1X_1 + \beta_2X_2 + \beta_3X_3$$

Once all the models were run the significant standardized Beta coefficients ( $\alpha \leq 0.05$ ) from the first and third model were plugged into the depiction of the theoretical model to look at direct and indirect effects of all the variables in the model to better understand the influence of each of the variables on family caregiver quality of life. The initial model proposed is represented by figure 4-1.

The direct effects are the standardized Beta coefficients, while the indirect effects had to be calculated. Based on the final model, indirect effects were calculated only for demands of caregiving and hassles of medication administration. This calculation was done by multiplying the direct effect coefficients of demands or hassles respectively on stress to the direct effect coefficient of stress on family caregiver quality of life.

Once the direct and indirect effects of the variables were calculated, the total effect of each of the three variables on family caregiver quality of life was determined. For demands and hassles, total effect was the sum of the direct effect plus the product of all the indirect effects for each variable. Total effect for stress appraisal was strictly the direct effect coefficient to family caregiver quality of life.

Along with determining the effects of the independent variable and mediating variable on family caregiver quality of life, the three regressions also assisted in establishing whether or not the final model was fully mediated or partially mediated.

A mediated model would meet the following conditions to show full mediation. First, the independent variables in equation one listed above would have an effect on the mediator variable. In the second equation listed, the two independent variables would have an effect on the dependent variable. Finally for the third equation listed the mediating variable would have an effect on the dependent variable while the effects of the two independent variables would no longer be present (Baron and Kenny, 1986).

### **Sample Size**

In order to establish an appropriate sample size required for this study a number of sample size estimates were calculated using value estimates from previous studies based on a cognitive appraisal model of stress. The calculations were done using NCSS and PASS (2004, Number Cruncher Statistical Systems).

To determine sample size requirements, estimates for total variance ( $R^2$ ) of the final model ranged from 0.4 to 0.9. A conservative alpha value of 0.01 was used along with a beta estimate of 0.2 (equating to a power level of 0.8). At a minimum there will be three independent variables (the mediator and both of the endogenous antecedents) in the final model predicting family caregiver quality of life. Estimates of sample size for a model with three independent variables ranged from 30 for a low  $R^2$  of 0.4 to 13 for a high  $R^2$  of 0.7. At a maximum, the final predictive model for family caregiver quality of life will contain 12 independent variables (the mediator and all antecedent variables). Estimates for sample sizes using 12 independent variables ranged from 50 for a low  $R^2$  of 0.4 to 26 for a high  $R^2$  of 0.7. Based on these estimates

a sample of 50 family caregivers will be used for this study. This size sample should allow for sufficient power in both reduced and full predictive models while not being overly powerful.

Table 4-1. List of items from the original CQOLC that were amended to fit the target population of family caregivers of pediatric oncology patients.

Original CQOLC items	Reworded items for the pediatric oncology setting
I worry about the impact my loved one's illness has had on my children or other family members	I worry about the effect of this illness on my other children
I fear the adverse effects of treatment on my loved one	I am worried about the harmful effects of the treatments on my child/infant
It upsets me to see my loved one deteriorate	It upsets me to see my child/infant get sicker
I fear my loved one will die	I am frightened my child/infant will die

Table 4-2. Study constructs and sources for data collection.

Exogenous Antecedent Variables		Operational Definition	Source of Data
Patient Characteristics:			
Gender		Female=1 Male=0	Patient Chart
Age		Age in months	Patient Chart
Illness Characteristics:			
Number of medications		Total number of prescription medications currently being taken	Patient Chart
Time since diagnosis		Number of months since diagnosis	Patient Chart
Family Caregiver Characteristics:			
Gender		Female=1 Male=0	Caregiver
Age		Age in Years	Caregiver
Marital Status		Married = 1 Not Married = 0	Caregiver
Employment Status		Part/Full Time=1 Unemployed=0	Caregiver
Presence of Social Support		Yes=1 No=0	Caregiver
Ethnicity		Asian/Pacific Islander=0 Caucasian=1 Black (non-Hispanic)=2 Hispanic/Latino=3 Native American=4 Refused=9	Caregiver

Table 4-2. Continued

Education Level		Grade School=0 Some High School=1 High School=2 Some College=3 College Degree=4 Some Graduate School=5 Graduate School=6 Refused=9	Caregiver
Relationship to patient		Parent=1 Other=0	Caregiver
Household Income		Under \$14,999=0 \$15,000-\$24,999=1 \$25,000-\$34,999=2 \$35,000-\$49,999=3 \$50,000-\$74,999=4 \$75,000-\$99,999=5 \$100,000-\$149,999=6 \$150,000-\$199,999=7 Over \$200,000=8 Refused=9	Caregiver
Endogenous Antecedent Variables			
Demand (Effort/Difficulty & Time)		5-point Likert-type scale (13 items)	Caregiver
Medication Hassles		6-point Likert-type scale (5 items)	Caregiver
Mediating Variable			
Stress Appraisal		5-point Likert-type scale (13 items)	Caregiver
Outcome Variable			
Caregiver Quality of Life		5-point Likert-type scale (13 items)	Caregiver

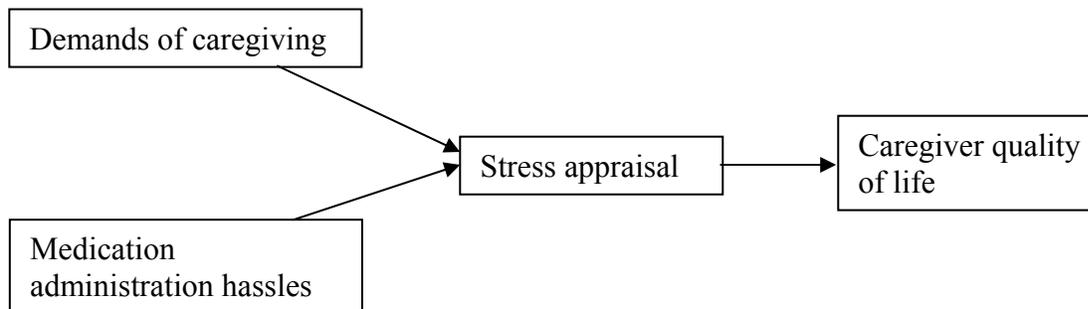


Figure 4-1. Proposed model of family caregiver quality of life

## CHAPTER 5 RESULTS

This chapter presents the results of the study. It presents the descriptive characteristics of the family caregivers that were surveyed. Descriptive data for patient and disease characteristics are also presented. Results from the surveys items tied to the four main variables in the cognitive appraisal of stress model will be described and finally the results tied specifically to the research hypotheses will be presented.

### **Family Caregiver Demographics**

A total of 50 caregivers completed questionnaires for this study. In all 55 caregivers were approached with five declining to participate. One caregiver declined to participate because she was the patient's grandmother and did not feel comfortable answering the questions. Another caregiver began the survey but never completed it. The other three who declined were part of a family unit. This equates to a response rate of 91% for all caregivers that were approached.

Demographic characteristics of the family caregivers are shown in table 5-1. Seventy-eight percent of the respondents were female with a mean age for all responding of 37.82 years old (SD=9.36). The youngest caregiver was 22 while the oldest was 61. Of those who responded, approximately 67% stated they were married and 51% said they were either working part-time or full time. Ninety-four percent of the caregivers were the parent of the child with cancer while three (6%) of those that filled out a questionnaire were the grandparent of the child.

The family caregivers were asked whether or not there was a presence of social support for them, which was defined as family or friends assisting with caregiving duties on a consistent basis. Seventy-two percent responded that they were receiving social support.

A breakdown of ethnic background revealed that those who participated, 74% were Caucasian, 22% were African American and 2% were Hispanic. One person refused to identify their ethnic background.

In terms of education level, 46% of the caregivers had an education level of high school or less. Sixty-two percent identified their annual household income during the previous year at less than \$35,000. Coverage for the child's medical expenses indicated, 48% relied on private insurance, 40% relied on some form of government insurance while only one caregiver said they paid for the care out of private funds.

### **Patient and Disease Characteristics**

The patient and disease characteristics were all obtained from chart reviews conducted by the primary investigator and research assistants. Chart reviews could only be conducted on patients under the age of 18 for whom the caregiver could grant access to the patients chart. Patients who were at least 18 years old at the time their family caregiver filled out their questionnaire packet were not asked for consent and therefore data was not pulled from their chart. There were eight caregivers that participated whose child was 18 or older.

Some of the patients (n=6) in the study had two caregivers fill out surveys. These units were all husband and wife pairs that saw themselves as sharing in the role of primary caregiver. Data about patients who had multiple caregivers fill out a survey was entered into the database only once. Because of the limited age restrictions and the fact that some patients had multiple caregivers fill out surveys, the results of the patient and disease characteristics are not the same N as in the family caregiver results described above. For one of the patients we could not clearly identify their date of diagnosis so the N for time since diagnosis is lower than the other three variables presented in Table 5-2.

On average the patients under 18 years of age who were being treated in the cancer center and whose family caregiver participated in this study had an age of 86.64 months (approximately 7 years) (SD=51.40 month). The youngest patient being treated at the time was 16 months old (1 year and 4 months) while the oldest being treated for whom we collected data was 17 years and 9 months. The majority of patients (61%) that were being cared for and that we collected data on were boys.

Looking at the disease characteristics it was found that it had been an average of 10.03 months (SD=8.56; range 1-34 months) since the children had been diagnosed or re-diagnosed with cancer. The average number of medications that the family caregivers were assisting the children in taking was 3.61 (SD=2.48). Some patients were currently taking no medications at home while one was currently on 11 different medications.

### **Cognitive Appraisal of Stress Model Components**

The main components of the cognitive appraisal of stress model that were measured were, the family caregiver's perceived quality of life, the level of demands associated with the caregiving role, the measure of hassles associated with administering medication to the sick child and the caregiver's appraisal of their stress level associated with their caregiving role. Table 5-3 outlines the results for the overall scores that were calculated for each of these components. The subsections that follow take a closer look at how the caregivers reacted to certain items within each of the scales used to measure the cognitive appraisal of stress model components.

#### **Family Caregiver Quality of Life**

Family caregivers answered 13 items that were used to measure their current quality of life. These 13 items accounted for two (burden and financial) of the four factors associated with the original CQOLC. All items were scored on a 5 point Likert scale ranging from 0 (not at all) to 4 (very much).

Most researchers consider a Cronbach's alpha ( $\alpha$ ) value of at least 0.70 to suggest reliability of the instrument therefore that is what we set as the criterion with the instruments used in this study. With regards to the CQOLC, the overall instrument had an alpha of 0.86 which suggested strong reliability. The subscale data produced alpha values of 0.85 for the burden component and 0.77 for the financial component indicating that the subscales also demonstrated good reliability. The results for the CQOLC reliability will be discussed in more detail later in the chapter.

Table 5-4 shows the results for each item on the modified CQOLC and includes the mean, standard deviation and median.

The average family caregiver had an estimated quality of life score of 31.04 (SD = 10.43). The maximum score possible was 52 (0 was the lowest score possible) with higher scores suggesting a better quality of life. The lowest score recorded for this group of caregivers was a five, suggesting that this caregiver had low reported quality of life.

A closer look at the individual items revealed three items that appeared to have the most impact on reducing the family caregivers overall quality of life. Individual items were reverse coded when the overall quality of life score was calculated. This was not done when looking at the items individually, therefore, higher scores on the individual items suggest a lower quality of life. The item that had the most negative contribution to quality of life scores was "It upsets me to see my child/infant get sicker". The average score for this item was 2.90 (SD = 1.34). Nearly 50% of the caregivers surveyed rated this item as a 4 (very much true) on the 0 to 4 Likert-type scale used.

The next item that seemed to have the greatest impact on reducing a caregiver's quality of life was "I am worried about the harmful effects of the treatment on my child". The average

score for this item was 2.42 (SD = 1.18). More than a quarter of the caregivers felt this statement was very much true. Both of these items were part of the burden factor from Weitzner's original CQOL factor analysis.

In terms of the financial factor, only one item appeared to stand out from the other two with regards to having a negative impact on the family caregiver's quality of life. Caregivers reported an average score of 1.94 for the item "I am under financial strain", with 36% feeling this item was quite a bit true or very much true when they thought about the impact of their caregiving role over the past seven days.

On the opposite side of the spectrum, one item stood out among the others as the one having the least negative impact on the family caregiver's quality of life and that was "I am discouraged about the future". The average score for this item was only 0.94 (SD = 0.98). Eighty percent felt that this item was only a little bit true or not at all true.

### **Demands of Caregiving**

The reliability results showed that the instrument had strong reliability with an alpha value of 0.84. The average score reported by the family caregivers in terms of how demanding they felt it was to handle some of the activities tied to their caregiving role was 37.37 (SD = 9.71). The lowest score reported was 16.90 while the highest assessment of demands was 54.69. All of the 13 items included from the original instrument, The Care of My Child with Cancer, were scored on a 5-point Likert-type scale. For each activity the family caregivers scored both the time they took to complete each activity (1 = did not do, 5 = >5 hours/week) and how much effort/difficultly was tied to completing the task (1 = none, 5 = a great deal). The instrument had a range of possible scores from 13 to 65 with higher scores suggesting the demands of caregiving to be more time consuming and difficult.

Table 5-5 contains the individual item results for the Care of My Child with Cancer demands instrument. Results listed include the mean, standard deviation and median score for each item. Tables 5-6 and 5-7 contain the means, standard deviations and medians for the time and effort/difficulty component of each item on the instrument respectively.

A closer look at individual item scores showed three caregiving activities that were rated in the “moderate” range of demanding. The most demanding task was “providing emotional support for your child with cancer,” which had an average score of 3.34 (SD = 1.19). Just over 50% of the caregivers stated they spent more than 5 hours a week providing emotional support to their child. Seventy-two percent saw the task to be at least moderately difficult to a great deal difficult.

The other two demanding tasks were “planning activities for your child around the treatment and illness” and “taking care of discipline and/or behavior problems of the child with cancer”. They each had overall means of 3.30 (SD = 1.30) and 3.02 (SD = 1.42) respectively. The time commitments for each activity were fairly high with 68% of the caregivers spending more than 2 hours a week planning activities for their child, while 48% spend the same amount of time taking care of discipline of their child. In terms of the difficulty completing each task, 64% found planning activities to be at least moderately difficult while 56% found discipline to be at least moderately demanding.

The least demanding task of all those scored was “communicating information about cancer to schools, day care, babysitters, extended family and friends”. On average this activity had a total demand score of 2.16 (SD = 1.31). Other tasks that were viewed as only slightly demanding included “getting information on your child’s illness and treatment”, 2.34 (SD = 1.17) and “providing emotional support for your spouse/partner,” 2.38 (SD = 1.31).

## **Hassles of Medication Administration**

For this study, only the items from the safety issues subscale of the Family Caregiver Medication Administration Hassles Scale were used to measure hassles. Reliability results tested produced an alpha value of 0.78 which suggested that the instrument measuring medication administration hassles had strong reliability. The overall average for the total hassles score was 3.92 (SD = 4.02). The highest score reported was 14 while almost one fourth of the caregivers had a total score of 0 suggesting medication administration was no hassle at all. The instrument had a possible range of scores of 0 to 25, with higher scores suggesting more hassles associated with medication administration.

Table 5-8 contains the results for each item on the Family Caregiver Medication Administration Hassles Scale and includes the mean, standard deviation and median.

Details with regard to the individual items do not show much of an impact of medication administration on the caregiving role. On every item, between 44% and 66% of the family caregivers did not see any hassle associated with the specific task listed. Two items showed slightly higher reported scores at the upper ends of the scale. Both “recognizing adverse (bad) side effects” and “knowing when to hold, increase, decrease a dose or discontinue the medication” had 12% of the respondent reporting that these activities were a moderate hassle to one of the worst hassles of all. The other three items measured showed only between 4% and 6% of the respondents in this high range of scoring medication administrative activities as being a hassle.

## **Appraisal of Caregiving**

The final instrument used was the threat subscale of the Appraisal of Caregiving. Like the other instruments used testing was also done for the Appraisal of Caregiving items to establish the reliability of the instrument. The results for this test like the others before suggested that the

instrument did in fact show high reliability ( $\alpha = 0.93$ ). The 13 items in this subscale had a total mean score of 28.26 (SD = 12.33). The scale had a potential range of scores between 13 and 65. The lowest score recorded from this sample was 13 while the person with the highest perception of their caregiving role as threatening had a score of 56. Higher scores indicated a higher level of stress appraisal for the family caregiver.

Table 5-9 contains the results for each item on the Appraisal of Caregiving and includes the mean, standard deviation and median.

The item that had the biggest impact on the caregiver's perceived stress was "I feel a sense of loss at not being able to meet all my responsibilities". The item carried an average score of 2.64 (SD = 1.38). Just over a quarter of the caregivers felt that for them this statement was more true than false or very true.

Another item that indicated higher levels of perceived stress was "I'm concerned that this situation will cause financial hardship for me in the future." The mean score was 2.48 (SD = 1.51). For this item 28% of the caregivers indicated that this statement was more true than false or very true. Looking at the frequencies for each response option, this item had the highest number of caregivers (n=8) indicate that this statement was appraised as very true.

Two items also had just over a quarter of the caregivers agree that they were more true than false or very true. The two items were "This situation threatens to overwhelm me" and "I'm afraid my own physical health will begin to suffer."

One other significant item was "I'm afraid that in the future I won't have the energy and endurance I have now." While the average score was not high, 2.30 (SD = 1.49), this particular item had the second highest frequency of responses (n=7) in terms of appraising the situation as very true.

The item that appeared to have the smallest impact on overall stress appraisal was “I worry that I won’t be able to help the person needing my care in the future.” The average score was 1.70 (SD = 1.22) and 82% of the caregivers saw this item as either more false than true or very false.

### **Psychometric Properties of the CQOLC**

The first objective of this study was to establish the reliability and validity of the modified CQOLC in a population of family caregivers of children with cancer to measure overall caregiver quality of life. The following sections will describe the results of these analyses.

#### **Internal Consistency Reliability**

The overall instrument had a Cronbach’s alpha of 0.86. Looking at the subscales, the burden subscale (items 1, 2, 3, 4, 5, 7, 8, 9, 10 and 11) had a Cronbach’s alpha of 0.85. The Cronbach’s alpha for the financial concerns subscale (items 6, 12 and 13) was calculated at 0.77. Item-total statistics were reviewed for the complete scale and no items were identified as improving the instrument should they be removed.

Table 5-10 contains the Cronbach’s alphas calculated for this study and also the results from the initial Cronbach’s alpha calculations that Weitzner and colleagues (1999a) calculated during the initial instrument development. The table shows the consistency in scores between the original data that Weitzner reported and what was found in this newly tested population of family caregivers of children with cancer.

#### **Convergent Validation**

The second step to confirm the validity of the instrument was to run convergent validity tests to see how well the CQOLC correlated with the other three main instruments used to measure caregiving demands (CMCC), medication administration hassles (FCMAHS) and stress

appraisal (ACS). Pearson's correlations were run during this phase of the validation process to look for convergence.

The correlation between the modified CQOLC and The Care of My Child With Cancer (measuring level of caregiving demands) was -0.61 ( $p \leq 0.01$ ). The Pearson correlation between the modified CQOLC and the Appraisal of Caregiving (measuring level of threat) was -0.82 ( $p \leq 0.01$ ) which as expected was highly negative and significant.

The calculated Pearson correlation between the modified CQOLC and the Family Caregiver Medication Administration Hassles Scale was -0.43 ( $p = 0.01$ ). While the result was significant it is only moderately negative.

### **Evaluation of the Cognitive Appraisal of Stress Model**

The goals of the next sections are to look at the results that focused on the research questions 2 through 6. These questions examine how well the data fit the predicted model.

#### **Evaluating CQOLC Correlations**

Before delving into how well the data collected fit the proposed model we first tested for relationships between the total CQOLC scores and the variables related to patient, caregiver and disease characteristics. The purpose of this step was to identify which of these factors had a significant relationship with the family caregiver's quality of life so that those variables could then be included in the final model testing.

The results from the analyses are included in Table 5-11. A look at the data shows that none of the variables tested had a significant relationship with the family caregiver's quality of life and therefore none of them were included in the testing of the final model.

#### **Stress Regressed on Demands and Hassles – Hypothesis 1**

As outlined in the methods section three separate regressions were run to establish whether or not the proposed mediated model was supported and to also establish the path coefficients for

the final model. The first equation involved regressing the mediator (stress) on the two independent variables (demands and hassles) to confirm if they were related. The results of the analysis show that demands and hassles accounted for 51% of the variance in stress appraisal. Both independent variables made significant contributions to the regression which offers support for Hypothesis 1. The path coefficients for the regression are in Table 5-12. These coefficients will be used in the final path model.

### **Quality of Life Regressed on Demands and Hassles – Hypothesis 2**

The second equation tested saw the family caregiver's quality of life being regressed on both demands and hassles. This step allowed for us to determine if a significant relationship existed between the dependent variable and the two independent variables. The analysis showed that the two independent variables accounted for 47% of the variance in quality of life. Both variables contributed significantly to the regression which offers support to Hypothesis 2. The path coefficients from this regression can be found in Table 5-13.

### **Quality of Life Regressed on Demands, Hassles and Stress – Hypothesis 3**

The third equation that was run was to establish how much variance in quality of life was accounted for by demands, hassles and stress. Hypothesis 3 suggested that while the regression equation would be significant, only stress would have a significant influence on quality of life since it was hypothesized that it would fully mediate the effects of demands and hassles. Overall, the three variables accounted for 71% of the variance in quality of life.

As predicted, stress contributed significantly to the regression and hassles did not. Demands of caregiving also contributed significantly to the regression which was not predicted. These results suggest that instead of a fully mediated model through stress, that the model is only partially mediated with demands having some direct effect on quality of life along with stress. These results fail to provide support for Hypothesis 3. The path coefficients from this regression

can be found in Table 5-14. The coefficient for stress and demands are used in the final path model.

### **Construction of the Final Model**

The final step in this project was to put together the final Cognitive Appraisal Model of Stress based on the data collected. Figure 5-1 is the revised model based on the shift in results from a fully mediated model to a partially mediated model. The figure contains the path coefficients to show the impact of the variables within the model.

**Decomposition of the direct and indirect effects:** To better understand the influence of each of the variables on family caregiver quality of life we took a closer look at the direct, indirect and total effects of the variables. Medication administration hassles had a significant indirect effect on family caregiver quality of life via appraisal of stress ( $\beta=-0.332$ ) as hypothesized. Demands of caregiving had a fairly large total effect on family caregiver quality of life but nearly 60% of that effect was indirect via appraisal of stress. As expected the direct effect of appraisal of stress was significant and largest in the model. The results all suggest that quality of life is negatively affected as family caregivers see higher levels of demands, hassles and stress associated with caregiving. Table 5-15 contains the decomposition of the three predictor variables with quality of life.

### **Summary of Results**

This chapter presented the results of the validation of the modified Caregiver Quality of Life Index – Cancer as a measure of family caregiver quality of life in a pediatric oncology setting. Also presented in the chapter was a test of the fit of the cognitive appraisal model of stress to predict family caregiver quality of life.

The analysis of the modified CQOLC indicated that it is a valid instrument for measuring family caregiver quality of life in caregivers of pediatric patients. The internal consistency of the

instrument ( $\alpha = 0.86$ ) and the subscales ( $\alpha = 0.85$  and  $\alpha = 0.77$ ) were all high suggesting that the instrument and the subscales were reliably measuring the constructs. Convergent validity testing suggested that the modified CQOLC had, as expected, a significant negative relationship with both the demands of caregiving and the stress associated with caregiving. Hypotheses 2a and 2c were also supported with the correlations between the modified CQOLC and the measures of demands and stress appraisal being highly negative and significant. When looking at the relationship of the modified CQOLC and the hassles associated with medication management the results were not as expected as the correlation between the modified CQOLC and the measure of medication administration hassles was only moderately negative although significant.

None of the variables related to patient, caregiver or disease characteristics was significantly correlated to family caregiver quality of life so none of these variables was included in the final model test. The analyses confirmed that medication administration hassles and demands of caregiving were significantly related to both stress appraisal and family caregiver quality of life which supported both Hypotheses 1 and 2. Hypothesis 3 had predicted that when the independent and mediating variable were all regressed on family caregiver quality of life, only stress appraisal would significantly contribute to the regression. The results however showed that not only did stress appraisal significantly contribute but demands of caregiving also had a significant direct effect.

The final model ended up being modified from the projected model as the results suggested a partially mediated model through stress appraisal rather than a fully mediated model. Stress appraisal and demands of caregiving each had negative direct effects on family caregiver quality of life with stress appraisal having the largest total effect of the three variables tested. Along with its direct effect, demands of caregiving also had a significant indirect effect on

family caregiver quality of life through stress appraisal. The indirect effect accounted for the majority of the demands effect on quality of life. Medication administration hassles had only an indirect effect on family caregiver quality of life through stress appraisal. It contributed the least to the prediction of family caregiver quality of life, with the lowest total effect of the three variables tested. As expected all three variables in the model to predict family caregiver quality of life had negative total effects.

Table 5-1. Family caregiver demographics

	Value	Percent	N*
Gender			50
Female	39	78	
Male	11	22	
Age (in years)			49
Mean (SD)	37.82 (9.36)		
Median	34		
Range (low to high)	22 to 61		
Marital Status			48
Married	32	66.7	
Not married	16	33.3	
Employment Status			49
Part/Full Time	25	51	
Unemployed	24	49	
Presence of Social Support			50
Yes	36	72	
No	14	28	
Ethnicity			50
Caucasian	37	74	
African American	11	22	
Hispanic	1	2	
Refused to answer	1	2	
Education (highest level)			50
Grade School	1	2	
Some High School	4	8	
High School	18	36	
Some College	12	24	
College Degree	8	16	
Some Graduate School	1	2	
Graduate School	6	12	
Relationship to the patient			50
Parent	47	94	
Grandparent	3	6	

Table 5-1. Continued

	Value	Percent	N*
Income			50
Under \$14,999	9	18	
\$15,000 - \$24,999	10	20	
\$25,000 - \$34,999	12	24	
\$35,000 - \$49,999	3	6	
\$50,000 - \$74,999	7	14	
\$100,000 - \$149,999	3	6	
\$150,000 - \$199,999	4	8	
Over \$200,000	2	4	
Primary Medical Expense Coverage			50
Private Insurance	24	48	
Government Insurance	20	40	
Personal Finances	1	2	
Personal & Government	2	4	
Government & Private	3	6	

\*Not all subjects answered every demographic item on the survey accounting for differences in N.

Table 5-2 Patient and disease characteristics

	Value	N*
Patient Age (in months)		36
Mean (SD)	86.64 (51.40)	
Median	61.5	
Range (low to high)	16 to 213	
Number of Medications (home use)		36
Mean (SD)	3.61 (2.48)	
Median	3.00	
Range (low to high)	0 to 11	
Time since diagnosis (in months)		35
Mean (SD)	10.03 (8.56)	
Median	6	
Range (low to high)	1 to 34	

\*Family caregivers could not consent for all the patients and time since diagnosis for one patient could not be identified so the patient N is lower than the family caregiver N.

Table 5-3. Caregiver perceptions on the primary components of the cognitive appraisal of stress model.

Scale	Mean	SD	Range	N = 50
Quality of life	31.04	10.43	5 - 49	
Demands	37.37	9.71	16.90 - 54.69	
Hassles	3.92	4.02	0 - 14	
Stress	28.26	12.33	13 - 56	

Table 5-4. Mean, standard deviation, and median score for each item on the modified CQOLC. Higher scores suggest a lower quality of life. All items range from 0 to 4.

Item*	Mean	SD	Median
I feel nervous	1.36	1.10	1.00
Increased stress and worries	1.56	1.42	1.50
I feel sad	1.24	1.21	1.00
Discouraged about the future	0.94	0.98	1.00
I feel frustrated	1.54	1.42	1.00
Under financial strain	1.94	1.43	2.00
Worry about other children	1.86	1.44	2.00
Harmful effects on child	2.42	1.18	2.00
Upset to see child sicker	2.90	1.34	3.00
I feel guilty	1.12	1.21	1.00
Frightened child will die	1.46	1.42	1.00
Concerned about insurance	1.18	1.41	1.00
Economic future uncertain	1.44	1.34	1.00

\*Exact item wording can be found in appendix A

4=very much 3=quite a bit 2=somewhat 1=a little bit 0=not at all

Table 5-5. Mean, standard deviation, and median score for the total demand score of each item ((effort \* time)<sup>1/2</sup>) on The Care of My Child With Cancer. Higher scores suggest higher demands. Item scores ranged from 1 to 5.

Item*	Mean	SD	Median
Emotional support for child w/ cancer	3.34	1.19	4.00
Emotional support for other children	2.70	1.25	2.50
Emotional support for extended family	2.38	1.31	2.00
Emotional support for spouse/partner	2.68	1.49	2.00
Meeting own emotional needs	2.46	1.20	2.00
Comforting child through pain	2.90	1.39	3.00
Planning activities for child with cancer	3.30	1.30	3.50
Planning activities for your family	2.92	1.31	3.00
Communicating information about cancer	2.16	0.98	2.00
Watching for and reporting symptoms	2.58	1.20	2.00
Getting information on illness	2.34	1.17	2.00
Discipline and behavior problems	3.02	1.42	3.00
Finances, bills and forms	2.70	1.23	3.00

\*Exact item wording can be found in appendix A

Table 5-6. Mean, standard deviation, and median score for the time component of each item on The Care of My Child With Cancer. Higher scores suggest higher demands. Item scores ranged from 1 to 5.

Item*	Mean	SD	Median
Emotional support for child w/ cancer	4.08	1.18	5.00
Emotional support for other children	3.16	1.42	3.00
Emotional support for extended family	2.80	1.40	3.00
Emotional support for spouse/partner	3.16	1.50	3.00
Meeting own emotional needs	2.56	1.37	2.00
Comforting child through pain	3.28	1.50	3.50
Planning activities for child with cancer	3.84	1.38	4.00
Planning activities for your family	3.26	1.38	3.00
Communicating information about cancer	2.58	1.25	2.00
Watching for and reporting symptoms	3.10	1.36	3.00
Getting information on illness	2.72	1.36	2.00
Discipline and behavior problems	3.42	1.57	3.00
Finances, bills and forms	3.04	1.40	3.00

\*Exact item wording can be found in appendix A

Table 5-7. Mean, standard deviation and median score for the effort/difficulty component of each item on The Care of My Child With Cancer. Higher scores suggest higher demands. Item scores ranged from 1 to 5.

Item*	Mean	SD	Median
Emotional support for child w/ cancer	3.10	1.23	3.00
Emotional support for other children	2.66	1.29	2.50
Emotional support for extended family	2.38	1.31	2.00
Emotional support for spouse/partner	2.60	1.53	2.00
Meeting own emotional needs	2.68	1.33	3.00
Comforting child through pain	2.86	1.43	3.00
Planning activities for child with cancer	3.12	1.47	3.00
Planning activities for your family	3.00	1.41	3.00
Communicating information about cancer	2.08	0.99	2.00
Watching for and reporting symptoms	2.50	1.28	2.00
Getting information on illness	2.40	1.28	2.00
Discipline and behavior problems	3.00	1.47	3.00
Finances, bills and forms	2.74	1.38	3.00

\*Exact item wording can be found in appendix A

Table 5-8. Mean, standard deviation and median for each item on Family Caregiver Medication Administration Hassles Scale.

Item*	Mean	SD	Median
Admitting made a mistake	0.56	0.93	0.00
Knowing about medication	0.84	1.18	0.00
Understanding medications	0.66	0.96	0.00
Recognizing adverse effects	1.16	1.41	1.00
Giving medication safely	0.70	0.93	0.00

\*Exact item wording can be found in appendix A

Table 5-9. Mean, standard deviation and median score for each item on the Appraisal of Caregiving instrument.

Item*	Mean	SD	Median
Things going to get worse	2.06	1.19	2.00
Haven't been doing well	2.22	1.06	2.00
Feel sense of loss	2.64	1.38	3.00
Worry I'll give up things	2.12	1.27	2.00
Won't have energy in the future	2.30	1.49	2.00
No longer anything I can do	1.94	1.28	1.00
Situation threatens to overwhelm me	2.50	1.27	2.00
Afraid my physical health will suffer	2.34	1.41	2.00
Worry less able to do things	1.94	1.17	1.00
Worry I won't be able to help	1.70	1.22	1.00
Worry emotional health will suffer	2.22	1.28	2.00
Concerned about financial hardship	2.48	1.52	2.00
Not sure can handle in the future	1.80	1.07	1.00

\*Exact item wording can be found in appendix A

Table 5-10. Cronbach's alpha results for this study and the original instrument development and validation by Weitzner et al.

	Number of Items	Cronbach's Alpha
Modified CQOLC		
Burden	10	0.85
Financial Concerns	3	0.77
Total	13	0.86
Initial Weitzner Instrument Validation		
Burden	10	0.89
Financial Concerns	3	0.81
Total	35	0.90

Table 5-11. Correlations and p values among family caregiver quality of life and the patient, caregiver and disease characteristics.

	Correlation with Quality of life
Caregiver Characteristics:	
Gender	-0.021 (p=0.88)
Marital Status	0.201 (p=0.17)
Age	0.004 (p=0.98)
Employment Status	0.022 (p=0.88)
Social Support	0.257 (p=.07)
Race	-0.179 (p=0.21)
Education Level	0.085 (p=0.56)
Relationship to patient	0.219 (p=0.13)
Income	0.118 (p=0.42)
Patient Characteristics:	
Gender	0.287 (p=0.9)
Age	-0.161 (p=0.35)
Disease Characteristics:	
Time since diagnosis	0.168 (p=0.34)
Number of medications	0.033 (p=0.85)

Table 5-12. Path coefficients for Hypothesis 1

Predictors	Regression Coefficients		Significance	R <sup>2</sup>	N
	Unstandardized (SE)	Standardized			
Demands	0.576 (0.132)	0.453	0.000	0.509	50
Hassles	1.433 (0.320)	0.467	0.000		

Table 5-13. Path coefficients for Hypothesis 2

Predictors	Regression Coefficients		Significance	R <sup>2</sup>	N
	Unstandardized (SE)	Standardized			
Demands	-0.580 (0.117)	-0.540	0.000	0.509	50
Hassles	-0.833 (0.283)	-0.321	0.005		

Table 5-14. Path coefficients for Hypothesis 3

Predictors	Regression Coefficients		Significance	R <sup>2</sup>	N
	Unstandardized (SE)	Standardized			
Demands	-0.233 (0.103)	-0.217	0.027	0.713	50
Hassles	0.30 (0.250)	0.011	0.906		
Stress	-0.602 (0.095)	-0.712	0.000		

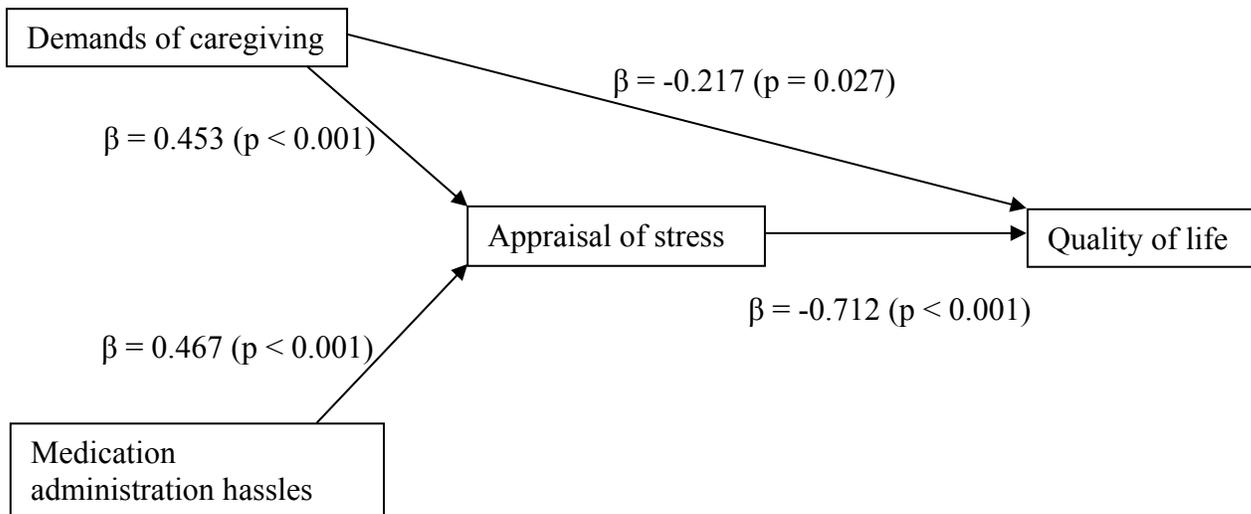


Figure 5-1. Summary of path model of family caregiver quality of life.

Table 5-15. Decomposition of the total associations of predictor variables with quality of life

Predictor Variable		Quality of Life
Medication Administration Hassles	Direct Effect	---
	Indirect Effect via Appraisal of Stress	-0.332*
	Total Effect	-0.332*
Demands of Caregiving	Direct Effect	-0.217**
	Indirect Effect via Appraisal of Stress	-0.322*
	Total Effect	-0.540**
Appraisal of Stress	Direct Effect	-0.712*
* p < 0.001		
**p = 0.027		

## CHAPTER 6 DISCUSSION

### **Overview**

This study had two main objectives. The first was to establish the reliability and validity of using the Caregiver Quality of Life Index-Cancer to measure the quality of life in family caregivers of children with cancer. The second objective was to then test a cognitive appraisal model of stress in this same population of family caregivers in order to identify factors that influence their quality of life. Specific focus was placed on how demands of caregiving, hassles of medication administration and the appraisal of stress related to caregiving affect the family caregiver's quality of life. This chapter provides a discussion of the study findings, addresses limitations of the study, suggests implications for health care providers and concludes with recommendations for future research.

### **Discussion of Findings**

#### **Psychometric Testing of the CQOLC**

Establishing reliability and validity in using the CQOLC to measure the quality of life of family caregivers of children with cancer was ascertained through various techniques. The results from the internal consistency reliability calculations suggested that the items in the instrument were measuring not only their respective domains but together were measuring the family caregiver quality of life construct. The overall items along with the two subscales all met the a priori value of Cronbach's alpha of greater than 0.70. While the results suggested high reliability in the measures they were not so high as to suggest that the items were redundant in what they were measuring.

Convergent validity was established between the CQOLC and the demands of caregiving, hassles of medication administration and stress appraisal. All the results suggested significant

negative relationships between the family caregiver's quality of life and the other three variables measured. As the caregivers saw increases in their demands of caregiving, the hassles associated with medication administration and their level of stress associated with caregiving, they saw a decline in their perceived quality of life. The results from reliability and validity testing were not unexpected based on the previous studies that have used or adapted the CQOLC and shown it to be a reliable instrument (Weitzner, et al., 1991ab; Boling, Macrina, & Clancy, 2003; Rhee et al., 2005).

### **Caregiver Quality of Life**

Overall the family caregivers that participated in this study appeared to have a slightly more positive perception of their quality of life. The median score for all caregivers was 31 which was just above the mid-point in the overall range of 0 to 52. Looking at the midpoint in the range of possible scores shows that 28% of the caregivers had a neutral or negative perception of their quality of life while the remaining 72% had a more positive leaning perception.

The items that contributed most to a lower perceived quality of life were not surprising when considering the patient population. Three of the four items that most contributed to lower quality of life were all focused on the child receiving treatment or the caregivers' other children and not on the caregivers themselves. These items included the statements, "I am worried about the harmful effects of the treatments on my child/infant," "It upsets me to see my child/infant get sicker," and "I worry about the effect of this illness on my other children." The only item focused on the caregiver was their concern that they were under financial strain.

Parents will generally do what they can to put their children's needs before their own and that is likely why the responses ended up as they did with 3 of the 4 most impactful items focused on the child/children and not on the caregiver. One item that did not score higher, that

was somewhat surprising when the results were reviewed, was the minimal impact that the statement “I am frightened my child/infant will die” had on the family caregiver quality of life. A number of factors contributing to this could include the possibility that the caregivers did not want to admit to such a negative thought. And that the caregivers had been properly educated about the improved treatments for children and the rise in survival rates due to these improved treatments.

### **Demands of Caregiving**

Family caregivers of children with cancer face many demands in providing support to their child, their family and themselves during their child’s illness. Overall the caregivers who were participants in this project perceived their level of demands to be somewhat high with an average score of 37.37 and a median score of 38.52 out of a possible score of 65. Assuming moderate demand levels around 32 to 33 then almost 68% of the participants had a high leaning perception of the amount of time and effort they put into the activities surrounding their child’s care.

The most demanding activity (combined effort and time commitment) reported, providing emotional support for your child with cancer, was also the one activity focused squarely on providing a level of care to the child. As with the highest ranking quality of life items being focused on the patient, this item for demands was also the most patient centric. These results mirror the original testing of the instrument by Keegan Wells and colleagues (2002) when their test of the complete 28 item instrument revealed that their test population of family caregivers of children with cancer also identified “providing emotional support for your child with cancer” as the most demanding task they faced. It also turns out that providing emotional support to the child with cancer ended up being the item that required the largest time commitment for our study participants, with an average commitment of at least two to five hours

a week with 50% of the family caregivers saying they spent over five hours a week on this one activity.

When it came to task difficulty in terms of completing the activity, the task that required the most effort turned out to be planning activities for your child with cancer around the treatment and illness. This was actually witnessed firsthand on numerous occasions while conducting surveys, as the family caregivers were constantly working with the staff to identify what activities the children could or could not do based on where they were in their treatment cycle. Common activities like swimming in a pool or going back to school were questioned, along with more complex activities like when to begin planning for a family vacation so as not to interfere with the patient's treatment schedule.

### **Medication Administration Hassles**

When it came to assessing the family caregivers hassles associated with medication administration, the results were unexpected. It was anticipated based on previous research with regard to medications and pain management for children with cancer that in fact dealing with medications would be more difficult than the results suggested. Overall the level of hassles was very low with an average score of just under 4 for a scale that ranged from a low of 0 for no hassles to a high of 25 being considered very much a hassle.

Individual items were considered not a hassle at all by the majority of caregivers. However, every item was viewed as at least a severe hassle, if not one of the worst of all hassles, by one or more of the caregivers. Because the focus of these items was on the safety of medication administration it was encouraging that overall most found these item not a hassle.

At least one caregiver found it a severe hassle to admit to their physician or others that a mistake had been made in medication administration. Another caregiver considered knowing when to hold, increase, decrease a dose or discontinue a medication to be one of the worst

hassles of all. Finally, four of the caregivers interviewed categorized recognizing adverse effects of medications as a severe hassle or one of the worst of all hassles. All three of these examples suggest a need to reevaluate the education that caregivers are being provided with regards to medication administration.

### **Stress Appraisal**

The caregivers interviewed perceived their level of stress to be moderate to low with approximately 80% of the caregivers at or below the midpoint (39) of the overall range of possible scores (13-65). These data suggest that while the caregivers did identify that there are some significant demands and hassles that they face in their roles as family caregiver they were not viewed as necessarily threatening to the family caregivers. Additionally, the results suggest that the caregivers perceived their ability to handle these demands and hassles as satisfactory.

While overall the caregivers perceived little stress associated with their caregiving duties, a closer look at the items, shows that in fact for every item measured there were family caregivers that categorized the items as more true than false or very true. These suggest that some family caregivers saw each item as being very stressful which in turn suggests that they were having some difficulty handling some of the demands and/or hassles they were facing. Of the 13 items measured, 25% of family caregivers indicated that four of the items were highly stressful. The item indicating the most family caregivers stress was “I’m concerned that this situation will cause financial hardship for me in the future.”

### **Family Caregivers**

The response rate for this study was just over 90% which is fairly high when compared with other studies that looked at family caregivers of pediatric patients (Fedewa & Oberst, 1996; Yamazaki, Sokejima, Mizoue, Eboshida & Fukuhara, 2005) both of which had response rates of around 60%. While it was suggested by health care providers working within the Pediatric

Oncology Department at Shands UF that a high response rate could be expected, one this high was not anticipated. A number of factors likely contributed to such a high response rate.

The first considered was that all the surveys were filled out by the family caregivers while their child was receiving treatment. No surveys were sent home with the caregivers, so there was no chance of them forgetting to either fill out the survey or to return it once they completed it.

Another factor that helped contribute to the response rate was the support of the study by the nursing staff working in the infusion room and by the lead nurse in particular along with the child life specialist that worked with the families. Often they informed the family caregivers about the fact that we were there looking for individuals to complete surveys for this project and by the time the family caregivers were approached to see if they wanted to participate in the study they were already versed on the project and ready to participate. It should be noted that not all caregivers approached had been versed by any member of the staff so that was not a sole reason for participation.

### **Theoretical Framework**

The underlying assumption for the cognitive appraisal model of stress used in this study was that as the family caregivers dealt with both the demands of caregiving and the hassles of medication administration they would periodically assess their situation and how they were responding to it. With this assessment they would then adapt how they were reacting to the situation and then ultimately this assessment would manifest into how they perceived their quality of life to be.

While the fully mediated model that was hypothesized was not realized, the results of the study still offered valuable insight into how the caregivers are affected by the roles they assume during their child's care and how health care professionals could use this information to improve the lives of both the patients and their family caregivers.

The total effect of administering the medications to the patient on family caregiver quality of life was fully mediated through stress appraisal. The influence of the demands of caregiving had the majority of its influence on family caregiver quality of life mediated through stress appraisal with some minor direct influence on family caregiver quality of life. As predicted, stress appraisal of the caregiving situation had the most influence on family caregiver quality of life.

Looking at the results, the findings suggest a number of things. Health care professionals need to be aware of the rising stress that family caregivers may be experiencing during their child's treatment. This rise in stress is an indication that the demands of the caregiving role and/or the administration of the patient's medications is beginning to overwhelm the family caregivers. By catching the increase in distress the family caregivers are experiencing early on, health care professionals can more closely work with the families to identify what factors are causing the most stress and to either eliminate them from the family caregivers functions or provide them with education to reduce their stress. Thereby making them more beneficial members of the child's health care team.

Because of the influence of the demands of caregiving on the caregiver's quality of life it behooves health care professionals to follow-up with the family caregivers about how they are handling certain demands. While this study identified some of the more demanding tasks the family caregivers are dealing with in terms of time and effort (providing emotional support for the child with cancer, planning activities for the child with cancer and comforting the child through pain) future studies may help to more closely pinpoint the activities that continue to be the most demanding overall.

Understanding which tasks are the most demanding for caregivers will afford health care professionals the opportunity to provide educational materials to the family caregivers as soon as their child enters into the treatment cycle to better prepare them for the role they will assume. It also gives the health care professionals areas to follow-up with the family caregivers on a continual basis to see how they are handling tasks to make sure they are not being negatively impacted to the point that they no longer effective members of the child's health care team.

### **Study Limitations**

While this study provides some valuable information about the effect that caregiving has on the family caregivers of children with cancer the study also has some limitations that need to be taken into account when reviewing the results.

Overall, this study lacks generalizability to other caregivers of other children with cancer based on the family caregivers that filled out surveys. The protocol for this project focused only on family caregivers of children being treated in the infusion room of the Shands Medical Plaza. This specific focus limited the different types of cancer that the patients had and also limited the primary treatment strategy to chemotherapy. In turn this could have had an effect on what types of demands, hassles and stresses these family caregivers were facing and then ultimately how they impacted their quality of life.

Another limitation to consider is that the analysis implies that there is causality among the variables. While the results of the analysis suggest that the data fit the cognitive appraisal model of stress it is important to understand that the use of path analysis does not establish true causality among the variables.

A final limitation to consider is the fact that the items used to measure the primary variables of interest were all subsections of their complete instruments. The impact of this limitation is likely greatest on the measurement of quality of life. Only items making up two of

the four factors from the instrument were used and additionally other items from the instrument that did not fall into one of the four factors were also not used. While the results reflect some level of quality of life measurement they do not fully measure quality of life as Weitzner had intended and so the scores may not be a true reflection of the quality of life of the family caregivers that participated in this study.

### **Implications for Health Care Providers**

While this study had some specific research oriented goals it also had some “soft” goals that were not included in the actual objectives of the study. All these “soft” or unmentioned goals had to do with improving the care that both the patients and family caregivers were receiving from all the health care team members that touch them during their visits to the cancer center.

First and foremost is the hope that other health care providers will begin to see the impact that the family caregivers have on the health care system and the need to follow the recommendation of the World Health Organization to treat not only the patient but the family caregiver as well (and the whole family unit for that matter). The family caregivers are a valuable asset that needs to be relied upon and therefore cared for as well.

Health care providers that can take the time to listen to the family caregivers and identify what areas the family caregivers are comfortable or good at handling are areas that the health care providers can ask them to focus on more specifically. The areas that the family caregivers are not comfortable handling are areas that the health care providers can remove from their plate of responsibilities or are areas that the health care providers can offer resources to increase the family caregivers ability to comfortably handle these situations.

The final area for health care providers to consider is asking all caregivers to fill out on a regular basis an instrument similar to the one used in this study to give the family caregivers the

chance to voice their thoughts and feelings. The instrument took approximately 20 minutes for each family caregiver to complete and can give the health care providers insight into the impact of the roles on the family caregivers. Tracking results over time can help health care providers identify areas that need to be focused on before they the family caregiver is overwhelmed to the point where they are no longer a valuable asset to the health care team.

### **Future Research**

This study lends itself to numerous future research projects. The first such project would be to conduct a series of roundtable discussions or one-on-one qualitative interviews with the family caregivers to make sure that the current instrument measures all the areas that the family caregivers feel are most important to them. While the instrument was reviewed for content validity, the review did not include any actual family caregivers.

Future projects could be expansion of studies to others areas within the Shands UF network. These studies could capture family caregivers of children with cancer over multiple cancer types, receiving different primary treatments aside from chemotherapy and to include those that have yet to start outpatient treatment or have finished their outpatient care but are still being seen for follow-up.

Another study to consider that could evolve from this project is a multi-site study that involves other facilities within the Children's Oncology Group (COG) network both here in Florida and outside the state. Expanding the study to additional sites will help to improve not only the amount and depth of information but the overall generalizability of the results. This would ultimately give health care providers a way to anticipate the needs of family caregivers in advance so that they can be addressed more efficiently and allow the family caregivers to continue to be active members of the health care team rather than passive bystanders.

Finally it makes sense to consider a longitudinal study to follow family caregivers during their child's treatment. This study would offer a number of benefits including understanding how the family caregiver quality of life changes over the course of treatment and how their perceptions of the demands, hassles and stresses associated with caregiving change over time. This study would also allow for an analysis of how responsive to change the quality of life instrument and other instruments in use are over time as none have been tested in this population of caregivers over an extended period of time.

APPENDIX A  
FAMILY CAREGIVER QUALITY OF LIFE AND THE IMPACT OF THE CAREGIVING  
ROLE QUESTIONNAIRE

# Family Caregiver Quality of Life and the Impact of the Caregiving Role



Pharmacy Health Care Administration  
College of Pharmacy  
University of Florida

***Section 1***

Below is a list of statements that other parents of ill children have said are important. By circling one number per line, please indicate how true each statement has been for you in the past 7 days.

0 Not at all	1 A little bit	2 Somewhat	3 Quite a bit	4 Very much
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During the past 7 days:

1. I am frightened my child/infant will die

0                      1                      2                      3                      4

2. My level of stress and worries has increased

0                      1                      2                      3                      4

3. I feel sad

0                      1                      2                      3                      4

4. I feel guilty

0                      1                      2                      3                      4

5. I feel frustrated

0                      1                      2                      3                      4

6. I feel nervous

0                      1                      2                      3                      4

7. I worry about the effect of this illness on my other children

0                      1                      2                      3                      4

8. I am worried about the harmful effects of the treatments on my child/infant

0                      1                      2                      3                      4

9. It upsets me to see my child/infant get sicker

0                      1                      2                      3                      4

10. I am discouraged about the future

0                      1                      2                      3                      4

11. I am under financial strain

0                      1                      2                      3                      4

12. I am concerned about insurance coverage

0                      1                      2                      3                      4

13. My economic future is uncertain

0                      1                      2                      3                      4

***Section 2***

The purpose of this section is to collect demographic data on yourself. Please answer the questions to the best of your ability by either choosing the most appropriate response or by filling in the blank. Additional information about your child and your child's condition will be pulled from their patient chart.

1. Gender..... Male \_\_\_\_\_  
Female \_\_\_\_\_
2. Age in years ..... \_\_\_\_\_ (years)
3. Marital Status..... Married \_\_\_\_\_  
Not Married \_\_\_\_\_
4. Work Status..... Part/Full Time \_\_\_\_\_  
Unemployed \_\_\_\_\_
5. Presence of social support (Family  
or friends assisting with caregiving  
duties on a constant basis)..... Yes \_\_\_\_\_  
No \_\_\_\_\_
6. Race..... White/Caucasian \_\_\_\_\_  
Black (non-Hispanic) \_\_\_\_\_  
Hispanic/Latino \_\_\_\_\_  
Native American \_\_\_\_\_  
Asian/Pacific Islander \_\_\_\_\_  
Refused \_\_\_\_\_

Section 2 continued next page>>>

7. What is the highest level of school you have completed?.....
- Grade School \_\_\_\_\_  
Some High School \_\_\_\_\_  
High School \_\_\_\_\_  
Some College \_\_\_\_\_  
College Degree \_\_\_\_\_  
Some Graduate School \_\_\_\_\_  
Graduate School \_\_\_\_\_  
Refused \_\_\_\_\_
8. What is your relationship to the patient?.....
- Parent \_\_\_\_\_  
Grandparent \_\_\_\_\_  
Other \_\_\_\_\_
9. What was your approximate household income last year?.....
- Under \$14,999 \_\_\_\_\_  
\$15,000-\$24,999 \_\_\_\_\_  
\$25,000-\$34,999 \_\_\_\_\_  
\$35,000-\$49,999 \_\_\_\_\_  
\$50,000-\$74,999 \_\_\_\_\_  
\$75,000-\$99,999 \_\_\_\_\_  
\$100,000-\$149,999 \_\_\_\_\_  
\$150,000-\$199,999 \_\_\_\_\_  
Over \$200,000 \_\_\_\_\_  
Refused \_\_\_\_\_
10. Primary source of medical expense coverage?.....
- Private Insurance \_\_\_\_\_  
Government Insurance  
(Medicaid/Medicare) \_\_\_\_\_  
Personal Finances \_\_\_\_\_

**Section 3**

Parents/Guardians put time and effort into taking care of their child with cancer. We want to better understand how much time and effort certain care-giving tasks require. Please indicate below the amount of time and effort during the past week that these tasks have required of you.

1. Providing emotional support for your child with cancer.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

2. Providing emotional support for other children in the family.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

3. Providing emotional support for the extended family (examples include: grandparents, aunts, uncles, friends, etc)

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

4. Providing emotional support for your spouse/partner.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

Section 3 continued next page>>>

5. Meeting your own emotional support needs.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

6. Comforting your child through the pain of the cancer and its treatment (examples include: procedures, mouth sores, bone pain, etc.).

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

7. Planning activities for you child with cancer around the treatment and illness (examples include: school , playtime, rest, things for the child to do, others).

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

8. Planning activities for your family around treatment and illness (examples include: recreation, vacation, school functions, other).

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

Section 3 continued next page>>>

9. Communicating information about cancer to schools, day care, babysitters, extended family and friends.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

10. Watching for and reporting your child's physical symptoms and medical condition to the medical team.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

11. Getting information on your child's illness and the treatment (examples include: library, medical team, community agencies, internet).

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

12. Taking care of discipline and/or behavior problems of the child with cancer (crying, irritability, moodiness).

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

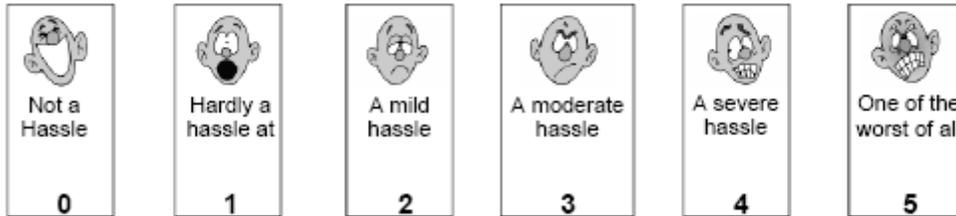
13. Taking care of finances, bills, and forms related to the child's illness.

<u>Time</u>	<u>Effort/Difficulty</u>
_____ > 5 hours/week	_____ A great deal
_____ >2-5 hours/week	_____ Quite a lot
_____ 1-2 hours/week	_____ Moderate
_____ < 1 hour/week	_____ A small amount
_____ Did not do	_____ None

**Section 4**

**INTRODUCTION:** Hassles are minor daily irritants. We are interested in knowing which of the following tasks associated with managing medications for your child are potential hassles for you and how much of a hassle they are to you.

**DIRECTIONS:** For each of the following items circle the number that represents the intensity of the hassle that you experience. The faces may help you decide which number to pick. For example, if the item is not a hassle or does not apply to your situation, circle 0. If the item is a mild hassle, circle the number 2. If the hassle is one of the worst of all hassles, circle the number 5.



1. Admitting to the physician or others that I made a mistake

**0                      1                      2                      3                      4                      5**

2. Knowing when to hold, increase, decrease a dose or discontinue the medication

**0                      1                      2                      3                      4                      5**

3. Understanding when medications can be crushed, mixed, dissolved, etc.

**0                      1                      2                      3                      4                      5**

4. Recognizing adverse (bad) side effects

**0                      1                      2                      3                      4                      5**

5. Knowing how to give medication safely

**0                      1                      2                      3                      4                      5**

**Section 5**

Each of the statements below represents a feeling, belief, or attitude that someone like yourself might have about the illness of a child and about your role of providing the care and support needed by your child. We refer to this care and support as "caregiving".

**Directions:**

Please think about how you have felt about your own caregiving situation during the past week. We would like to know how true each statement is of your own thoughts and feelings.

Read the following true or false choices. Use these choices to answer each of the statements about caregiving:

Very TRUE	5	You feel that way most of the time
More TRUE	4	You feel that way much of the time
Equally TRUE and FALSE	3	You feel that way some of the time and the opposite way some of the time
More FALSE than TRUE	2	You feel that way only sometimes or once in a while
VERY FALSE	1	You never feel that way or rarely feel that way

There are no right or wrong answers.

We are aware that your feelings about the illness situation and treatment will fluctuate and change from day to day and week to week. Read the following statements. Circle the answer that is closest to how you are feeling now and have been feeling over the past week (7 days).

	VERY FALSE	MORE FALSE than TRUE	EQUALLY TRUE and FALSE	MORE TRUE than FALSE	VERY TRUE
1. I feel things are going to get worse for me.	1	2	3	4	5
2. I haven't been doing very well since this situation started.	1	2	3	4	5
3. I feel a sense of loss at not being able to meet all my responsibilities.	1	2	3	4	5
4. I worry that I'll have to give up a lot of things in the future.	1	2	3	4	5
5. I'm afraid that in the future I won't have the energy and endurance I have now.	1	2	3	4	5
6. I feel a loss because it seems like there's no longer anything I can do that makes a difference in how the person needing care feels.	1	2	3	4	5

Section 5 continued next page>>>

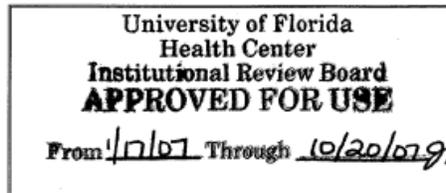
We are aware that your feelings about the illness situation and treatment will fluctuate and change from day to day and week to week. Read the following statements. Circle the answer that is closest to how you are feeling now and have been feeling over the past week (7 days).

	VERY FALSE	MORE FALSE than TRUE	EQUALLY TRUE and FALSE	MORE TRUE than FALSE	VERY TRUE
7. This situation threatens to overwhelm me.	1	2	3	4	5
8. I'm afraid my own physical health will begin to suffer.	1	2	3	4	5
9. I worry that in the future I will be less able to do things I like to do.	1	2	3	4	5
10. I worry that I won't be able to help the person needing my care in the future.	1	2	3	4	5
11. I worry that my emotional health will begin to suffer.	1	2	3	4	5
12. I'm concerned that this situation will cause financial hardship for me in the future	1	2	3	4	5
13. I'm not sure I can handle this situation in the future.	1	2	3	4	5

APPENDIX B  
CONSENT FORM FOR STUDY PARTICIPANTS

IRB# 191-2006

*Informed Consent to Participate in Research  
and Authorization for Collection, Use, and  
Disclosure of Protected Health Information*



You are being asked to take part in a research study. This form provides you with information about the study and seeks your authorization for the collection, use and disclosure of your and your child's protected health information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits to which you or your child would otherwise be entitled.

**1. Name of Participant ("Study Subject")**

---

**2. Title of Research Study**

Family Caregiver Quality of Life in a Pediatric Oncology Setting

**3. Principal Investigator and Telephone Number(s)**

Michael Mueller  
352-318-1147

**4. Source of Funding or Other Material Support**

University of Florida



**5. What is the purpose of this research study?**

To identify factors that influence family caregiver quality of life in a pediatric oncology setting. Primary factors of interest include the demands associated with caregiving, hassles associated with managing the patient's medications and stress related to the caregiving role.

**6. What will be done if you take part in this research study?**

Participants will be asked to fill out a questionnaire addressing caregiver quality of life, demands of caregiving, hassles associated with medication management and stress related to caregiving as well as information about themselves, their child and their child's illness.

If you have any questions now or at any time during the study, you may contact the Principal Investigator listed in #3 of this form.

**7. If you choose to participate in this study, how long will you be expected to participate in the research?**

Participants will only fill out the questionnaire and then be done with the research. It should take about 45 minutes to complete the questionnaire.

**8. How many people are expected to participate in this research?**

60

**9. What are the possible discomforts and risks?**

No risks are expected to arise from this particular study. Family caregivers may feel some emotional discomfort in sharing their feelings about their experience of caring for their child. They may also feel uncomfortable being the focus of attention when it is their child that many will feel deserves all the attention.

Participation in more than one research study or project may further increase the risks to you. Please inform the Principal Investigator (listed in #3 of this consent form) or the person reviewing this consent with you before enrolling in this or any other research study or project.

If you wish to discuss the information above or any discomforts you may experience, you may ask questions now or call the Principal Investigator listed on the front page of this form.



**10a. What are the possible benefits to you?**

There are no specific benefits to you or your child at this time.

**10b. What are the possible benefits to others?**

There are no immediate benefits to others

**11. If you choose to take part in this research study, will it cost you anything?**

There are no costs associated with participating in this study.

**12. Will you receive compensation for taking part in this research study?**

Yes. One (1) \$20 Publix gift card.

**13. What if you are injured because of the study?**

If you experience an injury that is directly caused by this study, only professional consultative care that you receive at the University of Florida Health Science Center will be provided without charge. However, hospital expenses will have to be paid by you or your insurance provider. No other compensation is offered. Please contact the Principal Investigator listed in Item 3 of this form if you experience an injury or have any questions about any discomforts that you experience while participating in this study.

**14. What other options or treatments are available if you do not want to be in this study?**

There is the option to not participate in the study.

**15a. Can you withdraw from this research study?**

You are free to withdraw your consent and to stop participating in this research study at any time. If you do withdraw your consent, there will be no penalty, and you will not lose any benefits you are entitled to.

If you decide to withdraw your consent to participate in this research study for any reason, you should let the investigator present know.

If you have any questions regarding your rights as a research subject, you may phone the Institutional Review Board (IRB) office at (352) 846-1494.



**15b. If you withdraw, can information about you still be used and/or collected?**

You or your child's data will not be used if you withdraw from the study.

**15c. Can the Principal Investigator withdraw you from this research study?**

Individuals that meet the inclusion criteria outlined by the primary investigator will be the only ones allowed to participate in this study so there is no reason that anyone who starts the study will be removed.

**16. If you agree to participate in this research study, the Principal Investigator will create, collect, and use private information about you, your child and your child's health. Once this information is collected, how will it be kept secret (confidential) in order to protect your privacy?**

Information collected about you and your child and your child's health (called protected health information), will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

If you participate in this research study, the researchers will collect, use, and share your and your child's protected health information with others. Items 17 to 26 below describe how this information will be collected, used, and shared.

**17. If you agree to participate in this research study, what protected health information about you and your child may be collected, used and shared with others?**

Your child's protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your child's current health records. More specifically, the following information may be collected, used, and shared with others:

- Child's cancer type
- Time since child's diagnosis
- Treatment strategy for your child
- Primary type of treatment
- Child's age at diagnosis
- Child's cancer stage



- Age of your child
- Number of medications your child is currently taking

We will also be collecting some protected health information from you as well including:

- Age
- Work status
- Marriage status
- Race
- Gender
- Highest level of schooling
- Income
- Insurance

If you agree to be in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set may only include information that does not directly identify you or your child. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If used, limited data sets have legal agreements to protect your identity and confidentiality and privacy.

**18. For what study-related purposes will your and your child's protected health information be collected, used, and shared with others?**

Your and your child's protected health information may be collected, used, and shared with others to make sure you are eligible to participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your and your child's protected health information may be collected, used, and shared with others for the following study-related purpose(s):

- To identify how the factors collected influence your overall quality of life.

**19. Who will be allowed to collect, use, and share your and your child's protected health information?**

Your and your child's protected health information may be collected, used, and shared with others by:

- the study Principal Investigator Michael Mueller and his sub-investigators
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures
- the University of Florida Institutional Review Board



**20. Once collected or used, who may your and your child's protected health information be shared with?**

Your and your child's protected health information may be shared with:

- the study sponsor the University of Florida
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and Federal, State and local health departments

**21. If you agree to participate in this research, how long will your and your child's protected health information be used and shared with others?**

Your and your child's protected health information will be collected until the end of the study. This information will be used and disclosed forever since it will be stored for an indefinite period of time in a secure database. If you withdraw your permission for the use and sharing of your and your child's protected health information, then your and your child's information will be removed from the database.

**22. Why are you being asked to allow the collection, use and sharing of your and your child's protected health information?**

Under a new Federal Law, researchers cannot collect, use, or share with others any of your and your child's protected health information for research unless you allow them to by signing this consent and authorization.

**23. Are you required to sign this consent and authorization and allow the researchers to collect, use and share with others your and your child's protected health information?**

No, and your refusal to sign will not affect you or your child's treatment, payment, enrollment, or eligibility for any benefits outside this research study. *However, you cannot participate in this research unless you allow the collection, use and sharing of your child's protected health information by signing this consent/authorization.*

**24. Can you review or copy your and your child's protected health information that has been collected, used or shared with others under this authorization?**

You have the right to review and copy your child's protected health information. However, you will not be allowed to do so until after the study is finished.



**25. Is there a risk that your and your child's protected health information could be given to others beyond your authorization?**

Yes. There is a risk that information received by authorized persons could be given to others beyond your authorization and not covered by the law. However, this risk is minimal because all data collected will be housed in a password protected computer that only the Primary Investigator has access to. Additionally once data is entered into the data set there will be no identifiable fields included in the data set that would allow any individual to ascertain whose data they were looking at.

**26. Can you revoke (cancel) your authorization for collection, use and sharing with others of your and your child's protected health information?**

Yes. You can revoke your authorization at any time before, during, or after your participation in the research. If you revoke, no new information will be collected about you or your child. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

**27. How will the researcher(s) benefit from your being in this study?**

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. If presented in results, individual data will not be presented. Instead aggregate data such as average scores for all subjects will be reported.



**28. Signatures**

As a representative of this study, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

\_\_\_\_\_  
Signature of Person Obtaining Consent and Authorization      Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your child's protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your child's protected health information as described in sections 17-26 above. By signing this form, you are not waiving any of your legal rights.

\_\_\_\_\_  
Signature of Person Consenting and Authorizing      Date

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## BIOGRAPHICAL SKETCH

Michael, a Florida native, attended high school at Tarpon Springs High School in Tarpon Springs, Florida. Following high school, he attended the University of Florida, where, in 1995, he earned his Bachelor of Science degree in psychology. Michael returned to the University of Florida in the fall of 2001 where he joined the Department of Pharmaceutical Outcomes and Policy as full time student. As a graduate student, Michael received a University of Florida Alumni Fellowship, an AACP Wal-Mart Scholarship and was elected the Teaching Assistant of the Year by the faculty of the Department of Pharmaceutical Outcomes and Policy.