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QUALITY OF LIFE OF CHILDREN WITH CANCER:
ANALYSIS OF A CONCEPT AND A MEASURE

by

Sherri L. M. Belton

A thesis submitted in conformity with the requirements
for the Degree of Master of Science
Graduate Department of Nursing Science
University of Toronto

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Quality of Life of Children with Cancer:  
Analysis of a Concept and a Measure

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ABSTRACT

Research on Quality of Life (QOL) for children with cancer is expanding. However, there is lack of clarity around the conceptualization and operationalization of the concept. Based on the conceptual and methodological inadequacies found in the literature, this study was undertaken to critically examine the concept of QOL of children with cancer and corroborate the defining attributes of QOL with an instrument that assesses QOL in children with cancer.

Walker and Avant’s (1995) approach to concept analysis was used to determine the defining attributes of QOL of children with cancer. The defining attributes were then compared to the items from the Pediatric Oncology Quality of Life Scale (Goodwin, Boggs, & Graham-Pole, 1994) and empirical findings from parents of children with Acute Lymphoblastic Leukemia (n=25). Finally, QOL for children with cancer was defined as the child’s perception of the extent to which he/she has the ability to function physically, emotionally and socially within his/her environment.
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# TABLE OF CONTENTS

Abstract ..................................................................................................................... ii
Acknowledgments ....................................................................................................... iii
Table of Contents ........................................................................................................ iv
List of Tables ............................................................................................................... vi
List of Figures ............................................................................................................. vii
List of Appendices .................................................................................................... viii

## CHAPTER I: THE PROBLEM AND PURPOSES

Introduction ............................................................................................................... 1
Problem Statement ..................................................................................................... 2
Review of the Literature ............................................................................................ 3

## CHAPTER II: METHODS AND PROCEDURES

Purpose ...................................................................................................................... 19
Research Questions .................................................................................................. 19
Definition of Terms .................................................................................................. 19
Study Design ............................................................................................................ 21
Part I: Qualitative/Retrospective Component .......................................................... 22
Part II: Quantitative/Prospective Component ............................................................ 30
Setting ...................................................................................................................... 32
Sample ..................................................................................................................... 32
Ethical Considerations ............................................................................................. 33
Data Collection ......................................................................................................... 34
TABLE OF CONTENTS (con’t)

Instrumentation............................................................................................................ 34

CHAPTER III: RESULTS

Part I: Qualitative Component...................................................................................... 41
Part II: Quantitative Component.................................................................................... 44
Summary......................................................................................................................... 51

CHAPTER IV: DISCUSSION

Discussion.................................................................................................................... 54
Summary of Discussion.................................................................................................. 65

CHAPTER V: SUMMARY, IMPLICATIONS, AND CONCLUSIONS

Summary of Study.......................................................................................................... 68
Limitations for Theory and Research............................................................................. 72
Implications for Practice................................................................................................. 75
Implications for Further Research................................................................................ 77
Conclusion..................................................................................................................... 79
REFERENCES............................................................................................................... 81
List of Tables

Table 1. Methodology for Determining the Quality of Life of Children with Cancer ................................................................. 21
Table 2. Application of Walker and Avant’s Concept Analysis to QOL of Children with Cancer ......................................................... 24
Table 3. Quality of Life as Defined by Happiness and Satisfaction ........ 28
Table 4. Data Analysis for the Quality of Life Study ............................ 40
Table 5. Sample Characteristics .......................................................... 47
Table 6. Descriptive Analysis for the POQOLS Total and Factor Scores ..... 48
Table 7. Analysis of Scores by Age Group ............................................. 50
Table 8. Analysis of Scores by Time Since Diagnosis ........................... 51
Table 9. Goodwin et al.’s POQOLS Scores by Age Group ......................... 59
Table 10. Goodwin et al.’s POQOLS Scores on Time from Diagnosis .... 63
Table 11. POQOLS Scores from Goodwin et al. versus Belton .............. 65
List of Figures

Figure 1. Cross-Reference of Items from the POQOLS and Concept Analysis of Quality of Life......................................................... 46
Chapter I: Problem and Purposes

Over the past two decades, research on quality of life (QOL) has flourished. Researchers have begun to use QOL measures to determine the efficacy and cost effectiveness of new treatments and the impact of chronic illness on QOL (Guyatt, Feeney, & Patrick, 1993). Although QOL has emerged as an important construct, ambiguity about the definition, meaning and measurement of QOL exists in all disciplines, including nursing (Ferrans, 1990). The majority of research about QOL has been conducted on adults, with minimal research in pediatrics (Hinds, 1990). Goodwin, Boggs and Graham-Pole (1994) identified an increase in research on the psychosocial sequelae of cancer treatment during childhood. However, these researchers stated that most research on psychosocial issues was based on the measurement of physiological variables. Literature on the QOL of children with cancer is very limited. This paucity may be due to the lack of congruence among measurement tools for assessing QOL and the multitude of definitions for QOL in general and in this specific population (Mulhern et al., 1989).

Childhood cancer previously was viewed as a disease that usually resulted in death. However, advances in treatment have dramatically improved the survival rates of children with cancer (Goodwin et al., 1994). As cancer treatment improved and survival time lengthened, negative physical, social, and psychological consequences became evident (Hinds, 1990). Diagnosis and treatment of cancer may leave children feeling isolated and different from other children. Physical effects such as weight fluctuations, hair loss, and fatigue have resulted in low self-esteem and self-confidence. Attendance at school is often disrupted leading to a sense of isolation from peers. Hospitalization and frequent clinic visits
interfere with extracurricular activities and social relationships. Uncertainty about the future leads to confusion and extraordinary dependence on parents and siblings (List, Ritter-Sterr, & Lansky, 1991). Clearly, the ramifications of cancer and it's treatment can have both short-term and long-term effects on the QOL of children with cancer and their families (Hinds, 1990).

**Problem**

Approximately 1250 children per year are diagnosed with cancer in Canada and 20% of these children have Acute Lymphoblastic Leukemia (ALL) (Hutchcroft et al., 1996). Children with ALL receive active treatment for approximately two to three years. Cancer is life-threatening and has both a physical and psychological impact on a child and family (Jenny, Kane & Lurie, 1995). Problems with reintegration into school, academic difficulties, fear of relapse, and the effects of treatment may impact the self-esteem, self confidence, and general physical and psychological well-being of the child.

Quality of life is an important outcome for a child receiving active cancer treatment. Traditional end points of treatment efficacy have been tumor response and survival. However, a movement to recognize and include QOL as an outcome in cancer treatment has emerged (Varricchio, 1990). The psychological impact as well as the physical benefits of new treatments need to be considered. Currently, there is inadequate knowledge about QOL for children with cancer who are receiving active treatment. This lack of knowledge may be the result of inadequate conceptualization and operationalization of QOL. In addition, QOL is often described without the use of an adjective, making the assumption that QOL is
synonymous with high or adequate QOL which is not necessarily true (McDaniel & Bach, 1994).

Nurses need to have a good understanding of QOL for the child being treated for cancer to (a) identify potential problems, (b) determine feasible interventions, (c) educate health professionals and families to deal with QOL issues, (d) promote health, and (e) restore a maximum level of functioning for the child and family. Information on QOL also is necessary for children and their parents to make informed decisions about treatment.

For QOL of children with cancer to be examined empirically, QOL should be clearly defined conceptually and adequately operationalized in a way that is applicable to this population. In this study, the conceptualization and operationalization of QOL of children with cancer will be explored. A concept analysis will be conducted to determine the defining attributes of QOL of children with cancer. The defining attributes from the concept analysis will be compared with the attributes of a pediatric QOL measure and empirical data.

**Review of the Literature**

The literature on QOL of children with cancer has derived from QOL research within the adult population. Review of the vast amount of literature related to QOL in adults is beyond the scope of this thesis (Testa & Simonson, 1996). The focus of the literature review for the thesis is on (a) concept analyses of QOL, (b) conceptual definitions of QOL of children with cancer, (c) health-related QOL of children with cancer, and (d) operationalization of QOL of children with cancer.
Concept Analyses of QOL

According to Creason, Camilleri, and Kim (1993), concepts are the foundation of theory development and concept analysis is a means of establishing and explicating the meaning of a concept. Concept analysis is based on three assumptions; (a) the meaning of a concept is purposefully created for that specific user, (b) concepts include interrelated components, and (c) concepts are constructed to identify specific characteristics of a particular concept. Knafl and Deatrick (1993) suggested that concept analysis involves synthesizing existing views of a concept and differentiating it from other concepts. Walker and Avant (1995) stated that a concept analysis is a formal exercise or strategy to examine and determine the defining attributes or characteristics of a concept. Wilson (1963) emphasized that concept analysis is a useful technique for improving communication and enhancing clarity of thought.

A concept analysis of QOL in children with cancer was not found, concept analyses of QOL of adults with cancer were reviewed. However, Walker and Avant’s (1995) approach to concept analysis has been used to clarify and examine QOL for adults with cancer. Meeberg (1993) performed a concept analysis of QOL to examine the meaning of quality in peoples’ lives. Meeberg defined QOL as “a feeling of overall life satisfaction, as determined by the mentally alert individual whose life is being evaluated” (1993, p.37). Other people, not directly related to the individual, needed to concur that the individual was living in a non life-threatening environment that was meeting his/her basic needs. Therefore, QOL had both a subjective and objective component.
McDaniel and Bach (1994) used Walker and Avant’s method of concept analysis to clarify the meaning of QOL for adults with cancer. McDaniel and Bach defined QOL as the congruence or lack of congruence between the actual life conditions and one’s hopes and expectations. QOL was unique, dynamic and influenced by the various dimensions of an individual’s life. The authors stated that practitioners need to have a clear understanding of the concept of QOL to incorporate patient’s desires and goals into the plan of care.

Subjectively perceived QOL was explored by Oleson (1990) using a modified version of Walker and Avant’s procedure for concept analysis. Oleson stated that happiness and satisfaction were the most prevalent elements used to define QOL and based her definition of QOL on these elements. QOL was defined as “a cognitive experience manifested by satisfaction with life domains of importance to the individual and an affective experience manifested by happiness with important life domains” (1990, p.188). QOL can be operationalized with instruments designed to measure satisfaction, happiness and global QOL.

Bond (1996) used a modified version of concept analysis to clarify QOL for critical care patients. Bond stated that QOL for critical care patients should incorporate both subjective and objective attributes to improve understanding, communication and meaning for issues related to QOL. Bond claimed that subjective evaluation of QOL referred to the quality of an individual’s life and the objective component referred to the quantity of an individual’s life.
Conceptual Definitions of Quality of Life of Children with Cancer

Treatments for cancer often were evaluated by assessing physiological outcomes; the side effects of treatment, the responsiveness of the tumor, the ability to remain in remission, and long-term survival. With the primary focus of treatment being cure, many of the psychosocial consequences of the treatment process were minimized (Hinds, 1990).

Bradyn et al. (1996) reviewed the conceptual and methodological issues related to QOL in children with cancer. The researchers characterized QOL as (a) patient or family based in its perspective; (b) multidimensional including, but not limited to, physical, social and emotional functioning; (c) incorporating the impact of treatment on the whole family, and (d) identifying the importance of developmental change. Operationalization of QOL was hindered by the use of generic measures or disease-specific measures, with selection based on the psychometric properties of the instrument and the specific goals of the study. Proxy responding (i.e. parents reporting on the QOL of their children) was concerning as QOL measurement favors subjective assessment. However, the use of a proxy is necessary for preverbal children or children with limited comprehension abilities.

Hinds (1990) stated that the literature on QOL of children with cancer who were receiving active treatment was lacking and that definitions of QOL were complicated because of the overlap of other related concepts. Hinds defined QOL of children with cancer as the subjective sense of well-being during and after the treatment. The sense of well-being was a comparison of the child or adolescent’s hopes and desires with actual experiences. Sense of well-being was affected by daily life events that changed frequently. Finally, well-being was
influenced from past experiences. Therefore, a toddler may have a limited sense of well-being versus an adolescent.

Mostow, Byrne, Connelly and Mulvihill (1991) assessed the QOL in long-term survivors of central nervous system (CNS) tumors of childhood and adolescence to identify individuals who would benefit from early interventions and ultimately have improved QOL. QOL was defined in terms of employment status, physical and emotional well-being and the ability to function 'normally'. Three hundred and forty-two adults who had reached 21 years of age, had CNS tumors, and had survived at least five years after remission were evaluated. This group, when compared with 479 matched siblings, were reported to have a higher percentage of premature death, were more likely to be mentally incompetent, had a higher rate of unemployment, had a health condition that affected their ability to work, were less likely to drive an automobile and described their current health as poor. Male survivors were at greater risk for adverse affects than female survivors who appeared to be functioning at a level similar to their siblings. Although this historical cohort study provided an assessment of QOL in survivors of CNS tumors, the interview to determine QOL was very general and only included medical and reproductive experiences and levels of functioning. The findings were not consistent with QOL literature that emphasizes physical, functional, emotional and social well-being (Aaronson, 1991). Also, many of the questions required the respondents to compare themselves with individuals with similar characteristics and to rank their level of functioning regarding activities of daily living. Measuring QOL as the ability to function normally did not reflect the individual's own assessment of his/her QOL.
Balduzzi et al. (1995) studied 88 children with differing types of leukemia or hematological diseases who received an unrelated donor marrow transplant. The purpose of the study was to identify the physiological factors that affect survival (i.e. the conditioning regime, the match of the donor, the presence of graft versus host disease, and the long-term effects). A conceptual definition of QOL was not evident but QOL was assessed by play performance and functional status. These researchers found that at one year post transplant, 40 children had survived. From this group, the Lansky Play Performance Scale (Lansky et al., 1987) and Karnofsky Performance (as cited in MacLeod, 1949) scores were collected in 36 of 40 children. The scores ranged from 70% to 100% with 100% being no affect on play or performance status. At the end of two years, play and performance scores were collected on 21 of 25 patients (11 had expired); two had scores of 70% to 80%, and 19 had scores of 90% to 100%. A score of 100% was reported for the 14 children who survived between three and seven years from transplant. The scores for the transplant survivors appeared elevated considering that the investigators reported that many of the children suffered long-term effects such as graft versus host disease, cataracts, avascular osteonecrosis, hypothyroidism and pulmonary abnormalities. There was no explanation of scoring or inter-rater and intra-rater reliability. A very small sample of the population that survived bone marrow transplantation was included and therefore, generalizability of the findings was questionable.

Barr et al. (1993) assessed the global health status of survivors of ALL in childhood using a multi-attribute health status classification system. This system consisted of three to five levels of function within each of seven attributes including; sensation, mobility, emotion, cognition, self-care, pain and fertility. The health status classification system was used (by a
nurse and four physicians) to assess the health status of 55 children who had completed treatment within a few months up to 20 years post treatment. The burden of cancer and its treatment were greater for children who were diagnosed as "high-risk" versus those children who were diagnosed as "low-risk or standard risk". Emotional and cognitive deficits were the most common in all groups but especially in younger children. A relationship between the age of the child at the time of cranial irradiation and cognitive deficit existed. The younger the child at the time of irradiation, the more likely that cognitive deficits occurred. In addition, the greater the total radiation dose, the more likely was the incidence of emotional deficits. A limitation of the study was the absence of information about inter-rater reliability among the five raters and the lack of an appropriate control group.

Sawyer, Crettenden and Toogood (1986) examined emotional, behavioral and psychological adjustment of children and adolescents (ages 4-16 years) treated for ALL and family adjustment. Forty-two children and adolescents treated for ALL were compared for the prevalence of emotional and behavioral problems with (a) a matched control group of healthy children from the general population, and (b) a group of siblings. The Achenbach Child Behavior Checklist (Achenbach & Edelbrock, 1983) was completed by parents and teachers, and the Rutter B2 Behavior Scale (Rutter, 1967) was completed by teachers. The Family Concept Inventory (Moss, Nannis, & Poplack, 1981) was completed by both parents and by older children or adolescents. Children and adolescents with ALL had significantly more problems and less social competence, in school related activities as compared to the control group or the siblings. There were no significant differences between the sibling groups or between the families. Lack of blinding was a problem in this study. The teachers
were aware of the children and adolescents who had leukemia and this knowledge may have biased their ratings.

Pastore et al. (1977) assessed the late effects and health status of 198 children with neuroblastoma, Wilm’s tumor, ALL or non-Hodgkin’s lymphoma who were followed from one to twelve years after the discontinuation of treatment. The long-term physiological effects of the treatment; musculoskeletal, cardiovascular, neurological, respiratory, digestive and endocrine problems were determined. There was no indication of the relationship between the physiological problems associated with treatment and the child or family’s QOL.

Kupst and Schulman (1988) assessed long-term coping in 43 families of children with ALL using semistructured interviews, the Current Adjustment Rating Scale (Berzins, Bednar & Severy, 1975) and the Family Coping Scale (Hurwitz, Kaplan, & Kaiser, 1962). Families with a child with ALL were reported to be coping well. However, there was no follow-up for the families who refused to participate in the study who may have been coping poorly.

Health-Related Quality of Life for Children with Cancer

QOL and health-related quality of life (HRQOL) frequently are used interchangeably. However, HRQOL has a specific definition and body of literature. Saigal, Feeney, Furlong, Rosenbaum, Burrows and Torrance (1994) state that QOL is an all encompassing concept that includes all factors that affect an individual’s life. “Health is one key factor that affects overall quality of life, which when considered separately for the purpose of evaluating health care programs is referred to as health-related quality of life” (Saigal et al., 1994, p. 419).

As with QOL, HRQOL was assessed using a generic approach and a specific approach, examples of HRQOL measures can be found in Appendix A. HRQOL was
frequently assessed using a subcategory of the generic approach; the preference or utility-based measure (Barr, Feeney, Furlong, Weitzman, Torrance, 1995; Feeney, Furlong, Barr, Torrance, Rosenbaum, Weitzman, 1992; Saigal et al., 1994). Preference measures were used to determine the worthiness of the outcomes of a specific health state. Utility was a preference measure that determined the individual’s preferences in a given health state under conditions of uncertainty. Value scores were measures of preference that an individual had under conditions of certainty. Value and utility scores were given a single score, usually between zero and one, where zero represented death and one was perfect health. This score represented HRQOL at a specific time in an individual's life.

Feeney et al. (1992) described the development and implementation of the multi-attribute health status classification system for survivors of childhood cancer. The investigators found that patients on therapy suffered a greater burden of morbidity than those who were off therapy. A multi-attribute system was found to be useful for classifying the health status of children with cancer. However, the psychometric properties of the instrument were not reported and warrant further investigation.

Feeney et al. (1993) used their multi-attribute system to describe the health status of long term survivors of high-risk acute lymphoblastic leukemia (ALL) in England. The retrospective study compared the health states of the long-term cancer survivors with the population norms of adolescents in Canada and individuals with disabilities in England. A greater burden of morbidity for the long-term survivors of ALL existed in comparison to the population in England with disabilities. However, a similar health state was found between the ALL survivors in England and the population norms for Canada.
Barr et al. (1994) described the use of the multi-attribute system to assess global morbidity burden of survivors of brain tumors in childhood. The investigators discussed the evolution of the multi-attribute health status (MAHS) classification system and its significance. However, the study design was not specified. Barr reported that (a) morbidity was present in all survivors of brain tumors, (b) morbidity burden may change with the passage of time, and (c) the appraisal of morbidity was inconsistent between the physician, nurse and parent. Although these findings were significant, the sample size was small (n=10) limiting generalizability and in-depth analysis. The authors also suggested that HRQOL, measured with the MAHS, can be used for the calculation of cost-utility ratios for health care interventions.

Apajasalo et al. (1996) developed a 16-dimensional (16D), generic self-assessment measure of HRQOL for adolescents. The measure was used with four populations of children aged 12 to 15 years of age; (a) normal school children, (b) children waiting for organ transplantation, (c) children with epilepsy and, (d) children with genetic skeletal dysplasias. The clinical usefulness of the 16D as a measure of HRQOL for adolescents was established. This study was prospective with a large sample size (n=295) but did not include children with cancer. The measure was easily completed by adolescents but may be difficult for younger children to complete. In addition, it was a generic measure which may be problematic for comparing children with specific diseases. Finally, the psychometric properties of the measure were not established.
Operationalization of Quality of Life of Children with Cancer

Inconsistent measurement exists in the assessment of QOL in children with cancer (Jenny, Kane, & Lurie, 1995; Mulhern et al., 1989). Quality of life has been assessed using a variety of methods such as functional status, play performance and utility-based measures (Rosenbaum, Cadman & Kirpalani as cited in Spilker, 1990). One disease-specific measure, the Pediatric Oncology Quality of Life Scale (POQOLS) has been developed for children with cancer (Goodwin et al., 1994).

The POQOLS is a 21-item questionnaire that assesses the parent's perception of the child's QOL (Goodwin et al., 1994). The scale consists of three factors that provide the investigator with a total QOL score and individual scores for the three factors including (a) physical function and restriction from normal activity, (b) emotional distress and (c) response to active medical treatment. Reliability and validity assessments provide support for the psychometric adequacy of the measure (see p.33-38). However, consistency and/or validity between parent’s and child’s perceptions of QOL has not been determined.

The Quality of Well-Being Scale (QWB) was a subcomponent of the General Health Policy Model (Bradlyn, Harris, Warner, Ritchey, & Zaboy, 1993). The QWB scale had been developed to measure the HRQOL of children with cancer. Physical functioning, social/role functioning and mobility were used to assess functional status. Additional questions were asked regarding physical symptoms. Parents were responsible for completing the questionnaire, however children may have some input. The total score of well-being consisted of the scores from the functional status assessment and the physical symptom assessment. This measure was responsive to incremental changes in a child’s state and was
reliable and valid. However, the measure’s focus was on function and physical symptoms. Although this measure included important components of QOL it did not represent all four essential dimensions of QOL; physical, functional, emotional and social well-being (Aaronson, 1991; Schipper, 1990; Spilker, 1990).

**Issues in Measuring QOL**

Due to the conceptual ambiguity of QOL, measurement was often based on the purpose of the study (Mast, 1995). A wide range of instruments for adults are available to measure QOL (Appendix B), making comparisons between studies difficult. The instruments used to measure QOL differed in terms of (a) the use of a single item versus a multiple item measure (or composite), (b) the types of measures and (c) the use of a subjective versus objective measurement approach.

**Single or Multiple Measures**

There were three approaches to the measurement of QOL; unidimensional measures, multidimensional single scale measures and multiple separate measures. Controversy exists regarding whether an instrument should be generic and very global with a wide variety of use or disease-specific, for use with a specific population.

A unidimensional measure included one dimension of the concept (Mast, 1995). Questions were raised with this approach in regard to representativeness. By looking at only one dimension of an individual’s QOL, it was difficult to represent all domains of the phenomenon.

Multidimensional measures of QOL referred to a single scale that included several dimensions or domains (Mast, 1995). Multidimensional measures captured the essential
components of QOL but variances in the measures made comparison between studies difficult (Mast, 1995). In addition, although the measures were comprehensive, they were not sensitive to cultural or ethnic differences that may have affected the meaning associated with QOL (Marshall, 1990).

The use of multiple measures was advocated because of the need for reliable, comparable, valid, and sensitive measurements (Dean as cited in Stromborg, 1988). This measurement approach also allowed flexibility in conceptualizing QOL and comparability of domains between studies. Jaloweic (1990) suggested that the use of multiple instruments was advantageous as a broad scope of dimensions would be assessed and changes resulting from illness would not be missed. In addition, the overall validity of QOL was established as the content validity and construct validity of all instruments used have increased.

Types of Measures

Aaronson (1991) identified three types of QOL measures; (a) ad hoc, (b) disease-specific and (c) generic. Ad hoc instruments were usually designed for a specific study. Ad hoc measures had dominated QOL research making cross-study comparisons difficult (Kinney, 1995). Disease-specific instruments were valid in certain populations making comparisons across studies of similar populations possible. The disadvantage of using disease-specific instruments was the need to generate multiple instruments for all types of diseases or disabilities. Generic instruments, which may be referred to as global instruments, represented a broad range of health concepts that pertain to general health and functioning (Stewart, Hays, Ware, 1988). These instruments were used in health policy research where resource allocation was the primary concern. A limitations of generic instruments was their
inability to assess adequately the needs of a particular population with specific concerns. The clinical utility of these instruments were limiting as they usually were very long and difficult to complete. Regardless of the type of instrument used, Goodinson and Singleton (1989) stated that a measure must be sensitive to changes over time and include ways of assessing an individual’s coping strategies.

**Subjective or Objective Measurement**

Subjective measurement involved the individual making a judgment on QOL, while objective measurement involved judgment by someone other than the individual (Baker, Curbow & Wingard, 1992). Demographic indicators such as income, housing, social supports, and work status also were considered objective measures of QOL as the judgment was external.

Cella and Tulsky (1990) stated that QOL was similar to the assessment of pain as they were both subjective phenomenon. Thorne and Jillings (1996) concluded that QOL assessment was only valid if completed by self-report. Although Ferrans (1990) agreed with the subjective approach to measurement, she also stated that objective indicators must not be completely disregarded. Ferrans suggested that subjective measurement of QOL was more direct but objective indicators can verify the subjective indicators. Campbell (1976), Strain (1990) and Zhan (1992) agreed that social indicators need to be included in the measurement of QOL as a supplement to subjective indicators. Goodinson and Singleton (1989) stated that a QOL instrument should be considered adequate if a subjective measure was used. However, for children and individuals incapable of communicating through self-report, subjective assessment of QOL was impossible. Although many researchers concluded that
subjective measurement of QOL was superior to objective assessment, it was not always feasible. However, an alternative to objective assessment of children's QOL is through proxy. Parents reporting on their child's QOL is not an objective assessment but rather assessment by proxy. The parents are assessing the child's QOL based on their own perceptions.

In conclusion, Goodinson and Singleton (1989) suggested the use of the following criteria to determine the adequacy of QOL measures: (a) information must be subjective, (b) coping strategies, past experiences and other variables must be included in the assessment, (c) the dimensions of the measure must be weighted in terms of importance to the individual, (d) the measure should be multidimensional and include a definition of QOL, and (e) the measure must be sensitive to change over time.

Researchers have begun to make recommendations for the development of instruments for QOL for the pediatric population and specifically, children with cancer. Mulhern et al. (1989) suggested that a pediatric QOL measure must be useful and convenient. The instrument must be simple to use so it becomes a part of the child's routine assessment. A QOL measure must be able to assess QOL continuously over time; to quickly determine changes in a patient from one visit to the next. The measure should attempt to obtain information through self-report, although this may not always be feasible. Finally, a relevant time interval must be established so an accurate representation of the patient's QOL is provided.

Jenny, Kane and Lurie (1995) stated that health status instruments that measure QOL must be reliable, valid and responsive to any changes in the child's condition. Assessment
must be specific for the child with cancer, but broad enough for comparison with the general population. The results of an assessment must be easily interpreted and overall scores assigned so group comparisons can be made. Finally, assessment of the child with cancer must be ongoing; during treatment, after the completion of treatment and at regular intervals after "cure" has been achieved.

Summary of the Literature Review

Literature on QOL with children with cancer is minimal, heterogeneous and not well defined. Many researchers focus on operationalizing QOL without providing a conceptual definition (Bradlyn et al., 1996). Concept analysis clarifies meaning and improves communication about a concept (Bond, 1996). Only QOL concept analyses related to the adult population exist and they do not provide an understanding of QOL of children with cancer.
Chapter II: Methods and Procedures

Purpose

The purpose of this study is to (a) critically examine the concept of QOL of children with cancer, and (b) to corroborate the defining attributes of QOL of children with cancer established from the concept analysis with an instrument that measures QOL in children with cancer.

Research Questions

1. How is QOL conceptualized for children with cancer?

2. How does a measure of QOL for children with cancer (i.e. POQOLS) corroborate the defining attributes of QOL outlined from the concept analysis of QOL of children with cancer?

Definition of Variables and Relevant Terms

Child: An individual between 2 and 16 years of age.

Cancer: High risk Acute Lymphoblastic Leukemia (ALL).

High Risk: The presence of at least two of the following criteria at diagnosis:

1. Age 1-2 years or >10 years

2. White Blood Cell Count > 50,000

3. Marrow morphology of > 50% blast cells (L²)

4. Sanctuary disease present: Central Nervous System or testicle

5. Lymphoma Syndrome: one criterion from each of the clinical and laboratory groups
Clinical Criteria:  
a) lymphadenopathy > 3 cm or node group > 5 cm.  
b) mediastinal mass  
c) massive splenomegaly/hepatomegaly

Laboratory Criteria:  
a) hemoglobin > 10 gm%  
b) White Blood Cell Count > 50,000  
c) E rosettes > 20%

Acute Lymphoblastic Leukemia: A malignant disorder of the hematopoietic system involving the bone marrow and lymph nodes. It is characterized by uncontrolled proliferation of white blood cells and their precursors.

Active Treatment: An individual receiving chemotherapy for ALL from phase II, III, IV or V of ALL Protocol C (Appendix C) during the course of this study. Each phase represents a different stage of treatment with different combinations of chemotherapy.

Phase I: Induction Phase  
Phase II: Central Nervous System Intensification  
Phase III: Interim Maintenance  
Phase IV: Reinduction/Reintensification  
Phase V: Maintenance

Defining Attributes: Unique characteristics of a concept that differentiates the concept from another similar or related one.
Design

The design of the study included a qualitative component (Part I) and a quantitative component (Part II) (see Table 1). The qualitative component (Part I) involved a concept analysis to determine the defining attributes of QOL for children with cancer. The concept analysis was performed using a modified version of Walker & Avant’s (1995) eight step approach (see Table 2, p.24). A concept analysis is useful for (a) refining ambiguous concepts, (b) clarifying overused vague concepts, and (c) forming precise operational definitions that have construct validity. The quantitative component (Part II) involved determining the defining attributes associated with the POQOLS (Goodwin et al., 1994) and comparing these with the defining attributes from the concept analysis of QOL. With the descriptive design, the variables were examined as they occurred naturally.

Table 1

<table>
<thead>
<tr>
<th>Method for Determining the QOL of Children with Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Question</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>How does the POQOLS corroborate the defining attributes of QOL outlined from the concept analysis of QOL of children with cancer?</td>
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The qualitative and quantitative components of the study will be presented in separate sections in the Methods and Procedures, and Results chapters. The Discussion chapter of
the study will incorporate the findings from the concept analysis of children with cancer and
the empirical findings.

**Part 1: Qualitative/Retrospective Component**

Walker and Avant's (1995) approach was used for the concept analysis in this study. Walker and Avant's purpose of concept analysis is to "...distinguish between the defining
attributes of a concept and its irrelevant attributes" (1995, p.38). Through concept analysis, the defining attributes of QOL as they relate to children with cancer were identified. As
corcepts change over time, the finished product only may capture the critical attributes at a
certain moment in time. The changing aspect of a concept was relevant for this study as
QOL was assessed by parents at one point from initial diagnosis to the end of treatment.

Walker and Avant (1995) state that the operational definition, list of defining
attributes, and antecedents from a concept analysis provide the basis for a new instrument or
a way of evaluating an old instrument. In the development of a new tool, items are
constructed to reflect the defining attributes. In evaluating existing instruments, results from
the concept analysis are used to determine if the instruments accurately reflect the defining
attributes of the relevant concept (Walker & Avant, 1995). In this study, the POQOLS
(Goodwin et al., 1994) (Appendix D) was analyzed to determine if the defining attributes from the concept analysis were present. Walker and Avant were among the first nurse
researchers to develop an approach to concept analysis. Their approach has been used by
many researchers as it was reliable, valid, and feasible.

Walker and Avant's (1995) approach to concept analysis is based on the entity view
that regards concepts as an entity or a "thing". Entity views focus on the entity itself,
regardless of the form of the concept, which may be viewed as rigid (Rodgers, 1989). However, Walker and Avant state that the “analysis is rigorous and precise but the end product is always tentative” (1995, p.37). The tentativeness is always present because two people will come up with different attributes for the same concept. Knowledge is always changing, so what is true one day may not be true the next day. Walker and Avant state that a concept analysis is crucial for capturing the critical attributes at the current moment in time, not unlike Rodgers (1989) who states that concepts are continually changing.

There are no clear distinctions among the methods of concept analysis (Rodgers, 1993). Walker and Avant’s (1995) approach, although reliable and valid, does have weaknesses. Walker and Avant contradict themselves as their philosophical foundation was based on a static, rigid view of a concept but later they stated that concepts were continually changing and the end point was always tentative. Therefore, their philosophical view is unclear. As well, there is potential for bias in the development of the cases that help identify the attributes of the concept. The researcher may construct the cases in ways that favor his/her views of the concept. In addition, the use of cases may not be applicable and it is not known whether cases could be deleted. Finally, Walker and Avant encourage a thorough review of the literature but they do not provide a specific method for reviewing the literature.

**Summary**

Concept analysis has been used to synthesize knowledge, define attributes of a concept, and improve communication (Knafl & Deatrick, 1993; Walker & Avant, 1995; Wilson, 1963). Walker and Avant’s (1995) approach to concept analysis has been chosen as it (a) has clear steps, (b) is iterative, (c ) uses an example to clarify the concept, (d) is reliable
and valid. (e) provides a means for evaluating instruments, and (f) identifies that concepts change over time. In Table 2, the steps of Walker and Avant’s (1995) methodology are outlined and applied to this study. Steps 1-3 are the method and procedure components of the concept analysis and can be found in the Methods and Procedures chapter. Steps 4-7 result from Steps 1-3 and are explored in the Results chapter.

Table 2

Application of Walker and Avant’s Concept Analysis to QOL of Children with Cancer

<table>
<thead>
<tr>
<th>Steps in the Concept Analysis</th>
<th>Application to QOL of Children with Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Select a concept.</td>
<td>QOL of children with cancer was selected.</td>
</tr>
<tr>
<td>2. Determine the aims or</td>
<td>To clarify and identify the defining attributes of QOL of children with cancer.</td>
</tr>
<tr>
<td>purposes of analysis.</td>
<td></td>
</tr>
<tr>
<td>3. Identify all uses of the</td>
<td>QOL was reviewed in the literature in terms of conceptual definitions, operational definitions, health-related QOL and research on children with cancer.</td>
</tr>
<tr>
<td>concept you can discover.</td>
<td></td>
</tr>
<tr>
<td>4. Determine the defining</td>
<td>From the literature defining attributes were determined. Attributes are the essential characteristics that frequently occur in the literature.</td>
</tr>
<tr>
<td>attributes.</td>
<td></td>
</tr>
<tr>
<td>5. Construct a model case.</td>
<td>A model case was developed from the defining attributes. It is a pure case of the concept and can be a real life example or constructed by the researcher.</td>
</tr>
<tr>
<td>6. Identify antecedents and</td>
<td>These were developed from the literature review and case development to further refine the critical attributes. “Antecedents are factors that shape an individual’s perception of the concept; consequences are factors influenced by an individual’s perception of the concept” (McDaniel &amp; Bach, 1994, p.21).</td>
</tr>
<tr>
<td>consequences.</td>
<td></td>
</tr>
<tr>
<td>7. Define empirical referents.</td>
<td>Empirical referents were determined for the critical attributes from the previous six steps. Empirical referents are useful for identifying the concept in the “real world”. For example, empirical referents are actions or clues that a child or family has evaluated their QOL.</td>
</tr>
</tbody>
</table>
Step 1: Selection of a Concept

QOL has been discussed in a variety of contexts, but QOL is predominantly found in literature relating to health and social welfare. QOL is a broad encompassing concept that includes health, standards of living, community and family life (Reaman & Haase, 1996). Health is one of the many components that constitute QOL. For the purpose of this study, QOL has been discussed in relation to health. For the concept analysis, the focus of the literature review was on children with cancer. Literature on QOL for children with cancer is minimal. Therefore, all articles that related to the QOL of life with children with cancer were identified. Health-related QOL is often used interchangeably with QOL. Therefore, articles that focused on health-related QOL in relation to children with cancer were also used for the concept analysis. Research on QOL for children with cancer has originated from the adult population. Because the literature relating to the adult population is so vast, the articles selected for the concept analysis focused on five key areas (a) normal life, (b) happiness and satisfaction, (c) achievement of personal goals, (d) social utility, and (e) natural capacity.

Step 2: Determining the Aims or Purposes of the Concept Analysis

The purpose or aim of the concept analysis was to clarify and identify the defining attributes of QOL of children with cancer. Once the defining attributes of QOL of children with cancer have been identified (see p. 40) it is possible to evaluate or develop instruments used to measure QOL and to establish a definition of QOL. When the defining attributes were determined, the extent to which they were reflected in the POQOLS (Goodwin et al., 1994) was explored.
Step 3: Identifying the Uses of the Concept

The concept has been examined in many contexts such as dictionaries, thesauruses and available literature to determine all uses of the concept. Neither dictionaries or thesauruses contained the term QOL, which is not surprising as QOL is a phrase. However, the Oxford English Dictionary (1992) defined quality as “degree of excellence” (p.734) and life as “capacity for growth, functional activity, and continual change until death” (p.510). According to The Oxford Thesaurus (1994) quality is synonymous with “grade, value, merit, attribute, characteristic” (p.660) and life is synonymous with “existence, aliveness, human activity, essence, vigor, period of usefulness” (p.471). When the terms are used together, a definition for QOL remains elusive.

The literature review of QOL began with the definitions of quality and life from the dictionary and the thesaurus. A computerized literature search was then undertaken using Medline and CINAHL for identifying QOL literature for the past 20 years. Key words such as QOL, cancer, pediatrics, children, leukemia, health-related QOL, measurement of QOL, happiness, satisfaction and combinations of all seven words or phrases were used. Once key articles were identified, the references and bibliographies from these articles were manually reviewed and relevant literature obtained. The literature was then grouped into a variety of categories (a) concept analyses of QOL, (b) conceptual definitions of QOL of children with cancer, (c) health-related QOL of children with cancer, (d) measurement of QOL of children and adults with cancer, (e) QOL as ‘normal life’, (f) QOL as happiness and satisfaction, (g) QOL as achievement of personal goals (h) QOL as social utility, and (e) natural capacity.

During the literature review different themes relating to QOL became evident. The themes
became the categories for the literature review. The first, four categories of QOL were identified earlier in the literature review that related specifically to QOL. The remaining five categories of QOL will be reviewed in the following section. During the review of the literature, the characteristics of QOL were noted and their frequency was established. The most frequently cited characteristics of QOL that were unique to the concept were used to determine the defining attributes of QOL for children with cancer.

**Normal Life**

Normal life refers to the individual’s ability to live and lead a normal life (Edlund & Tancredi, 1985). Karnofsky (as cited in MacLeod, 1949), a pioneer in QOL research, suggested that QOL could be determined by how well a person could perform activities of daily living. Karnofsky developed the Karnofsky Performance Status Scale where a high score equaled normal functioning. Zubrod (as cited in Stromborg, 1988) equated QOL with normal activity or the ability to live a normal life. He developed the Zubrod Scale which evaluated the ability of a person to perform activities of daily living and to remain ambulatory. Katz, Ford, Moskowitz, Jackson and Jaffe (1963) also used activities of daily living as a way of determining QOL. However, their scale, the Index of Activities of Daily Living, not only measured the physical functioning of the individual but also explored the importance of physical functioning to every day activity. The ability to live a normal life may be considered one means of evaluating QOL. However, problems arose as to what was considered “normal”. One person’s idea of a normal life could be quite different from another person’s definition.
Happiness and Satisfaction

Happiness and satisfaction have been used interchangeably (see Table 3) in QOL.

Table 3
Quality of Life as Happiness and Satisfaction

<table>
<thead>
<tr>
<th>Author</th>
<th>Happiness</th>
<th>Satisfaction</th>
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<tbody>
<tr>
<td>Campbell, Converse &amp; Rodgers (1976)</td>
<td></td>
<td>The satisfaction of one’s needs.</td>
</tr>
<tr>
<td>Ferrans &amp; Powers (1992)</td>
<td></td>
<td>A sense of well-being that stems from a satisfaction or dissatisfaction with the areas of life that are important to an individual.</td>
</tr>
<tr>
<td>Padilla, Ferrell, Grant &amp; Rhiner (1990)</td>
<td></td>
<td>A personal evaluation of the positive and negative attributes of one’s life.</td>
</tr>
<tr>
<td>Meeberg (1993)</td>
<td></td>
<td>A feeling of overall life satisfaction that is experienced by a capable individual.</td>
</tr>
<tr>
<td>Dalkey &amp; Rourke (in Ferrans &amp; Powers, 1985)</td>
<td>A sense of happiness or unhappiness with life.</td>
<td>A sense of satisfaction or dissatisfaction with life.</td>
</tr>
<tr>
<td>Zhan (1992)</td>
<td></td>
<td>The degree to which an individual’s life experiences are satisfying.</td>
</tr>
</tbody>
</table>

Research leading to confusion and misinterpretation (Zhan, 1992. Campbell (1976) found that happiness decreased and satisfaction increased as people aged, suggesting the two concepts are not interchangeable.
Achievement of Personal Goals

Achievement of personal goals is related to satisfaction and happiness, as achieving or not achieving goals will inevitably lead to satisfaction or dissatisfaction (Ferrans, 1990). However, this category of QOL includes the success or failure of personal goals versus the emotional aspects of happiness and satisfaction. Goodinson and Singleton (1989) referred to achievement of goals as one's life plans. For example, QOL was dependent on whether an individual was living his/her life according to their goals and aspirations. Cohen (1982) proposed that a basis for theorizing about QOL was to consider how an individual was living his/her life in comparison to the plan he/she has set out for him/herself. Calman (as cited in Ferrans, 1990) reiterated that QOL was concerned with the discrepancy between the individuals' present experience and his/her actual goals. Calman also stated that hopes and expectations are time dependent and may change given a different situation or time. Cella and Tulsky (1990) referred to QOL as an appraisal of the individual's current level of functioning as compared to what he/she believed to be ideal. These researchers emphasized the importance of the appraisal process. For example, a patient must not only appraise his/her level of dysfunction but also appraise how their perception matches their expectation. Achievement of personal goals may be an important component of QOL, but it should not be considered the only variable in assessing QOL. A person may have achieved his/her personal goals but may not be satisfied with their QOL. Alternatively, a person may not achieve his/her personal goals but may remain satisfied with his/her QOL.
Social Utility

Social utility in relation to QOL is the ability to lead a useful life. Social utility was most commonly used in decision making about health care policies (Kinney, 1995). Social utility includes resource allocation and determines the value of a life by estimating a person’s lifetime earnings (Ferrans, 1990). Calculations were based on predetermined criteria that indicate economic productivity. Using this conceptualization of QOL, a homemaker is not considered economically prosperous in comparison to a president of a company. Therefore, a homemaker has less value. There are many problems with using social utility as a criteria for defining QOL, such as discriminating prejudices and bias against those who are not gainfully employed. Outside the political arena, social utility refers to a person’s ability to fulfill socially valued roles such as parent, teacher or “breadwinner”.

Natural Capacity

Natural capacity in relation to QOL refers to the physical and/or mental capabilities of an individual (Ferrans, 1990). Quality of life, in terms of natural capacity, is used when decisions are made regarding the cessation of treatment or the decision about not to treat. This definition is often used for the terminally ill patient or those individuals lacking in brain activity and dependent on technology (Ferrans, 1990).

Summary

To determine the defining characteristics of QOL of children with cancer, a vast amount of literature was reviewed. In the initial review of the literature the focus was on QOL of children with cancer. During this review, all literature relating to children and cancer was identified and reviewed. The literature included QOL as a concept, health-related QOL
and the measurement of QOL in children and adults. The previous section reviewed the literature on the different uses of QOL in the adult population. For example, QOL has been used interchangeably with normal life functioning, happiness, satisfaction and achievement of personal goals. During the review of the literature the characteristics of QOL were recorded and categorized. The characteristics of QOL were used to determine the defining attributes of QOL of children with cancer.

**Part II: Quantitative/Prospective Component**

The quantitative component of this study involved the application and analysis of the POQOLS (Goodwin et al., 1994). Comparing the defining attributes from the concept analysis with the POQOLS involved (a) the formation of a matrix and (b) empirical validation. A matrix was used to depict the similarities and differences between the defining attributes of the concept analysis and the defining attributes related to the POQOLS (see Figure 1, p.45). The empirical data collected from the parents of children with cancer were used to substantiate the defining attributes outlined from the concept analysis of QOL of children with cancer.

This portion of the thesis was part of a larger study (Stevens et al., HSC Grant XG96-089) comparing the acceptability, safety, clinical and economic outcomes for hospital and home chemotherapy for children with ALL on a high risk cancer treatment protocol. Data collected from the larger study (August 1996 to May 1997) were used to determine the parent’s perception of their child’s QOL. Data for both studies were collected simultaneously. The author of the present study was involved in the large study from the conceptualization of the problem to the completion of the data collection.
Setting

The study took place in the Oncology/ Hematology Clinic at a large metropolitan pediatric hospital in Toronto, Ontario. This site was affiliated with a major university and was one of the five sites in the Pediatric Oncology Group of Ontario (POGO) network. The site was representative as it accommodated children from a variety of areas around Ontario and was the largest site with the greatest number of children with ALL.

Sample

Children with ALL were chosen for this study as ALL was the most common type of childhood cancer that affects children of all ages. Parents of two families out of 27 eligible children, or 7%, refused to participate in the larger study as they did not want home chemotherapy and therefore were not a part of the present study, leaving 25 children with ALL in the sample. Data were collected from August 1996 to April 1997.

Inclusion Criteria:

1. The child was between 2 and 16 years of age.
2. The child was diagnosed with ALL within the past 3 years and was currently treated on Protocol C (Appendix B) by an oncologist at the hospital.
3. The child was cared for by a parent(s) at home who could speak and read English.

Exclusion Criteria:

1. Children whose cancer had reoccurred (relapsed) while on Protocol C.
2. Children who were diagnosed with another major congenital or acquired illness prior to or during their diagnosis of ALL.
**Ethical Considerations**

Approval for human subjects was obtained from the joint research/ethics board for the hospital and the University of Toronto. The data manager for the Oncology program provided the nurse manager with a list of all children diagnosed with high-risk ALL on Protocol C. The nurse manager informed the primary nurses of the children with high risk ALL and the primary nurses determined if the children met the inclusion criteria. If the children met all the inclusion criteria, parents were approached by the primary nurse, regardless of age, gender, race/ethnic background and socioeconomic status, to determine their interest in the study. Using a standardized approach, the primary nurses asked parents of eligible children if they would they be interested in hearing more about the study. The parents, if interested, were approached by the research nurse, presented with verbal and written information and asked to give consent for their participation (Appendix E). Children 7 years and older were asked to give assent (Appendix F) for their participation. All information obtained from the parents and from the child’s hospital records remained confidential through the use of code numbers. The master code list was stored in a locked filing cabinet at the researcher’s office, away from the subjects data files. The data obtained for each child were kept in individual files and stored in a locked filing cabinet in the research office of Dr. B. Stevens. Data were kept in a separate filing cabinet from the consent forms. The data and consent forms will be kept by the investigator in separate locked filing cabinets for five years and then destroyed.

At the completion of the study, the master code list was destroyed. Parents were informed that they could withdraw from the study or refuse to answer questions at any time. There were no known risks or benefits for the children who participated in the study.
However, they were informed that knowledge gained from the results of the study may provide healthcare providers with a better understanding about the effects of cancer on QOL. Parents were informed that the results of the study may be published or presented. If interested, parents were provided with an abstract of the study findings. The information was presented in aggregate form without identifying individual subjects.

If the families were not interested in hearing about the study, their names were not given to the research nurse and they were not approached. The families that refusal to participate were asked for permission to collect demographic data from their medical records to determine the representativeness of the sample.

**Data Collection Procedures**

Data collection took place in an office in the Oncology/Hematology outpatient clinic at a large pediatric teaching hospital. Demographic information was collected from the parent using the Chart Abstraction Sheet (Appendix G), developed specifically for this study, and from the child’s hospital records. After the demographic data were collected, the POQOLS (Goodwin et al., 1994) was administered. Some children were present while their parent(s) completed the questionnaire and some children remained in the playroom. Data collection took approximately 20 minutes and was conducted on the day the child had a scheduled clinic appointment.

**Instrumentation**

The POQOLS (Goodwin et al., 1994) was used to assess the parent’s perception of the child’s QOL. The POQOLS is the only published disease-specific measure known to the investigator for assessing the QOL of children with cancer. Assessing parent’s perceptions of their child’s QOL was relevant as the age range is large and young children under 10 years
would be unable to complete the questionnaire. The POQOLS also was not designed or listed for self-report. The POQOLS is a 21 item, 7-point Likert scale including three factor scores and a total score for the child’s QOL. Factor 1 assessed restrictions in physical functioning and the ability to maintain a normal physical routine. Factor 2 was a measure of emotional distress. Factor 3 assessed the reaction to the current medical treatment.

Face validity of the POQOLS was established by the authors. The authors reported that the POQOLS seemed like an appropriate tool for assessing the QOL of children with cancer. They stated that the 21 questions will provide the researcher with a description of QOL.

The generation of items for the instrument originated from the literature and from children with cancer, parents of children with cancer, and health care professionals that worked in pediatric oncology. Twenty parents of children with cancer (inpatient and outpatient) were asked how cancer and its treatment had affected their child’s life. Ten adolescents with cancer and ten younger children with cancer also were asked about the effects of cancer on their lives. Finally, fifteen health care professionals were asked to describe the aspects of a child’s life that were affected by cancer. From this survey, the most frequent responses were retained. Forty-four items were generated. The 44 items were formulated using a 7-point Likert response scale. The five scale descriptors ranged from never to very frequently.

Content validity of the 44 item scale was established with a new group of parents of children with cancer (n=210). The mean age of the children was 9.8 years and the diagnoses included a variety of childhood cancers, with the largest percentage being ALL (62%). At the time of the testing, the children were both inpatients and outpatients and ranged from
newly diagnosed patients to those diagnosed within the past five years. Evidence of validity was also established from factor analysis. Factor analysis with the common factor model was used to extract the principal factors from the correlation matrix. Items with low item-total score correlations were disregarded (r <.3). The revised POQOLS was a 21-item questionnaire.

The 21-item questionnaire was administered to a second group of parents of children with cancer who had not participated in the previous validity study (n=107). The mean age of the children was 9.5 years and they had a variety of childhood cancers, with the majority being ALL (71%). At the time of testing, the group consisted of both inpatients and outpatients, newly diagnosed patients, and those diagnosed within the past five years. The results of the 21-item measure were factor analyzed using the principal factors as the method of extraction. Factors with Eigenvalues of >1 or near 1 were retained. Factor 1 had an eigenvalue of 5.27, Factor 2 had a value of 2.67 and Factor 3 had a value of .92. Varimax and promax rotations were performed but the three-factor solution was retained as it accounted for 80% of the total variance. Although all three factors were kept after the analysis, it is questionable if Factor 3 warranted inclusion as a factor. Some researchers contend that factors should only be retained if their eigenvalue is > 1.0. Using this rationale, Factor 3 with an eigenvalue < 1.0 should not have been considered a factor (Burns & Grove, 1997).

Concurrent validity of the POQOLS was determined by administering three other measures to the parents of children with cancer that related to the three factors of the scale (Goodwin et al., 1994). The Child Behavior Checklist (CBCL) (Achenbach & Edelbrock, 1983) was administered to 40 parents to assess behavior problems of their children aged 4
through 16. The CBCL was administered to examine the correlation between behavioral problems and emotional adjustment (Factor 2) and the presence of illness symptoms and reaction to current medical treatment (Factor 3). The authors hypothesized that there would be a high correlation between emotional adjustment and behavioral problems, indicating that the items on the POQOLS were appropriate. Goodwin et al. also suggested that there would be a high correlation between the presence of illness symptoms and Factor 3. The Play Performance Scale for Children (PPSC) (Lansky, List, Lansky, Cohen, & Sinks, 1985) was administered to 50 parents to assess the extent of restrictions in their child’s physical activity. The PPSC was administered to establish a relationship between restrictions in physical activity and Factor 1 (physical function). The developers of the measure hypothesized that there would be a high correlation between the scores from Factor 1 and the scores from the PPSC. The Reynolds Adolescent Depression Scale (RADS) (Reynolds, 1987) was administered to 15 adolescents to examine the relationship between depression and emotional adjustment (Factor 2 items) of adolescents. Although the additional questionnaires did not directly measure QOL, they were related to the three factors incorporated in the POQOLS and were hypothesized to have a moderate to strong relationship with them. In addition, factor scores and total scores were examined for age differences and time since diagnosis.

A significant correlation (r=.60, p<.001) between Factor 1 (restrictions in physical functioning and the ability to maintain a normal routine) and the PPSC existed but there was no correlation between Factor 1, the CBCL, and the RADS. The correlation between Factor 1 and the PPSC indicated a significant association between Factor 1 scores and functional performance.
The scores from Factor 2 (emotional distress) were moderately correlated with the CBCL total, internalizing and externalizing scores (r=.67, .68, .67, p<.001), suggesting that this factor was an indicator of general emotional adjustment. The researchers reported, according to their criteria of r=.70 for concurrent validity, that the RADS score was nonsignificantly correlated (r=.60, p<.003) to the Factor 2 score. Streiner (1993) stated that correlation between two tests should be around 0.70. A larger sample size may have provided significant results.

Factor 3 (response to active medical treatment) scores were correlated with time since diagnosis and with the externalizing score on the CBCL (r=.51, p<.001). Factor 3 scores were higher for those children who were newly diagnosed and most likely to experience the detrimental effects of treatment. Factor 3 indicated frequency of nausea, vomiting and pain (which appeared to covary with behavioral disruption and restriction in activity) were more evident in the early phases of treatment. The results indicated that Factor 3 may be seen as an indicator of physical discomfort.

The POQOLS is a multi-dimensional measure with three factors that correspond to the four domains (physical, functional, emotional and social well-being) outlined by researchers as relevant dimensions of the QOL concept (Aaronson, 1991; Goerge & Bearon, 1980; Schipper, 1990; Spilker, 1990). The three factors of the POQOLS were comparable with the four domains that defined QOL, suggesting that beginning construct validity had been established (Goodwin et al., 1994).

Evidence of construct validity was also assessed by comparing the QOL of children with cancer who were recently diagnosed and receiving active treatment with children who had completed treatment and were in remission. The children were divided into two groups
based on time from diagnosis. Group 1 were children diagnosed more than 30 months
previously and group 2 were children diagnosed within the past 9 months. Differences
between the two groups were assessed by using one-way analysis of variance (ANOVA).
Group 2 scored significantly higher than group 1 on the total score and Factor 1 score.
Group 1 scored higher than group 2 on the Factor 3 score. For Factor 2, there were no
significant difference between the two groups.

Reliability of the POQOLS was determined by assessing the internal consistency and
inter-rater reliability of the measure. Internal consistency was determined by calculating the
coefficient alpha. The coefficient alpha was calculated for the total measure and for the three
individual factors (item to total) (Goodwin et al., 1994). The coefficient alpha for the total
measure was calculated as .85. For Factors 1, 2, and 3, the internal consistency reliability
coefficients were .87, .79, and .68. Coefficient alpha’s for scales should be >.70 (Streiner,
1993). The coefficient alpha for the total score and Factor 1 was very good. Factor 2 had a
good coefficient alpha, but the coefficient alpha for Factor 3 was slightly below the accepted
value. The low score for Factor 3 may be a result of fewer questions contributing to the
factor and a eigenvalue less than 1.0.

Inter-rater reliability was calculated between mothers and fathers of 15 children.
Using the Pearson product-moment correlation, the total POQOLS score between parents
was r = .87. For Factors 1, 2, & 3 the inter-rater reliability correlations were r = .91, r = .87,
and r = .75. The inter-rater reliability values were very good for the total score and the factor
scores as the minimum acceptable value for inter-rater reliability is 0.60 (Streiner, 1993).
Chapter III: Results

As in the previous chapter of the study, the results chapter also is presented in two parts; the qualitative component (Part I) and the quantitative component (Part II). The qualitative component involves Steps 4-7 of Walker and Avant's concept analysis (see p. 24) and includes the (a) defining attributes, (b) model case, (c) antecedents and consequences, and (d) empirical referents. The quantitative component includes the development of a matrix that compares the defining attributes from the concept analysis with a measure of QOL for children with cancer, the POQOL (Goodwin et al., 1994) and the empirical data results. The data were analyzed using the SPSS-PC statistical analysis package to answer the research questions (Table 4). Descriptive statistics including the mean, range, medians and standard deviation were performed to determine the central tendencies and the normal distribution of the data.

Table 4

Data Analysis for the QOL Study

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<thead>
<tr>
<th>Research Question</th>
<th>Measure/Method</th>
<th>Level of Data</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How is QOL conceptualized for children with cancer?</td>
<td>Qualitative/Retrospective Concept Analysis</td>
<td>Nominal</td>
<td>Descriptive</td>
</tr>
<tr>
<td>2. How does the POQOLS corroborate the defining attributes of QOL outlined from the concept analysis of QOL of children with cancer?</td>
<td>Quantitative/Prospective: Pediatric Oncology QOL Scale (POQOLS)</td>
<td>Interval</td>
<td>Descriptive: Median, Range</td>
</tr>
</tbody>
</table>
Part I: Qualitative Component

Step 4: Determining the Defining Attributes

The defining attributes of QOL of children with cancer were identified from the review of the literature. Defining attributes are the characteristics of a concept that differentiates the concept from other similar or related concepts (Walker & Avant, 1995). In critically analyzing the literature, items from instruments, descriptions, definitions and uses of QOL in research studies were identified and isolated. The characteristics of QOL that were found repeatedly in the literature were categorized and tallied. The items or characteristics that were the most prevalent in the tally were identified as the characteristics of QOL for children with cancer. These characteristics were identified as the defining attributes. Therefore, the defining attributes of QOL for children with cancer were: (a) QOL was experienced and perceived by the child with cancer and his/her family; (b) QOL was multidimensional and included the child's physical, emotional and social well-being; (c) QOL was dependent on the age of the child and developmental stage of the child; and (d) QOL was impacted by the environment in which the child and family interact.

Step 5: Constructing a Model Case

From the defining attributes, a model case was developed for QOL of children with cancer. A model case is an example (real or fiction) of the concept as an ideal case. The model case illustrates the defining attributes (see above) or characteristics that help differentiate QOL of children with cancer from other concepts.
Mark is a 5 year old boy who was diagnosed with cancer 2 years ago. He comes to the hospital every 2 weeks for chemotherapy with his mother and sister. Mark states he now likes coming to the hospital because the nurses and doctors are so nice. Mark likes talking to the social worker and visiting with his new “cancer” friends. Mark’s mother states she likes coming to the hospital because the doctors and nurses are so helpful and patient. Mark’s mother states it was difficult coming to the hospital when Mark was first diagnosed with cancer as their whole life was turned upside down and Mark was much younger. Mark is older now and understands the reasons for treatment. Mark’s mother states it is much easier dealing with the cancer now as it is part of their family’s routine and Mark is doing so well. Mark has become an expert at imagery and is able to cope with painful procedures. Mark’s mother states that Mark is no longer affected by the cancer or the treatment. He only misses one half day of school every two weeks. Mark states he does everything he wants, just like before the cancer. Mark is excited and tells the nurse to hurry with his treatment as he is going to a friend’s birthday party at the “Jungle Gym” today where he will run and play on all the gymnastic equipment.

The model case exemplifies all the defining attributes of QOL for children with cancer. Mark stating that he does everything he wants and his mother stating that Mark is no longer affected by the cancer or the treatment provides an example that QOL is perceived by the child and his family. Physical well-being is illustrated by Mark in his statement about running and playing at the “Jungle Gym”. Emotional well-being is evidenced by Mark talking with the social worker and coping with painful procedures with the use of imagery. Social well-being is noted with Mark’s ability to attend school and birthday parties and visiting with “cancer” friends. Mark’s ability to understand his treatment now versus when he was
diagnosed and the routine related to treatment illustrates that QOL changes with age and stage of development. Mark stating that he likes coming to the hospital illustrates that Mark has responded to this new and different environment.

**Step 6: Identifying the Antecedents and Consequences**

From reviewing the literature and developing a model case related to QOL, antecedents and consequences were identified to help refine the attributes of QOL. Antecedents are events or incidents that must occur prior to the occurrence of the concept. Consequences are events or incidents that occur as a result of the occurrence of the concept (Walker & Avant, 1995). Antecedents and consequences are helpful in determining how the concept is normally used. The antecedent for QOL of children with cancer was the diagnosis of a child with cancer and the child and family's response to the diagnosis. The event or incident is the diagnosis of cancer. Therefore, to assess QOL for children with cancer, the child has to be diagnosed with cancer. The consequences for QOL of children with cancer are the child and family's perception of QOL. As a result of the diagnosis of cancer, there is a perception of QOL. The perception of QOL can be positive or negative. When positive, the child and family are able to deal with the event in a constructive manner to promote optimal family and personal functioning. When negative, the event is dealt with in an unconstructive way that leads to suboptimal family and personal functioning.

During the literature review and in the development of the model case incidents and events related to QOL were noted. The most prevalent incidents and events found in the literature and confirmed from the model case were considered the antecedents and consequences for QOL of children with cancer.
Step7: Defining the Empirical Referents

Empirical referents are actions or clues that demonstrate that an individual has evaluated his/her QOL (McDaniel & Bach, 1994). Empirical referents are “actual phenomena that by their existence or presence demonstrate the occurrence of the concept itself”(Walker & Avant, 1995 p.46)). The empirical referents stem directly from the defining attributes. The empirical referents were determined by analyzing the items found in QOL instruments that were consistent with the defining attributes. In the review of QOL instruments, the most common items were identified and similar items grouped into categories. The most prevalent categories related to physical, emotional and social functioning of the child. Therefore, the empirical referents for QOL of children with cancer are physical, emotional and social functioning.

Part II: Quantitative Component

Matrix of Defining Attributes

The defining attributes and the empirical referents have been identified for QOL of children with cancer. They are closely related and often identical (Walker & Avant, 1995). The empirical referents are linked directly to the theoretical base of the concept and essential in the development of instruments. Goodwin et al. (1994) suggest that the three factors identified in the POQOLS, (a) physical functioning and restriction from normal activity, (b) emotional distress, and (c) response to active medical treatment, are congruent with the attributes outlined by Aaronson and Beckman (1987) and indicate construct validity of the
measure. Comparison of the defining attributes of the POQOLS and the concept analysis involved cross-referencing the items from the POQOLS with items that represent the defining attributes of QOL from the concept analysis (Figure 1). The components in the matrix representing the defining attributes from the concept analysis were identified from the literature review and may have been used previously to measure QOL in children with cancer.

The results of the cross-referencing indicate that many of the items from the POQOLS were found in the items representing the attributes of QOL from the concept analysis. However, not all the items (less than half) representing the attributes from the concept analysis were present in the items from the POQOLS. The similarities were in the items related to physical well-being which represents many items from the POQOLS but only one component from the concept analysis. Physical functioning and restriction from normal activity represent a large proportion of the items on the POQOLS. Therefore, overlap was evident with items from the concept analysis representing physical functioning. Energy level, sleep and rest, pain, nausea and vomiting and play represented items from both the POQOLS and the concept analysis. However, other important items relating to physical functioning such as appetite, maintenance of weight, activity level and developmental milestones were not present in the POQOLS. Cross-referenced items related to emotional well-being only included anger, happiness/sadness and embarrassment. Items such as anxiety, depression, frustration, fear, coping strategies and communication that were identified as the attributes of the concept analysis were not included in the POQOL. However, emotional states such as anxiety, depression, frustration and fear share many overlapping constructs and therefore may be identified differently in either the measure or the referents. Items such as extracurricular activities and school attendance represented social well-being in the concept analysis and
**Figure 1: Cross-Reference of Items from the POGO’S and Concept Analysis of GOL**

<table>
<thead>
<tr>
<th>Concept Analysis Items</th>
<th>Activities</th>
<th>Level of Energy</th>
<th>Level of Attention</th>
<th>School Sleep</th>
<th>Fear</th>
<th>Sadness</th>
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<th>Nausea</th>
<th>Pain</th>
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<th>POGO’S Items</th>
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</table>
cross-referenced with the same items from the POQOLS. However, the POQOLS does not have a factor representing social well-being or functioning. Items representing support networks and friendships were found only in relation to the concept analysis.

**Empirical Validation**

Empirical validation of the POQOLS was conducted with a sample of 25 children who met the inclusion criteria. The characteristics of the sample are summarized in Table 5. The phase of treatment the child was in at the time of the interview also was recorded (see Appendix C for explanation of treatment phases). One child was in phase 3, five children were in phase 4, and 19 children were in phase 5.

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Sample Characteristics (n=25)</th>
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</thead>
<tbody>
<tr>
<td>Characteristics</td>
<td>Mean</td>
</tr>
<tr>
<td>Age at Interview (in years)</td>
<td>9.32</td>
</tr>
<tr>
<td>Time (in months) from diagnosis</td>
<td>17.04</td>
</tr>
<tr>
<td>Travel time (in minutes) to hospital</td>
<td>57.80</td>
</tr>
<tr>
<td># of other children at home</td>
<td>1.68</td>
</tr>
</tbody>
</table>

Demographic information was collected from the parents of the 25 children and included age, marital status and employment status. The mean age of the fathers was 43 years and the mean age of the mothers was 40 years. From the sample of 25 children, 19 of the children's parents were married to their biological parents, 1 child lived with his biological father and stepmother, and 5 parents were separated or divorced. Three of the children had
fathers that were not involved with their care. Data were not collected from these fathers: therefore the number of fathers participating in the study was 22. From the 22 fathers who participated, 21 were working full-time and one father was unemployed. From the group of 25 mothers, 12 mothers were employed for pay and 13 worked in the home without pay. From the 12 mothers who were employed for pay, 7 worked full-time and 5 worked part-time.

The possible range of POQOLS scores is 21 to 147, with a low score reflecting a high QOL. The scores from Factor 1 (physical functioning and restriction from normal activity) can range from 9 to 63. The scores from Factor 2 (emotional distress) can range from 7 to 49. The scores from Factor 3 (response to medical treatment) can range from 5 to 35. The POQOLS total and factor scores can be found in Table 6. The POQOLS scores provide an

Table 6
Descriptive Analysis for the POQOLS Total and Factor Scores

<table>
<thead>
<tr>
<th>POQOLS</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Score</td>
<td>61.48</td>
<td>22.43</td>
<td>60.00</td>
<td>48.2,68.4</td>
</tr>
<tr>
<td>Factor 1 Score (physical functioning)</td>
<td>25.40</td>
<td>12.08</td>
<td>21.00</td>
<td>18.3,29.0</td>
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<tr>
<td>Factor 2 Score (emotional distress)</td>
<td>19.44</td>
<td>7.66</td>
<td>21.00</td>
<td>14.9,22.2</td>
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<tr>
<td>Factor 3 Score (response to medical treatment)</td>
<td>16.64</td>
<td>6.50</td>
<td>17.00</td>
<td>13.2,19.1</td>
</tr>
</tbody>
</table>
overall QOL and factor score. The factor scores relate to the second defining attribute outlined from the concept analysis of QOL of children with cancer. This attribute emphasized the multidimensionality of QOL and includes but is not exclusive to physical, social and emotional well-being. The scores from the POQOLS may help determine the importance of these attributes by illustrating whether physical, emotional and social well-being are important components of QOL for the child with cancer.

In addition to the descriptive analysis for the POQOLS, the effect of time from diagnosis and age of diagnosis were examined. Nonparametric tests were used as the scores were not normally distributed and the sample size was small. The Kruskal-Wallis test was used to compare the total score and factor scores for three different age groups (see Table 7). The Kruskal-Wallis one-way analysis of variance is used to identify differences among multiple groups (Brink & Wood, 1994). Exploring the results of the POQOLS by age relates to the defining attributes identified in the concept analysis. The third defining attribute states that QOL of children with cancer changes with age, thus the need to analyze the data related to age. Also, age was shown to have an influence on POQOLS scores when examined by Goodwin et al. (1994). The Mann Whitney U was used to compare the total score and factor scores of children at different times from diagnosis (see Table 8). The Mann-Whitney U is a non-parametric test that is used to identify significant differences between two groups. Examining the scores of the POQOLS in relation to “time since diagnosis” may provide information on the fourth defining attribute of QOL. This attribute states that QOL is impacted by the environment in which an individual interacts. The more time that a child spends receiving treatment, the more comfortable he/she may be in the healthcare
environment, possibly affecting QOL. The level of significance for both tests was set at p<.05. There was no significant differences in POQOLS scores between any of the groups in relation to age or time from diagnosis.

Table 7
Analysis of Scores by Age Group

<table>
<thead>
<tr>
<th>POQOLS</th>
<th>Age at Interview (years)</th>
<th>Mean POQOLS Score (by age group)</th>
<th>Mean Rank</th>
<th>Level of Significance</th>
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<tbody>
<tr>
<td>Total Score</td>
<td>0-7</td>
<td>67.44</td>
<td>14.89</td>
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<td></td>
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<td>8-12</td>
<td>24.78</td>
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<td>8-12</td>
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<td>13-16</td>
<td>15.14</td>
<td>11.00</td>
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</table>

Although significant differences were not obtained for children of different age groups or in time since diagnosis, there were some trends in the scores. Overall, the 13-16 year-olds had lower scores on the total and factor scores than the other two groups. Younger children (0-7 years) had the highest scores on the total score and on Factor 1 and Factor 3 but not on Factor 2. Children 8-12 year-olds had the highest scores on Factor 2. There were no significant differences in the scores of the two groups in relation to time from diagnosis. However, the total score showed a trend towards significance (p<.07). A larger sample may
have produced significant results, that would have been similar to the findings by Goodwin et al. (1994) where there was a decrease in POQOLS scores (an increase in QOL) as time since diagnosis increased.

Table 8
Analysis of Scores by Time Since Diagnosis

<table>
<thead>
<tr>
<th>POQOLS</th>
<th>Time Since Diagnosis (months)</th>
<th>Mean POQOLS Score (by time since diagnosis)</th>
<th>Mean Rank</th>
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<td>10.31</td>
<td>82.50</td>
<td>.074</td>
</tr>
<tr>
<td></td>
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<td>56.50</td>
<td>6.69</td>
<td>53.50</td>
<td></td>
</tr>
<tr>
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<td>10.13</td>
<td>81.00</td>
<td>.127</td>
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<tr>
<td></td>
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<td>23.13</td>
<td>6.88</td>
<td>55.00</td>
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</tr>
<tr>
<td>Factor 2</td>
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<td>9.50</td>
<td>76.00</td>
<td>.172</td>
</tr>
<tr>
<td></td>
<td>&gt;23</td>
<td>17.38</td>
<td>7.50</td>
<td>60.00</td>
<td></td>
</tr>
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<td>0-9</td>
<td>18.63</td>
<td>10.63</td>
<td>85.00</td>
<td>.398</td>
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<tr>
<td></td>
<td>&gt;23</td>
<td>16.00</td>
<td>6.38</td>
<td>51.00</td>
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</tr>
</tbody>
</table>

Summary of Results

From the concept analysis of QOL of children with cancer, defining attributes were established. Defining attributes are essential for differentiating the unique characteristics of a concept from other related concepts. From the concept analysis, four defining attributes of QOL were developed:

1. QOL for children with cancer is experienced and perceived by the child and the family.

2. QOL for children with cancer is multidimensional and includes physical, social and
emotional well-being.

3. QOL for children with cancer is dependent on the age of the child or the developmental stage of life.

4. QOL for children with cancer is impacted by the environment in which the child interacts.

With the defining attributes established, a conceptual definition for children with cancer can be generated. QOL for children with cancer is the child’s perception (or the parents’ perception of the child’s QOL, i.e. proxy) of the extent to which he/she has the ability to function, physically, emotionally and socially within his/her environment. Physical functioning is the child’s capacity to play, eat (without experiencing nausea or vomiting), maintain weight, rest and sleep accordingly, attain developmental milestones for his/her age, maintain appropriate activity and energy levels, and minimize painful experiences. Emotional functioning is the extent to which the child is anxious, depressed, frustrated, angry, happy/sad and embarrassed. It includes the degree to which the child communicates to others and develops coping strategies. Social functioning is the child’s capacity to attend school, participate in extracurricular activities, maintain and build friendships, interact with others and develop a support network (i.e. friends, nurses, social workers).

Empirical referents are related to the defining attributes as empirical referents demonstrate the occurrence of the concept, which is determined from the defining attributes. The empirical referents may be identical to the defining attributes. The empirical referents stem directly from the defining attributes. Empirical referents for children with cancer are physical, emotional and social functioning. Examples of empirical referents may be the
expression of feelings, the use of imagery when dealing with painful procedures, attending school regularly, participating in support groups, playing practical jokes, laughing, crying, having tantrums, running and gaining weight.

Empirical data was used in an attempt to validate the defining attributes and to explore the presence of the defining attributes in the POQOLS. The defining attributes of the concept analysis were compared with the POQOLS indicators (Goodwin et al., 1995) through the use of a matrix and validated with empirical data. The matrix was used to depict similarities and differences between the indicators of the POQOLS and defining attributes originating from the concept analysis. Similarities between the attributes and indicators only exist in relation to the QOL dimensions of physical, social and emotional well-being. Many indicators from the POQOLS are related to the second defining attribute from the concept analysis. The subjective nature of the POQOLS relates to the first defining that refers to QOL as perceived by the child and family. Using the POQOLS with children of different ages is related to third attribute that identifies the importance of age and stage of development on QOL. Finally, time from diagnosis is an initial attempt at identifying the impact of the environment on the child with cancer.
Chapter 4: Discussion

QOL has emerged as an important concept in theory, research and practice. Lack of consensus on definitions and descriptions of QOL may threaten clinical and research initiatives for health professionals caring for adults and children with cancer (King et al., 1997). Using Walker and Avant’s (1995) approach to concept analysis, QOL for children with cancer was analyzed and the corroboration between the results of the concept analysis and the operationalization of the concept through the POQOLS (Goodwin et al., 1994) was explored.

Conceptualizing QOL for children with cancer involved using a modified version of Walker and Avant’s (1995) eight steps to concept analysis. A concept analysis is useful for (a) clarifying vague concepts, (b) preparing for research or theory construction, (c) developing or evaluating instruments, and (d) developing or evaluating nursing diagnoses. Through the concept analysis of QOL for children with cancer, defining attributes and a conceptual definition for QOL were established. Although the defining attributes of a concept are the unique distinguishing characteristics, they may be identical to the empirical referents (Walker & Avant, 1995). The empirical referents are actual manifestations that demonstrate the occurrence of the concept. The empirical referents for this study are different from the defining attributes. QOL as a concept and the defining attributes of QOL are abstract, therefore the need for concrete empirical referents exists. Lack of conceptual definitions for QOL may be related to the high level of abstraction. The literature review revealed studies that measured QOL without providing conceptual definitions (Balduzzi et al., 1995; Barr et al., 1993; Mostow et al., 1991).
The first defining attribute is that QOL is experienced and perceived by the child with cancer and his/her family. The subjective nature of QOL is supported by Bradlyn et al. (1996) and Hinds (1990). Bradlyn et al.'s definition of QOL for children with cancer states that QOL is patient or family based in its perspective which is similar to the first attribute. Hinds (1990) describes QOL for children with cancer as the subjective sense of well-being. Subjective sense of well-being is similar to the first attribute, however Hinds does not offer alternatives for children who are unable or incapable of reporting QOL. The first defining attribute may also be consistent with the POQOLS (Goodwin et al., 1994) where the measure is completed by parents of children with cancer, on their perception of their child's QOL. The POQOLS has not been used as a self-report measure by older children and teenagers but could be in the future. Issues are raised concerning the parents completion of the questionnaire, reflecting their perception of the child's QOL rather than the child's. Questions are raised about whether the parents' perceptions of the child's QOL is truly representative of the child's QOL. Assessment of QOL is essential for children of all ages and developmental stage, therefore completion by proxy is unavoidable. Although the parent completes the POQOLS, supporting the first attribute, the measure does not include questions around the communication or verbalization of QOL.

The results from the concept analysis were compared with empirical data from the POQOLS (Goodwin et al., 1994) to further validate the measure and the concept. Although initial psychometrics established beginning reliability and construct validity, construct validity only accumulates with ongoing testing. The Pearson correlation coefficient is the most commonly used calculation for assessing reliability, but it is not necessarily the best (Streiner, 1993). The Pearson correlation coefficient can only accommodate two observers, with each
observer's data is entered into the calculation more than once. This is a violation of
correlation that states all tests are independent. In addition, "Pearson correlation is sensitive
to differences in association, but not in agreement" (Streiner, 1993, p.144). For example,
rater A always scores 2 points above rater B, therefore there is perfect association between
the two raters but the agreement is zero. The most accurate statistic for establishing
reliability is intra-class correlation (ICC) which provides a more accurate estimate of
reliability if biases were present. Intra-class correlation takes into account true variances plus
error variances over time (Norman, 1997).

Although Goodwin et al. do not complete a concept analysis as a preliminary step in
the development of the POQOLS, they do establish beginning construct validity for the
instrument. Goodwin et al. state that there is concordance between the three factors of the
POQOLS and the four QOL domains outlined by Aaronson and Beckman (1987), therefore
suggesting that construct validity has been established. Therefore, comparison between the
defining attributes of the concept analysis and the POQOLS included the exploration of
physical, emotional and social well-being. Cross-referencing was performed between
indicators from the POQOLS that were representative of each factor and empirical referents
relating to physical, emotional and social well-being (see Figure 1, p.46).

The POQOLS (Goodwin et al, 1994) identifies physical functioning and restriction
from normal activity and emotional distress as large components of their instrument. These
different components support the multidimensionality of the second defining attribute of the
concept analysis and is evidenced by the overlap between the items. Similarities were found
between items that related to energy level, pain, nausea and vomiting, play and rest, and
sleep. Although these items represent a large proportion of physical well-being, they do not
represent all items. Appetite, maintenance of weight, activity level and developmental milestones were also included as part of the concept analysis items but not found in the POQOLS. Lack of agreement is also evident for items relating to emotional and social well-being. The POQOLS identifies emotional distress as a factor, which may be similar or opposite to emotional well-being. However, results from the matrix indicate that only anger, happiness and embarrassment relate to both the POQOLS and the concept analysis. The POQOLS does not identify key items such as anxiety, depression, frustration and the use of coping strategies in the assessment of emotional well-being. Although the POQOLS does not include a factor related to social well-being, items related to the concept analysis that represent social-well-being such as school attendance, extracurricular activities, communication and interaction with others are present in the POQOLS. The POQOLS does not specifically address items such as support networks and friendships which are significant components of QOL for children with cancer, although these may be embedded in the interaction with others and communication indicators. The POQOLS addressed the multidimensional nature of QOL for children with cancer but in essence has captured only some of the relevant indicators relating to the four components of QOL. The POQOLS has identified some key items relating to physical, emotional and social well-being, however a greater representation of items relating to all dimensions of QOL is needed.

The multidimensional aspect of QOL is also supported by Bradlyn et al. (1996), Hinds (1990) and Balduzzi et al. (1995). Bradlyn et al. also describe QOL as multidimensional including, but not limited to physical, emotional and social functioning. Hinds (1990) description of QOL for children with cancer as the subjective sense of well-being during and after treatment vaguely relates to the second defining attribute outlined by the concept.
analysis. Hinds envisions well-being as the comparison between the child or adolescent's hopes and desires with what was actually happening to them. Balduzzi et al. did not define QOL but assessed it by play performance and functional status. Play performance and functional status may be related to the second defining attribute that states that QOL is multidimensional and includes but is not exclusive to physical, emotional and social well-being. However, play performance and functional status are only two components of QOL and would not provide a complete description of a child's QOL. Balduzzi et al.'s description of QOL, through play performance and functional status, would not provide an adequate assessment of QOL for children with cancer, but does provide some support for the multidimensional nature of the second defining attribute identified from the concept analysis.

The third defining attribute of QOL in children with cancer illustrates that QOL is dependent on the child's age or developmental stages of life. The third attribute relates to the empirical referent that demonstrates the achievement of personal goals. Bradlyn et al. (1996) support the changing element of QOL in relation to age and developmental stage. One component of Bradlyn et al.'s definition of QOL includes identifying and incorporating developmental change in QOL assessment. The inclusion of developmental change in their definition of QOL illustrates the importance of age and stage of development in QOL assessment. When assessing QOL for children with cancer, all stages of development from infancy to adolescence must be considered. Children's physical and cognitive abilities change dramatically throughout childhood and the differences in development must be taken into account during instrument development and assessment of QOL. The POQOLS (Goodwin et al., 1994) has been used with children of different ages and at different stages of treatment but there are no items on the questionnaire that specifically relate to different stages of
development. The instrument's questions relate to how the child is functioning at the present time, with no comparison to how the child functioned at an earlier date. There are no indicators of personal achievement or the attainment of developmental milestones. The measure needs to be further tested over time (with a repeated measures or longitudinal study) to determine its ability to detect change.

Although the POQOLS (Goodwin et al., 1994) does not include items that directly relate to the third attribute, the POQOLS has been used in this study and the previous study with children of different ages. Goodwin et al. encouraged the use of the POQOLS with children of all ages. These researchers found no significant differences by age in the total POQOLS scores (see Table 9). However, there were differences between the groups for Factor 1 (physical functioning) and Factor 2 (emotional distress). Children 13 years or older

Table 9
Goodwin et al.'s POQOLS Scores by Age Group

<table>
<thead>
<tr>
<th>POQOLS</th>
<th>Age</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 7</td>
<td></td>
<td>63.9</td>
<td>18.6</td>
</tr>
<tr>
<td>8-12</td>
<td></td>
<td>66.2</td>
<td>22.4</td>
</tr>
<tr>
<td>&gt; 13</td>
<td></td>
<td>69.5</td>
<td>19.5</td>
</tr>
<tr>
<td>Factor 1 (physical functioning)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 7</td>
<td></td>
<td>23.4</td>
<td>9.8</td>
</tr>
<tr>
<td>8-12</td>
<td></td>
<td>24.6</td>
<td>11.9</td>
</tr>
<tr>
<td>&gt; 13</td>
<td></td>
<td>31.9</td>
<td>11.3</td>
</tr>
<tr>
<td>Factor 2 (emotional distress)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 7</td>
<td></td>
<td>20.3</td>
<td>7.4</td>
</tr>
<tr>
<td>8-12</td>
<td></td>
<td>22.4</td>
<td>8.8</td>
</tr>
<tr>
<td>&gt; 13</td>
<td></td>
<td>16.5</td>
<td>6.4</td>
</tr>
<tr>
<td>Factor 3 (reaction to medical treatment)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 7</td>
<td></td>
<td>18.3</td>
<td>7.5</td>
</tr>
<tr>
<td>8-12</td>
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<tr>
<td>&gt; 13</td>
<td></td>
<td>18.2</td>
<td>6.7</td>
</tr>
</tbody>
</table>
had higher scores in physical functioning and restrictions in normal routines than the two younger groups. In addition, children between 8-12 years-old had higher scores on the emotional adjustment factor than the other two groups. In the present study, there were no statistically significant differences between the total scores of the three groups (see Table 7, p.50). However, the trend in the scores, although not significant, are similar and in the same direction as Goodwin et al.’s study. In the present study, only Factor 2 showed a trend in differences between the three groups. The trend is similar to the Goodwin et al. study and indicated that children between 8-12 years had higher scores on the emotional adjustment factor than the other groups. Developmentally, this age group is known as middle childhood or school age. During this period of development, the child’s focus is on relationships with friends versus family and the development of skill competencies (Whaley & Wong, 1997). Therefore, it is not surprising that children aged 8-12 years had higher scores on emotional adjustment than the other groups. Children in this age group are trying to establish relationships outside the family boundaries. A diagnosis of cancer hinders the development of peer relationships and supports the dependence on family members, possibly leading to problems with emotional adjustment. The sample in the present study, when stratified by age, was inadequate to detect a significant difference, should it be present. Although the scores from the three groups did not reach a level of significance, the trend supported the POQOLS’s discriminative ability and the importance of age and stage of growth and development in relation to QOL.

The final defining attribute suggests that QOL is impacted by the environment in which the child interacts. The empirical referent that demonstrates that this attribute is present involves the ability of the child with cancer to initiate and respond to change within
his/her environment. Bradyn et al.’s (1996) fourth component of their definition of QOL relates somewhat to the final attribute outlined from the concept analysis. Bradyn et al. emphasize ‘the incorporation of the impact of treatment on the whole family’ which may relate to the fourth defining attribute that states that QOL is impacted by the environment in which the child interacts. For example, the diagnosis and treatment of cancer may cause the whole family system and individual within that system to change to meet the needs of the child. Therefore, the environment that the child and the family were accustomed to may be changed. The working mother may have to give up her job to care for the child and in turn, the child and mother may spend more time together and away from the rest of the family. In this example, the child and family’s QOL may be affected by the changing environment. The similarity between the two views of QOL may be a positive step towards the consensus of a conceptual definition for QOL of children with cancer.

The fourth attribute that explores how QOL is impacted by the environment in which the child interacts is not reflected in the items of the POQOLS (Goodwin et al., 1994). The POQOLS does not include items relating to changes in QOL as familiarization with the health care environment occurs. There are no items that relate to coping strategies that the child may have developed to help deal with new surroundings and treatments. Questions on the use of imagery and relaxation techniques could provide information on the child’s ability to adapt to his/her new environment (i.e. hospital). In addition, questions on the child’s support network may enlighten healthcare providers as to how the child is impacted by his/her new surroundings. For example, an indicator such as ‘my child talks to the social worker or nurse about how he/she is feeling’ may provide valuable information about how
the child is reacting to his/her diagnosis and treatment and how comfortable he/she is in talking about it with health care providers in a new environment.

Although the POQOLS does not have items that directly relate to the fourth defining attribute, exploring the scores from the POQOLS at different times from diagnosis may provide pertinent information that supports the fourth attribute. Time from diagnosis does not equal interaction with the environment. However, time from diagnosis may provide information about familiarization with the environment over time. The time from diagnosis is significant for the type of treatment children with ALL receive. Most children are on the maintenance phase of their treatment (i.e. Phase 5) after approximately 9 months. In the maintenance phase, treatment usually is completed on an outpatient basis approximately every two weeks. The goal of chemotherapy during this phase is to keep the child in remission. Therefore, the amount and type of chemotherapy is not as intense as the initial stages of treatment. During the maintenance phase, most children are able to attend school and return to normal activities of daily living. Goodwin et al. found a significant difference (see Table 10) between the total POQOL scores and Factors 1 (physical restrictions) and Factor 3 (response to medical treatment) scores for children diagnosed within 9 months and those diagnosed within the past 30 months. However, there were no significant differences between the scores for Factor 2 (emotional distress).

Overall, the children diagnosed more recently had a lower quality of life compared to the children who were diagnosed later but there were no significant differences between the two groups in terms of emotional adjustment. These findings are similar to the findings from
Table 10
Goodwin et al.'s POQOLS Scores on Time from Diagnosis

<table>
<thead>
<tr>
<th>POQOLS</th>
<th>Time from Diagnosis</th>
<th>Mean</th>
<th>SD</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(Months)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Scores</td>
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<td>70.7</td>
<td>22.3</td>
</tr>
<tr>
<td></td>
<td>&gt; 30</td>
<td>57.3</td>
<td>18.3</td>
</tr>
<tr>
<td>Factor 1</td>
<td>≤ 9</td>
<td>27.8</td>
<td>11.4</td>
</tr>
<tr>
<td></td>
<td>&gt; 30</td>
<td>20.5</td>
<td>10.7</td>
</tr>
<tr>
<td>Factor 2</td>
<td>≤ 9</td>
<td>22.3</td>
<td>8.7</td>
</tr>
<tr>
<td></td>
<td>&gt; 30</td>
<td>19.6</td>
<td>8.0</td>
</tr>
<tr>
<td>Factor 3</td>
<td>≤ 9</td>
<td>18.8</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td>&gt; 30</td>
<td>14.2</td>
<td>6.5</td>
</tr>
</tbody>
</table>

the present study (see Table 8, p.51). However, due to the small sample size in the present study, the groups are divided into those children diagnosed within the past 9 months and those children diagnosed greater than 23 months previously. Thirty months was not used as only 3 out of 25 children would be included in this group thus making comparisons impossible. At 23 months there were equal numbers in both groups and the children would have been in the maintenance phase of treatment for over 1 year.

The total and factor scores did not reach statistical significance but the trend appears to be in a similar direction as the study by Goodwin et al (1994). The trend for the present study indicates differences between the two different time groups for the total scores, Factor 1 (physical functioning) scores, and Factor 2 (emotional distress) scores but no differences between Factor 3 (response to active medical treatment) scores. Goodwin et al. report differences between the two groups for total scores, Factor 1 scores, and Factor 3 scores but no differences between the Factor 2 scores. Goodwin et al.'s findings are similar to the
present study except for the factor scores. In the present study, the trend for the Factor 3 scores appears to indicate no differences between the two groups but differences between Factor 2 scores. The differences between the two groups may be related to the actual time from diagnosis; within 9 months there may be a great amount of variance. For example, the present study may have more children around 7 months from diagnosis and the previous study may have more children at 2 months from diagnosis. In reviewing the data, 6 of the 8 children were already 6 months into their treatment. Factor 3 involves reactions to current medical treatment. Differences between the two groups for Factor 3 scores in the Goodwin et al. study may be the result of having more children in the initial phases of treatment as compared to the current study. During the initial phase, the treatment is usually more intense and involves more invasive procedures than the maintenance phase. For Factor 2, emotional adjustment, the two groups were more similar in the present study versus the study by Goodwin et al. Emotional adjustment after 30 months until at least 5 years may be quite different from children diagnosed between 24 months and 34 months. The way children respond emotionally may be more similar within 34 months of diagnosis than after 34 months or after treatment is completed (e.g. 36 months). Goodwin et al. have studied participants that have finished treatment as well as those still undergoing treatment. The participants that have completed treatment may have a very different QOL than those subjects who are continuing with treatment, even if they are near completion. The completed group does not return to the hospital every two weeks, school and extracurricular activities are not missed, blood tests are not regularly performed and their life is no longer affected by cancer. Many of these rationale may effect the POQOLS scores. Although the scores from the current study were not the same as the Goodwin et al. study, there is evidence that the POQOLS
does account for differences in the time from diagnosis and thus shows some indirect support for response to change over time. The ability to capture the change in the scores between the two groups is important in relation to the fourth attribute. The empirical referent for the fourth attribute involves the ability to initiate and respond to change. Time from diagnosis appears to relate to QOL which supports the attribute that states that QOL is impacted by the environment in which the child interacts. In addition, the POQOLS could be considered an appropriate instrument for measuring QOL over time in regards to time from diagnosis.

Summary

The POQOLS (Goodwin et al., 1994) was used to collect empirical data from the parents of children with cancer to help corroborate the defining attributes established from the concept analysis. Time from diagnosis and age were factors that potentially may influence QOL that Goodwin et al. also explored in their study. The results are similar between the two studies (see Table 11), however statistical comparison between the two groups was impossible as individual participant scores were not available from the Goodwin et al. study. As well, Goodwin et al. had a larger sample size (n=107) of whom 71% had

Table 11

<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Total Scores</td>
<td>65.2</td>
<td>20.3</td>
</tr>
<tr>
<td>Factor 1</td>
<td>25.5</td>
<td>11.6</td>
</tr>
<tr>
<td>Factor 2</td>
<td>20.6</td>
<td>8.4</td>
</tr>
<tr>
<td>Factor 3</td>
<td>18.1</td>
<td>7.1</td>
</tr>
</tbody>
</table>
ALL. Differences in the scores may be related to the child’s inpatient/outpatient status at the time of testing and the time from diagnosis. In the present study, all 25 children were outpatients in comparison with Goodwin et al.’s study where 82% were outpatients and 18% were inpatients. Hospitalization may have a greater effect on the child’s QOL resulting in a higher score on the POQOLS. The researchers do not provide separate scores for the outpatient population. As well, in these researchers’ study, 22% of the children had been diagnosed in the past 6 months, 37% within 1 year, and 60% within 2 years. In the present study, 14% of the children had been diagnosed in the past 6 months, 23% within 1 year, 71% within 2 years, and all were diagnosed within the past 34 months, in comparison to the Goodwin et al.’s study where 86% had been diagnosed within 5 years. The length of time from initial diagnosis was much larger in the study by Goodwin et al. than in the present study and this difference in time may be reflected in the results of the total score. Fourteen-percent of the total population had been diagnosed for more than 5 years which may have a significant effect on the scores of the POQOLS.

Although the items from the POQOLS (Goodwin et al., 1994) relate primarily to the second attribute outlined by the concept analysis, it was still important to analyze the scores in relation to time and age from diagnosis. The items from the POQOLS support the multidimensionality of QOL for children with cancer, however the use of the POQOLS at different stages of treatment and with different age groups support the remaining attributes. The results from Goodwin et al.’s study and the present study illustrate the importance of incorporating age and time from diagnosis in the assessment of QOL of children with cancer. The results of both studies also provide support for the defining attributes identified from the
concept analysis. Differences in QOL are evident in children of different ages and developmental stages. As well, the environment in which the child interacts impacts QOL. The subjective component of QOL is supported for the parents when using the POQOLS but changes should be made in the measure and in the items to incorporate differences in the child’s perception of QOL, should they exist.
Chapter V: Summary, Implications, Conclusions

Summary of Study

Research on QOL in the adult and pediatric populations is expanding rapidly. The surge of interest in QOL has led to the development of numerous measures, despite the lack of conceptual definitions and ambiguous terminology. King et al. (1997) suggest that disease specific concept analyses need to be performed to understand the history of the concept and clarify the definition of QOL within a specific context.

The assessment of QOL in pediatric oncology is an important component in the care of the child with cancer and his/her family. Literature on QOL of children with cancer remains limited in comparison to the literature relating to the adult oncology population. QOL research on children with cancer during active treatment is also limited. The literature confirms that many of the researchers of childhood cancer assess QOL in long-term survivors (e.g. > 5 years after treatment) rather than during active treatment. (Kuspt & Schulman, 1986; Mostow, Byrne, Connelly & Mulvihill, 1991; Pastore et al., 1977). In addition, QOL is often operationalized without being defined, thus making comparisons between studies difficult (Barr et al., 1993). Finally, QOL is being measured through instruments that assess functional status, play performance, coping and physiological determinants (Balduzzi et al., 1995). Based on these conceptual and methodological inadequacies, this study was undertaken to add to the QOL literature by analyzing QOL for children with cancer through a concept analysis, evaluation of a QOL measure and empirical validation.

Walker and Avant’s (1995) approach to concept analysis was used to determine defining attributes of QOL for children with cancer. The literature review revealed a limited number of concept analyses on QOL. Meeberg (1993) used Walker and Avant’s approach to
clarify and examine QOL in the adult population. Meeberg concluded that QOL was both subjective and objective and involved an overall sense of life satisfaction as determined by a mentally capable individual. McDaniel and Bach (1994) used Walker and Avant’s approach to clarify the meaning of QOL in an effort to enhance precise communication. These researchers defined QOL as the congruency or lack of congruency between actual life conditions and hopes and expectations. QOL was unique, dynamic and was influenced by factors in an individual’s life such as the ability to set goals and the ability to verbalize feelings. McDaniel and Bach stated that health care practitioners must clearly understand the concept of QOL to incorporate patient’s desires and goals in planning care. Oleson (1990) used a modified version of Walker and Avant’s steps for a concept analysis to explore subjectively perceived QOL. Oleson concluded that happiness and satisfaction were the defining attributes that best characterized QOL for the adult population. Concept analyses for QOL of children with cancer were not found in the literature.

QOL for children with cancer was clarified using Walker and Avant’s (1995) approach to concept analysis. After reviewing the literature on QOL in relation to cancer from the adult and pediatric populations, the most common characteristics were identified. The most prevalent characteristics were chosen as the defining attributes for QOL for children with cancer. The defining attributes have been identified and include:

1. QOL for children with cancer is experienced and perceived by the child and the family.

2. QOL for children with cancer is multidimensional and includes physical, social and
emotional well-being.

3. QOL for children with cancer is dependent on the age of the child or developmental stage of life.

4. QOL for children with cancer is impacted by the environment in which the child interacts.

From the concept analysis, a conceptual definition for QOL for children with cancer has also been established. QOL for the child with cancer is the child’s perception (or the parents’ perception of the child’s QOL, i.e. proxy) of the extent in which he/she has the ability to function physically, emotionally and socially within his/her environment. Physical functioning refers to the child’s capacity to play, eat (without experiencing nausea or vomiting), maintain weight, rest and sleep accordingly, attain developmental milestones for his/her age, maintain appropriate activity and energy levels and minimize painful experiences. Social functioning is the child’s capacity to attend school or play groups, participate in extracurricular activities, maintain and build friendships, interact with others and develop a support network. Emotional functioning is the extent to which the child is anxious, depressed, frustrated, angry, happy/sad and embarrassed. Emotional functioning includes the degree to which the child communicates to others and develops coping strategies. Physical, emotional and social functioning must be assessed in children in relation to their age and developmental stage of life. Indicators of physical, emotional and social functioning must be representative of the developmental stage the child is in at the time of assessment. For example, an infant or toddler must not be penalized for not attending school when school attendance may not be appropriate for this age group. Another example of the importance of
developmental appropriate measurement of QOL is anxiety. Anxiety in a toddler may be manifested by crying and screaming whereas a teenager may demonstrate his/her anxiety by attempting to avoid the situation entirely. Both examples of anxiety are valid for both age groups, therefore neither should be minimized when measuring QOL.

The defining attributes of QOL outlined from the concept analysis were similar to the definition outlined by Bradlyn et al. (1996). Bradlyn et al. also suggested that QOL was multidimensional, including but not exclusive to physical, emotional, and social well-being, and was child or family based and was dependent on developmental stages. Other studies on the QOL of children with cancer failed to provide conceptual definitions (Balduzzi et al., 1995; Hinds, 1990).

Once the defining attributes were identified and the empirical referents developed, the items of the POQOLS (Goodwin et al., 1994) were used to corroborate the findings from the concept analysis. A matrix was used to depict the similarities and differences between the items of the POQOLS and items related to the defining attributes. The POQOLS items were similar to the second defining attribute that states that QOL is multidimensional and includes physical, emotional and social well-being. The defining attributes were also reflective of the empirical data collected from 25 parents of children with cancer using the POQOLS. Although the items from the POQOLS do not represent all the defining attributes, the exploration of factors such as age and time from diagnosis in relation to QOL may provide valuable information about the concept. The findings from this study and the study by Goodwin et al. (1994) indicate that age and time from diagnosis are important factors to consider when exploring QOL for children with cancer.
Changes in the treatment of cancer have prompted researchers to evaluate the effects of treatment on QOL. Although QOL research has flourished in the adult population, research in the pediatric population remains limited. Increasing the awareness of research on the QOL of children with cancer may result in health care professionals taking a more active interest in QOL research. As well, incorporating QOL assessment in health care practitioners daily practice may assist with children and families understanding and coping with the changes that occur when a child has cancer.

Limitations

Theoretical Limitations

Perceptions of QOL may change over time. For the purpose of the present study, QOL was assessed at one point in time. To have a better understanding of the child’s QOL, QOL needs to be assessed on more than one occasion to capture the true essence of the phenomena or concept over time. Literature on the QOL of children with cancer was limited and ambiguous, thus making defining QOL difficult. A concept analysis was done to clarify the concept for children with cancer. To the best of the author’s knowledge, there were no other published concept analyses on QOL of children with cancer. The literature on QOL of children with cancer was primarily on long-term survivors of children with cancer versus children receiving active treatment. Using an instrument that reflects all the defining attributes identified from the concept analysis QOL would be beneficial as all aspects of the child’s QOL would be assessed.

In retrospect, the use of Walker and Avant’s (1995) approach to concept analysis for children with cancer may not have been the most appropriate method. Walker and Avant’s
emphasis on the literature to develop defining attributes may not be suitable the literature on QOL of children with cancer is minimal and limited to long-term survivors of childhood cancer. By using the adult literature, literature related to survivors of childhood cancer and the limited literature on QOL with children with cancer it is questionable if the true characteristics or defining attributes of children with cancer have been completely identified. Because there is limited literature on QOL of children with cancer, a method that combines the literature and qualitative data from this population may be more insightful. Schwartz-Barcott and Kim’s (1986) hybrid approach to concept analysis focuses on the literature and empirical data to identify the key components of a concept, which may be a more appropriate for a concept analysis when limited relevant literature exists such as in children with cancer. A hybrid approach would also serve to establish content validity for QOL of children with cancer.

Clarification of the steps in Walker and Avant’s (1995) approach to concept analysis could also add to the reliability and validity of the method of concept analysis. The literature review is the major focus of Walker and Avant’s method to concept analysis. However, they do not provide guidelines or steps for critically reviewing the literature. In addition, Walker and Avant emphasize the inclusion of characteristics of the concept that appear in the literature repeatedly. However they do provide a threshold for determining which characteristics are kept and which are discarded. Reliability of the method could be enhanced by having different people review the literature independently to establish reliability and discuss the results to determine the validity and defining attributes of the concept. Validity could further be enhanced by interviewing the children and families of children with cancer to
gain a better understanding of their perceptions of QOL and/or confirm the results of the literature review.

**Research Limitations**

The sample was obtained through convenience sampling and was small (n=25). Only one measure of QOL was used as it was the only one available for the desired purpose and population at this point in time. The measure used involved a proxy measure of QOL as parents completed the questionnaire for their children. The use of proxy measures for subjective concepts is a source of debate. Many children were too young to answer questions regarding QOL. However, older children may be capable of completing the questionnaire or speaking for themselves. Older children completing the questionnaire would add to the validation of the established attributes of QOL.

The findings for this study have limited generalizability because the study takes place in only one setting, in a specific geographic location with a limited number of subjects, with a specific disease entity. By utilizing more pediatric oncology centers or a greater range of children and diagnoses within one setting, the findings may be more applicable to a larger population. A qualitative method may have added additional data to enhance understanding on the meaning of QOL to these children and families. Differences in QOL may be evident with different cultures, warranting further research about cultural variations and QOL.

Ideally, a measure should be developed that directly relates to the findings of the concept analysis. The study may be improved by using a measure for assessing the child’s perception of his/her QOL. Assessing the child’s perceptions can be difficult due to differences in development and therefore the measure would need to be sensitive to the child’s age and
stage of growth and development. Finally, interpretation of QOL scores could be improved by comparing the scores to children at the same developmental stage who do not have cancer. Using a control group (i.e. siblings) consisting of children of a similar age or developmental group would be helpful in interpreting the results of the study.

The findings of the study also may be limiting as a large number of the children were in the final stage of treatment. Generalizing to other phases of treatment may be inappropriate. Having more children at different phases of treatment involved in the study would enhance generalizability of the findings to children in all phases of treatment.

Implications for Practice

QOL in the adult population often is assessed in research studies but it is also important for nurses to include QOL as part of their total assessment in clinical practice. This study has provided defining attributes of QOL for children with cancer. With a better understanding of QOL, nurses may begin to identify key attributes of the child’s QOL. Nurses must understand that QOL changes with age or stage of development and treatment and the importance of the environment in which the child interacts. Nurses must also assess the emotional and social well-being of the child in addition to the physical aspects of caring for a child with cancer. Health care professionals need to discuss QOL with their patients and families to gain a better understanding of how their goals can be met. Assessment of QOL may include both formal and informal strategies. Questionnaires or instruments may be used at the beginning of each phase of treatment to identify the child’s perception of his/her QOL. A framework could be developed that represents the attributes of QOL to assist nurses in assessing QOL. On regular clinic visits, the nurse can ask the child questions
related to his/her physical, social and emotional well-being. To ensure consistency of practice, guidelines or standards related to addressing QOL could be established.

The scores from the POQOLS (Goodwin et al., 1994) indicate that QOL was affected by age differences and time from diagnosis. Health care professionals need to understand that QOL may be significantly affected during the initial phases of treatment. During the initial phase of treatment, nurses must ensure that support is provided to help children and families deal with the changes in their QOL. As the treatment progresses, QOL may change in a positive way and only minimal support may be needed for the child and family. However, QOL of the child and family must continue to be assessed throughout treatment. The potential for differences in the factor scores between the age groups also is important for nurses in their assessment of QOL. Goodwin et al. found that children 13 years and older were more negatively affected by physical functioning and restrictions in normal routines than the younger children. This finding is important for nurses caring for older children as interventions for care should include plans to enhance physical functioning and normal routines. If physical functioning and normal routines cannot be established, the nurse must assist the child in finding alternative ways of functioning that are acceptable to the child. Children aged 8-12 years had more difficulty with emotional adjustment than children less than 8 years-old and adolescents. This information is important in planning care for this group of children. Interventions should focus in particular on the emotional needs of these children. If nurses are aware of the factors that effect the child’s QOL in a positive or negative way, he/she can intervene in a way that promotes adaptation and individual and family coping.
Implications for Further Research

Research on QOL is flourishing with individuals from all age groups and differing diagnoses. QOL research in the adult population is abundant whereas QOL in the pediatric population remains limited. Many studies focus on the QOL of long-term survivors of children with cancer rather than during the active treatment phase. The present study has provided an initial description of QOL for children with cancer.

Further research should involve the implementation of a disease-specific conceptual model for children with cancer. A conceptual model will foster more rigorous empirical research for this group of children. Generalizations between studies may be feasible with the use of a consistent conceptual model. In addition, more concept analyses should be undertaken to provide researchers and practitioners with a consistent definition for QOL of children with cancer. Concept analyses also must be published and presented to front line health care providers to ensure communication about definitions of QOL and the use of consistent definitions.

The POQOLS (Goodwin et al., 1994) is a reliable and valid tool for assessing parent's perceptions of their child's QOL. The POQOLS incorporates some of the important attributes of QOL for children with cancer. However, the POQOLS does not include attributes from this study that were deemed as important for children with cancer. Further instrument development is needed, either by revising the POQOLS or by developing new QOL measures, to include all defining attributes of QOL for children with cancer. The POQOLS does not offer guidelines for scoring. For example, a low score indicates a good QOL but there are no standardized parameters to define good or poor QOL. The POQOLS
is simple to use and could be modified for use in clinical practice. The items from the POQOLS must be reevaluated to reflect all attributes of QOL of children with cancer. Scoring of the items of the POQOLS is simple, however standardized scoring parameters are needed to determine the levels of QOL (i.e. good versus poor QOL). Further work with the instrument is necessary to provide these guidelines and standardized scoring parameters.

In the development of new QOL instruments, it is also essential to consider the clinical usefulness of an instrument for use in practice. According to Irvine and Sidani, “to be clinically useful, the instrument needs to be simple, appropriate for the intended use in clinical practice, and the scores derived from the instrument must be interpretable (1997, p.17). In addition, instruments developed to measure QOL in children must be sensitive to the different developmental stages of children. The use of cognitive psychology and/or developmental psychology as a framework for the developmental of an instrument for measuring QOL in children with cancer may be essential in capturing all aspects of QOL from infancy to adolescence. An instrument used with children and adolescents must be sensitive to stages of development when determining questions. Instruments may need to be developed for children of different ages with the incorporation of the same defining attributes of QOL but with developmentally specific questions.

Further research could include a new instrument in combination with a qualitative component for assessing the QOL of children with cancer. Further research should include a larger sample size and have more children who are in the initial phases of treatment. In addition, further research could compare QOL from the parents perspective, the child’s perspective, and possibly the health care providers perspective. Methods of analyzing
agreement between quantitative and qualitative methods also need to be determined. Further research could capture QOL at different phases throughout active treatment by assessing QOL at different times. Perhaps a longitudinal study could assess QOL during active treatment and continue after the child has completed treatment.

Finally, to establish the meaning of QOL for children with cancer, it is important to establish what the baseline QOL is for children who do not have cancer. The POQOLS could be tested with healthy children to determine QOL parameters. Further research could include a cohort group to compare the QOL of children with cancer to children who do not have cancer.

Conclusions

In this study, the concept of QOL for children with cancer was critically examined. Walker and Avant's (1995) approach to concept analysis was used to establish four defining attributes of QOL. The POQOLS (Goodwin et al., 1994) was used to corroborate the defining attributes of QOL through the comparison of indicators from the POQOLS and empirical validation. The indicators from the POQOLS only supported one defining attribute. The remaining three attributes were related to the POQOLS through empirical validation. Although no significant differences were found between children of varying age groups and time from diagnosis, the trend indicated that with a larger sample size, there may be significant differences. A clear definition for QOL and the factors that affect QOL are important for theory, research and practice. A definition of QOL for children with cancer provides a basis for conceptual frameworks, aids in the development of QOL measures, and provides guidelines for health care professionals in the assessment of QOL in the clinical
setting. Future research may include the presence of a cohort group to compare the QOL of children with cancer to the QOL of children without cancer. Longitudinal studies, and instrument development that incorporates the findings from concept analyses and stages of development of children.
References


### Appendix A

#### Examples of Health-Related QOL Measures

<table>
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<tr>
<th>Instrument</th>
<th>Author</th>
<th>Comments</th>
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<tr>
<td>Cancer Rehabilitation Evaluation System (CARES)</td>
<td>Ganz, P.A., Schag, C.A.,</td>
<td>The CARES is a cancer specific, 31 item, self-administered rehabilitation &amp; QOL instrument. The CARES can provide an overall score or scores for the five summary scales: physical, psychosocial &amp; sexual function, &amp; marital and medical interaction.</td>
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<td>Lee, J.J., &amp; Sim, M.S.</td>
<td>(1992)</td>
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<tr>
<td>HIV Overview of Problems/Evaluation System (HOPES)</td>
<td>Schag, C.C, Ganz P.A., Kahn, B. et al. (as cited in Hays &amp; Shappiro, 1992)</td>
<td>The HOPES is a direct descendant of the CARES. It includes 165 items with patients answering a maximum of 162 items and a minimum of 106 items. It is self-administered &amp; assess the QOL &amp; rehabilitation needs of HIV patients.</td>
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<tr>
<td>Health Utilities Index-Mark III (HUI)</td>
<td>Boyle, M.H., Furlong, W.,</td>
<td>The Mark III is one of three HUI systems developed to define health states according to a functional health classification system. The Mark III focuses on functional capacity and consists of 8 attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, &amp; pain/discomfort.</td>
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<tr>
<td>MOS 36-Item Short-Form Health Survey (SF36)</td>
<td>Ware, J.E., &amp; Sherbourne, C.D. (1992)</td>
<td>The SF 36 is one of the many surveys to come from the Medical Outcomes Study. The SF 36 can be used in clinical practice, research, health policy evaluations and general population surveys. The self-administered, multi-item scale assesses 8 health concepts.</td>
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<tr>
<td>Multiattribute Health Status Classification System (MAHS)</td>
<td>Feeney, D., Furlong, W., Barr, R.D., Torrance, G.W., Rosenbaum, P., &amp; Weitzman, S. (1992)</td>
<td>The MAHS was designed to describe the health status of cancer survivors. The system consists of 7 attributes: sensation, mobility, emotion, cognition, self-care, pain &amp; fertility. Within each attribute there are 3 to 5 levels of functioning and a single summary score of HRQOL can be achieved.</td>
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<tr>
<td>Quality of Well-Being Scale (QWB)</td>
<td>Kaplan, R.M., &amp; Bush, J.W.</td>
<td>The QWB scale is used to summarize the health status of individuals. The QWB quantifies HRQOL in a single number, representing death to complete well-being. Symptoms or problems are classified in terms of mobility, physical activity &amp; social activity.</td>
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<tr>
<td>Sixteen-Dimensional HRQOL Measure (16D)</td>
<td>Apajasalo, M. et al. (1996)</td>
<td>The 16D is a generic, self-assessment measure of HRQOL for early adolescents. The measure consists of 16 multiple choice questions, each representing one-health related dimension. Each dimension has 5 levels and the subject marks the level that best describes his/her health status. The overall HRQOL score ranges from 0 (worst possible) to 1 (best possible).</td>
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### Appendix B

**Examples of Approaches to QOL Measurement**

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<tr>
<th>Instrument</th>
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<tr>
<td>Cain &amp; Henke Survey</td>
<td>Cain, M., &amp; Henke, C. (1983)</td>
<td>The qualitative survey takes 20 minutes to complete and is used with cancer patients. The survey identifies specific areas such as pain, nausea and vomiting, work, leisure activity, dependency needs, religions beliefs &amp; overall QOL.</td>
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<tr>
<td>Danoff et al. Questionnaire</td>
<td>Danoff, B., Kramer, S., Irwin, P., &amp; Gottlieb, A. (1983)</td>
<td>An interview questionnaire that has 4 sections: descriptive demographic items, medical data, perceptual QOL questions &amp; health status questions. QOL is defined objectively and subjectively.</td>
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<tr>
<td>Ferrans &amp; Powers QOL Index</td>
<td>Ferrans, C., &amp; Powers, M. (1985)</td>
<td>The instrument has 35 items and consist of 2 sections. One section measures satisfaction with various domains of life and the other measures the importance of the domain to the subject.</td>
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<tr>
<td>Index of Overall Life Satisfaction</td>
<td>Campbell, A., Converse, P. &amp; Rodgers, W. (1976)</td>
<td>This measure assesses overall life satisfaction and satisfaction with individual items. A 7-point Likert scale is used that ranges from completely satisfied to completely dissatisfied.</td>
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<tr>
<td>Karnofsky Performance Status Scale</td>
<td>Karnofsky, D., &amp; Burchenal, J. (1949)</td>
<td>An objective tool that focuses on the patient's ability to perform activities of daily living. The scale rates physical activity in increments of 10 percent, from 1 to 100 percent.</td>
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<tr>
<td>Linear Analog Self-Assessment (LASA)</td>
<td>Priestman, T., &amp; Baum, M. (1976)</td>
<td>A self-assessment tool for patients to assess their own QOL during and after treatment. Ten areas of QOL are assessed by having patients marks a point on a 10 cm line that is appropriate to his/her feelings at that moment.</td>
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<tr>
<td>Quality of Life Index (QLI)</td>
<td>Padilla, G. et al. (1983)</td>
<td>A subjective, self-evaluation questionnaire that includes three general areas of QOL: psychological well-being, physical well-being and symptom control.</td>
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<tr>
<td>Quality of Life Questionnaire (QLQ)</td>
<td>Young, K., &amp; Longman, A. (1983)</td>
<td>A short questionnaire that asks subjects to rate their current QOL from poor to excellent and to rate feelings of satisfaction with their current QOL.</td>
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<tr>
<td>Quality of Life Index</td>
<td>Spitzer, W. (1981)</td>
<td>An objective scale that measures health, family support, activity, daily living, and outlook. It is used by health professionals and takes about 1 hour to complete. The scores range from 0 to 10.</td>
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<tr>
<td>Romasaas et al. Questionnaire</td>
<td>Romasaas, E., Julianni, L., &amp; Briggs, A. (1983)</td>
<td>This instrument involves a checklist of 15 categories and some open-ended questions. The purpose is to identify the continuous needs of ambulatory cancer patients and enable them to develop intervention to improve QOL.</td>
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<td>Scale</td>
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<td>Self-anchoring Life Satisfaction Scale</td>
<td>Cantril, H. (1965)</td>
<td>The scale is designed to measure a general sense of well-being. The subjective scale looks at two extremes related to a ladder. The subjects are asked to identify where they were 5 years ago, at present and in 5 years.</td>
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<td>Sickness Impact Profile (SIP)</td>
<td>Bergner, M., Bobbitt, R., &amp; Pollard, W. (1976)</td>
<td>The measure contains 136 items that are grouped into 12 categories of life activities. The instrument takes about 30 minutes to complete with the scores ranging from 0 to 100 for the total score or for each category.</td>
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<td>Zubrod Scale</td>
<td>Zubrod, C.G., Scheidnerman, M., &amp; Frei, E. (1960)</td>
<td>The scale evaluated the ability of patients to ambulate and perform activities of daily living. The scores range from 0 to 4 in increments of one.</td>
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ELIGIBILITY CRITERIA

1. Age 1 - 2 years or ≥ 10 years.

2. WBC > 50,000

3. L₂ marrow morphology (>50% L₂ blasts)

4. Lymphoma syndrome - One criterion from each of the clinical and laboratory groups is required for lymphoma.

   **Clinical criteria**
   a) lymphadenopathy > 3 cm. or node group > 5 cm.
   b) mediastinal mass
   c) massive splenomegaly/hepatomegaly (down to umbilicus)

   **Laboratory criteria**
   a) Hgb > 10 gm%
   b) WBC > 50,000
   c) E rosettes > 20%

5. Sanctuary disease - CNS or testicle

PRETREATMENT STUDIES

1. Hematologic - complete blood count, platelet count, retic count, PT and PTT, 5 cc. clotted blood to Dr. Poon for serum storage

2. Biochemical - BUN, creatinine, electrolytes, uric acid, calcium, phosphorus, liver function tests, protein electrophoresis, and immunoglobulin quantitation

3. Urinalysis - including pH

4. Chest X-ray

5. Bone Marrow Aspirate - When possible, the aspirates should be done in the morning to allow time to perform the required tests.

   a) at least 12 slides for routine Wright stain, PAS, Sudan Black, Peroxidase and other special tests as deemed necessary

   b) Immunology requires 1/2 cc/ of bone marrow in preservative-free heparin for cell surface marker identification
The following labs need notification that a bone marrow will be performed (24 hours notice, if possible).

c) Cytogenics - call Sandy Tosh at ext. 4220. She will attend the procedure and obtain the necessary samples.

d) Hematology Research - call Mr. Tom Grunberger at ext. 4200. He will send culture tubes with medium. Approximately 1 cc. of bone marrow is required.

e) Genetics - call Dr. Beth Cairney at ext. 6363. If no answer, call 6386 and leave a message. She will attend the procedure and obtain the necessary samples. On weekends, leave the specimens in Rm. 11104 (cold room).

6. Varicella - zoster antibody

7. M-mode echocardiogram with ejection fraction and shortening fraction

8. MUGA (baseline) if possible.
A. L. L. PROTOCOL C
PHASE I - INDUCTION

Name ____________________________________________  I. D. No. ________________
Height ____________________  Weight ____________________  Surface Area ____________

Vincristine 1.5 mgm / sq m (max 2.0 mgm); day 0, 7, 14, 21 = mgm Vcr
Daunomycin 25 mgm /sq m; day 0, 7, 14, 21 IV = mgm Dauno
L-asparaginase 6,000 U / sq m IM; q MWF x 9 doses = U Lasp
Prednisone 60 mgm / sq m (max 60 mgm); day 1 - 27 = mgm Pred
IT AraC 30 mgm < 2; 50 mgm < 3; 70 mgm > 3; day 0 = mgm AraC
IT Methotrexate 8 mgm < 2; 10 mgm < 3; 12 mgm >3; day 14 & 28 = mgm MTX

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N. B. Bone marrow day 28

Please complete the attached from Re: Eligibility for Pharmacokinetics Study.
A. L. L. PROTOCOL C
PHASE II - CNS INTENSIFICATION

Name ___________________________________________ I. D. No. ____________
Surface Area (at diagnosis) __________________________

Cyclophosphamide 1,000 mg/m²; day 0, 14
6MP po 60 mg/m²; day 0 - 27
IV AraC 75 mg/m²; day 1 - 4, 8 - 11; 15 - 18; 22 - 25
IT Methotrexate 8 mg/m² < 2; 10 mg/m² < 3; 12 mg/m² > 3; day 1, 8, 15, 22
Septra 3 mg/m² / kg / day in 2 divided doses
CNS Radiation

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<td>Start interim maintenance</td>
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<td>(i.e., one week no therapy)</td>
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</table>
**A. L. L. PROTOCOL C**

**PHASE III - INTERIM MAINTENANCE**

6MP po 60 mgm / sq m; day 0 - 41

IV Methotrexate 74 mgm / m²; day 0, 14, 28, 42

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Bactrim 2 - 3 mgm / kg / day TMP po throughout if blood counts allow
A. L. L. PROTOCOL C

PHASE IV - REINDUCTION/REINTENSIFICATION

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<thead>
<tr>
<th>Name</th>
<th>I. D. No.</th>
<th>Surface Area</th>
</tr>
</thead>
</table>

- **Vincristine** 1.5 mgm / sq m (max 2.0 mgm); day 0, 7, 14, 21 = mgm Vcr
- **Adriamycin** 25 mgm / sq m; day 0, 7, 14, 21 = mgm Adria
- **L'asparaginase** 10,000 U / sq m IM; day 1, 4, 7, 10 = U Lasp
- **Dexamethasone** 10 mgm / sq m (max 12 mg); day 0 - 27 = mgm DXM
- **Cyclophosphamide** 1,000 mgm / sq m; day 35 = mgm CPM
- **6Thioguanine** 60 mgm / sq m; day 36 - 49 = mgm 6TG
- **IV AraC** 75 mgm / sq m; day 36 - 39, 43 - 46 = mgm AraC
- **IT Methotrexate** 8 mgm < 2; 10 mgm < 3; 12 mgm > 3 day; day 39, 46 = mgm IT MTX

N. B.

- **Bactrim** 3 mgm TMP / kg / day in 2 divided doses; day 1 - 56 = mgm Bact

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<th>Date given</th>
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<th>Lasp</th>
<th>DXM</th>
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- **CPM**

- **6TG**
- **AraC**
- **IT MTX**

- **AraC**
- **IT MTX**
** A. L. L. PROTOCOL C

PHASE V - MAINTENANCE

** The minimum interval between Phase IV Day 46 and Phase V Day 0 is one week.

** Maintenance phase begins when polys ≥ 1,000 and platelets ≥ 100,000.

Vincristine 1.5 mgm / sq m (max 2.0 mgm); day 9, 28, 56 = mgm Vcr
Prednisone 40 mgm / sq m / day; day 0 - 4, 28 - 32, 56 - 60 = mgm Pred
IT Methotrexate 8 mgm < 2; 10 mgm < 3; 12 mgm > 3; day 0 = mgm IT MTX
IV Methotrexate 75 mgm / sq m every 2 weeks; day 14, 28, 42, 56, 70 = mgm IV MTX
6MP 75 mgm / sq m / day; day 0 - 83 = mgm 6MP

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Bactrim 2 - 3 mgm / kg / day TMP po throughout
Appendix D

PEDIATRIC ONCOLOGY QUALITY OF LIFE SCALE (POQOLS)

IN THE PAST TWO WEEKS

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<th>Frequency</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very freq.</th>
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<td>1. My child has had anger outbursts</td>
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<td>2</td>
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<tr>
<td>2. My child has expressed fear about the disease and its treatment</td>
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<tr>
<td>3. My child has been sad</td>
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<tr>
<td>4. My child has been able to participate in recreational activities (sports, games etc.)</td>
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<tr>
<td>5. My child has had less energy and has been easily tired out</td>
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<tr>
<td>6. My child has required active medical treatment</td>
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<tr>
<td>7. My child has been able to interact/play with friends completely normally</td>
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<tr>
<td>8. My child has complained of pain from medical procedures</td>
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<tr>
<td>9. My child has been embarrassed about physical changes (hair loss, weight change etc.)</td>
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<tr>
<td>10. My child has been physically capable of performing as usual</td>
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<td>11. My child has had trouble sleeping</td>
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<tr>
<td>12. My child has complained about physical pain from his/her cancer</td>
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<td>13. My child has been bothered by other people treating him/her differently</td>
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<td>14. My child has been satisfied with his/her recent physical ability</td>
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### IN THE PAST TWO WEEKS

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<tbody>
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<td>15. My child has played/visited with friends</td>
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<td>rarely</td>
<td>sometimes</td>
<td>often</td>
<td>very freq.</td>
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<td>16. My child has been able to attend school</td>
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<td>17. My child has demanded more help with daily tasks than he/she needs</td>
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<td>18. My child has been hostile</td>
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<td>19. My child has spent time during the day resting</td>
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<td>20. My child has had nausea and/or vomiting due to treatment</td>
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<td>6</td>
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<tr>
<td>21. My child has needed extra help with daily living skills (dressing, washing, etc.)</td>
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<td>3</td>
<td>4</td>
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Appendix E

Explanation of the Study and the Consent Form

Home Chemotherapy Study

Primary Investigator:
Bonnie Stevens, RN, PhD,

Co-investigators:
Marilyn Booth, RN, MHSc,
Patricia McKeever, RN, PhD,
Mark Greenberg, MD, FRCP(C),
Carol Millar, RN, DPHN,

EXPLANATION OF THE STUDY AND CONSENT

Purpose:
The purpose of this study is to compare the acceptability, safety, impact on quality of life of the child and parents and costs of chemotherapy administered at home and in the hospital outpatient clinic. Although many similar studies of home chemotherapy have been carried out with adults with cancer, very few studies have been done with children.

Description of the Research:
In order to compare home chemotherapy and hospital chemotherapy, children and their parents who participate in this study will be involved in one of two groups. The group you and your child will be in depends on where you live. If you do not live in metropolitan Toronto your child will receive all of his/her chemotherapy in the hospital oncology clinic. If you do live in metropolitan Toronto, your child will receive some of his/her chemotherapy in the clinic and some at home. Home chemotherapy will be given by a community nurse to your child at home. All children will be closely monitored during chemotherapy administration according to standard practice at the Hospital for Sick Children. You will need to be at home to care for your child after the chemotherapy is given. The nurse will negotiate a time to come to your home that is convenient for you and your child.

If you decide to participate in the study, you and your child will be asked to participate in data collection three times. Each time, you will be asked to participate in a short interview and complete 3 questionnaires. You will be asked questions about the effects of your child’s illness and treatment on your daily
lives. This should take approximately 30 minutes. Your child will not be asked any questions. You will also be asked to keep a diary of all expenses during the study time. Your child’s medical chart will be reviewed by the research nurse to gather information about his/her age, diagnosis, and treatment.

Potential Harms/ Discomforts:
There are very few immediate side effects associated with the low doses of chemotherapy given during this study. Some children feel nauseated and/or vomit after they receive these drugs. There are no known additional harms for children who receive chemotherapy at home. Your child will be closely monitored during chemotherapy administration by a nurse trained in the administration of chemotherapy and emergency procedures. If any unforeseen harmful consequences occur, the study will be stopped, appropriate emergency procedures will be initiated and the physician in charge will be notified immediately.

Potential Benefits:
You and your child may not benefit directly by participating in this study. If your child receives his/her chemotherapy at home, it may be more convenient and less costly.

Alternatives:
If you and your child do not participate in the study, s/he will receive chemotherapy in the hospital outpatient clinic in the usual manner.

Confidentiality:
Confidentiality will be respected and no information that discloses the identity of you or your child will be released or published without consent unless required by law. For your information, the research consent form will be inserted in your child’s health record.

All verbal and written information collected during the study will be identified by a code number. One master copy of your child’s code and name will be kept in a file at the University of Toronto Faculty of Nursing. Group results may be presented at a later time, but children will not be individually identified. These group results will be made available upon request.

Participation:
Participation in this study is voluntary. If you chose not to participate, the care you and your family receive at The Hospital will not be affected in any way. If you choose on behalf of your child to participate in this study, you can withdraw your child from the study at any time. Again, the care you and your family receive will not be affected.
CONSENT FORM

I acknowledge that the research procedures described on the attached form and of which I have a copy have been explained to me and that any questions that I have asked have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I also understand the benefits (if any) of joining the research study. The possible risks and discomforts have been explained to me. I know that I may ask now, or in the future, any questions I have about the study or research procedures. I have been assured that records relating to my child and his/her care will be kept confidential and that no information will be released or printed that would disclose personal identity without my permission.

I understand that I am free to withdraw my child from the study at any time. I further understand that if my child does not participate in the study, or if there is withdrawal from it at any time, the quality of care for my child and for other members of the family will not be affected.

I hereby consent for my child __________________________ to participate fully in the study.

I do not consent for my child to participate in the study, but I give permission for the medical record to be examined by the researchers ____________.

_________________________  __________________________
namename  witness

_________________________
signature and capacity (parent, guardian)

_________________________
date

The people who may be contacted about the research are:
Appendix F

Child's Assent Form

Home Chemotherapy Study

Primary Investigator:
Boggie Stevens, RN, PhD,
Co-investigators:
Marilyn Booth, RN, MHSc.
Patricia McKeever, RN, PhD,
Mark Greenberg, MD, FRCP(C),
Carol Millar, RN, DPHN,

Information Form For Children and Adolescents
Why are we doing this study? The reason that we are doing this study is because we want to find out what it is like for you and your family to have your chemotherapy at home/ in the hospital. We need to know this so that we can give you and your family the best possible care.

What will happen during the study? If you live in Toronto, you will start getting the same chemotherapy that you have been getting at the day unit at the hospital (except that you will have it at home). If you get your chemotherapy at home a nurse will come to your house to give it to you.

Are there good things and bad things about the study? You may like to be at home while you have your treatment or you may miss coming to the hospital. If you get your chemotherapy at home, you may feel uncomfortable with a nurse that you do not know coming to your home.

Who will know what I did in the study? If you are part of the study, your name and address will not be given to anyone. Only the person who asks you to be part of the study will know your name.

Can I decide if I want to be in this study? If you do not want to be part of this study that is O.K. No one will be upset or disappointed. If you say yes now, but change your mind you can say no to the research nurse later. Your mother and father will also read some information about this study. You can ask them questions too, if you do not understand what you have heard or read. They will help you to understand.

Assent
I was present when ____________________________ read this form and gave his/her verbal assent.
Name ____________________________ Signature ____________________________
Date ____________________________
Appendix G
Study Entry Chart Abstraction Sheet

1. Abstraction date: day [ ] mon [ ] year [ ]

2. Study group:
   ○ 1: Home
   ○ 2: Hospital

Child data:

3. Birthdate: day [ ] mon [ ] year [ ]

4. Sex:
   ○ 1: Male
   ○ 2: Female

5. Date of diagnosis: day [ ] mon [ ] year [ ]

6. Oncologist:
   ○ 01 [ ]
   ○ 02 [ ]
   ○ 03 [ ]
   ○ 04 [ ]
   ○ 05 [ ]
   ○ 06 [ ]
   ○ 07 [ ]
   ○ 08 [ ]
   ○ 09 [ ]
   ○ 10 [ ]
   ○ 11 [ ]
   ○ 12 [ ]
   ○ 13: Other: (please specify)

7. Primary care nurse:
   ○ 01 [ ]
   ○ 02 [ ]
   ○ 03 [ ]
   ○ 04 [ ]
   ○ 05 [ ]
   ○ 06 [ ]
   ○ 07 [ ]
   ○ 08 [ ]
   ○ 09: Other (please specify)

8. Phase of treatment at study entry:
   ○ 0 II
   ○ 1 III
   ○ 2 IV
   ○ 3 V

9. Date phase started: day [ ] mon [ ] year [ ]

10. Date phase finished: day [ ] mon [ ] year [ ]
Family data:

1. What method of transport do you use to reach HSC?
   - Walk
   - Car
   - Public transit
   - Other (please specify)

2. How long does it take?
   - [ ] hr [ ] min

3. What are the first three digits of your postal code?
   - [ ] [ ] [ ]

4. Child’s current schooling pattern:
   - [ ] Pre-school
     - hrs/week [ ]
   - [ ] School
     - grade [ ]
     - attendance
       - [ ] Full day
       - [ ] Half day
       - [ ] Irregular
         - hrs/week [ ]
   - [ ] Other (please specify)

5. Number of other children living at home:
   - if >0 record ages:
     - sibling #1 [ ]
     - sibling #2 [ ]
     - sibling #3 [ ]
     - sibling #4 [ ]
     - sibling #5 [ ]
     - sibling #6 [ ]

6. Others living at home?
   - [ ] No
   - [ ] Yes
     - if yes, record relationship(s):
       - [ ] Grandparent(s)
       - [ ] Other relative(s)
       - [ ] Other non-relative

7. Marital status:
   - [ ] Married/stable relationship
   - [ ] Single/separated/divorced/widowed
Study Sheet

Birthdate: [ ] [ ] [ ] [ ] [ ] [ ] [ ]

Study Number [ ] [ ]

[ ] [ ] [ ] [ ]

(please specify)

Senior management
Middle management
Woman
Labourer
Sales/trades
L/erical/sales/manual, farmer
Cal/sales/manual, labourer
Home and Hospital Chemotherapy Study

Family/Parent Data Sheet

Father data: (continued)

13. Are you employed for pay?

☐ No  → if no, are you
☐ a student
☐ a homemaker/househusband
☐ currently unemployed
☐ something else

☐ Yes  → if yes, occupation:
☐ Professional/senior management
☐ Technician/middle management
☐ Supervisor/foreman
☐ Skilled clerical/sales/trades
☐ Semi-skilled clerical/sales/manual, farmer
☐ Unskilled clerical/sales/manual, labourer

is this occupation
☐ Full-time
☐ Part-time

(please specify)

(please specify)

(please specify)