Title of Capstone: Promotion of Comfort through Early Palliative Care Consultation for Children and Adolescents Undergoing Hematopoietic Stem Cell Transplantation (HSCT): Feasibility of Implementation and Evaluation of a Proposed Practice Change

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Promotion of Comfort through Early Palliative Care Consultation for Children and Adolescents Undergoing Hematopoietic Stem Cell Transplantation (HSCT):

Feasibility of Implementation and Evaluation of a Proposed Practice Change

By

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July 2, 2012

Capstone Project Submitted to the Faculty of the School of Nursing Of the University of Maryland, Baltimore
In partial fulfillment of the requirements for the degree of Doctor of Nursing Practice Summer 2012

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Dedication

This is dedicated to my friend and mentor, Debra L. Spunt, DNP, RN, FAAN in memory of her commitment and dedication to the discipline of nursing. Debbie unfortunately passed away as she was finishing with the first cohort of DNP students at the University of Maryland, School of Nursing, but her tireless efforts to advance the practice of nursing inspired me to enroll in the DNP program and to complete this project.

This capstone project is equally dedicated to my husband, Mike, and my children, Michael and David, who supported me faithfully all along the journey. In addition, this project honors my goddaughter, Ellen Spunt, who walked through her mother’s DNP journey as well as my own.

Finally, this project is dedicated to the children, with advanced cancers and other non-malignant diseases, and their families who teach me something new every day and inspire me to be a better person.
Acknowledgements

I would like to acknowledge and extend my profound thanks to my Capstone Project Committee, Michele Michael PhD, CRNP, RN, Chairperson, Pamela Hinds, PhD, RN, FAAN, and Katherine Patterson Kelly, PhD, RN for their unfailing support and guidance throughout the Doctor of Nursing Practice program. I would also like to acknowledge the extremely important contributions of Ann Sill, BS, for without her expertise in guiding my statistical analysis this project would not have been possible.

I also acknowledge the contributions of my colleagues at Children's National Medical Center, Dr. Shana Jacobs, Cheryl Reggio, RN, Rose Szeles, RN, and Bonnie Yates, RN, whose untiring dedication to improving the lives of children undergoing stem cell transplant and their families highlight the excellence of the art of nursing.
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Abstract

**Purpose:** The purpose of this project was to investigate the feasibility of a proposed practice change to integrate early palliative care consultation that would promote transcendent comfort in children and adolescents with advanced or high-risk cancers or other non-malignant diseases undergoing hematopoietic stem cell transplantation (HSCT).

**Background and Significance:** Hematopoietic stem cell transplantation (HSCT), a modality used to treat a variety of advanced cancers and other serious non-malignant diseases in children and adolescents, may have significant symptom distress. The goal of enhanced comfort is the utmost concern of children and adolescents undergoing HSCT and their families (Mayer, Tighouart, Terrin, Stewart, Peterson, Jeruss, & Parsons, 2009). Multiple pediatric professional organizations have set a standard to promote relief of symptom distress and promote quality of life and enhanced comfort (AAP, 2000; Freibert & Huff, 2009). Clinical research on the effectiveness and benefits of interventions to relieve symptom distress is paramount to expanding the evidence base of pediatric palliative care and the science of HSCT in prioritizing comfort.

**Methods:** A single-site, feasibility study was used to examine the primary aims of (1) willingness of patients and families of a vulnerable population to receive the palliative care intervention, (2) willingness of the health care team to refer families, (3) resource allocation, and (4) family and provider satisfaction. Secondary aims included evaluation and concordance of comfort from parent and child perspectives. A convenience sample of 12 families (child undergoing HSCT and their parent) were enrolled on the study. Data collection included referral and enrollment patterns, and time and resources required for palliative care interventions. Additional data included child self-report and parental reports of their child's comfort at baseline, T1 (~14 days following HSCT), and T2 (~ 30 days following HSCT). Family and provider satisfaction were measured at the end of enrollment.

**Findings:** 100% of eligible families were referred and consented to participate (N = 12). Each family received a minimum of one visit per week, however, an average of 3 visits per week were made. Visits ranged from 15 minutes to 2 hours, depending upon individual circumstances. The top interventions requested or required, in addition to standard HSCT care interventions, included supportive care counseling, massage therapy, aromatherapy, play therapy, acupuncture, acupressure, and other integrative medicine techniques. Children and adolescents consistently rated comfort as "very good", however, parents tended to rate their child's level of comfort lower. There were 3 deaths of participants during the study. Families and providers expressed high satisfaction with this approach to care.

**Conclusion:** This intervention is a novel approach to providing early palliative care services with curative intent therapy. Early palliative care intervention was well received by providers and families of children undergoing HSCT. Parents rate their child's level of comfort somewhat lower than child self-report, however, distress of parents impacts the entire family system thus interventions aimed at improving the child's comfort may improve parental distress and support better family functioning. Early palliative care services helped palliative care practitioners better meet the needs of the families who experienced the death of their child. Because of this additional support, end of life was peaceful and coordinated. This approach to care will be integrated as a standard of care for HSCT at the study site.
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“To cure sometimes, to relieve often, to comfort always – this is our work.” - Author unknown

Section One

Promoting patient comfort is a universal goal in health care. The practice problem of concern is that children and adolescents with advanced cancers and other non-malignant diseases undergoing hematopoietic stem cell transplantation may encounter a number of distressing physical symptoms as well as existential distress, but are not afforded timely access to palliative care services which may assist in obtaining a state of transcendence of the experience to live life as fully as possible (Foster, Lafond, Reggio, & Hinds, 2010). Care in this setting should be from a holistic perspective and not isolated to treating physical symptom distress alone. Current measures often assess the lack of symptoms rather than the presence of positive traits that promote transcendence of living with a serious, potentially life-limiting disease (Novack, Kolcaba, Steiner, & Dowd, 2001). This capstone project will evaluate a practice change designed to promote patient and family comfort by implementing and evaluating palliative care consultation for children and adolescents with high risk or advanced cancers and other potentially life-limiting non-malignant diseases undergoing hematopoietic stem cell transplantation (HSCT).

Background

Pediatric cancers have traditionally been studied in terms of progression free survival and/or overall survival, without much attention to quality of life, symptom distress, and functional status for pediatric patients with advanced cancers or non-malignant diseases undergoing HCST. However, it is essential to have clear definitions of the concepts prior to
planning any change in practice. For the purposes of this project, the concepts of interest are *suffering, comfort, and transcendence.*

**Definition of the Concepts: Suffering, Comfort and Transcendence**

**Suffering.** Suffering is experienced in a variety of ways: physical, social, emotional, and/or spiritual. Pain in any of these domains may cause distress (O'Neill & Mako, 2011). Distress, or suffering, may occur in varying degrees at any time during the trajectory of a serious, life-limiting illness. Suffering is what the person says it is (Cassell, 1999). What is defined as suffering or distress by one child or family may or may not be distressing to another child or family. Existential distress is suffering that affects the integrity of the person, integrating into every domain of human existence, impacting quality of life and activities of daily living (Cassell, 1999). Providing palliative care for the child or family experiencing existential distress is one way of promoting comfort (O'Neill & Mako, 2011).

**Comfort and transcendence.** *Comfort* is defined as meeting the physical, psychospiritual, sociocultural, and environmental needs of patients and families to provide relief, ease and transcendence (Kolcaba, 1992; Kolcaba, 2003; Kolcaba, 2009). *Transcendence* is defined as the ability to rise above problems or pain (Kolcaba, 2003). Bridging the definitions of comfort and transcendence, a new concept of *transcendent comfort* emerges. Comfort therefore is more than just the *relief* of physical signs and symptoms; it extends to *ease* of physical as well as existential distress to promote optimal functioning that goes beyond the limits of traditional nursing intervention experiences to a perception of well-being despite the circumstances (*transcendence*). For the purposes of the exploration of comfort in the context of this project, *transcendent comfort* is conceptually defined as a state of ease and well-being influenced by the caring and actions of nursing, which lead to transcendence of the circumstances of symptom
distress, functional status and quality of life to promote a sense of well being despite the circumstances of life-limiting or advanced pediatric cancer or other non-malignant disease undergoing hematopoietic stem cell transplant. This capstone project was conducted to examine the use of palliative care to promote transcendent comfort in children and adolescents undergoing HSCT.

**Exploration of Comfort in Children with Advanced Illness**

Comfort and palliative care, defined as “care that seeks to prevent, relieve, reduce, or soothe the symptoms produced by serious medical conditions or their treatment and to maintain patients’ quality of life” (33), become the focus of the care efforts when cancer or serious life-limiting non-malignant diseases are advanced (Field & Behrman, 2003). Comfort is equally as important in the setting of high-risk therapies with the potential for greater morbidity and the potential for death. The concept of comfort remains ill defined in the available evidence for children and adolescents with life-limiting cancers or other non-malignant diseases treated with hematopoietic stem cell transplantation (Lafond & Hutton, 2011).

In two landmark studies, Wolfe et al (2000 & 2008) reported that attempts at alleviating pain and distressing symptoms of dying children with cancer are often unsuccessful. In the initial cohort of bereaved parents of children with advanced cancers, Wolfe et al (2000) reported that 89% felt their child “suffered a lot” or “a great deal” during their last month of life. In a follow-up study following institution of palliative care consultation, a second cohort of bereaved parents of children with advanced cancer reported less suffering (e.g. 19% Relative Difference [RD] of parents reporting that their child suffered from pain and 21% RD reporting suffering from dyspnea), and that they felt more prepared at the end of the child’s life (Wolfe, Hammel, Edwards, Duncan, Comeau, Breyer, Aldridge, Grier, Berde, Dussel, & Weeks, 2008). However,
these landmark studies reviewed the absence of physical symptoms (pain, fatigue, dyspnea and anxiety) with little discussion of existential suffering or the ability of the child and family to transcend the cancer experience to experience activities or circumstances important to the child, such as going to school, attending important social events, interacting with peers, or finding meaning in a life-limiting illness. These studies evaluated general oncology patients and were not specific to patients undergoing hematopoietic stem cell transplantation (HSCT). Consideration of indications and morbidities associated with HSCT is essential for promoting transcendent comfort in this population.

Hematopoietic stem cell transplantation (HSCT) is a therapeutic modality employed in a variety of high-risk pediatric cancers and other non-malignant disorders. There is a spectrum of severity of illness that are recommended for HCST, from newly diagnosed high-risk cancers, such as acute leukemias, to advanced, refractory or relapsed cancers, such as the use of autologous HSCT for advanced brain tumors, neuroblastomas, or other non-malignant disorders including a variety of metabolic and genetic disorders, such as severe combined immune deficiency syndrome (SCIDS), sickle cell disease, Hurler’s syndrome and others (Bollard, Krance, & Heslop, 2006; Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011).

Stem cell transplantation is not without substantial risks, thus increasing stress upon the child and family (Jobe-Shields, Alderfer, Barrera, Vannatta, Currier, & Phipps, 2009). This stress extends beyond physical symptoms to include a myriad of stressors, including social isolation from family and peers, fear from invasive procedures, potential for sibling/donor fear, donor guilt if child does not survive, financial stressors, and other discomforting stressors. Many children, adolescents and their families tolerate the stem cell transplantation process with relative ease, while others encounter varying degrees of physical and/or existential distress. Higher
levels of distress may impact the psychosocial and emotional outcomes as well as the medical outcomes of stem cell transplantation (Jobe-Shields, Alderfer, Barrera, Vannatta, Currier, & Phipps, 2009). Promotion of comfort may decrease levels of distress with the potential of fostering more positive outcomes in a population at high risk for morbidity and mortality.

**Significance of the Problem**

Approximately 13,500 children and adolescents from birth to 19 years of age are diagnosed with cancer each year in the United States (Cure Search, 2012). Over 400,000 more children and adolescents are living with other potentially life-limiting illnesses (Field & Behrman, 2003). Over the past decade, tremendous strides have been made in treating cancer resulting in improved disease free survival. Despite these advances, 10,742 children and adolescents died from cancer from 2003 to 2007 (Centers for Disease Control and Prevention, 2012; U.S. Cancer Statistics Working Group, 2009). The 2000 census reported a mortality rate of 808.3 per 100,000 from all causes in children and adolescents from birth to 24 years of age (Xu, Kochanek, Murphy, & Tejada-Vera, 2010). Many of these deaths result from progression of a disease or in some cases mortality is a result of complications of therapy.

Significant morbidities may also occur as result of high risk intensive therapies, such as stem cell transplantation (HSCT). Children who undergo HSCT may suffer from a number of acute and chronic health conditions which carry high risk of morbidity and mortality. Risks for acute morbidity include infection, graft versus host disease (GVHD), pancytopenia (low blood counts), mucositis, pain, diarrhea, vomiting, malnutrition, fatigue, caregiver burden, and others (Jacobsohn, 2008; Mayer, et al., 2009; Cohen & Maruice, 2010; Baggott, et al., 2010; Ullrich, et al., 2010). Examples of chronic health conditions which carry a potential for life-long suffering, include chronic GVHD, kidney disease, cardiomyopathy, neurocognitive deficits,
endocrinopathies, caregiver burden, and others (Hingorani, Guthrie, Schoch, Weiss, &
McDonald, 2007; Jacobsohn, 2008; Barrera & Atenafu, 2008; Daly, et al., 2011). HSCT is one
modality used at Children’s National Medical Center to treat a wide variety of advanced cancers
and other serious non-malignant diseases in children and adolescents, which has a high symptom
burden that may persist long-term. This adds to the distress for patients, families and staff.

Children's National Medical Center (Children’s National), located in Washington, DC, is a
large tertiary care freestanding children's’ hospital (Children’s National Medical Center, 2011).
The Division of Stem Cell Transplantation, within the Department of Hematology/Oncology,
oversees the process of hematopoietic stem cell transplants for children with advanced cancers
and a variety of other serious non-malignant diseases. From 2007 to 2011, 87 allogeneic
(unrelated and related donors) HSCT's and 93 autologous (patient harvested) HSCT's were
performed at Children's National (Perez, 2011). Types of diseases amenable to HSCT at
Children's National included a variety of high risk cancers, severe aplastic anemia, SCIDS, sickle
cell disease, Thalassemia, Fanconi anemia, Wiscott-Aldridge Syndrome, metabolic storage
diseases, Lupus erythematosus, and immune dysregulation polyendocrinopathy enteropathy X-
linked (IPEX) syndrome.

Allogeneic HSCT is inherently associated with greater risk for co-morbidities, such as
graft versus host disease (GVHD), donor graft rejection, infection, mucositis, immune
deficiency, endocrinopathies, among others (Jacobsohn, 2008). In the past 2 years, 43 children
or adolescents (59.7% of 72 transplants performed) have died at Children's National as result of
morbidities related to HSCT or progressive disease (Perez, 2011). Anecdotal discussions with
nursing staff on the inpatient Bone Marrow Transplant unit indicated that nursing staff felt that
children and adolescents face a variety of challenges during the transplant experience including
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Reports of suffering and distress (Reggio, 2011). This presents a substantial moral burden for the nursing staff, especially when promotion of comfort and quality care is a priority goal of nursing at Children's National (Children's National Medical Center, 2011a; Children's National Medical Center, 2011b).

The Practice Problem

Care promoting comfort should be offered to children and adolescents with high-risk cancers or serious non-malignant disease and certainly in the setting of relapsed or refractory disease or high-risk therapies with significant morbidities (Johnson, Nagel, Freidman, Meza, Hurwitz, & Freibert, 2008). Pediatric palliative care services are not readily available in general, but even when they are available often include significant restrictions, which preclude concurrent palliative care services while receiving anti-cancer directed therapies, including HSCT (Byock & Miles, 2003). Families are often faced with making a decision to pursue one versus the other. The decisions regarding pursuing aggressive therapy and the impact on comfort in the face of potentially life-limiting disease are difficult ones for both parents and clinicians (Tomlinson, et al., 2011). Services aimed at assisting families with these difficult decisions are paramount to supporting the "good parent" and decreasing decisional regret (Dussel, Kriecksbergs, Hilden, Watterson, Moore, Turner, Weeks & Wolfe, 2009).

Palliative care consultation is currently not a routine part of care for patients undergoing HSCT and their families at Children's National. Children's National has an established palliative care consultation service available to all inpatients and selected outpatient units: The Pediatric Advanced Needs Assessment and Care Team (PANDA Care Team). The PANDA Care Team served a few families on the Stem Cell and Bone Marrow Transplant Unit and received positive feedback on the impact of palliative care services in this population. The PANDA Care Team is
a nurse driven initiative requested frequently by HSCT nursing staff but had met with some resistance from medical staff who felt that the focus of care should be towards cure. The general impression of the HSCT team was that palliative care is synonymous with end of life care (Reggio, 2011). While it is true that end of life care is under the umbrella of palliative care, palliative care is aimed at reducing distressing symptoms and promoting quality of life during every phase of illness, from diagnosis to cure or end of life (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000; Field & Behrman, 2003; Foster, Lafond, Reggio, & Hinds, 2010). The use of palliative care services early in the HSCT trajectory was considered as a possible intervention to promote patient comfort, lessen symptom distress and improve family as well as nurse satisfaction.

**Clinical Research Hypothesis**

The clinical research hypothesis was that the proposed clinical practice change would provide children and adolescents diagnosed with advanced or high-risk cancers or other non-malignant diseases undergoing stem cell transplantation and their families access to palliative care services early in the transplantation process to promote enhanced comfort through relief, ease and transcendence of physical and existential distress. Enhanced comfort would be evidenced by increasing health-seeking behaviors to promote a perception of well being despite the circumstances of life-limiting advanced cancers in childhood. Health-seeking behaviors (HSB’s) were defined as those which consciously or subconsciously led the child or adolescent and family towards well-being, such as finding meaning in a life-limiting illness, congruence with faith beliefs, feeling motivated, determined and strengthened (Kolcaba, 2003). These HSB’s may be internal (i.e. reflection, prayer, meditation, relaxation, quality of life.) or external (i.e. improved functional status, relief of physical symptom distress, interaction with family and
friends) or those behaviors that lead to a peaceful death, if that is the eventual outcome. An exploration of nursing theory was undertaken as a framework to guide testing of the research hypothesis.

**Theoretical Framework**

**Nightingale's Grand Theory**

Florence Nightingale’s grand theory would postulate that children with advanced cancer or other non-malignant diseases potentially facing life-limiting illness must be cared for with comfort as a primary goal and not just with the goal of cure (Nightingale, 1992; McEwen & Wills, 2011). She further elucidates that nursing needs to meet the basic needs of a healthy environment, social interaction with others, and promotion of the person by humane and competent care. She viewed nursing as an art, which complements the science of medicine to provide holistic patient care (McEwen & Wills, 2011). In the context of advanced illness in childhood, this could be defined as child-family centered care with a calm, nurturing environment and nursing care focused on promotion of quality of life and transcendence of symptom distress (physical, psychospiritual, sociocultural and environmental) whether cure is possible or not. Nightingale's grand theory was a guiding force for the development of Kolcaba's comfort theory, a middle range nursing theory applicable to the clinical problem under investigation (Kolcaba, 2003).

**Kolcaba's Comfort Theory**

The concept of comfort is integral to the practice of pediatric palliative care (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000; Field & Behrman, 2003). A search of potentially relevant middle range theories of nursing was conducted to examine the concept of comfort to guide clinical research efforts to address gaps in evidence for interventions
to enhance quality of life and functional status while decreasing symptom distress in children and adolescents with life-limiting advanced cancers. A relevant middle range nursing theory, Comfort Theory (Kolcaba, 1994; Kolcaba, 2003) was chosen to best reflect the concept of interest after critique for application to this practice problem. A diagram of the Comfort Theory is seen in Figure 1. Patients and families strive for optimal comfort to promote relief of symptom distress, quality of life, and functional status (Hinds, Quargnenti, & Wentz, 1992; Dodd, Jansen, Facioine, Faucett, Frolicher, Humphreys, et al, 2001; Goodwin, Sener, & Steiner, 2007; Angstrom-Brannstrom, Norberg, Strandberg, Soderberg, & Dahlquist, 2010). The Comfort Theory has the ability to influence nursing practice by defining the concept of comfort outside the traditional bounds of relief of symptom distress and expanding strategies to promote transcendence.

Kolcaba’s Comfort Theory was chosen to guide the investigation of the concept of comfort in children and adolescents with life-limiting advanced or high-risk diseases undergoing HCST and their families. The practice problem under investigation was to determine if providing access to palliative care services early in the disease trajectory would promote enhanced comfort through relief, ease and transcendence of physical and existential distress throughout the childhood cancer journey as evidenced by increasing health seeking behaviors to promote a perception of well being despite the circumstances of life-limiting childhood cancers (see Table 1 and Figure 1). Kolcaba defines comfort as meeting the physical, psychospiritual, sociocultural, and environmental needs of patients and families to provide relief, ease and transcendence (Kolcaba, 1991; Kolcaba, 2003; Kolcaba, 2009; Kolcaba, 2010). She further defines related terms to better describe the attributes of her theory. The terms comfort place,
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comfort interventions, and comfort needs are intertwined with health-seeking behaviors, institutional integrity and intervening variables, which are defined in Table 2.

Understanding the key terms of the Comfort Theory is integral to its application. The addition of definitions of transcendence and transcendent comfort provide further depth in understanding the underpinnings of the Comfort Theory. The application of the key concepts is evident in the assumptions and propositions of the Comfort Theory, seen in Table 3. Kolcaba’s assumptions fit well into the metaparadigm of nursing. The concepts of person, environment, health and nursing are the essential concepts of the metaparadigm (McEwen, 2011). The Comfort Theory focuses on the interaction of these concepts and their impact on relief, ease, and transcendence of pain and existential distress. The propositions link the concepts together to form a conceptual framework, which will be discussed in relation to this capstone project.

The concept of comfort has broader application across the disease entities of advanced pediatric illness. There are assessment tools for pediatrics and hospice that have already been used and tested in multiple populations, thus allowing further clarity of testability. Exploration of comfort in this population will compliment the well-established body of work investigating symptom distress and provide a depth to understanding the experience of cancer and other non-malignant diseases undergoing hematopoietic stem cell transplant.

**Intervention Related to Conceptual Framework**

The Comfort Theory provided a map upon which to base operationalization of the clinical practice question. Kolcaba’s original conceptual definitions, assumptions and propositions were revised and refined to reflect those of interest in the population of children and adolescents with advanced or high risk cancers and other non-malignant diseases undergoing
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This section will briefly describe the hypothesis derived from the application of Comfort Theory in the population of interest and a proposed intervention strategy.

Redefining the Conceptual Framework in Context

The conceptual framework is a visual depiction of the relationships between concepts, originally outlined by Kolcaba in Figure 1. Operationalizing the framework to children and adolescents with life-limiting advanced cancers, one must identify the specific properties of the framework in context. These properties are discussed below and are also outlined in the revised taxonomy (see Table 1):

1. **Health care needs of the child/adolescent with life-limiting advanced cancer** – physical symptom distress (e.g. pain, GVHD, dyspnea, fatigue, body image changes, lack of mobility, pancytopenia, etc.), psychospiritual distress (e.g. fears and anxiety, depression, neurocognitive deficits, faith beliefs, hopelessness, being a “good parent”, etc.), environmental needs (e.g. setting of choice, noise, temperature, furniture and bedding, adaptive equipment, etc.), and sociocultural distress (e.g. family presence, influence of extended family on decision making, absence or presence of culturally sensitive care, financial constraints, lack of pediatric palliative care providers in community, etc.);

2. **Comforting Interventions** – technical comfort measures (e.g. pharmacological and non-pharmacological techniques such as massage, Reiki therapy, and other integrative medicine strategies), coaching (e.g. therapeutic listening, improving communication strategies of health care team members as well as the family, bundling care, memory making activities, art therapy, music therapy, etc.), as well as other non-traditional nursing interventions that may be viewed as antiquated or non-technical (e.g. AM & PM care with limited hand/foot/back massages by nurses who are not licensed massage therapists, prayer with patients and families if asked and congruent with personal beliefs, singing, poetry, etc.);

3. **Intervening Variables** – factors that influence comfort but which nurses and health care institutions have little control over, but may directly or indirectly influence comfort (e.g. age and developmental stage of child, gender, type and stage of cancer diagnosis, financial and/or payer contraints, lack of pediatric palliative care providers in institution or community, pediatric cancer cooperative group mechanisms, scope of practice limitations of state boards of nursing for certain IV pain medications such as ketamine or propofal outside of ICU settings, etc.);

4. **Enhanced Comfort** – the immediate experience of meeting comfort needs through relief, ease and transcendence of physical and existential distress throughout the childhood cancer journey as evidenced by increasing health-seeking behaviors to promote a perception of well being despite the circumstances of life-limiting advanced cancers or other non-malignant diseases undergoing HSCT in childhood;

5. **Health seeking behaviors (HSB’s)** - defined as those behaviors which consciously or subconsciously lead the child or adolescent and family towards well-being, such as finding meaning in a life-limiting illness, congruence with faith beliefs, feeling motivated, determined and strengthened (Kolcaba, 2003). These HSB’s may be internal (i.e. reflection, prayer, meditation, relaxation, quality of life, etc.) or external (i.e. functional status, relief of...
physical symptom distress, interaction with family and friends, etc.) or those behaviors that lead to a peaceful death, if that is the eventual outcome;

6. **Institutional Integrity** – the quality of the health care institution focused on optimizing comfort of the child or adolescent with advanced cancer and their family in a holistic perspective, practicing in an ethical and professional manner to impact comfort care. This may also include reflection in payer and legal responses to promoting access to palliative care earlier in the trajectory of childhood cancer to optimize comfort throughout the cancer journey. Normand (2009) proposes a new economic metric for palliative care, the Palliative Care Yardstick (PalY). This modified cost-utility analysis approach builds in contextual factors that comprise a “good” end of life experience. Adoption of a philosophy of providing care in a “Comfort Place”, utilizing the standards of pediatric palliative care set forth by profession organizations, would also promote institutional integrity (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000; Field & Behrman, 2003; Freibert & Huff, 2009).

The operationalization of the conceptual framework is best illustrated in Figure 3, which outlines the specific linkage between Kolcaba’s conceptual framework and the adaptation in the context of children or adolescents with life-limiting advanced diseases undergoing HSCT. The underlying premise is that children or adolescents with life-limiting advanced disease present with a number of comfort needs related to desire for or deficit in relief/ease/transcendence in physical, psychospiritual, sociocultural, and environmental contexts of the childhood cancer experience. These are added to the skilled comfort interventions by the health care team but are impacted (positively, negatively or neutrally) by intervening variables over which the nurse and often the family have little control. Interventions may be aimed at relief, ease and/or transcendence as outlined in the taxonomy of comfort in the context of pediatric advanced illness, as illustrated in Table 1. An additional intervention strategy, implementing pediatric palliative care consultation, is discussed in greater detail to follow. These three variables (comfort needs, comfort interventions and intervening variables) together promote enhanced comfort. Comfort in this context is defined as a state of ease and well-being influenced by the caring and actions of nursing, which lead to transcendence of the circumstances of symptom distress, functional status and quality of life to promote a sense of well being despite the circumstances of life-limiting advanced pediatric cancer. Enhanced comfort leads to increased
health seeking behaviors (HSBs) and in turn, increased HSBs (see definition of HSBs in this context above) may promote enhanced comfort in a bidirectional relationship. Enhanced comfort and increased health seeking behaviors may lead to greater institutional integrity and in turn, embracing the philosophy of comfort care as an institution will promote patients to adopt HSBs and enhance comfort in a bidirectional relationship. The schematic drawing in Figure 3 illustrates examples of these relationships within the conceptual framework of the Comfort Theory.

**Redefining the Operational Definitions in Context**

Operational definitions allow these concepts to be measured. The conceptual definitions were discussed in the previous section and are depicted in Line 4 of Figure 3. The operational definitions are depicted in Line 5 of Figure 3. These concepts are defined as follows:

1. *Comfort needs of children or adolescents with advanced life-limiting cancers* – those symptoms (physical, psychospiritual, environmental and sociocultural) which are manifest in children or adolescents with advanced diseases undergoing HCST by virtue of each unique diagnosis and stage. Based upon the review of the literature, several key symptoms would be anticipated, including pain, dyspnea, fatigue, nausea/vomiting, anxiety, and weight loss/cachexia (Hinds, Quargnenti, & Wentz, 1992; Hongo, et al., 2003; Prichard, et al., 2008; Houlahan, Branowicki, Mack, Dinning, & McCabe, 2006; Woodgate, Degner, & Yanofsky, 2003; Walker, Gedaly-Duff, Miaskowski, & Nail, 2010). In addition, comfort needs should be qualified by which are of most concern to patients and families. Pritchard et al (2009) found the following comfort needs to be of most concern to families: unrelieved parental or child distress (39.84%); new or unexpected symptoms (39.45%); behavioral or emotional changes (10.35%); child unable to communicate (5.08%); seeing other-worldly beings/speaking of dying (2.73%); parent and/or child’s fear (2.54%);

2. *Comfort interventions* – those interventions aimed at providing relief, ease and/or transcendence of comfort needs, including pharmacological, non-pharmacological, and/or integrative medicine techniques. Examples of such interventions include things such as opioids for pain management, opioids for dyspnea as well as positioning and fan/cool mist humidifiers, guided imagery and relaxation techniques for reducing fears and anxieties, antidepressants and/or counseling services for depression, exercise and/or psychostimulants for fatigue and somnolance, antiemetics for nausea/vomiting as well as aromatherapy techniques, etc. Some of these strategies are outlined in Table 1;
3. **Demographics** – including information regarding age, gender, type and stage of diagnosis, social support available, financial and payer limitations, availability of pediatric palliative care providers in the patient/family community, siblings, and family dynamics;

4. **Physical, Psychospiritual, Environmental and Sociocultural comfort** – the state of having comfort needs met to the best possible outcome for physical (body and homeostatic mechanisms that may or may not be related to the cancer diagnosis) distress, whatever gives meaning to the life of the child or adolescent with advanced cancer and their family to promote self-esteem, self-concept, being a “good parent”, and relationship to a higher power or spiritual being, maximizing external surroundings, conditions and influences to promote comfort, and support of interpersonal, family, societal and cultural relationships including finances, education, play, customs and traditions important to each unique child or adolescent and their family;

5. **Health seeking behaviors (HSBs) through internal and/or external factors as well as peaceful death if so anticipated** - internal behaviors such as reflection, prayer, meditation, relaxation, quality of life, etc.; external behaviors such as, functional status, relief of physical symptom distress, interaction with family and friends, play, etc.; or those behaviors that lead to a peaceful death, defined by the family as the child or adolescent with advanced disease undergoing HSCT being in a state of enhanced comfort with all comfort needs met to the maximum effort possible, if death is the eventual outcome;

6. **Satisfaction** – ratings on family satisfaction surveys as well as other measures of institutional satisfaction including such factors as decreased ICU days, decreased use of non-essential medications or procedures, decreased length of stay by providing care in setting of choice, adoption of the standards of pediatric palliative care by the institution as a whole to provide care in a “Comfort Place” (Kolcaba, 2003).

**Research Question**

These operational definitions clarified the conceptual framework of Kolcaba’s Comfort Theory and provided a context to develop research and/or clinical practice questions. The clinical practice problem of interest for the capstone project was how to promote enhanced comfort in children and adolescents with high-risk or advanced cancers or non-malignant diseases undergoing HSCT and their families. The research question under investigation was:

Do children or adolescents with potentially life-limiting advanced or high-risk cancers, or other non-malignant diseases, undergoing hematopoietic stem cell transplantation and their families achieve enhanced comfort through coordinated consultation and caring interventions from a pediatric palliative care team to promote relief, ease and transcendence of the treatment experience?
Intervention

Pediatric palliative care seeks to “prevent, relieve, reduce, or soothe the symptoms produced by serious medical conditions or their treatment and to maintain patients’ quality of life” (Wolfe, et al., 2000; American Academy of Pediatrics (AAP) Committee on Bioethics, 2000). These precepts echo the concepts of the Comfort Theory. Prevent and relieve are illustrated by Kolcaba to promote relief of symptom distress. Reduce or soothe is illustrated by the concept of ease of symptoms which may not be able to be totally ameliorated but hopefully can promote improved quality of life so that a transcendent state may be achieved to allow children or adolescents with advanced cancers and their families to live the best possible life under the circumstances. The intervention developed a trigger point for every child diagnosed with a high-risk cancer requiring hematopoietic stem cell transplant, which alerted staff to the need to integrate palliative care early in the disease process. Palliative care consultation services were offered to those existing patients who were already admitted and in the midst of the stem cell transplantation so as to avoid perception of exclusion or selection bias. Palliative care consult was not intended to be a one-time intervention but rather a series of meetings with the patient and family to assess goals of care and degree of symptom distress. A time period of 3 months was electively chosen to aide in clarifying the data collection points to demonstrate feasibility of this approach to integrated care. Baseline assessments of holistic comfort were obtained prior to initiation of each consult and at two time points following palliative care consultation. The comfort scale instruments did not replace any standard institutional assessments but augmented those already being done, such as pain scales, nausea/vomiting scales, and others, which aided in determining validity. A brief schematic drawing of the project is seen in Figure 2.
Significance of the Project

Involvement of representatives from each discipline improved system readiness and provided a broad spectrum of viewpoints for adoption of the innovation on a wider scale once the project feasibility period was completed. The PANDA Care Team parent advisory council was recruited to participate in the planning stages to consider patient and family preferences, within the confines of institutional and HIPPA confidentiality restrictions. The use of thorough systematic assessment from the child, parent and health care provider perspectives of comfort as defined by symptom distress, functional status and quality of life of children and adolescents with advanced cancer, may optimize integration of intervention and supportive services early in the trajectory of potentially life-limiting illness, thus potentially avoiding prolonged suffering for this vulnerable population and fostering more positive outcomes.

Anticipated Outcomes

Integration of palliative care consultation for children and adolescents with high risk or advanced cancers undergoing stem cell transplantation, as implemented by this capstone practice change project, strived to achieve the following outcomes:

1. Improved or no worsening from baseline level of comfort of children and adolescents with high risk or advanced cancers or other non-malignant diseases undergoing hematopoietic stem cell transplantation,

2. Improved or no worsening from baseline level of caregiver comfort of parent or guardian whose child is undergoing hematopoietic stem cell transplantation,

3. Improved levels of patient and family satisfaction, and
4. Improved levels of provider satisfaction in resource availability to augment care for children and adolescents with high-risk or advanced cancers or other non-malignant diseases undergoing hematopoietic stem cell transplantation.

**Summary**

Comfort is a universal goal of health care and multiple pediatric professional organizations have set a standard to promote relief of symptom distress and promote quality of life (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000; Freibert & Huff, 2009). Exploration of Kolcaba’s Comfort Theory validates and adds depth and richness to the childhood hematopoietic stem cell transplant experience, moving past the traditional goals of alleviating physical symptom distress to define concepts that promote transcendence. The goal of enhanced comfort is the utmost concern of children and adolescents with advanced or high-risk cancers or other non-malignant diseases undergoing HSCT and their families (Mayer, Tighouart, Terrin, Stewart, Peterson, Jeruss, & Parsons, 2009). The Comfort Theory is an adequate guidepost for addressing clinical practice issues within this patient population. Physicians and health care providers must provide access to therapies that are likely to improve quality of life (AAP, 2000). Clinical research on the effectiveness and benefits of interventions to relieve pain and symptom distress is paramount (AAP, 2000). Palliative care is about the living, and if the eventual outcome is death, then to promote peace and transcendence.
Section Two

A literature review was undertaken to investigate the evidence regarding integration of palliative care for children and adolescents with advanced cancers or other non-malignant diseases undergoing HSCT. The literature review included studies addressing: 1) symptoms (physical and/or existential distress) in pediatric advanced cancers or other non-malignant diseases; 2) symptoms (physical and/or existential distress) specific to hematopoietic stem cell transplant in children or adolescents; 3) quality of life; and 4) pediatric palliative care.

Using the PICO Format as a Framework to Search the Literature

To address the practice problem, an evidenced-based solution was sought utilizing the PICO framework to begin the literature search (Newhouse, Dearholt, Poe, Pugh, & White, 2007). The PICO question was developed by identifying the four key components:

- **P (Patient, Population or Problem):** Pediatric patients, ages 1 month to 21 years of age, with advanced cancers or other non-malignant diseases undergoing hematopoietic stem cell transplant (HSCT)
- **I – (Intervention):** Palliative care consultation and intervention
- **C – (Comparison with other treatments, if applicable):** No palliative care consultation or interventions provided, i.e. current standard of medical and nursing care
- **O – (Outcomes):** Enhanced comfort

Thus the PICO question explored was:

Do children or adolescents with potentially life-limiting advanced or high-risk cancers, or other non-malignant diseases undergoing hematopoietic stem cell transplantation and their families achieve enhanced comfort through coordinated consultation and caring interventions from a pediatric palliative care team to promote relief, ease and transcendence of the treatment experience as compared to standard medical and nursing care alone?
The Search for Evidence

The quest for evidence to answer this question was undertaken with searches of the CINAHL, Cochrane, OVID, PsychInfo and PubMed databases. Palliative care is a relatively new field of practice. Finding relevant literature was limited by the lack of key search keywords and MeSH terms pertinent to palliative care (Sladek, Tieman, & Currow, 2007; Sladek, Tieman, Fazekas, Abernathy, & Currow, 2006). There is a paucity of research in palliative care, with pediatric palliative care research even more sparse, thus limiting the ability to locate high quality evidence. Other strategies to identify evidence included reviewing references cited in studies identified from database search and searching known journals, which have featured articles on pediatric advanced cancers, stem cell transplant and/or pediatric palliative care. Examples of such journals included: Bone Marrow Transplantation, Journal of Hospice and Palliative Medicine, Journal of Hospice and Palliative Nursing, Journal of Pain and Symptom Management, Journal of Pediatric Hematology Oncology, Journal of Pediatric Oncology Nursing, and Pediatrics.

Keywords and MeSH terms. Keywords that were used in the search included “pediatric cancer”, “symptom distress”, “quality of life”, “palliative care”, and “hematopoietic stem cell transplantation”. MeSH terms used included “neoplasms” and “pediatrics” and “signs and symptoms” or “quality of life”. A separate search was done using “palliative care” or “terminal care” and “pediatrics” and "hematopoietic stem cell transplantation" as relevant MeSH terms. These search terms were used after consultation with a medical librarian and recommendations provided in the literature (Sladek, Tieman, & Currow, 2007; Sladek, Tieman, Fazekas, Abernathy, & Currow, 2006).
**Inclusion criteria.** Initially 2,987 articles were returned from the MeSH search. Screening of titles and abstracts was done to quickly exclude those that were not pertinent to pediatrics or palliative care. Inclusion criteria regarding study design was broad to include qualitative as well as experimental studies. Only pediatric studies were included and further narrowed to those specifically with a sample of pediatric oncology patients or other non-malignant diseases commonly referred for HSCT. The search was narrowed for recent articles from 2008 to 2012, but when this did not yield significant results, the time period was broadened to include articles from 2000 to 2012. Studies were only considered if they included information on symptoms and/or quality of life in pediatric patients, with preference given to those for children with advanced diseases or if related to palliative care for pediatric oncology or HSCT patients.

**Exclusion criteria.** Studies were excluded if they related to adult patients only, were greater than ten years old or did not include information regarding symptoms, quality of life, HSCT, or palliative care. Studies were also excluded after critical review if they were deemed to have significant limitations and thus were of poor quality, as per the criteria set forth by Newhouse, Dearholt, Poe, Pugh, and White (2007). When narrowed down to pediatric oncology, hematopoietic stem cell transplant and palliative care, 155 articles were identified as potentially relevant. After in-depth review of the articles, there were 23 articles specific to symptoms, 6 articles specific to quality of life, and 11 articles relevant to pediatric palliative care in general, with some overlapping in categories. There were 40 articles reviewed which are included in the summary, found in Appendix II.

**Review of the Evidence**

Review of the 40 pertinent articles was done using the Johns Hopkins Nursing Evidence-Based practice model (Newhouse, Dearholt, Poe, Pugh, & White, 2007). Rating of the evidence
was accomplished using the same model and confirmed using the GRADE model of evidence assessment (DiCenso & Guyatt, 2005). A summary of the evidence is in Appendix I and an individual summary of the evidence in Appendix II.

Most of the evidence regarding pediatric advanced cancers and other non-malignant diseases, symptom distress and quality of life is Level III (Sladek, Tieman, & Currow, 2007; Sladek, Tieman, Fazekas, Abernathy, & Currow, 2006). This is due to qualitative measures being the best available methods to examine these phenomena given the current state of the science. Pediatric patients with advanced disease are a vulnerable population who may undergo treatment on randomized clinical trials as a part of frontline therapy. A limiting factor in pediatric palliative care research is the discomfort of researchers to approach families in such a vulnerable state (Hinds, Pritchard, & Harper, 2004). Nevertheless, the synthesis of the available evidence yielded sufficient support to investigate the integration of early palliative consultative services for children and adolescents undergoing HSCT.

**Synthesis of the Evidence**

**Symptom distress in advanced pediatric cancers or serious non-malignant diseases.**
Little of the literature is research-based and is descriptive in nature, but pain and its medical management is most commonly addressed (Kane & Primomo, 2001; Kane, Barber, Jordan, Tichenor, & Camp, 2000; Frager, 1996; Liben, 1996; Attig, 1996; Collins, 1996; Hunt, Goldman, Devine, & Phillips, 2001; Kenny & Frager, 1996). A wide variety of symptoms are reported in pediatric patients with advanced cancers and other advanced non-malignant diseases. The most common symptoms included pain, fatigue, dyspnea, nausea/vomiting, anxiety and weight loss/cachexia (Hinds, Quargnenti, & Wentz, 1992; Hongo, et al., 2003; Prichard, et al., 2009; Houlahan, Branowicki, Mack, Dinning, & McCabe, 2006; Woodgate, Degner, &
Yanofsky, 2003; Walker, Gedaly-Duff, Miaskowski, & Nail, 2010; Baggott, Dodd, Kennedy, Marina, & Miaskowski, 2009). This section reviews pertinent studies of symptom distress in pediatric advanced cancers.

Prichard, Burghen, Sirvastava, Okuma, Anderson, Powell, et al (2009) conducted a qualitative, descriptive exploratory study of 65 bereaved parents of 52 children to describe symptoms of children with advanced cancers. They found 18 symptoms noted by parents. The most frequently noted were pain, changes in behavior, change in appearance, breathing difficulties, weakness and fatigue, and changes in heart rate. More symptoms were reported in children with brain tumors than other cancers. The sample size was moderate and limited to only inpatient deaths, thus limiting generalizability. The study was conducted approximately 6 to 10 months after the child's death so there may have been threats to history and maturation over time with difficulty recalling symptoms or embellishment with perseveration. This study is useful as it is limited to pediatric oncology and described numerous symptoms which potentially may increase distress and suffering.

Wolfe and colleagues conducted a qualitative descriptive study, in which they interviewed 103 parents of 103 children who had died, to specifically determine symptoms experienced by dying children as perceived by their parents (Wolfe, et al., 2000). Parents reported their child was “suffering”, and in many cases interventions were not adequate to relieve symptom distress. Symptoms most frequently experienced by these dying children were pain, fatigue, or dyspnea. Sadly, parent perceptions were that only 27% of children with pain and 16% with dyspnea received symptom relief. Study conclusions were that attempts to alleviate symptoms in dying children were often unsuccessful, thus these children experienced substantial suffering at the very end of life (Wolfe, et al., 2000). As one of the first pediatric studies, this is a landmark
study in palliative care, illustrating the need to focus on symptom management and promotion of comfort.

The comfort needs of children or adolescents with advanced life-limiting cancers or other non-malignant diseases are those symptoms (physical, psychospiritual, environmental and sociocultural) which are manifest in children or adolescents with advanced disease by virtue of each unique diagnosis and stage. However, the presence or absence of symptoms is not enough to determine existential distress. What may be viewed as a minor inconvenience to one child, or family, may be a great source of existential distress to another. In a qualitative, descriptive study, Pritchard, Burghen, Gattso, West, Gajjar, Srivastava, Spunt, Baker, Kane, Furman, and Hinds (2010) interviewed bereaved parents (n=48 mothers and 4 fathers of 52 children) 6 to 10 months after their child's death. Parents noted 109 symptoms, however, not all symptoms were noted to be distressing for the child and/or parent. Prichard et al (2010) found the following comfort needs to be of most concern to families: unrelieved parental or child distress (39.84%); new or unexpected symptoms (39.45%); behavioral or emotional changes (10.35%); child unable to communicate (5.08%); seeing other-worldly beings/speaking of dying (2.73%); and parent and/or child’s fear (2.54%).

Fatigue is a common symptom in children with advanced illness. Ullrich, Dussel, Hilden, Sheaffer, Moore, Berde, and Wolfe (2010) conducted a retrospective, cross-sectional study of 141 bereaved parents of children with advanced cancer, which noted that 96% of parents reported their child experienced fatigue, and 56% of those reported significant suffering from fatigue. Ullrich et al (2010) also reported that increased suffering from fatigue correlated with the presence of other symptoms including pain (68.7%), dyspnea (59.1%), anorexia (34.9%), nausea/vomiting (31.8%), diarrhea (27.3%), anxiety (38.2%), sadness (73.9%), or fear (70%).
Another interesting finding of their study is that parents whose children had less experienced primary oncologists (mean = 4.9 years) versus more experienced oncologists (mean = 9.9 years), reported greater suffering from fatigue. In this cohort of parents, only 13% reported that their child had interventions directed at relieving fatigue and of those only 25% reported any improvement (Ullrich, et al., 2010). These studies describe significant symptom distress experienced by children with cancer, yet highlight the lack of attention to promotion of comfort through providing and evaluating effective interventions to relieve suffering.

Parents' perceptions of their child's suffering from symptoms may impact their own distress (Poder, Ljungman, & Von Essen, 2010; Pritchard, et al., 2010). In a large (n=214), prospective, longitudinal descriptive study of cancer-related symptom using parental report, on the Memorial Symptom Assessment Scale (MSAS) and the Post-Traumatic Stress Disorder (PTSD) Checklist - Civilian version, investigators found symptoms that were most distressing included emotional distress, fatigue, nutrition and pain (Poder, Ljungman, & Von Essen, 2010). Symptom prevalence and burden increased over time and parents of adolescents reported greater burden than did parents of younger children. Parents' ratings of their own distress correlated with the rating of their child's distress. There was good concordance with previously published studies of child self-report with most parents (96-100%) providing information about prevalence, frequency, intensity and level of distress (Poder, Ljungman, & Von Essen, 2010). Results of this study should be reviewed with caution as the study was done in Sweden so it may not be generalizable to the childhood cancer population in the United States. Concordance between parent and child is significant, as parents must often serve as surrogates in reporting symptom distress due to the age, developmental state, or clinical status of the child. Even with
concordance, ratings of symptom distress should not be considered in isolation to the meaning of that symptom.

Children with cancer often attach meaning to symptom; thinking that the cancer experience must always be distressing, one must have pain to obtain cure/improvement in disease, and that one never gets used to having symptom distress (Woodgate, Degner, & Yanofsky, 2003). Children do understand the definitions of common symptoms but those with cancer commonly use alternate words to describe their symptoms, which may lead to misinterpretation by the health care team or parent caregivers (Vatne, Slaughter, & Ruland, 2009). They also report stages of symptom distress, with some symptoms starting out as tolerable and sometimes progressing to intolerable (Woodgate, Degner, & Yanofsky, 2003). Woodgate, Degner and Yanofsky (2003) conducted a qualitative, exploratory study of 39 children with various cancers at three pediatric cancer centers. They found that self-report scales were not adequate for representation of symptom distress. Children may not fully understand the context of a symptom or cluster of symptoms, thus the clinician must use any self-report as a starting point for communication about the child's insights into frequency, intensity and distress of symptoms (Vatne, Slaughter, & Ruland, 2009). Meaning is assigned to symptom distress by children and families, which may impact the meaning of the cancer experience. The assigned meaning may be different for each unique child and/or family (Woodgate, Degner, & Yanofsky, 2003; Woodgate, 2008). Clinicians must explore the attached meaning of symptoms and its perceived role in the cancer experience for each family. Clinicians need to be aware that some children and families may not report symptoms that they feel may be a normal expectation of the cancer experience or in some extremes, that they feel may be indicative of worsening disease for fear of diagnosis of relapse (Woodgate, Degner, & Yanofsky, 2003; Woodgate, 2008).
Finally, a systemic review of symptoms in pediatric oncology patients compared nine recent pediatric studies to summarize the evidence regarding multiple symptoms in children with cancer. Symptom management research is increasing in pediatrics, however, there is still little describing the phenomena of multiple symptoms or symptom clusters. Although some symptoms are measurable, i.e. pain, nausea/vomiting, diarrhea, other symptoms causing distress are not easily quantifiable, making management strategies challenging. Baggott, Dodd, Kennedy, Marina and Miaskowski (2009) reviewed nine pediatric studies to examine the instruments used, prevalence, characteristics, and relationship between multiple symptoms. Their search criteria and review criteria were systematic and well described, leading to a well-done systematic review with clinical implications for recognizing and treating symptoms early. They found that descriptions of prevalence, severity and levels of distress varied greatly across instruments, so comparison between instruments is not possible. Only four of the studies reported symptom distress, thus supporting the need for more investigation into this phenomenon. Baggott et al also recommended administration of instruments within 24 – 48 hours to decrease the risk of recall bias. All of the reviewed studies were cross-sectional, prospective designs. Convenience samples were used consistently. However, only three of the reviewed studies were conducted in the United States making generalizability of the findings questionable.

The ten most prevalent symptoms reported (in order of grand mean between all studies) were weight gain/loss, fever, sore throat, lack of energy, alopecia, drowsiness, bruising, pain, anorexia, and infections. When categorized by severity (% of respondents answering moderate, severe or very severe), the most common symptoms included: difficulty paying attention (90%), problems with urination (90%), irritability (85.7%), pain (84.2%), difficulty swallowing (83.8%),
shortness of breath (83.3%), constipation (81.8%), and sadness (60%). When categorized by level of distress (% of respondents answering quite a bit or very much) the most common symptoms included difficulty swallowing (76.1%), mouth sores (70%), nausea (65%), insomnia (58.7%), sadness (50%), altered body image (49.5%), and insomnia (39%) (Baggott, Dodd, Kennedy, Marina, & Miaskowski, 2009). This systematic review illustrates the need to standardize instruments measuring symptom distress and to assess not only the presence of symptoms but also to address severity and distress. Interventions must address all components of the symptom experience to promote comfort. Symptom distress may be exacerbated by the morbidities of treatment. HSCT is a modality used to treat a variety of childhood malignancies and non-malignant diseases. In the context of this review, hematopoietic stem cell transplantation was explored with respect to symptom distress related to treatment.

**Symptom distress in hematopoietic stem cell transplantation.** There is limited evidence regarding multiple symptoms in HSCT. The evidence reviewed focused on a single symptom, such as GVHD, in detail with little discussion on the presence of multiple symptoms or symptom distress. Most studies were either case reports or limited to a single disease entity, thus making findings difficult to generalize to the HSCT population at large. The most common symptom reported was acute and chronic graft versus host disease. GVHD can be mild to severe and acute or chronic. Flares of GVHD can occur at any time post-transplant, potentially adding to distress and discomfort (Jacobsohn, 2008). Symptoms of GVHD can include rash, crampy abdominal pain, diarrhea, persistent nausea/vomiting, and hepatitis (Jacobsohn, 2008). Acute symptoms often experienced during HSCT include infections and pancytopenia requiring frequent blood product transfusion (Reggio, 2011; Maltezou, Kafetzis, Abisaid, Mantzouranis, Chan, & Rolston, 2000). Other common symptoms include pain, mucositis, fluid imbalance,
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veno-occlusive disease, pulmonary hypertension and alterations in nutrition (Rawlinson, Fung, Gross, Termuhlen, Skeens, Garee, Soni, Piertryga, & Bajwa., 2011; Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011). Symptom distress impacts the ability of the child or adolescent to perform activities of daily living, including school, play and peer activities (Roeland, et al., 2010). The impact of symptom distress on quality of life must be considered for children and adolescents undergoing HSCT and their families.

**Health-related quality of life.** Quality of life endpoints are considered a significant clinical outcome for treatment success (Lipscomb, Reeve, Clauser, Abrams, Watkins Bruner, Burke, Denicoff, Ganz, Gordek, Minasiam, O'Mara, Revicki, Rock, Rowland, Sgambati, & Trimble, 2007). Few studies to date have addressed symptoms or the quality of life experienced by children with advanced cancer or who are dying of cancer (Hinds, et al., 2009). The few reports that are available do not include study sample information regarding whether or not the patients were or had been receiving anti-cancer directed therapies. Both pediatric oncology professionals and families have questions about the burden of HSCT for patients where cure seems unlikely. Questions about burden relate to potential toxicities of the HSCT and to requirements for medication administration and for monitoring the child's response to the treatment. Questions about benefit also relate to the child and family’s likely quality of life if the child is to undergo HSCT, and possible symptom and disease responses to the transplant process. Having information about patients’ quality of life, symptom experience and family burden may assist professionals and parents with the decision-making process regarding whether or not to consider enrolling the ill child in a clinical trial or pursuing other anti-cancer directed therapies, including HSCT. In addition, this information may prove valuable to assisting with provision of
hospice and palliative care services for this vulnerable population who is often left with few options for terminal care.

HRQOL is dramatically impacted by symptom distress (Roddenberry & Renk, 2008). Perceived suffering of the child impacts the entire family (Woodgate, Degner, & Yanofsky, 2003). Symptom distress and OOL improved with integration of palliative care (Wolfe, et al., 2008). Many children are able to participate in EOL decision-making (Hinds, Drew, Oakes, Fouladi, Spunt, & Furman, 2005). Patients with metabolic and genetic disease who have undergone HCST continue to require life-long complex care requiring follow-up by multiple specialties (Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011). Consideration must be made prior to transplant of the additional burden of toxicity and continued adaptive functioning needs of these children despite successful HSCT (Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011). Transplant options should be discussed early with families of children with metabolic and genetic disorders amenable to HSCT to maximize intellectual and functional status, which may decline as a result of the underlying disease if HSCT is not done early in the disease process. However, despite continued symptoms and toxicities of HSCT, parents feel that their child has meaningful life following HCST (Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011).

HRQOL on patients with advanced cancers or refractory non-malignant diseases is often not reported in studies of treatment modalities or symptom distress. Brandt, Dietrich, Meissner, Neben, Ho and Witzens-Harig (2010) reported no difference in HRQOL of patients with relapsed leukemia or lymphoma who underwent HSCT as compared to similar patients who received conventional chemotherapy, however, these patients did have decreased HRQOL as compared to normal controls (Brandt, Dietrich, Meissner, Neben, Ho, & Witzens-Harig, 2010; Borchmann,
Burden, benefit and quality of life must be thoughtfully considered in decision-making discussions with patients and families. Palliative care may assist families with difficult decision-making and provide an outlet for discussions regarding burden/benefit, quality of life and symptom distress.

**Pediatric palliative care as an intervention.** The previous sections have demonstrated the need for improvement in symptom management to affect improved health related quality of life. Palliative care seeks to "prevent, relieve, reduce, or soothe the symptoms produced by serious medical conditions or their treatment and to maintain patients’ quality of life" (Field & Behrman, 2003, p.33). Palliative care is one method of planning interventions addressing the whole person, promoting comfort by relief, ease and transcendence of the illness experience. How then can we insure that children and adolescents with advanced cancer and other serious non-malignant disease undergoing HSCT have access to these services? Several key agencies have published statements regarding the need to improve palliative and end of life care.

The Agency for Healthcare Research and Quality (AHRQ) (2004) commissioned a report to evaluate progress in end-of-life care research and to establish priorities for palliative care research, however, this report focused on adults and excluded pediatric studies (Lorenz, Lynn, Morton, Dy, Mularski, Shugarman, Sun, Wilkinson, Maglione, & Shekelle, 2004). In 2008, a survey was conducted of 232 member institutions of the Children's Oncology Group, the largest pediatric cancer cooperative group in the United States (Johnston, Nagel, Friedman, Meza, Hurwitz & Friebert, 2008). Of the respondents, only 58% replied they had a palliative care program, while 90% identified the presence of a pain service. Psychosocial support programs were identified in 80% and bereavement programs were available in 59% (Johnston, Nagel, Friedman, & al, 2008). However, this survey was completed by a representative at each
institution and no description of the services or staffing of programs was given, thus this may be an over estimate of the palliative care services actually available for practical use by patients and families. This study illustrates the lack of available palliative care services for a highly vulnerable population with great need for palliation of symptom distress.

The American Academy of Pediatrics supports integrated palliative care services for children with advanced, potentially life-limiting illnesses (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000). The AAP identified the following principles as the minimum expectations for integrated pediatric palliative care: respect for the dignity of patients and families, access to competent and compassionate palliative care, support for caregivers, improved professional and social support for pediatric palliative care providers, and continued improvement of pediatric palliative care through education and research (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000). Palliative care should be integrated from diagnosis, throughout curative treatment into survivorship or death, if that is the ultimate outcome (American Academy of Pediatrics (AAP) Committee on Bioethics, 2000; Foster, Lafond, Reggio, & Hinds, 2010).

The Institute of Medicine (IOM) published a report in 2003, which highlighted the need to focus efforts on improving care for children at end of life as well as those with potentially life-limiting illness. The IOM also noted that care for children who are dying or have serious, life-limiting illness, must be compassionate, competent and consistent in addressing physical, emotional, and spiritual needs. Families often face difficult choices regarding curative therapies when forced to choose between active treatment approaches and palliative care. Finally, the IOM recognized the need for research into ways to provide evidence based care for patients and
families, and to educate healthcare providers to provide compassionate, competent care (Field & Behrman, 2003).

Significant challenges exist for institutions to develop pediatric palliative care services. One challenge is that there is little research in pediatric palliative care to guide practice. Much of medicine is driven by evidence based practice and clinical trials to guide decision making and treatment choices (Houlahan, Branowicki, Mack, Dinning, & McCabe, 2006). Another challenge is lack of funding. Many programs exist on grant funding or philanthropic support. Competing priorities for healthcare dollars often force institutions to minimize funding support for palliative care programs (Harper, Hinds, Baker, Hicks, Spunt, & Razzouk, 2007).

Two institutional surveys of health care professionals at Children's National, including physicians, advanced practice nurses, staff nurses, patient care technicians, social workers, child life therapists, and pastoral care providers were undertaken in 2003 and 2010 to ascertain attitudes and beliefs regarding palliative care practices within the institution and integration into practice. The first survey (n=84) was undertaken in 2003 prior to planning and implementation of the Pediatric Advanced Needs Assessment and Care Team (PANDA Care Team). Results of this survey included that the majority of respondents (78.3%) felt that palliative care services would be beneficial but that they should not be offered until near death. Respondents (66.4%) also noted that they felt uncomfortable in discussing advanced directives with patients and families (Lafond & Silva, 2003).

The second survey, conducted in 2010 after approximately 4 years of hospital wide PANDA Care Team services, featured the majority of responses (n=489) from nurses (47.5%) and attending physicians (21%), who are the front line providers of care for children and adolescents with potentially life-limiting illnesses. The remaining respondents (38.5%) included fellows, residents,
social work, child life, and pastoral care providers. The following were indicated as of essential importance in caring for children with serious illness: pain management (84.1%), family support (82.8%), symptom control other than pain (61%), psychological/psychiatric assessment and care (60.5%), assistance with referrals to supportive care services (57%), and spiritual care (53.7%). Respondents (63.8%) felt that palliative cares should be introduced at the time of diagnosis of a potentially life-limiting illness. Respondents (58.6%) also indicated that discussions of advanced directives should always occur for children under the age of 13 and for adolescents (age 13-17 years) who are able to comprehend and understand their wishes and 91.2% felt that these discussions should always occur for young adults 18 years and older (Lafond & Jacobs, 2010). These two surveys underscore the need to offer palliative care services to children/adolescents and their families to promote quality of life and relief from symptom distress.

Summary

For patients and families, quality of life and survivorship continue to be the primary goals even as the underlying disease advances. Data from this review supports that symptom distress is significant for children with advanced cancers, and other serious life-limiting, non-malignant diseases, and impacts quality of life. Health care must not merely be vested in tumor outcomes but address quality of life and functional status outcomes. Quality of life endpoints are considered to be a significant clinical outcome for treatment success (Patrick, et al., 2007). Data is lacking regarding the impact on quality of life and overall long-term distress for children with advanced cancers or non-malignant diseases who undergo HCST. Improvement in these areas through early integration of palliative care services may provide patients, parents, and the healthcare team with strategies to promote transcendent comfort throughout the HCST experience, whether the outcome leads to cure or to death.
This capstone project evaluated the feasibility of a clinical practice change to implement coordinated palliative consultation to provide caring interventions to promote comfort, defined as relief and ease of symptom and existential distress, and transcendence of the treatment experience. The project evaluated the time required to provide consultation and interventions, satisfaction of families and the health care team with integration of palliative care services into the HSCT treatment experience, and concordance of assessment of comfort by children/adolescents and their parents. The Methodology section describes the methods for sample selection, the setting, methods for data collection and analysis, a discussion of the findings, and a proposed translation plan for the evidence gained from this project.
Stem cell transplant is described as one of the most stress provoking treatment modalities, often resulting in physical, psychological and emotional distress for patients and families during and after the transplant experience (Roeland, et al., 2010). Care promoting comfort should be offered to children and adolescents with high-risk cancers or serious non-malignant disease and certainly in the setting of relapsed or refractory disease or high-risk therapies with significant morbidities, such as HSCT (Johnson, Nagel, Freidman, Meza, Hurwitz, & Freibert, 2008). Families frequently report dissatisfaction with information provided initially in the HSCT process when reflecting back on distress from morbidities experienced during the transplant journey (Roeland, et al., 2010). Palliative care seeks to promote comfort and transcendence of distress from the morbidities of treatment.

Palliative care consultation is currently not a routine part of care for patients undergoing HSCT and their families at Children's National. The clinical practice hypothesis is that providing children and adolescents with advanced or high-risk cancers or other non-malignant diseases undergoing stem cell transplantation and their families access to palliative care services early in the transplantation process will promote enhanced comfort through relief, ease and transcendence of physical and existential distress. If distress is mitigated, then patients and families may have improved satisfaction with the transplant experience. Evidence regarding the use of palliative care strategies in the setting of HSCT is limited and palliative care consultation is currently not a standard of care for this population. The HSCT team, including advanced practice nurses, and nursing staff at Children's National strive to develop strategies to improve care that promotes comfort and transcendence of the HSCT experience, which may include
palliative care interventions. Nurses are committed to changing practice to improve care promoting comfort.

**Design**

The capstone project evaluated the feasibility of a proposed practice change, utilizing the intervention of palliative care consultation to promote comfort, through a prospective, longitudinal cohort study of children and adolescents with high-risk cancers or other serious non-malignant diseases undergoing HSCT and their families. This feasibility study examined willingness of patients and families of a vulnerable population to receive the palliative care intervention, willingness of the health care team to refer patients and families for the intervention, resource allocation (time and activities), and the perceived value added of the intervention as evidenced by family and provider satisfaction. These outcomes are hallmarks of feasibility studies (Arain, Campbell, Cooper, & Lancaster, 2010). Although the secondary aims included evaluation of comfort, the main focus of this study remained the feasibility of a unique care intervention directed toward this specialized population. The primary aims of the study were to evaluate the practicality of the proposed practice intervention and satisfaction of palliative care consultation in this patient population from the perspectives of patients and families as well as the health care team.

**Aims.** The primary project aims included:

1) To assess and describe the feasibility of providing palliative care consultation for children and adolescents with high-risk or advanced cancer or other non-malignant diseases undergoing stem cell transplantation at Children's National and their families as evidenced by:
a. at least 70% percent of patients and families who are approached for enrollment will consent to participate in the project,

b. at least 70% of interventions identified by families as needed to promote comfort are provided for each patient/family unit, and

c. resource allocation including the time required for interventions from palliative care team personnel and interventions provided as tracked by a Time and Activity Log.

2) To describe satisfaction of families and satisfaction of Hematopoietic Stem Cell Team providers (attending physicians, fellows, nurse practitioners/physician assistants, and unit based staff nurses) with the palliative care consultation process, as evidenced by at least 70% of families and providers indicating an overall rating of 4 on a 5 point Likert scale PANDA Care Team Family and Provider Satisfaction Survey.

The secondary project aims included:

1) To assess and describe comfort levels of children and adolescents with high-risk or advanced cancer or other non-malignant diseases undergoing stem cell transplantation at Children's National by self-report on the Pediatric Comfort Scale or Comfort Line Visual Analog Scale.

2) To investigate and describe concordance of assessment of comfort of children and adolescents with high-risk or advanced cancer or other non-malignant diseases undergoing stem cell transplantation at Children's National as reported by parent or guardian on the General Comfort Scale – Parent Form.
Sample

A non-probability, convenience, sampling strategy was used. This method was chosen as it was the most economical and practical approach in a single institution setting. Children and adolescents with high-risk cancers or other non-malignant diseases undergoing HSCT were recruited to participate in this study. As previously established, this was a vulnerable population with a high probability of physical and existential distress. Determining inclusion criteria assisted in establishing the desirable sample.

**Inclusion criteria.** Potential participants were identified by the HSCT team. Only English speaking families were recruited as the assessment questionnaires were not available in other languages in the format used for this study. Children and adolescents from 1 month to 21 years of age were included in the study sample, as the study was limited to pediatrics HSCT. Ideally, participants were recruited at the time of initial consideration for HSCT, however, participants were offered enrollment in the study up until the time of admission for transplant. Patients and families who were already admitted (N = 3) to study site and in the midst of the transplant process were also offered the same interventions to avoid the bias of exclusion from potentially beneficial services. Information for this rationale relates to the setting, which is discussed in more depth in the subsequent section. A representative sample was recruited to establish feasibility of the proposed practice change.

**Sample demographics.** Traditional calculation of sample size is not required for feasibility studies (Arain, Campbell, Cooper, & Lancaster, 2010). Sample size was estimated by determining a reasonable number of participants to demonstrate the practicality of the project. An estimated 3-5 children and adolescents are considered for HSCT at the study site each month. The prediction of an exact number of children and adolescents who would be available during
the study period was difficult, however, it was estimated that a minimum sample of 10 would be adequate to establish feasibility of this capstone project. All patients and families who were considered for HSCT at the study site were considered for enrollment on this study.

Demographics of the sample are presented in Table 4. This study achieved 100% enrollment with all English-speaking patients and families approached giving informed consent. Several non-English speaking families (N=4) were referred for enrollment by the HSCT team, however, they were not offered enrollment as the data collection tools were not available in languages other than English. One participant was referred by the HSCT team but the transplant was delayed multiple weeks, therefore data for this participant is incomplete and is not included in the analysis. This represented a 100% referral pattern by the HSCT team (Reggio, Yates, & Tosca, 2012).

Of the English-speaking families enrolled, there were 6 males (50%) and 6 females (50%), and their parents, who participated in the study. Patients ranged in age from 14 months to 20 years, with a mean of 8.8 years. The majority of participants were under the age of 7 years (N = 5, 41.7%) or in the school age group 7 to 13 years (N = 5, 41.7%), with only one adolescent (8.3%), and one participant over the age of 18 years (8.3%). Mothers were most often the primary caretaker during HSCT (N = 7, 58.3%), followed by both parents equally sharing care responsibilities (N = 3, 25%). Fathers also served as primary caretakers for a small minority of the sample (N = 2, 16.7%). Participants had a variety of diseases, including leukemias (N = 3, 25%), solid tumors (N = 4, 33.3%), underlying genetic diseases (N = 4, 33.3%), and other non-malignant diseases (N = 1, 8.3%). The majority of participants (N = 7, 58.3%), underwent allogeneic (from a donor) stem cell transplant with three participants (25%) undergoing autologous (their own harvested stem cells) stem cell transplant and two participants (16.7%)
receiving cord blood (from a donor placenta) transplant. This convenience sample was recruited from a single site.

**Setting**

The site for this feasibility project was Children's National Medical Center, a tertiary care center serving over 360,000 patients and families from the nation and around the world each year (Children's National Medical Center, 2011). The Blood and Bone Marrow Transplant program at Children's National is the only dedicated pediatric stem cell transplant program in the region and is a National Institutes of Health funded BMT clinical trials center. Over 400 stem cell transplants have been performed at Children's National since 1988 (Children's National Medical Center, 2011).

The multidisciplinary HSCT team consisted of attending physicians, fellows, advanced practice nurses, physician assistants, registered nurses, social workers, psychologists, child life therapists, and pastoral care specialists committed to providing state of the art care in a dedicated 10-bed bone marrow transplant unit. The HSCT unit is an intimate setting where parents are able to meet informally to network and discuss common stressors. For this reason, patients and families who were already admitted to the unit at the time of the implementation of this feasibility study (N=3) were offered the same interventions to avoid a perception of bias. This setting served well to measure feasibility of implementing palliative care interventions for children and adolescents with high-risk cancers and non-malignant diseases undergoing HSCT and their families, as it was a nationally accredited HSCT program, affiliated with national pediatric cancer and HSCT consortia, representative of most pediatric HSCT centers in the United States (Children's National Medical Center, 2011).
Measures and Analysis of Procedures

This feasibility study could also be described as a descriptive, correlational study as it sought to describe the feasibility of palliative care intervention and its relationship to comfort of children with advanced cancers and other non-malignant diseases undergoing HSCT rather than investigating cause and effect (Polit & Beck, 2008). This was a non-experimental design because there was no random selection or assignment for this sample. Feasibility was measured by accrual and by describing the time and activities of palliative care personnel in the consultation process. Satisfaction of families and the HSCT team with palliative care consultation and interventions to indicate a value added service that promotes comfort also served as a measure of feasibility. Primary success of the proposed practice change was measured by satisfaction, as the best ideas are not feasible if the ones receiving the intervention do not view the practice change as a value added service to improve comfort, also a variable of interest.

Variables

The dependent variables were feasibility, satisfaction and transcendent comfort. Feasibility was operationally defined as patients and families wanting palliative care services, the ability to provide the palliative care interventions that are identified by patients and families as important to them, and documentation of the time required to provide these services. Satisfaction was defined as the perception of the family, and primary HSCT team, that the intervention provided improved comfort for a specific child and that family views the intervention as a value added service that improved the experience of HSCT. Transcendent comfort was operationally defined as a state of ease and well-being influenced by the caring and actions of nursing, which lead to transcendence of the circumstances of symptom distress, functional status and quality of life to promote a sense
of well being despite the circumstances of life-limiting or advanced pediatric cancer or other non-malignant disease undergoing hematopoietic stem cell transplant. The independent variable was the process of palliative care consultation and intervention. The data collection instruments assessed feasibility, satisfaction and comfort, as described in the study aims.

**Instrumentation**

Primary and secondary aims of this study were measured using the following instruments/tools: Study Participant Log and Demographic Data Collection Tool, Time and Activity Log, PANDA Care Team Family Survey, PANDA Care Team Provider Survey, General Comfort Questionnaire – Parent/Guardian Form, and the Children's Comfort Daisies and Comfort Line Visual Analog Scale. Consideration of issues related to human subjects was paramount and all efforts were made to ensure confidentiality, privacy and respect, as is the standard of ethical research. Data was de-identified to protect patient confidentiality. Demographic data, including: patient initials, age, sex, diagnosis, date of admission, date of discharge, were collected by electronic medical record review and recorded on the Study Participant Log and Demographic Data Collection Tool (see Appendix III) upon study enrollment. The section on description of instruments/tools provides further information for each instrument used.

**Description of instruments/tools.**

**Time and activity log.** A primary aim of this feasibility study was to describe the time and activities required of the palliative care team to provide services for patients and families. A time and activity log was created by the principal investigator to include the following data: the subject number identifier, the number and dates of visits made, the name of the palliative care team provider providing the intervention at each visit, time in and out of each visit or intervention, the types of interventions requested by patients and families, the date and time each intervention is
provided or the reason why an intervention was not provided. See Appendix IV for a sample of the Time and Activity Log.

This information was collected in the Time and Activity Log to demonstrate the time required by the palliative care team practitioners to provide care, the types of interventions requested by patients and families, and if the requested interventions were available and were provided in a timely manner. Referrals for care that could not be directly provided by the palliative care team were recorded as appropriate but the time and activities of these supplemental personnel were not directly measured. In addition to the time and resources required to provide this care, satisfaction, the second primary aim, was measured from both the family and the health care team perspective.

**PANDA Care Team family survey and provider survey.** Satisfaction was measured using a satisfaction tool adapted from the Center to Advance Palliative Care (CAPC). CAPC is a nationally recognized organization committed to the improvement of palliative care services across the lifespan. Members of the PANDA Care Team attended CAPC training prior to beginning palliative care services at Children's National. CAPC provides standard satisfaction surveys for patients and families, as well as the health care team. The satisfaction survey used in this project was adapted from a satisfaction survey used at the University of California San Francisco and was found on the CAPC website. The instruments consisted of six questions answered on a 5-point Likert scale. Two satisfaction instruments were used, the PANDA Care Team Family Survey and the PANDA Care Team Provider Survey (Appendices V and VI).

To establish face and content validity, the Family Survey was pre-tested with six parents of children with serious life-limiting illnesses who found the tool easily understood and representative of relevant areas to measure satisfaction. The Provider Satisfaction Survey was
pre-tested with 10 oncology providers at Children’s National Medical Center (excluding HSCT Team staff), consisting of 3 attending physicians, 2 fellows, 3 nurse practitioners, and 2 staff nurses, who found the tool was easy to use and representative of information they would report on program satisfaction. The use of a nationally recognized survey, originally from a highly reputable academic institution, and pre-testing the instruments with family and providers, established that these instruments were indicators of satisfaction.

Family satisfaction was assessed using the PANDA Care Team Family Survey (Appendix V) which asked about: 1) comfort in receiving care from the PANDA Care Team, 2) help to improve comfort by managing symptoms and stresses associated with HSCT, 3) importance of offering palliative care interventions, 4) likelihood of recommending the PANDA Care Team to others, and 5) influence of care provided by the PANDA Care Team to recommend the institution to others. Provider satisfaction was assessed using the PANDA Care Team Provider Survey (Appendix VI), which asked about comfort level in referring patients/families for palliative care services prior to implementation of this project, help of the PANDA Care Team in promoting comfort for patients and families by managing symptoms and stresses of the transplant admission, helpfulness in improving access to services for patients and families, importance of the PANDA Care Team at Children’s National, and likelihood of recommending the PANDA Care Team to other patients/families. A secondary aim of the study was to evaluate comfort in this population.

*General Comfort Questionnaire – Parent/Guardian Form.* Family perception of their child's comfort impacts the ability to transcend the HSCT experience and may impact satisfaction with their decision to pursue HSCT for their child. The General Comfort Questionnaire (GCQ) (Appendix VII) was originally developed by Kathryn Kolcaba, PhD in
1992 as a 48-item self-report and observational scale to measure comfort in the domains of relief, ease, and transcendence of physical, psychospiritual, sociocultural, and environmental stressors (Kolcaba, 1992). The GCQ has been widely used in multiple patient populations including pediatrics, medical-surgical patients, psychiatric, oncology, acute care, and community patients. The GCQ has superior internal consistency to measure the construct of comfort with an overall Cronbach’s alpha of .88. A shorter 28-item form of the GCQ was subsequently developed which improved reliability on all subscales with an overall Cronbach's alpha of .90. Four subscales of the GCQ measure physical (α = .70), spiritual (α = .78), environmental (α = .80) and social (α = .66) comfort (Kolcaba, 1992). The GCQ is written at a 6.1 grade level.

The GCQ has been used for family report in a similar setting with hospice and oncology patients. Although self-report is the ideal measure of comfort, one must recognize that in the care of pediatric patients, the family is of equal importance (Leventown & Committee on Bioethics, 2008; Pritchard, et al., 2010). Self-report is the most reliable assessment of comfort, however, for children under the age of 3 years, parent-report alone was used. Children age 3 years and older were assessed using self-report measures of comfort. Permission to use the GCQ form with parents/guardians was obtained via email from Dr. Kolcaba.

**Children's Comfort Daisies and Comfort Line Visual Analog Scale.** Self-report of comfort from the child's perspective was measured using a one question assessment, using the Comfort Daisies, a 4-point Likert scale, for children ages 3 to 7 years of age (Appendix VIII). This tool has been validated with children as young as 3 years of age and is similar to the standard Face's Pain Scale (Kolcaba & DiMarco, 2005). Similar scales adapted from the standard Face's Pain Scale and used in a variety of settings, have been shown to be valid and reliable instruments with little evidence of differences between instrument adaptations (e.g.
Wong & Baker Faces Pain Scale, \( r = .89-.91 \) in self-report and \(.81-.88\) for parent report of child's pain) (Tomlinson, von Baeyer, Stinson, & Sung, 2010; Wong & Baker, 1988). For older children and adolescents, age 7 to 21 years of age, the Comfort Line Visual Analog Scale (VAS) was used (Appendix X).

The Comfort Line is a standard Visual Analog Scale (VAS) with ratings from 1 to 10. The VRS is a valid instrument in children as young as 5 years of age (\( R^2 = .921 \)) (McGrath, Seifert, Speechley, Booth, Stitt, & Gibson, 1966; Miro & Huguet, 2004). The VAS ratings were grouped into four ranges of scores to correspond to similar ratings of the Comfort Daisies scale for ease in analysis. Correlations between the two scales are adequate (\( r = .94 \)) (Tomlinson, Von Baeyer, Stinson, & Sung, 2010). Methods of data collection were standardized and consistent to avoid threats to validity and reliability.

Data Collection Procedures

Participant identification. The HSCT team identified potential participants. Members of the HSCT team were informed of the study and eligibility requirements during a monthly HSCT team meeting prior to implementation of the study and all questions and concerns were addressed. Monthly email reminders were sent to the HSCT team alerting them of the status of the study (open to enrollment or closed to enrollment) with a request to consider referral of new patients and families for enrollment on the feasibility study as appropriate. All patients and families considered for HSCT at Children’s National were approached, by a member of the HSCT team, to ascertain their interest in obtaining more information about potentially participating in this feasibility study. If a family was interested in learning more about the feasibility study for potential enrollment, the HSCT team notified the PANDA Care Team attending physician or nurse practitioner who then met
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with the family to discuss the study and complete informed consent. As indicated, 100% of all eligible participants referred by the HSCT team (N=12) were enrolled.

**Participant recruitment and enrollment.** The timeframe for this feasibility study was 6 months. Once the study was opened, participants were recruited until a minimum of 10 new HSCT patient/families were enrolled to the study and continued through completion of the three data time points for the majority of participants (N=12). At the time the study was initiated, all families currently admitted to the transplant unit were approached and offered the same services. This was done to avoid any perception of selection bias. The PANDA Care Team attending physician or nurse practitioner were the only team members who enrolled participants and completed informed consent. Participation in the study was voluntary. Informed consent was obtained from the parent for children and adolescents under the age of 18 years. Participants 18 years and older provided their own informed consent. Assent was obtained for children 7 to 17 years of age. All enrolled participants were provided with palliative care consultation and individualized interventions.

**Palliative care interventions.** Palliative care consultation and interventions were provided by two members of the PANDA Care Team, the attending physician and/or nurse practitioner. These two PANDA personnel were trained in pediatric palliative care through the Harvard Medical School Program in Palliative Care Education and Practice – Pediatric Track (Harvard Medical School, 2012). The attending physician is board certified in palliative care. The nurse practitioner is a certified hospice and palliative care pediatric nurse with extensive training in pediatric palliative care nursing and is a doctoral student at the University of Maryland, School of Nursing with a focus on pediatric palliative care. These were the only two persons providing palliative care consultation services to maintain consistency and minimize threats to validity. In addition, palliative care
interventions were provided using a standard set of guidelines as described below to insure consistency between providers.

Interventions were based upon the Association of Pediatric Oncology Nurses and Children's Oncology Group Palliative Care Resource, an extensively peer-reviewed and published set of guidelines of palliative care assessment and interventions from diagnosis of a potentially life-limiting illness throughout the trajectory of the illness and treatment (Ethier, Rollins & Stewart, 2010). Palliative care interventions were provided dependent upon the individual needs of each patient and family. Specific interventions were not evaluated in this feasibility study. The intent was to provide a standardized intervention approach to minimize potential inequities in intervention approaches between patients and families. PANDA Care Team services were available Monday through Friday, during normal business hours. This feasibility study provided services as per standard PANDA Care Team practice. Data collection was done at a time that was convenient for the patient and family as much as possible.

Assessment of comfort. Assessment of comfort was accomplished using the GCQ-Parent/Guardian Form and the Pediatric Comfort Daisies Questionnaire or Comfort Line VAS, as age appropriate. The comfort instruments were administered by the PANDA Care Team attending physician or nurse practitioner at the time of study enrollment (T₀), approximately two weeks after the HSCT conditioning regimen was completed (T₁), and at the time of discharge or the first outpatient clinic follow-up visit (T₂), approximately 30 days post-HSCT.

**Time 1** – Baseline assessment at time of study enrollment, either prior to admission for HSCT or on the day of admission. For those patients already admitted and in the midst of the HSCT process (hence referred to as existing HSCT), comfort assessments were not completed due to inability to compare the two groups;

**Time 2** – Assessment at 2 weeks post HSCT conditioning;

**Time 3** – Assessment at the time of discharge or the first return outpatient clinic visit, approximately 30 days post HSCT.
Assessment of satisfaction. Family satisfaction was measured at the time of the first outpatient clinic follow-up visit by the HSCT Nurse Coordinator. This was coordinated with the standard institutional family satisfaction survey, which was routinely administered during this clinic visit by the nurse coordinator. Provider satisfaction was measured by the nursing director of the inpatient HSCT unit who was not involved in the day-to-day care of patients and families. Provider satisfaction was collected at completion of the interim data analysis period (5 months from study opening). Using study team members other than those who obtained informed consent and provide the palliative care consultation/interventions allowed participants to be as open and honest as possible, thus improving validity of satisfaction responses. All human participant data was protected and remained confidential.

Human Participants Protection

This feasibility study underwent review and approval by the Children's National Nursing Research Advisory Council (NRAC). Once the study was approved by NRAC, it was forwarded to the Children's National Institutional Review Board (IRB) for review and approval. Symptom assessment and palliative care interventions were approved methods of assessment and patient care at Children's National, thus minimal risk to patients was anticipated. Expedited review was requested. The Children's National IRB approved study was then submitted to the University of Maryland, School of Nursing and the University of Maryland Baltimore IRB for review and approval. The timeframe for IRB approval from both institutions took 8 months, from submission through revisions to final approval. Once IRB approval from both institutions was obtained, the study was opened to accrual (see Appendix XI for IRB approval letters).

The HSCT team identified potential participants and approached the family in a private setting to ascertain their interest in speaking with the principal investigator to obtain more
information about the study. Demographic data was obtained by the principal investigator via
review of the electronic medical record and then de-identified. Participants were assigned a
numerical study ID number without notation of names, dates of birth, medical record number, or
other identifiable information. All instruments were coded with the study ID number and no other
identifiable information. Once identified, potential participants met with the PANDA Care Team to
discuss study enrollment.

The PANDA Care Team attending physician or nurse practitioner were the only team
members who obtained informed consent and assent for this study. The study was explained in age
appropriate terminology through consent and assent. Informed consent was obtained from the
parent for children and adolescents under the age of 18 years. Participants 18 years and older
provided their own informed consent. Assent was obtained for children 7 to 17 years of age.
Participation in this study was voluntary and it was made explicit to the families that they could
withdraw from the study at any time without loss of caring interventions. A copy of the signed
informed consent document was provided to the participants. All reasonable efforts were made to
insure confidentiality by using de-identified data, informed consent, limitations on the number of
providers privy to the knowledge that a participant is enrolled on the study (i.e. HSCT Nurse
Navigator, PANDA Care Team attending physician and nurse practitioner only), and privacy for
palliative care consultation and interventions. No participants declined enrollment.

Participants were provided with information on the study aims, definitions of palliative care
services, and frequency of visits and data collection. Participants were offered ample time to have
all questions and concerns addressed. Palliative care consultation and interventions occurred in
the inpatient setting, in a private room. Visits and interventions were conducted at a chosen time
by the participants, which was convenient for them. Visits and interventions could be declined
or rescheduled at any time, at the discretion of the participants. Data collection instruments were kept in a locked box used for transport of documents between the setting of care and the principal investigator's office. Data was kept in the locked box, in a locked drawer, in a locked office.

All sensitive psychosocial/emotional information disclosed during the interventions was kept confidential unless the participant gave explicit permission for the information to be shared with others, such as members of the HSCT team. The potential risks and benefits of sharing any information were discussed with the participants in advance of sharing any information with other members of the health care team for clinical care purposes only. All data collected was de-identified as described previously and kept in a locked box by the principal investigator. No one had access to this data other than the members of the study committee and the Institutional Review Board, if requested for data monitoring purposes only. Statistical analysis was done using PASW Statistics GradPack18 software (SPSS, Inc., 2009).

**Summary**

This feasibility study is a longitudinal, cohort design that examined willingness of patients and families of a vulnerable population to receive the palliative care intervention, willingness of the health care team to refer patients and families for the intervention, resource allocation (time and activities), and the perceived value added of the intervention as evidenced by satisfaction. A secondary aim was to investigate child and adolescent self-report of comfort at three time points and parental report of their child's comfort at the same time points. Differences over time and by diagnosis and type of HSCT were examined. Reports of comfort were also analyzed by four subscales of physical, psychospiritual, environmental, and sociocultural comfort. Analysis and results are presented in Section Four.
Section Four

This capstone project addressed the research question:

Is it feasible to provide coordinated consultation and caring interventions from a pediatric palliative care team to promote relief, ease and transcendence of the treatment experience for children or adolescents with potentially life-limiting advanced or high-risk cancers, or other non-malignant diseases, undergoing hematopoietic stem cell transplantation and their families to enhance comfort?

Transcendent comfort was operationally defined as a state of ease and well-being influenced by the caring and actions of nursing, which lead to transcendence of the circumstances of symptom distress, functional status and quality of life to promote a sense of well being despite the circumstances of life-limiting or advanced pediatric cancer or other non-malignant disease undergoing hematopoietic stem cell transplant. This capstone project was conducted to evaluate feasibility of providing early palliative care consultation and intervention, satisfaction of families in receiving these services, satisfaction of providers as a value-added service, and the description of comfort in the domains of relief, ease, and transcendence of physical, psychospiritual, sociocultural, and environmental stressors. Review and evaluation of the results is critical to translation of the proposed practice change into practice.

Data Quality Assurance Procedures

It was imperative to ensure accuracy in data entry and quality control measures to maximize data integrity. The following data quality assurance measures were followed in data collection, data entry and analysis:

a. Consistent and limited number of providers to describe study to participants, to ensure consistency in information provided for informed consent;
b. Consistent providers (PANDA Care Team MD and NP) with same training for palliative care consultation to ensure consistency in interventions;
c. Development of a data codebook, which described each variable name, variable description, and coding instructions for data entry;
d. Immediate entry of data, as soon as possible after collection, into SPSS database by primary investigator;
Analysis and Results

The primary outcomes of interest included the inclusion of palliative care consultation and intervention early in the trajectory of hematopoietic stem cell transplantation for children and adolescents as feasible and acceptable to parents and health care providers. Feasibility was defined as the ability to enroll at least 70% of families who are approached for participation in this study and that the palliative care interventions that the families identify as needed could be provided at least 70% of the time. The outcome of satisfaction was analyzed to ascertain if at least 70% of parent and provider respondents indicated a mean rating of $\geq 4$ out of 5 on a Likert scale rating satisfaction from 1 (Very unhelpful) to 5 (Very helpful).

To address the primary aims, analyses employed both statistical and graphical presentations of demographic, recruitment, consenting and enrollment percentage statistics, feasibility (from the time and activity log of palliative care consultations), measures of comfort (GCQ-Parent Form and Comfort Daisies and Visual Analog) and satisfaction (Family and Care Team Provider Satisfaction Surveys), including measures of central tendency and non-parametric analyses to ensure proper understanding of all data at each level. Non-parametric analyses were used due to the small sample size. Descriptive analysis of means and medians and proportions were employed to characterize study participants and parameters overall. Statistical analysis was accomplished using PASW Statistics GradPack18 software (SPSS, Inc., 2009) for demographic data, as well as the data for comfort, satisfaction (family and provider), and tracking of palliative care time and resource requirements.
Demographic Data

The demographic data as described earlier (Table 4) elucidated the sample characteristics of age in months/years, diagnosis using name and was categorized by ICD-9 coding into categories (leukemias, solid tumors, genetic diseases, or other non-malignant diseases), and length of stay described by date of admission and date of discharge. In addition, the primary caregiver during the transplant hospitalization was ascertained during the initial palliative care consult. These data were analyzed using measures of central tendency (mean and standard deviation) for ordinal/interval level data and with frequency distribution (N and %) for nominal level data. Primary aims of recruitment, availability of interventions and staffing metrics were also analyzed.

Primary Aims of Recruitment, Availability of Interventions, and Staffing Metrics

Aim #1a – recruitment. A primary aim of this feasibility study was to assess and describe the feasibility of providing palliative care consultation for children and adolescents with high-risk or advanced cancer or other non-malignant diseases undergoing stem cell transplantation at Children's National and their families as evidenced by at least 70% percent of patients and families who were approached for enrollment would consent to participate in the project. To answer this question, recruitment data was analyzed by measures of frequency for nominal level data. The outcome of interest was how many families who were approached for enrollment actually enrolled; and this was considered to be an indicator palliative care interventions being acceptable to families in the setting of HCST. The HSCT team referred 13 English speaking and 4 non-English speaking potential participants. Of the potential participants referred, 12 are included in the results of this analysis. Of the 13 initial English-speaking participant referrals, one was not included in this analysis as the HSCT procedure was delayed and did not meet the
timeframe for data collection. The 4 non-English speaking participants were not eligible for enrollment, as the data collection tools were in English only. Once participants were enrolled, it was essential to assess if the interventions families requested or the palliative care team recommended were provided.

**Aim #1b – availability of interventions.** A second primary aim was that at least 70% of interventions identified by families as needed to promote comfort were provided for each patient/family unit. Availability of interventions was analyzed by measures of frequency for nominal level data and by measures of central tendency for ordinal level data. The outcome of interest was the type and frequency of interventions requested by families and if these interventions could actually be provided. A variety of interventions were provided for this cohort of children and adolescents with advanced cancers and other non-malignant diseases. See Table 5 for a list of interventions requested and provided. The average number of types of interventions per participant was 13 (Md =13, Range = 8 to 19, SD = 2.778). The HSCT team routinely provides a variety of supportive care interventions during the trajectory of HSCT, including art therapy, dietary modifications (such as enteral feeds or TPN), music therapy, and pain team, psychology, social work and child life consults. The most frequent additional palliative care interventions (excluding the initial family meeting and assessment) provided by the PANDA Care Team included supportive care counseling (N = 12, 100%), acupuncture/acupressure (N = 8, 66.7%), massage therapy (N = 7, 58.3%), aromatherapy (N = 5, 41.7%), guided imagery and relaxation techniques (N = 5, 41.7%), and team meetings to facilitate discussion of goals of care (N = 3, 25%). These interventions are time intensive and identification of staffing metrics to provide these interventions is paramount to translation of this proposed practice change.
**Aim #1c – staffing metrics.** An additional primary aim examined resource allocation including the time required for interventions from palliative care team personnel and interventions provided as tracked by a Time and Activity Log. Data included the number of visits needed for each participant and the time commitment for each visit. Measures of central tendency were used to analyze this data. All participants had an initial visit with assessment of potential palliative care needs, by the PANDA Care Team attending physician and/or the nurse practitioner. The majority of visits were made by the nurse practitioner. The number of visits for each participant ranged from 6 to 18, with a mean of 11 visits over the 30-day data collection period per participant. The time required for each visit ranged from 15 minutes to 120 minutes, and was dependent upon each participant’s needs. Although acceptance of the intervention and resource allocation were of utmost importance, satisfaction was equally important in determining feasibility. If families and/or health care providers were not satisfied with the services, then the practice change would not be successful. Therefore, measurement of satisfaction was also of primary importance. The second primary aim, satisfaction, was measured from the family and provider perspectives.

**Aim #2 – satisfaction.** The final primary aim was to describe satisfaction of families and satisfaction of Hematopoietic Stem Cell Team providers (attending physicians, fellows, nurse practitioners/physician assistants, and unit based staff nurses) with the palliative care consultation process, as evidenced by at least 70% of families and providers indicating an overall ≥ rating of 4 on a 5 point Likert scale PANDA Care Team Family and Provider Satisfaction Survey. Measures of frequency and central tendency were analyzed to describe the levels of satisfaction for each item of measure on the satisfaction tools as well as an overall satisfaction score.
Overall family satisfaction was high (N = 10, M = 29.00, Md = 30.00, SD = 1.333).

Satisfaction question data was analyzed separately for each question as well as a total satisfaction score. Missing data represents one family whose child was still hospitalized and one child who died and the family asked to defer filling out the questionnaire until later due to the immediacy of the death experience. See Table 9 for descriptions of scores on each question. Possible responses ranged from 1 (indicating low satisfaction) to 5 (indicating high satisfaction). Families indicated they were very comfortable with receiving care from the PANDA Care Team (N = 10, M = 4.90, Md = 5.00, SD .316). Families also felt that the PANDA Care Team was very helpful in managing symptoms and stresses during their child's admission for HSCT (N = 10, M = 4.80, Md = 5.00, SD = .4222). Families were satisfied with improving access to services (N = 10, M = 4.60, Md = 5.00, SD = .699). All families felt it was very important to offer palliative care services and that they were very likely to recommend the PANDA Care Team to others (N = 10, M = 5.00, Md = 5.00, SD = .000). Families were also very likely to recommend Children's National to other patients and families based upon their experiences with the PANDA Care Team (N = 10, M = 4.70, Md = 5.00, SD = .483). Overall, families were very satisfied with PANDA Care Team services. It was equally important to ascertain satisfaction of the providers, as they are the referral base.

Overall, providers (N = 20) indicated satisfaction, with a mean score of 4.40 (Md = 4.50) on a 5-point Likert scale. See Table 10 for descriptions of scores for each question and per types of HSCT providers. The first question on the satisfaction survey asked about providers level of comfort in referring patients for palliative care services prior to the implementation of this study. Most physician and PA/NP providers indicated that they were comfortable or very comfortable with referring patients for palliative care consultation prior to the implementation of this study,
with a mean score of 4 (N =7, 43.8%), however 56.2% (N =9) providers indicated that they were uncomfortable or neutral in referring patients for palliative care consults prior to this study. Licensed independent providers (LIP = physician and PA/NP) were somewhat more comfortable (N = 7, M = 4.11) in palliative care referrals prior to this study as compared to other non-LIP providers (N = 9, M = 3.0). Of note, several staff nurses (N = 4) did not respond to this question. At the conclusion of the study, providers indicated the PANDA Care Team was helpful in managing symptoms and other stressors (N =17, M = 4.24), and in improving access to services (N = 17, M = 3.88) for patients and families during the trajectory of HSCT admission. Providers also indicated that it was very important that Children's National offer palliative care services (N = 20, M = 4.80, Md = 5.00) and they were very likely to recommend the PANDA Care Team to other patients and families (N = 20, M = 4.60, Md = 5.00). Satisfaction across types of providers was also analyzed.

A Kruskal-Wallis Test, a non-parametric alternative to one-way between-groups analysis of variance, was done to investigate if there were differences in satisfaction scores across five types of HSCT providers (attending physicians, fellow, PA/NP, staff nurses, and social work). The Kruskal-Wallis Test revealed no significant difference in satisfaction scores across five different types of HSCT providers for comfort in palliative care referral, $X^2 (4, N=16) = 6.416, p = .170$, importance of offering palliative care services, $X^2 (4, N = 20) = 3.167, p = .530$, and likelihood to recommend PANDA Care Team services, $X^2 (4, N = 20) = 6.667, p = .155$. The Kruskal-Wallis Test revealed significant differences in satisfaction scores across five different types of HSCT providers for managing symptoms and other stressors, $X^2 (4, N = 17) = 12.360, p = .015$, improving access to services, $X^2 (4, N = 17) = 9.388, p = .025$, and in total satisfaction scores, $X^2 (4, N = 20) = 14.773, p = .005$. LIP providers rated these areas with higher satisfaction.
than other providers (see Tables 8 and 9). However, the ultimate goal of this proposed practice change will be to promote improve comfort, thus an understanding of child/adolescent self-report of comfort, parental report of their child's comfort, and the concordance between the two is essential.

**Secondary Aims of Comfort and Concordance of Child Self-Report with Parent Report**

Secondary aims of the study addressed the description of comfort in the sample population.

**Aim #1 – child self-report of comfort.** The first secondary aim was to assess and describe comfort levels of children and adolescents with high-risk or advanced cancer or other non-malignant diseases undergoing stem cell transplantation at Children's National by self-report on the Pediatric Comfort Scale or Comfort Line Visual Analog Scale. To address this aim, the same exploratory analyses were conducted (as above) to describe the comfort levels in children and adolescents by reporting on the statistical parameters of the Pediatric Daisies Comfort Scale or Comfort Line Visual Analog Scale. Children under the age of 3 years did not complete self-report of comfort. Children from the ages of 3 to 6 years completed the Comfort Daisies instrument, indicating their level of overall comfort from 1 (Very Bad) to 4 (Very Good). Older children, ages 7 to 21 years, completed the Comfort Line Visual Analog Scale (VAS) from 0 to 10. For purposes of analysis, the results of the VAS were re-grouped into four categories so that scores on the two instruments could be compared over time. Scores from 0 to 2 were grouped as comparable to "Very Good", scores from 3 to 5 were grouped as comparable to "Sort of Good", scores from 6 to 8 were grouped as "Sort of Bad", and scores of 9 to 10 were grouped as "Very Bad".

Children and adolescents over the age of 3 years (N = 10) rated their baseline comfort as a mean of 3.6, with a median of 4 ("Very Good"). Only one participant rated their level of
comfort as "Sort of Bad" and no participant rated their level of comfort as "Very Bad" at the baseline assessment. At Time 1 (N = 9), 14 days after completion of conditioning, self-report of comfort for the same group was slightly less overall with a mean of 3.22 "Sort of Good", however the median remained at 4 "Very Good". The range of self-report scores was broader with ratings of 1 ("Very Bad", N = 1, 11.1%), 2 ("Sort of Bad", N = 1, 11.1%), 3 ("Sort of Good", N = 2, 22.2%), and 4 ("Very Good", N = 5, 55.6%). Ratings at Time 2, were consistently rated as 4 ("Very good", N = 8, 100%). Missing data represents one participant who was unable to complete assessment at T1 or T2 due to clinical status, and one participant who remained hospitalized at the time of final analysis. The differences over time were also analyzed.

*Child self report of comfort over time.* The Friedman Test, a non-parametric alternative to the one-way repeated measures ANOVA, was used to measure differences in child and adolescent self-report over time from baseline (prior to beginning conditioning) to T1 (~14 days after HSCT) to T2 (~30 days post-HSCT). A non-parametric analysis was chosen due to the small sample size. The results of the Friedman Test indicated that there was no statistical significance in child and adolescent self-reports of comfort across the three time points, $X^2 (2, N = 8) = 3.500, p = .174$. Inspection of the mean values did suggest a trend to decrease in comfort scores from baseline (M = 3.63, SD = .744) to T1 (M = 3.25, SD = 1.165) and an increase at T2 (M = 4, SD = .000). A Wilcoxon Signed Rank Test confirmed no statistical significance for child and adolescent self-report of comfort from baseline to T1 ($z = -.816, N = 9, p = .414$) and from T1 to T2 ($z = -1.604, N = 8, p = .109$). Self-report baseline levels of comfort were also analyzed by diagnosis and type of HSCT.

*Comparison of child self report by diagnosis and type of HSCT.* Baseline child and adolescent self-reports of comfort per diagnosis revealed that participants with leukemias (N = 3)
felt "Sort of Good" (M = 3.33, Md = 4, SD = 1.155). Children with solid tumors (N = 4) rated their baseline comfort slightly higher (M = 3.5, Md = 4, SD = 1.000), and children with genetic disorders (N = 3) had the highest baseline comfort scores (M = 3.67, Md = 4, SD = .577), both consistent with self-reports of "Very Good" comfort. A Kruskal-Wallis test revealed no significant difference between diagnostic groups, $X^2(2, N = 10) = .080, p = .961$. When compared for type of HSCT, children and adolescents who underwent allogeneic HSCT (N = 5, M = 3.40, SD = .894) and those who underwent autologous HSCT (N = 3, M = 3.33, SD = 1.155) rated their baseline comfort as "Sort of Good", as compared to children/adolescents who underwent cord blood HSCT (N = 2, M = 4, SD = .000) who rated their baseline level of comfort as "Very Good". Child and adolescent self-report median scores of baseline comfort for all types of HSCT showed agreement of comfort (Md = 4, Very Good). A Kruskal-Wallis test revealed no significant difference between type of HSCT groups at baseline, $X^2(2, N = 10) = .939, p = .625$. Comparisons of self-report were also analyzed for T1 and T2.

Child and adolescent self-reports of comfort at T1 per diagnosis revealed participants with leukemias (N = 3) felt "Sort of Good" (M = 2.67, Md = 3.00, SD = 1.528). Children with solid tumors (N = 3) rated their baseline comfort slightly higher but still as "Sort of Good" (M = 3.33, Md = 4, SD = 1.155), and children with genetic disorders (N = 3) had the highest baseline comfort scores (M = 3.67, Md = 4, SD = .577), consistent with self-reports of "Very Good" comfort. A Kruskal-Wallis test revealed no significant difference between diagnostic groups at T1, $X^2(2, N = 9) = 1.051, p = .591$. When compared for type of HSCT, children and adolescents who underwent allogeneic HSCT (N = 4, M = 3.50, SD = .577) rated their comfort at T1 as "Very Good". Those who underwent autologous HSCT (N = 3, M = 3.33, SD = 1.155) rated their comfort at T1 as "Sort of Good", as compared children/adolescents who underwent cord
blood HSCT (N = 2) who had polar reports of comfort at T1 as "Very Bad" (N = 1) or "Very Good" (N = 1). A Kruskal-Wallis test revealed no significant difference between type of HSCT groups at T1, $X^2 (2, N = 9) = .418, p = .812$. Child and adolescent self-reports of comfort at T2 were consistent (100%) at "Very Good" for all diagnostic and type of HSCT group. Although self-report is the ideal measure of comfort, one must recognize that in the care of pediatric patients, the family is of equal importance (Leventown & Committee on Bioethics, 2008; Pritchard, et al., 2010).

**Parental report of their child's comfort.** Measures of comfort from the parental perspective (secondary aim # 1) were analyzed using an overall score and with individual scores for each of the subscales: physical (6 items), psychospiritual (9 items), environmental (7 items) and sociocultural (6 items). Analysis using measures of central tendency described the overall score and individual subscales at each time point. The General Comfort Questionnaire-Parent Form is a 6-point Likert scale, ranging from 1 indicating strongly disagree and 6 indicating strongly agree with the comfort item variable. Negative comfort items were re-coded to reflect the same direction of comfort report as the positive comfort items. Total comfort scores as well as scores in each subscale, were re-coded to reflect an overall score comparable to the 6-point scale of the General Comfort Questionnaire-Parent Form.

**Parental baseline report of their child's comfort.** Parents (N = 12) rated their child's baseline comfort as a mean of 4.67, with a median of 5 (with 6 indicating parents strongly agreed that their child was comfortable to 1 indicating parents strongly disagreed that their child was comfortable). Total parental scores of comfort were broad, with a slight majority of parents (N=5, 41.7%) rating their child's level of comfort at a score of 5 (indicating agreement that their child was comfortable), three (25%) parental participants rated their child's level of comfort
lower at a score of 4 (somewhat agreeing) and one (8.3%) at a score of 3 (somewhat disagreeing). A few parental participants (N = 2, 16.7%) rated their child's level of comfort higher at a score of 6 (indicating strong agreement that their child was comfortable) at the baseline assessment. No parents strongly disagreed that their child was comfortable at the baseline assessment. Mean scores of parental ratings of their child's baseline comfort were also compared for diagnosis and type of HSCT.

**Parental baseline report of their child's comfort by diagnosis and type of HSCT.**

Baseline parental reports for their child's comfort per diagnosis revealed that parents of children with leukemias (N = 3) agreed that their child was comfortable (M = 5, Md = 5). Parents of children with solid tumors (N = 4) rated their child's baseline comfort slightly lower but somewhat agreed that their child was comfortable (M = 4.75, Md = 4.5), and parents of children with genetic disorders (N = 4) also somewhat agreed that their child was comfortable at baseline (M = 4.25, Md = 4.5). A Kruskal-Wallis Test revealed no significant difference between diagnostic groups (Leukemias, N = 3; Solid Tumors, N = 4; Genetic Disorders, N = 4; Other, N = 1), $X^2 (3, N = 12) = 1.204, p = .752$. When compared for type of HSCT, parents of children who underwent allogeneic HSCT (N = 7) rated their child's baseline comfort slightly lower (M = 4.43), as compared to parents of children who underwent autologous (N = 3) or cord blood (N = 2) HSCT, where both groups agreed that their child was comfortable at baseline (M = 5). Parental median reports of baseline comfort for all types of HSCT showed agreement of comfort (Md = 5). A Kruskal-Wallis test revealed no significant difference between type of HSCT groups, $X^2 (2, N = 12) = .898, p = .638$. The GCQ-Parent Form was completed again at T1.

**Parental report of their child's comfort at T1.** At Time 1 (N = 11), 14 days after completion of conditioning, parental report of their child's comfort for the same group was
slightly less overall with a mean of 4.5 and median of 4.0 (Agree). The range of parental report of their child's comfort scores was broader with a range of scores from 3 (Somewhat Disagree) to 6 (Strongly Agree). Only one parent reported that they somewhat disagreed that their child was comfortable (N = 1, 12.5%), compared to 36.4% of parents who somewhat agreed that their child was comfortable (N = 4). The majority (N = 4, 50%) of parents agreed (N = 5, 45.5%) or strongly agreed (N = 1, 9.1%) that their child was comfortable at T1. Parental comfort scores at T1 were also analyzed by diagnosis and type of HSCT.

**Parental report of their child's comfort at T1 by diagnosis and type of HSCT.** A Kruskal-Wallis Test was run to compare parental reports of comfort at T1 according to diagnosis and type of HSCT. The Kruskal-Wallis Test revealed no significant difference in parental reports of comfort at T1 across the four diagnostic groups (Leukemias, N = 3; Solid Tumors, N = 3; Genetic Disorders, N = 4; Other, N = 1), $X^2 (3, N = 11) = 3.349, p = .341$. The leukemia group had a slightly higher mean score (M = 4.67) than the other two main diagnostic groups (solid tumors, M = 4.33 and genetic disorders, M = 4.25). When compared for type of HSCT, parents of children who underwent allogeneic HSCT (N = 6), rated their child's comfort at T1 slightly higher (M = 4.67), as compared to those parents whose children underwent cord blood (N = 2, M = 4.5) or autologous (N = 3, M = 4.33) HSCT. The Kruskal-Wallis Test revealed no significant difference in parental reports of comfort at T1 across the three types of HSCT, $X^2 (2, N = 11) = .544, p = .762$.

**Parental report of their child's comfort at T2.** At Time 2, 30 days after completing conditioning and HSCT, parental report (N = 9) of their child's comfort for the same group was higher overall with parents scoring a mean of 5.44 and a median of 6.00 (SD = .726), indicating they agreed their child was comfortable. The range of parental report of their child's comfort
scores was narrower with a range of scores from 4 (Somewhat Agree) to 6 (Strongly Agree). The majority of parents (N = 8) agreed (N = 3, 33.3%) or strongly agreed (N = 5, 55.6%) that their child was comfortable. Only one parent reported that they somewhat agreed that their child was comfortable (N = 1, 11.1%). Parental comfort scores at T2 were also analyzed by diagnosis and type of HSCT.

**Parental report of their child's comfort at T2 by diagnosis and type of HSCT.** A Kruskal-Wallis Test, a non-parametric alternative to one-way between-groups analysis of variance, was run to compare parental reports of comfort at T2 according to diagnosis and type of HSCT. The Kruskal-Wallis Test revealed no significant difference in parental reports of comfort at T2 across the four diagnostic groups (Leukemias, N = 2; Solid Tumors, N = 3; Genetic Disorders, N = 3; Other, N = 1), $X^2 (3, N = 9) = 1.778, p = .620$. The genetic disorder group and other disease group had higher mean scores (M = 6) than the other two main diagnostic groups (leukemias, M = 5.5 and solid tumors, M = 5.0). When compared for type of HSCT, parents of children who underwent allogeneic HSCT (N = 4), rated their child's comfort at T2 higher (M = 6), as compared to those parents whose children underwent cord blood (N = 2, M = 5.5) or autologous (N = 3, M = 5.0) HSCT. The Kruskal-Wallis Test revealed no significant difference in parental reports of comfort at T2 across the three types of HSCT, $X^2 (2, N = 9) = 1.556, p = .459$. Analysis was also done to compare trends over time.

**Parental report of their child's comfort over time.** The Friedman Test, a non-parametric alternative to the one-way repeated measures ANOVA, was used to measure differences in parental reports of their child's overall comfort over time from baseline (prior to beginning conditioning) to T1 (~14 days after HSCT) to T2 (~30 days post-HSCT). A non-parametric analysis was chosen due to the small sample size. The results of the Friedman Test indicated that
there was statistical significance in parental reports of comfort across the three time points, $X^2 (2, N = 9) = 9.750, p = .008$. Inspection of the mean values showed a decrease in comfort scores from baseline ($M = 4.89$) to T1 ($M = 4.67$) and an increase at T2 ($M = 5.44$). A Wilcoxon Signed Rank Test confirmed no statistical significance for parental report of their child's comfort from baseline to T1 ($z = -1.000, N = 11, p = .317$), however, did reveal statistically significant increase from T1 to T2 ($z = -2.646, N = 9, p = .008$).

**Parental report of physical, psychospiritual, environmental, and sociocultural comfort subscales.** In addition to parental reports of their child's overall comfort, scores were analyzed for each of the four subscales: physical, psychospiritual, environmental, and sociocultural comfort.

**Parental report of physical comfort.** At baseline, parents ($N = 12$) rated their child's physical comfort level as somewhat comfortable ($M = 4.25, Md = 4.00, SD = 1.06$), however the range was broad from "Somewhat Disagree" ($N = 3, 25\%$), "Somewhat Agree" ($N = 5, 41.7\%$), "Agree" ($N = 2, 16.7\%$), to "Strongly Agree" ($N = 2, 16.7\%$). At T1, parents ($N = 11$) overall rated their child's physical comfort as somewhat comfortable ($M = 4.09, Md = 4.00, SD = 1.044$), however, the range was very broad; with scores from disagree to strongly agree. The majority of parents somewhat agreed (score of 4) that their child was physically comfortable at T1 ($N = 6, 54.5\%$), however 2 parents disagreed or somewhat disagreed that their child was comfortable (18.2\%) and 3 parents agreed or strongly agreed that their child was comfortable at T1 (27.3\%). At T2, parents ($N = 9$) overall agreed that their child was comfortable ($M = 5.22, SD = .972$), however the reports were less polar with ratings of somewhat agree ($N = 3, 33.3\%$), agree ($N = 1, 11.1\%$), and strongly agree ($N = 5, 55.6\%$). Parental ratings of psychospiritual comfort were also analyzed.
Parental report of psychospiritual comfort. At baseline, parents (N = 12) strongly agreed their child was comfortable in the psychospiritual domain (M = 5.50, SD = .674). At T1, parents (N = 12) continued to strongly agreed their child had overall psychospiritual comfortable (M = 5.50, SD = .687), however, the range was broader with scores from somewhat agree to strongly agree. The majority of parents strongly agreed (score of 6) that their child was comfortable (N = 5, 38.5%), with one parent somewhat agreeing (7.7%) and two parents agreeing (15.4%) that their child had psychospiritual comfort at T1. At T2, all parents (N = 9) strongly agreed that their child had psychospiritual comfort. Parental ratings of environmental comfort were also analyzed.

Parental ratings of environmental comfort. At baseline, parents (N = 12) rated their child's environmental comfort as comfortable (M = 5.33, SD = .779. At T1, parents (N = 11) overall agreed their child was comfortable in the environmental domain (M = 5.27, SD = 1.00), however, the range was broader with scores from somewhat disagree to strongly agree. The majority of parents agreed (score of 5) or strongly agreed (score of 6) that their child was comfortable at T1 (N = 9, 81.8%), however, one parent somewhat agreed (.09%) that their child experienced environmental comfort and one parent somewhat disagreed (.09%) that their child had environmental comfort at T1. At T2, all parents (N = 9) overall strongly agreed that their child was comfortable (M = 5.89, SD = .333). No parents disagreed that their child was uncomfortable in the environmental domain, at T2. Parental ratings of sociocultural comfort were also analyzed.

Parental reports of sociocultural comfort. At baseline, parents (N = 12) agreed their child was overall comfortable in the sociocultural domain (M =4.83, Md = 5.00, SD = 1.11), however, the range was broad from somewhat disagreeing (N = 2, 16.7%) to somewhat agreeing (N = 2,
16.7%) to agreeing (N = 4, 33.3%) to strongly agree (N = 4, 33.3%). At T1, parents (N = 11) overall continued to agreed their child experienced sociocultural comfort (M = 4.73, Md = 5.00, SD = 1.19), however, the range was again broad with scores from disagree to strongly agree. The majority of parents agreed (score of 5) that their child was comfortable at T1 (N = 4, 36.3%), however, 3 parents strongly agreed (score of 6) that their child was comfortable at T1 (27.3%), 3 parents somewhat agreed (score of 4) that their child was comfortable (27.3%) and 1 parent (0.1%) disagreed that their child experienced sociocultural comfort at T1. At T2, parents (N = 9) overall agreed that their child was comfortable (M = 5.33, SD = .866), however the reports ranged from somewhat agree (N = 2, 22.2%), agree (N = 2, 22.2%) and strongly agree (N = 5, 55.6%). Parental ratings of comfort over time per each subscale were also analyzed.

**Parental reports of comfort over time per each subscale.** When analyzed by subscale, the Friedman Test revealed no statistical significance in parental report of their child's psychospiritual comfort \[X^2 (2, N = 9) = 4.500, p = .105\], environmental comfort \[X^2 (2, N = 9) = 3.895, p = .143\], or sociocultural comfort \[X^2 (2, N =9) = 5.333, p = .069\] across the three time points. Statistical significance was demonstrated in physical comfort \[X^2 (2, N = 9) = 6.462, p = .040\], which is expected in the natural history of acute recovery from HSCT.

**Aim #2 – Concordance of child and parent reports of comfort.** An additional secondary aim was to investigate and describe concordance of assessment of comfort as reported by parent or guardian on the General Comfort Scale – Parent Form, as reported by the child (ages 3 – 6 years) on the Children’s Comfort Daisies form, and as reported by older children/adolescents (ages 7-21 years) on the Comfort Line Visual Analog Scale. Parental reports of total comfort were re-coded to a 4-point scale to better correlate with the child and
adolescent's self-reports of comfort. Chi-square test for independence was used to explore the relationship between parent and child reports of comfort.

At baseline, the Chi-square test for independence indicated no significant difference between parental and child reports of comfort, $X^2 (6, N = 10) = 4.881, p = .559)$. Correlation of parent to child reports of comfort at baseline showed medium correlation by the Spearman rho ($r = .305, N = 10, p = .391$). At T1, the Chi-square test for independence again indicated no significant difference between parental and child reports of comfort, $X^2 (9, N = 9) = 10.650, p = .300)$. Correlation of parent to child reports of comfort at T1 showed large correlation by the Spearman rho ($r = .534, N = 10, p = .138$). At T2, all children (N = 8) reported their comfort levels as "Very Good", while parents had greater range of responses from "Sort of Bad" (N = 1), "Sort of Good" (N = 1) to "Very Good" (N = 6).

The Friedman Test, a non-parametric alternative to the one-way repeated measures ANOVA, was used to measure differences in child and parent level of agreement over time from baseline (prior to beginning conditioning) to T1 (~ 14 days after HSCT) to T2 (~30 days post-HSCT). A non-parametric analysis was chosen due to the small sample size. The results of the Friedman Test indicated that there was no statistical significance in reports of comfort across the three time points, $X^2 (2, N = 8) = 3.200, p = .202$. A Wilcoxon Signed Rank Test confirmed no statistical significance in differences in child and parent level of agreement over time from baseline to T1 ($z = -.447, N = 9, p = .655$) and from T1 to T2 ($z = -.577, N = 8, p = .564$). Analyses of concordance revealed no significant differences between child self-report and parental reports of their child's comfort at the three time points (baseline, T1, and T2) or over time.
Assumptions

These results need to be interpreted with caution due to the small sample size. The researcher acknowledges that effect of the intervention was less likely to be seen due to the small sample size. The following assumptions for non-parametric analysis were considered and controlled as noted during statistical analysis:

1. Random samples – This assumption was violated as a convenience sample was used;
2. Homoscedasticity – Scatter plots were examined for variability in scores for all variables;
3. Independence of observations – Assessments were done independently by the child or adolescent and parent with controls for minimal interaction;
4. Level of measurement – Freidman Test for repeated measures and correlations was used with ordinal level data, however analysis was interpreted recognizing the small sample size; Chi-square tests were used, however, the expected cell frequency assumption was violated as not all cells had 5 or more.
5. Linearity – Scatter plots were examined to assure that there are no curvilinear relationships. If a curvilinear relationship was noted, the variables were recoded and scatter plots were re-examined to insure linearity;
6. Missing data – Any participant with missing data was removed from the sample, for the specific data being tested;
7. Normality – Histograms will be examined to insure normality as well as evaluating z skew and Kolmogorov-Smirnov scores;
8. Outliers – Histograms and boxplots were examined to determine the presence of outliers. Trimmed mean scores were also examined. If significant differences were noted between the mean and trimmed mean scores, then extreme outliers were deleted from analysis but noted in the descriptive;
9. Related pairs – Each participant provided a score on each measure or the data was dropped from analysis;
10. Sample size – The small sample size is a recognized violation of assumptions, however, multiple studies of symptom distress in pediatric advanced cancers have been reported with as little as 1 to 5 participants. (Cohen, 1992; Pallant, 2007; Rawlinson, et al., 2011; Jaing, Huang, Chen, Yang, Liang, & Hung, 2011; Wilson, Mazhar, Rojas-Cooley, DeRosa, & Van Cleve, 2011).

Limitations and Threats to Validity

Several potential limitations exist for this study. Violation of the potential for selection bias and the inability to generalize to the population of children with advanced cancer or other serious non-malignant disease at large is of consideration; however, the availability of potential subjects was limited in this setting and would be in most pediatric HSCT clinical sites. Of note
is that this pilot work will set the stage for a similar approach for a multi-institutional study or as a routine part of assessment for children and adolescents undergoing hematopoietic stem cell transplant. Threats to validity were also considered in designing and implementing this feasibility study.

Threats to single group validity included: history (participants received standard care to address pain and suffering as part of the HCST process so the palliative care interventions may not have caused the effects), maturation (counts usually recover by the time of discharge so participants may have felt better regardless of the palliative care interventions), testing threat (the same measures were used at each time point), mortality (attrition), and regression (distress improved just because of time) (Trochim, 2006). Diffusion or imitation of treatment is a recognized threat to social validity because families did interact within the intimate setting of the HSCT inpatient unit. Other threats included those of construct and external validity.

Construct validity threats may include the interaction of testing and treatment as participants may have been more sensitive to the constructs simply by the initiation of testing. Social threats to construct validity included evaluation apprehension since some participants were young children, and researcher expectancies as there is a vested interest in the outcomes (Trochim, 2006). Measures were taken to have satisfaction measures performed by the Nurse Coordinator or unit based Nursing Director, who were not involved in direct day-to-day care of participants in the HSCT unit, to decrease this threat for satisfaction data. The main threat to external validity was the small sample size and single-site setting, which limit generalizability. The design and procedures of this feasibility study attempted to control for the treats to validity.

Strengths of the study design were that the participants underwent similar treatment (HSCT) despite having differing underlying diagnosis. The participants were in the same setting
throughout the intervention. Standardized interventions were provided using the COG/APHON Pediatric Oncology Palliative Care Resource and standardized training of the palliative care practitioners through the same training program. Since the primary aims measured feasibility, the threats to validity were somewhat tempered as an effect on comfort was not expected due to the small sample and short timeframe of data collection. Translation of this feasibility study into practice will be dependent upon buy-in by participants, satisfaction and resource availability. A discussion of the results and implications for translation into practice is paramount to dissemination.
Section Five

Discussion

This study examined the feasibility of a practice change to provide early palliative care consultation and intervention for children and adolescents with advanced or life-limiting cancers or other non-malignant diseases undergoing hematopoietic stem cell transplant (HSCT), to promote transcendent comfort. Feasibility was defined by the primary aims of referral and enrollment patterns, the ability to provide requested interventions, and satisfaction from the family and provider perspectives. Ultimately, the goal of the practice change was to promote transcendent comfort for the child and family to improve symptom management, access to supportive care services, and improving overall satisfaction with care. This study was designed based upon anecdotal feedback, from nursing staff at the study site that patients and families experienced a myriad of stressors during the trajectory of HSCT, thus increasing discomfort for the family system and moral distress of the nurses caring for these patients. Review of the literature supported the significance of the problem and the use of palliative care intervention as a potential practice change to assist the child or adolescent and their family in transcending the circumstances of illness to achieve comfort. The Comfort Theory guided the development and implementation of this study.

Link of Conceptual Framework to this Study

Kolcaba's Comfort Theory provided a logical framework for design and implementation (Figure 1). Health care needs of the child or adolescent undergoing HSCT and their family were demonstrated in all domains of comfort, leading to the provision of comforting interventions to promote physical, psychospiritual, environmental, and sociocultural comfort. The HSCT team provides an excellent standard of care for these patients and families, however, the unique needs
in each comfort domain revealed in this study illustrate the complexity of health care needs of this population and support the need for adjunctive, supportive care services above and beyond the standard of care. This study highlights the need for individualized care focused on comfort.

**Health care needs and comforting interventions.** Review of the literature suggests that children and adolescents undergoing HSCT experience distressing symptoms (Rawlinson, Fung, Gross, Termuhlen, Skeens, Garee, Soni, Piertryga, & Bajwa., 2011; Gassas, Raiman, White, Schechter, Clarke, & Doyle, 2011, Jacobsohn, 2008). This cohort of participants demonstrated similar symptoms reported in the literature, including pancytopenia, pain, mucositis, fatigue, nausea/vomiting, anxiety and weight loss/cachexia (Hinds, Quargneti, & Wentz, 1992; Hongo, et al., 2003; Prichard, et al., 2009; Houlahan, Branowicki, Mack, Dinning, & McCabe, 2006; Woodgate, Degner, & Yanofsky, 2003; Walker, Gedaly-Duff, Miaskowski, & Nail, 2010; Baggott, Dodd, Kennedy, Marina, & Miaskowski, 2009). This sample included slightly more participants undergoing allogeneic HSCT, as compared to autologous and cord blood transplants, which is consistent with the pediatric HSCT population. This study demonstrated no significant difference in self-report or parental reports of comfort according to type of HSCT. Health care needs and comforting interventions in each comfort domain were also not significantly different according to diagnosis or type of HSCT. Overall, the use of the Association of Pediatric Hematology Oncology and Children's Oncology Group Palliative Care Resource provided an excellent template upon which to base assessment and interventions. The use of these guidelines, in addition to extensive pediatric palliative care training of the PANDA Care Team providers, allowed a systematic approach to care delivery. Future opportunities exists for investigating this specific resource as a guide for assessment and intervention, and to evaluate it as an effective link to the Comfort Theory.
Physical comfort needs demonstrated by this cohort of patients illustrated the need for close collaboration with the institutional pain team. In some incidences, there were discrepancies between recommendations from the pain team and the HSCT team. The PANDA Care Team has expertise and training in chronic pain management, which assisted both teams in achieving consensus. One suggested change in practice would be that the PANDA Care Team have more responsibility and oversight for patient controlled analgesia (PCA) or nurse assisted analgesia (NCA) in the HSCT unit to improve timely pain interventions. This practice change would increase the pain team’s overall access to other hospitalized patients requiring acute pain management. In addition, the HSCT would be able to focus more specifically on the needs of other HSCT patients and families.

Expansion of integrative medicine therapies may improve comfort for patients and families in the physical domain as well as other domains. Other measures to improve physical comfort included the use of integrative medicine techniques; such as massage therapy, Reiki therapy, acupuncture, acupressure (including SeaBands® for nausea relief), use of ginger gum for nausea, use of adaptive equipment to allow patients to move about more easily in the room and/or allowing parents to hold younger children, and bundling of care to provide for rest and improvement of fatigue. Integrative medicine equipment and personnel are not readily available in the institution. For example, SeaBands® and ginger gum were not available but were provided by the PANDA Care Team. The findings from this study would suggest that some patients may benefit from these types of interventions, thus the institution should consider adding these to the supply inventory. In addition to supplies, additional trained integrative medicine specialists were required.
The institution contracts with a community acupuncturist, however, data from this study suggests the need to have such services readily available on staff as there was a waiting time for the community provider to come in. Similarly, massage therapy services were contracted through community therapists, yet this was a frequently requested service by both patients and families. Currently licensed massage therapist are available once a week. Although a licensed massage therapist was not readily available, the PANDA Care Team was able to provide limited hand and foot massage to promote comfort. This type of intervention could be taught to staff nurses to offer as part of routine morning and/or evening care. Providing massage therapy as a means of relaxation for parents may improve parental stress, which may already be heightened by their child's discomfort. Parents commented how massage therapy was helpful for them, as well as their child, during prolonged hospitalizations. Yoga or other stress relieving physical interventions for parents may also be considered. Attention to promotion of the child's comfort is paramount, as parental reports of their child's discomfort may affect their own distress (Poder, Ljungman, & Von Essen, 2010; Pritchard, et al., 2010).

Psychospiritual comfort needs and interventions included support of families in being "good parents" through supportive care counseling (Hinds, Oakes, Hicks, Powell, Srivastava, Spunt, Harper, Baker, West, and Furman, 2009; Foster, Lafond, Reggio, & Hinds, 2010). Additional psychospirtual interventions included requests for prayer or quiet reflection with families. Educational materials on dealing with stressors of life-limiting illness were helpful as resources, but also as means of facilitating difficult conversations and assisting children and parents with improving health-seeking behaviors, e.g. using a book on teaching self-relaxation techniques. Parents also expressed fears of abandonment after discharge or hospice referral. The PANDA Care Team was able to bridge the communication between outside home hospice
agencies, the HSCT team and families. Other psychospiritual interventions included the use of guided imagery/relaxation, encouraged journaling for parents and/or video diaries, use of a family bed (use of creative interventions to allow parent to rest with child), daily schedule with choices allowed for child, and play therapy (augmenting Child Life interventions). Pastoral Care and Child Life consultation are a standard of care for HSCT patients and families. Services of the palliative care interventions augmented these services and did not replace interventions provided by these very important consultants.

Comments from families on satisfaction surveys included that they appreciated the extra time the palliative care team was able to spend with their child, as additional supportive counseling services. Conversations regarding goals of care and potential death are difficult. Providers who have training and expertise in facilitating these conversations are paramount to improving communication (Feudtner, 2007; Leventown & The Committee on Bioethics, 2008).

The use of the palliative care team early in the HSCT trajectory, prior to critical life-threatening events, facilitated these difficult discussions regarding goals of care and in some cases foregoing further life-sustaining treatment. Fostering a more home-like setting also assisted in promoting an environment that was conducive to decreasing existential distress. Environmental comfort was equally as important for both patients and families.

Environmental comfort factors included the discomforting smell of stem cell product preservative and general medical smells in the hospital environment. One participant did not like people coming in the room discussing the "bad smell", stating this made her feel like she smelled bad, impacting her self-esteem. Her response was to limit visitors, which increased isolation. Aromatherapy was a frequently requested intervention; however, aromatherapy machines were not available for each room. More aromatherapy machines should be purchased and made
available in each HSCT room. Another suggested response includes development of a policy and procedure for returning specialized equipment, such as the aromatherapy machines, and to consider use of commonly available room fresheners, which are more economical. Aromatherapy oils were used to improve the sensation of nausea by applying a small amount on the upper lip, but this was limited due to the unique needs of HSCT patients and consideration of skin integrity with GVHD.

Other environmental comments focused on parental comfort. Each patient room contains a parent bed, in addition to the patient bed, to allow parents to stay with their child during hospitalization. Parents found their beds very uncomfortable which impacted their sleep and rest cycle. This is of concern because parental lack of sleep directly affects the care and support parents can provide their child. Egg crate mattresses could not be ordered for parents as patients had specialty beds. The PANDA Care Team provided egg crate mattress toppers for several parents; however, one suggested change is to allow ordering egg crate mattress toppers through normal Central Supply mechanisms in special circumstances, such as prolonged hospitalizations. Parents also reported difficulty sleeping and resting in the noisy hospital environment. A suggested change in practice is to provide "white noise machines" for each HSCT room to promote distraction from noise pollution. This intervention was not available during the time of this project, but is an outcome of discussion with parents and providers to be addressed in the future. Other environmental comfort measures were directed in assisting the child’s direct environment.

Child Life routinely helps children and adolescents to decorate their hospital rooms with items from home. Palliative care interventions also included the use of adaptive equipment to allow children to ambulate outside their room, but still within the HSCT unit, to improve
opportunities for exercise and socialization. Other PANDA Care Team interventions included promotion of privacy by developing signs for patients and families to put on their doors to allow for uninterrupted time alone or with visitors, depending upon the medical needs, and developing a speech board for one participant who became non-verbal as the clinical status deteriorated. Allowing children and families to be in the setting of choice was difficult, especially when counts were low and they required prolonged hospitalization. This was particularly illustrated in two cases where children were referred to hospice. The PANDA Care Team was able to facilitate specialized order sets for these patients to allow discharge to home and provided continued consultation with hospice and the HSCT team to coordinate care. Sociocultural comfort factors were also considered in interventions.

Sociocultural factors included the need for staff to know general cultural approaches to illness and death. This setting hosts a large number of international and ethnic families. Nurses expressed concern that they did not know how these families interpreted changes in the trajectory of illness or how to help families whose child experienced a relapse of disease or was approaching death. A suggested educational intervention would be to include a session on cultural competency in this setting in the nursing orientation curriculum for new HSCT staff. Consideration of including a family panel with representatives from several different cultures may improve retention of this educational material. Nurses were supported in asking families of special cultural considerations and the PANDA Care Team was available to facilitate these discussions as needed. As an example of cultural sensitivity, following the death of one study participant, the PANDA Care Team facilitated the return of the body through international channels to facilitate adherence to cultural traditions for funeral and burial. In this situation the use of interpreters, although necessary, was difficult as the mother was not able to communicate
easily and stated she felt left out of end of life care discussions, as well as not able to communicate her own needs. Such discussions were held with the father, who was English speaking and an interpreter. Family presence, at all ages of children and adolescents, was also demonstrated as a strong sociocultural need. The HSCT team routinely encourages family presence and participation in family-centered care. Regardless of the health care needs and palliative care interventions provided, consideration of intervening variables was paramount.

**Intervening variables.** Intervening variables that influenced comfort included the age and developmental stage of many of the participants. Most participants were under the age of 7 years. Frequently self-report of comfort is often not considered for young children; however, this study demonstrates that children as young as 3 years of age are able to give reliable self-report of comfort. The focus on comfort rather than rating of a specific symptom may reflect positive outcomes to children and families, rather than the focus on the level of symptom distress, which may be viewed as a negative outcome. (Kolcaba, 2003). Parental reports of their child's comfort showed concordance with child self-report, thus routine inclusion of parental assessment should be taken into consideration. Financial constraints were an additional intervening variable.

Families often take time off from work to stay with children and adolescents as they go through HSCT. This may lead to lost wages, but families certainly may incur additional costs for hospital meals, local lodging, and travel costs, as examples. Philanthropic or other institutional support mechanisms should be explored to provide additional financial aid to families in these unique circumstances, for example providing gas cards, pre-paid cell phones and/or telephone cards, gift cards to local stores for personal supplies, and other needs of families. HSCT patients often suffer significant symptom distress requiring transfer to and from the pediatric intensive
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care units. Efforts should be made to facilitate communication between units to provide
continuity of care. Mutual respect of the unique talents of all teams is paramount. Consideration
of health care needs, comfort interventions and intervening variables will lead to enhanced
comfort and the promotion of health seeking behaviors.

Promotion of enhanced comfort and health seeking behaviors. The novel approach of
this capstone project provided early palliative care intervention in a curative intent setting. This
approach allowed families to transcend the experience of HSCT by focusing on the immediate
relief and ease of physical and existential distress. As children and families were assisted in
strategies to promote comfort, they were able to demonstrate improved health seeking behaviors,
such as reliance on faith beliefs, finding meaning in a life-limiting illness, feeling motivated and
strengthened. One parent commented that she was able to "let it all out" with the PANDA Care
Team providers as opposed to the HSCT team, with whom she always focused on medical needs
of her child. Another parent commented, "It was easier to talk about the hard stuff with them,
since they already knew my child." These comments echo the benefit of early integration of
palliative care services (Baker, et al., 2008; Beider, 2005). Health seeking behaviors were
demonstrated by several parents learning limited massage techniques to promote interaction with
their child as well as increased ability to comfort their child, seeking counseling from social
work and psychology services, and the ability to participate in family meetings to discuss goals
of care. Four participants died, three enrolled on this study and one patient who was admitted to
the HSCT unit at the beginning of this study. The PANDA Care Team facilitated discussion of
goals of care and advanced directives in all cases. One suggested practice change is to establish
a discussion of advanced directives for all HSCT candidates prior to admission. Research has
shown that discussion of goals of care in advance of acute care needs facilitates communication
and the ability to establish agreement on interventions that may or may not be appropriate based upon the circumstances and sociocultural needs (Bioethics Committee, Canadian Paediatric Society, 2008; Wolfe, Freibert, & Hilden, 2002). Increased health seeking behaviors improve the ability of children and families to achieve transcendent comfort; however, institutions have a responsibility to focus on optimizing comfort by providing holistic care and adopting a philosophy of comfort as a priority of institutional integrity.

**Institutional integrity.** This capstone study has facilitated a culture change within the setting. Although the tenets of palliative care were embraced in general, the PANDA Care Team was not a funded, fully recognized medical specialty within the institution. An outcome supported in part by the findings of this study, is that the institution is taking steps towards developing a formal palliative care medical specialty to promote patient and family comfort. Adoption of a philosophy of comfort, such as outlined in Kolcaba's Comfort Theory of care in a "Comfort Place", may improve patient outcomes by providing reassurance, information, and personalized care (Kolcaba, 2003). At the very least, satisfaction seems to be increased with attention to comfort needs, as demonstrated in this study.

Nurses rated satisfaction lower than physicians, advanced practice nurses or physician assistants. This may be due in part to less than optimal communication about the study aims, as well as specific interventions done with each family. Comments by nurses in real time were positive; however, comments on the satisfaction survey indicated lack of feeling connected with the study and the desire for improved communication about exactly what interventions the PANDA Care Team was providing for their patient. Communication strategies used during the study included verbal communication with the HSCT team and the nurse navigator on a regular basis; however, individual nurses were contacted depending upon the needs of each individual
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A lesson learned is to include the staff nurse for a short report on palliative care interventions after each patient encounter or at the least to communicate better in written documentation. A disadvantage of the current electronic medical record system is that LIP, nursing and Family Services (Child Life, social work and pastoral care) documentation is separate. Often there is less than optimal viewing of intradisciplinary documentation. Current PANDA Care Team staffing metrics did not allow for a team member to regularly attend rounds. Regular attendance at HSCT inpatient rounds is suggested as a strategy for quality improvement. Nurse sensitive indicators are also outcomes of interest.

Comfort may serve as a nurse sensitive outcome for quality improvement, as it reflects the universal goals of health care and the discipline of nursing, as elucidated in Nightingale’s Grand Theory, that nursing needs to meet the basic needs of a healthy environment, social interaction with others, and promotion of the person by humane and competent care (McEwen & Wills, 2011). The comfort questionnaires used in this study were easy for children, adolescents and families to complete. Answers to the General Comfort Questionnaire – Parent Form often served as conversation starters, which led to more in-depth conversations. Asking questions about comfort reflected an overall concern for the whole patient and family, not just specific to one system, such as pain scores. Goals of care can focus on holistic comfort. This approach of early integration of palliative care services may be a standardized approach to promoting comfort and has been validated as a feasible approach in the pediatric HSCT population. Nurses may request palliative consult and may consider comfort as an outcome measure for the HSCT unit. This project is also recognized within the institution as an exemplar of a nurse driven initiative to improve patient care and family satisfaction. In addition, inclusion of nursing as a leader in comfort care, nurse satisfaction may increase.
A goal of nursing, at the setting of this study, is to become an employer of choice. Several initiatives to increase the visibility of nursing and the contributions of nursing to patient care, education and research are in progress. The inclusion of nursing as a leader in promotion of institutional integrity may impact nurse recruitment, retention, and job satisfaction. The promotion of comfort embodies the art of nursing, as well as the science. Improved patient outcomes, such as improved patient comfort and improved patient satisfaction, serve to document the productivity and value of nursing (Kolcaba, 2003). In addition, integration of palliative care services in high stress environments will allow planning for interventions to relieve compassion fatigue for nursing and other staff. The focus of this capstone intervention was family and patient centered, however, future opportunities exist to promote the comfort of the staff who care for these children and families. The outcomes of this study demonstrate feasibility of early palliative care consultation for children and adolescents undergoing HSCT and their families.

**Outcomes**

Integration of palliative care consultation for children and adolescents with high risk or advanced cancers undergoing stem cell transplantation, as implemented by this capstone practice change project, achieved the following outcomes:

1. Improved or no decrease from baseline level of comfort of children and adolescents with high risk or advanced cancers or other non-malignant diseases undergoing hematopoietic stem cell transplantation,
2. High levels of patient and family satisfaction, and
3. High levels of provider satisfaction in resource availability to augment care for children and adolescents with high-risk or advanced cancers or other non-malignant diseases undergoing hematopoietic stem cell transplantation.

The sample was representative of the pediatric HSCT population. This sample included slightly more patients with solid tumors and underlying genetic disorders, however, leukemias were represented, so the results should be fairly generalizable to the pediatric HSCT population. The
sample size was small and this was a single-site study, thus findings may not be as generalizable. This sample was younger, many less than 7 years of age, thus these findings may not be as applicable to an older adolescent and young adult population. Most caregivers were mothers, although there was fair representation of fathers as caregivers. This is similar to the trend in HSCT. The primary aims of enrollment and satisfaction were met. This study achieved 100% referral and enrollment; however, these results should be interpreted with caution, as the principal investigator was well known to the HSCT team, which may have biased referral patterns. Enrollment at 100% is unbiased, as the principal investigator was not known to patients and families, thus this supports feasibility that families are accepting of early palliative care consultation. Time and resources were another primary concern.

Supportive Counseling. Time and resources were another primary concern. The time commitment was substantial to provide these intense services. The principal investigator had a vested interest in ensuring that visits and interventions were provided, however, without a dedicated palliative care team these types of services may be less feasible. The time spent in supportive care counseling was substantial and it was imperative to be available when the family needed services, which was challenging in the midst of other clinical responsibilities. Interventions aimed at demonstrating compassionate care/supportive counseling are integral to the profession of nursing, thus improving the communication skills of HSCT staff nurses may be one way of improving satisfaction for nursing and the families who receive this care. Nursing, in the modern age, is a technical profession. Although desired, nurses are often unable to dedicate extended time for therapeutic listening. In this study, all families desired supportive care counseling, or simply described, time taken by the palliative care team provider to just listen to their fears and concerns. Training in therapeutic communication regarding the comfort needs of
patients undergoing HSCT and their families may increase the competency level of nurses to provide more efficient communication, particularly when the palliative care team is not readily available. A dedicated palliative care team would improve access to this model of care delivery. The institution has made a commitment to improving access to palliative care services, so inclusion of PANDA Care Team consultation as a standard of care for all HSCT patients may be a realistic goal in the immediate future.

**Early integration of palliative care services.** The early integration of palliative care was well received by families as well as providers. Families indicated high overall satisfaction with early integration of palliative care services. Families were comfortable in receiving palliative care interventions and felt that the service was very helpful in managing symptoms and others stressors of HSCT. They indicated that provision of palliative care services were very important and that they were very likely to recommend not only these types of interventions to other families, but they were very likely to recommend Children's National to others due to the influence of this service. Providers were also very satisfied with the intervention; however, attention must be paid to integrating nursing into the planning and implementation of the proposed practice change. Both families and providers indicated that early palliative care intervention was a value-added service that was very beneficial for patients and families. Based upon the data from this study, plans will be made to translate this intervention into practice.

**Plan for Translation into Practice**

This feasibility study set the stage for investigation of palliative care interventions in a larger group of HSCT patients and families. A larger sample across transplant centers would improve generalizability and translation of this proposed practice change into the standard of
care for children and adolescents undergoing HSCT and their families. The credibility and feasibility of this study are paramount to translation.

**Challenges of translation into practice – considerations of credibility and feasibility**

This was a feasibility study to evaluate a proposed practice change. Although the findings of this study support the underlying aims and concepts, the practical application of the findings to implement a practice change need further consideration. This study had a small sample size (N=12), thus enrolling more participants is one way to improve credibility of the findings. However, achievement of 100% referral and 100% enrollment lends to the strength of the findings. Feasibility can be improved with integration of this model of care into the framework of HSCT nursing practice. Increasing the competency of the HSCT staff nurses to provide supportive care counseling, and other palliative interventions such as limited hand/foot massages, as well as empowering them to access supportive care services (such as palliative care consultation) independently will increase feasibility by diffusion of responsibility beyond one or two individuals on the palliative care team. As a next step, nursing competencies in supportive care counseling and other supportive care interventions need to be defined. If comfort is to be considered as a nurse sensitive indicator (NSI), then the parameters of this NSI need to be defined. A workgroup from nursing and HSCT leadership will be formed to do further work on these initiatives. The findings of this study will provide additional support for expansion of current palliative care resources within the institution.

**Plans for dissemination**

As an interim step, the results of this feasibility study will be shared with the Children's National HSCT team and the Department of Hematology/Oncology to develop standards of care implementing palliative care consultation for children with advanced or high-risk cancers and
other non-malignant diseases cared for by this group of providers. A larger innovation would include presentation of the results of this study to the hospital at large through the monthly Palliative Care Discussion Series, which is a Grand Rounds type of format. Discussion with other health care providers may illicit other disease triggers for which a similar innovation may be beneficial. The PANDA Care Team serves patients and families from any inpatient area in the hospital, so it is hypothesized that a similar approach in other settings within Children's National may be appropriate. Growth of the PANDA Care Team to provide extensive services as is outlined in this feasibility study will require institutional support, in terms of financial and personnel resources. Data from this study has been useful to justify expansion of services as well as continued support of the current PANDA Care Team services.

**Role of the DNP**

The PANDA Care Team has presented a plan to hospital administration for expansion of services. The Doctor of Nursing Practice (DNP) is well poised to play an integral role in program development and evaluation. The DNP educational preparation is at the highest level of leadership, practice, and science (American Association of Colleges of Nursing, 2006). Expansion of PANDA Care Team services would allow integration of the philosophy and practice of palliative care to outpatient clinics and eventually to home palliative and hospice services. The DNP program will fulfill this goal as:

1) a collaborator within the transdisciplinary palliative care team,

2) an expert clinician in pediatric palliative care,

3) a collaborator with PhD scholars for nursing research in pediatric palliative care,

4) an advocate for pediatric palliative care health care policy and reform, and
an educator for patients, families, nurses, other health care team members, and society regarding pediatric palliative and end of life care (Chism, 2010).

What matters most in advanced nursing practice are the patients and families. The DNP is trained as an expert clinician, a change agent and a collaborator. Expert clinicians are essential to moving the field forward and providing the highest quality of care for children with life-limiting illnesses. The DNP is uniquely trained to act as a change agent in the setting of pediatric palliative care. Effective communication and interdisciplinary collaboration is the only way to develop standards of practice to revolutionize the care delivery model in pediatric palliative care. This capstone project exemplifies translation of the evidence to promote a practice change and interdisciplinary collaboration to advance the science of palliative care nursing.

**Summary**

This capstone project demonstrated feasibility of early integration of palliative care interventions with the curative intent therapy of hematopoietic stem cell transplant for children and adolescents with advanced cancers and other non-malignant diseases and their families. Feasibility was evidenced by 100% enrollment and recruitment, the ability to provided interventions requested by families (more than 70% of the time), and high satisfaction of families and providers. This approach to care will be implemented at the study site as a standard of care, with further data collection to aid in understanding of the phenomena of transcendent comfort and to improve credibility of the findings. This feasibility study is one of the first to examine palliative care consultation and intervention in the pediatric HSCT population, a curative intent therapy. The impact of the findings may reach further than the initial setting and considerations
of multi-site studies across HSCT centers is another future direction of this work. *Existential distress* is suffering that affects the integrity of the person, integrating into every domain of human existence, impacting quality of life and activities of daily living (Cassell, 1999).

Providing palliative care for the child or family experiencing existential distress is one way of promoting comfort (O'Neill & Mako, 2011). Palliative care is not about the dying, as historically thought. It is about helping children and families to live well in the midst of a potentially life-limiting illness or treatment, such as HSCT.

“Palliative care no longer means helping children die well. It means helping children and their families to live well and then, when the time is certain, to help them die gently.”

*Mattie Stepanek 1990-2007*
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http://www.thecomfortline.com/comfort_theory.html


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### Table 1

**Taxonomy of Comfort** (Kolcaba, 2003)

<table>
<thead>
<tr>
<th>Taxonomy Structure for Life-Limiting Pediatric Advanced Diseases Undergoing HCST</th>
<th>Relief</th>
<th>Ease</th>
<th>Transcendence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td>Pain – analgesia</td>
<td>Positioning</td>
<td>Patient recognizing they can tolerate some degree of symptom distress to allow for more wakeful time or ability to participate in ADL’s</td>
</tr>
<tr>
<td></td>
<td>Nausea/Vomiting – antiemetics</td>
<td>Aromatherapy</td>
<td>Family perception that child has good symptom control and is comfortable</td>
</tr>
<tr>
<td></td>
<td>Dyspnea – opioids</td>
<td>Fan and/or cool mist humidifier</td>
<td>Recognizing symptoms that are of most concern or not of concern (Pritchard, et al., 2010)</td>
</tr>
<tr>
<td></td>
<td>Lack of mobility – adaptive equipment</td>
<td>Elevate HOB 30⁰</td>
<td>Enrollment on Phase I clinical trials in the desire to help others</td>
</tr>
<tr>
<td></td>
<td>Fatigue – psychostimulants</td>
<td>Adaptive equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Somnolence – psychostimulants</td>
<td>Bundling of care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pancytopenias – blood product transfusion, stool softeners</td>
<td>Exercise</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Etc.</td>
<td>Relaxation/Distraction techniques</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Massage, Reiki and other integrative medicine techniques</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use of colored towels to minimize trauma of visual effect of blood loss</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Avoid rectal temperatures</td>
<td></td>
</tr>
<tr>
<td><strong>Psychospiritual</strong></td>
<td>Fears and Anxiety – antianxiolytics</td>
<td>Guided imagery and relaxation and/or meditation</td>
<td>Understanding uncertainty of prognosis</td>
</tr>
<tr>
<td></td>
<td>Depression – antidepressants</td>
<td>Activities of distraction and engagement</td>
<td>Reconciling faith beliefs/God’s will</td>
</tr>
<tr>
<td></td>
<td>Neurocognitive deficits – neuropsychological testing</td>
<td>Adapting educational and intervention strategies to developmental level of child</td>
<td>Anticipatory grief support</td>
</tr>
<tr>
<td></td>
<td>Faith beliefs – prayer, meditation, religiosity</td>
<td>Clergy and/or Pastoral Care</td>
<td>Journaling</td>
</tr>
<tr>
<td></td>
<td>Etc.</td>
<td>Psychology/Counseling services</td>
<td>Video diaries</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reassurance that health care team will not abandon child and family at end of life</td>
<td>Memory making activities</td>
</tr>
<tr>
<td><strong>Environmental</strong></td>
<td>Home vs. Hospital vs. Inpatient hospice</td>
<td>Setting of choice</td>
<td>Need for calm, familiar environment</td>
</tr>
<tr>
<td></td>
<td>Noise – strategies for reduction</td>
<td>Promoting privacy and calm, nurturing, quiet surroundings</td>
<td>Need for privacy with personal care</td>
</tr>
</tbody>
</table>
### Cold or Heat – temperature modulation

Physical limitations of environment – adaptive equipment

- Providing opportunity for personal items used in care and décor to promote home-like environment

  Cheerful, age-appropriate comforters and blankets (heating or cooling as appropriate)

  Adaptive equipment – Use of stretchers, beds, wheelchairs to promote outdoor excursions if desired, speech and language boards individualized to child

Creative use of equipment and resources to optimize function

---

### Sociocultural

| Family presence – Encourage family to participate in active, advanced care planning |
| Influence of extended family on decision making – Promotion of communication strategies |
| Absence or presence of culturally sensitive care – Culturally competent care |
| Language barriers – interpreters, family mentor programs |
| Promotion of family centered care |
| Parent showers and beds in inpatient settings |
| Parent/family members as part of care team |

Need for support from family and friends

Information seeking strategies – Professional journals, NCI, Caring Bridge, Internet

Provision of adequate, developmentally appropriate information re: diagnosis, prognosis, trajectory of illness and death, and interventions

---

### Type of Comfort:

*Relief* – the state of having a specific comfort need met

*Ease* – the state of calm or contentment

*Transcendence* – the state in which one can rise above problems or pain

### Context in Which Comfort Occurs:

*Physical* – pertaining to bodily sensations, homeostatic mechanisms, immune function, etc.

*Psychospiritual* – pertaining to internal awareness of self, including esteem, identity, sexuality, meaning in one’s life and one’s understood relationship to a higher order or being.

*Environmental* – pertaining to the external background of human experience (temperature, light, sound, odor, color, furniture, landscape, etc.)

*Sociocultural* – pertaining to interpersonal, family, and societal relationships and also to family traditions, rituals, and religious practices

---

Table 2
**Table 3**

<table>
<thead>
<tr>
<th>Key Concept</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>The immediate experience of being strengthened by having needs for relief, ease, and transcendence met in four contexts (physical, psychospiritual, sociocultural, and environmental; much more than the absence of pain or other physical discomforts.</td>
</tr>
<tr>
<td>Comfort Place</td>
<td>An institution practicing a philosophy of health care that focuses on addressing physical (including homeostatic mechanisms as well as sensations), psychospiritual, sociocultural and environmental comfort needs of patients and nurses. This type of care has three components: (a) appropriate and timely comfort interventions, (b) delivery of comfort interventions that projects caring and empathy, and (c) the intent to comfort. All components are based on an in-depth understanding of the patient’s medical history and current medical problems.</td>
</tr>
<tr>
<td>Comfort interventions</td>
<td>Skilled actions of the health care team intentionally designed to enhance patients’ or families’ comfort. Also changes in the health care environment that enhance the comfort of nurses.</td>
</tr>
<tr>
<td>Comfort needs</td>
<td>Patients’ or families’ desire for or deficit in relief/ease/transcendence in physical, psychospiritual, sociocultural, and environmental contexts of human experience.</td>
</tr>
<tr>
<td>Health-seeking behaviors (HSBs)</td>
<td>Behaviors in which patients, families, or nurses engage consciously or subconsciously moving them toward well-being; HSBs can be internal, external, or dying peacefully (when that is the most realistic option for patients).</td>
</tr>
<tr>
<td>Institutional integrity</td>
<td>The values, financial stability, and wholeness of health care organizations at local, regional, state and national levels. In addition to hospital systems, the definition of “institutions” includes public health care agencies, Medicare and Medicaid programs, home health agencies, nursing home consortiums, etc. Examples of variables related to this expanded definition of institutional integrity include cost savings, improved access, decreased morbidity rates, decreased hospitalizations and readmissions, improved health-related outcomes, efficiency of services and billing, and positive cost-benefit ratios. Any health care unit or system that applies Comfort Theory is called a Comfort Place.</td>
</tr>
<tr>
<td>Intervening variables</td>
<td>Positive or negative factors over which the health care team has little control, but which affect the direction and success of comfort care plans, comfort studies, or comfort interventions. Examples are presence or absence of social support, poverty, positive prognosis, concurrent medical or psychological conditions, health habits, environmental design, administrative philosophy, etc.</td>
</tr>
<tr>
<td>Transcendence (added)</td>
<td>The ability to rise above problems or pain. In Kantian philosophy “being beyond the limits of all possible experience and knowledge” (Merriam-Webster, 2010). Another definition is “lying beyond the ordinary range of perception” (The Free Online Dictionary, 2010).</td>
</tr>
<tr>
<td>Transcendent comfort (added)</td>
<td>Bridging the definitions of comfort and transcendence, comfort therefore is more than just the relief of physical signs and symptoms; it extends to ease of physical as well as existential distress to promote optimal functioning that goes beyond the limits of traditional nursing intervention experiences to a perception of well-being despite the circumstances (transcendence). For the purposes of the exploration of comfort in the context of pediatric advanced cancers, comfort is defined as a state of ease and well-being influenced by the caring and actions of nursing, which lead to transcendence of the circumstances of symptom distress, functional status and quality of life to promote a sense of well being despite the circumstances of life-limiting advanced pediatric cancer.</td>
</tr>
</tbody>
</table>
Comfort Theory Assumptions and Propositions Applied to Children and Adolescents with Life-Limiting Advanced Cancers or Other Serious Non-Malignant Diseases Undergoing Hematopoietic Stem Cell Transplant

Assumptions

1. Children and adolescents with advanced cancers or other serious non-malignant diseases undergoing HCST have holistic responses to their disease manifested by physical, psychospiritual, environmental and sociocultural distress (See Table 1 for definitions and taxonomy structure).
2. Nurses strive to promote comfort for children and adolescents with life-limiting advanced diseases undergoing HCST and their families.
3. Children and adolescents and their families strive to meet comfort needs in the context of the physical, psychospiritual, environmental and sociocultural experience.
4. Comfort is more than the absence of physical symptom distress, but the ability to transcend the HCST experience to find meaning in human existence and the HSCT experience.

Propositions

1. Nurses and other members of the health care team identify comfort needs of children and adolescents with life-limiting advanced diseases undergoing HCST and their family members, especially those needs that have not been met by existing support systems. Symptoms (physical as well as existential) convey meaning to patients and families as well as the health care team as to clues to problem areas requiring interventions. Nurses also identify their own comfort needs in caring for children at end-of-life, and work constructively for the resolution of these needs.
2. Comfort interventions are designed and coordinated to address those outstanding comfort needs of children and adolescents with life-limiting advanced diseases undergoing HCST and their families. The illness experience may change over time and strategies to provide symptom management need to adapt to the current situation. Children and adolescents with high risk diseases undergoing HCST and their families face the reality of a life-limiting illness from the moment of diagnosis while other children and adolescents with advanced diseases and their families may face the reality of life-limitation at different time points in the disease trajectory. Intervention strategies must be individualized to the circumstances of each patient and family as well as within that child or adolescent's disease trajectory.
3. Children and adolescents with advanced diseases undergoing HCST have varying degrees of symptom distress, thus care should be taken to individualize interventions for each unique patient and family promptly and with creativity, taking into account intervening variables for designing the interventions and determining their probability for success.
4. When interventions are coordinated through a pediatric palliative care consult team, and delivered in a caring manner, the immediate outcome of enhanced comfort is attained. The child or adolescent and family's perception of a symptom, the meaning of the symptom in the context of advanced disease and the physical, psychospiritual, sociocultural and environmental responses to a symptom are related to creative interventions to control distress (relief), promote a calmness and contentment in the given circumstances (ease) and the promotion of optimal perception of well being despite the circumstances that goes beyond the limits of traditional nursing intervention experiences in finding ways to experience living in the midst of the HCST experience (transcendence).
5. Children and adolescents with life-limiting advanced diseases undergoing HCST, their families, nurses, and other members of the health care team agree upon desirable and realistic health-seeking behaviors (HSBs).
6. If enhanced comfort is achieved, children and adolescents with life-limiting advanced diseases undergoing HCST, family members, and/or nurses are strengthened to engage in HSBs, which further enhances comfort.
7. When children and adolescents with life-limiting advanced diseases undergoing HCST and their family members engage in HSBs as a result of being strengthened by comfort interventions, nurses, families, and the child or adolescent are more satisfied with health care and demonstrate better health-related and institutional outcomes.
8. When children and adolescents with life-limiting advanced diseases undergoing HCST their families, and nurses are satisfied with health care delivery in a specific institution, system, region, state, or country, public acknowledgement about the institution's contributions in health will lead to those institutions remaining viable and flourishing. Research for best practices (evidence-based practice) or policy improvements at regional, state, or national levels is thus guided by these propositions and this theoretical framework.

Table 4
Demographic Characteristics ($N = 12$)

<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>%</th>
<th>Range</th>
<th>Mean</th>
<th>SD</th>
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<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Male</td>
<td>6</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Caretaker during HSCT</td>
<td>11*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>7</td>
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<td>Father</td>
<td>2</td>
<td>16.7</td>
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<td></td>
</tr>
<tr>
<td>Both equally</td>
<td>3</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Age (in years)</td>
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<td></td>
<td>1.2 – 20</td>
<td>8.8</td>
<td>5.87</td>
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<tr>
<td>0-3 years</td>
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<tr>
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<td></td>
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</tr>
<tr>
<td>7-10 years</td>
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<td>25.0</td>
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<td></td>
<td></td>
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<tr>
<td>11-13 years</td>
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<td>16.7</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>14-18 years</td>
<td>1</td>
<td>8.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>➔ 18 years</td>
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<td>8.3</td>
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<tr>
<td>Diagnosis</td>
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<td></td>
</tr>
<tr>
<td>Leukemias</td>
<td>3</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Solid Tumors</td>
<td>4</td>
<td>33.3</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Genetic Disorders</td>
<td>4</td>
<td>33.3</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
<td>1</td>
<td>8.3</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Type of Transplant</td>
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<td></td>
<td></td>
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<tr>
<td>Allogeneic</td>
<td>7</td>
<td>58.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autologous</td>
<td>3</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cord Blood</td>
<td>2</td>
<td>16.7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Missing data for 1 patient

Table 5
### Palliative Care Interventions Requested By Patients and Families

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>Requested N (%)</th>
<th>Provided N (%)</th>
<th>% Provided per Request</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial family meeting/assessment</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td>Required by study</td>
</tr>
<tr>
<td>Supportive care counseling</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Acupuncture/Acupressure</td>
<td>8 (66.7)</td>
<td>4 (33.3)</td>
<td>50</td>
<td>Community referral</td>
</tr>
<tr>
<td>Advanced Directive</td>
<td>2 (16.7)</td>
<td>2 (16.7)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Aromatherapy</td>
<td>5 (41.7)</td>
<td>4 (33.3)</td>
<td>80</td>
<td>Equipment need</td>
</tr>
<tr>
<td>Art Therapy</td>
<td>10 (83.3)</td>
<td>10 (83.3)</td>
<td>100</td>
<td>Standard referral</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CAM* approaches</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Dietary Modifications</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td>Standard HSCT care</td>
</tr>
<tr>
<td>Guided Imagery/Relaxation techniques</td>
<td>5 (41.7)</td>
<td>5 (41.7)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>In-house consults</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Child Life</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td>Standard referral</td>
</tr>
<tr>
<td>- Pastoral Care</td>
<td>3 (25)</td>
<td>3 (25)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>- Pain Team</td>
<td>6 (50)</td>
<td>6 (50)</td>
<td>100</td>
<td>Standard HSCT care</td>
</tr>
<tr>
<td>- Social Work</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td>Standard referral</td>
</tr>
<tr>
<td>- Other</td>
<td>2 (16.7)</td>
<td>2 (16.7)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Hospice Referral</td>
<td>2 (16.7)</td>
<td>2 (16.7)</td>
<td>100</td>
<td>Community referral</td>
</tr>
<tr>
<td>Massage Therapy</td>
<td>7 (58.3)</td>
<td>7 (58.3)</td>
<td>100</td>
<td>Community referral</td>
</tr>
<tr>
<td>Music Therapy</td>
<td>11 (91.7)</td>
<td>11 (91.7)</td>
<td>100</td>
<td>Standard referral</td>
</tr>
<tr>
<td>Non-pharmacological Interventions (NOS*)</td>
<td>8 (66.7)</td>
<td>8 (66.7)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Oxygen</td>
<td>3 (25)</td>
<td>3 (25)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Palliative Chemotherapy</td>
<td>1 (8.3)</td>
<td>1 (8.3)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Palliative Radiation Therapy</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Pharmacological Interventions</td>
<td>12 (100)</td>
<td>12 (100)</td>
<td>100</td>
<td>Standard HSCT care</td>
</tr>
<tr>
<td>Psychology/Psychiatry</td>
<td>7 (58.3)</td>
<td>7 (58.3)</td>
<td>100</td>
<td>Standard referral</td>
</tr>
<tr>
<td>Team Meeting</td>
<td>3 (25)</td>
<td>3 (25)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Others not otherwise specified*</td>
<td>2 (16.7)</td>
<td>2 (16.7)</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

Table 6
## Descriptive Statistics for Self-Report of Comfort for Baseline, Time 1 and Time 2

<table>
<thead>
<tr>
<th>Time Period</th>
<th>N</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Daisies Comfort Questionnaire or Visual Analog Scale Comfort Line <strong>Baseline</strong>$^*$</td>
<td>10</td>
<td>3.60</td>
<td>4.00</td>
<td>2</td>
<td>.894</td>
</tr>
<tr>
<td>Child Daisies Comfort Questionnaire or Visual Analog Scale Comfort Line <strong>Time 1</strong>$^*$</td>
<td>9</td>
<td>3.22</td>
<td>4.00</td>
<td>3</td>
<td>1.093</td>
</tr>
<tr>
<td>Child Daisies Comfort Questionnaire or Visual Analog Scale Comfort Line <strong>Time 2</strong>$^*$</td>
<td>8</td>
<td>4.00</td>
<td>4.00</td>
<td>0</td>
<td>.000</td>
</tr>
</tbody>
</table>

$^*$Child Daisies Comfort Questionnaire completed for children age 3 to 6 years
Visual Analog Scale Comfort Line completed for children ages 7 to 21 years of age

# Scoring criteria: 1 = Very Bad
2 = Sort of Bad
3 = Sort of Good
4 = Very Good

$ Baseline assessment completed prior to beginning conditioning
Time 1 assessment completed ~ 14 days post-conditioning and HSCT
Time 2 assessment completed ~ 30 days post-conditioning and HSCT or at 1st outpatient clinic visit

---

### Table 7

*Descriptive Statistics for Child Self-Report of Comfort Related to Diagnosis and Type of Transplant*
Palliative Care Consultation in Pediatric Stem Cell Transplant

<table>
<thead>
<tr>
<th>Type of HSCT</th>
<th>Diagnosis</th>
<th>Baseline (N = 10)</th>
<th>Time 1 (N = 9)</th>
<th>Time 2 (N = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allogeneic</td>
<td>Leukemias</td>
<td>N 1 Mean 2.00 SD .000</td>
<td>N 1 Mean 3.00 SD .000</td>
<td>N 0</td>
</tr>
<tr>
<td>Solid Tumors</td>
<td>Mean 4.00 SD .000</td>
<td>N 1 Mean 0.0</td>
<td>N 0</td>
<td></td>
</tr>
<tr>
<td>Genetic Disorders</td>
<td>Mean 3.67 SD .577</td>
<td>N 3 Mean 3.67 SD .577</td>
<td>N 3</td>
<td></td>
</tr>
<tr>
<td>Total (Allogeneic)</td>
<td>Mean 3.40 SD .894</td>
<td>N 5 Mean 3.50 SD .577</td>
<td>N 3</td>
<td></td>
</tr>
<tr>
<td>Autologous</td>
<td>Leukemias</td>
<td>N 0 Mean 3.33 SD 1.15</td>
<td>N 0 Mean 3.33 SD 1.15</td>
<td>N 0</td>
</tr>
<tr>
<td>Solid Tumors</td>
<td>Mean 3.33 SD 1.15</td>
<td>N 3 Mean 3.33 SD 1.15</td>
<td>N 3</td>
<td></td>
</tr>
<tr>
<td>Genetic Disorders</td>
<td>Mean 3.33 SD 1.155</td>
<td>N 3 Mean 3.33 SD 1.155</td>
<td>N 3</td>
<td></td>
</tr>
<tr>
<td>Total (Autologous)</td>
<td>Mean 3.33 SD 1.155</td>
<td>N 3 Mean 3.33 SD 1.155</td>
<td>N 3</td>
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</tr>
<tr>
<td>Cord Blood</td>
<td>Leukemias</td>
<td>N 2 Mean 4.00 SD .000</td>
<td>N 2 Mean 2.50 SD .12</td>
<td>N 2</td>
</tr>
<tr>
<td>Solid Tumors</td>
<td>Mean 4.00 SD .000</td>
<td>N 0 Mean 2.50 SD .12</td>
<td>N 0</td>
<td></td>
</tr>
<tr>
<td>Genetic Disorders</td>
<td>Mean 4.00 SD .000</td>
<td>N 2 Mean 2.50 SD .12</td>
<td>N 2</td>
<td></td>
</tr>
<tr>
<td>Total (Cord Blood)</td>
<td>Mean 4.00 SD .000</td>
<td>N 2 Mean 2.50 SD .12</td>
<td>N 2</td>
<td></td>
</tr>
</tbody>
</table>

*Missing data represents participant unable to participate due to clinical status
#Missing data represents participant not yet at T2 at time of interim analysis

Table 8
Descriptive Statistics for Parental Report of Their Child’s Comfort

<table>
<thead>
<tr>
<th>Comfort Domain</th>
<th>Baseline (N = 12)</th>
<th>T1 (N = 11)</th>
<th>T2 (N = 9)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>M (Md)</td>
<td>SD</td>
</tr>
<tr>
<td><strong>Physical</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>2 (16.7)</td>
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<tr>
<td>Agree</td>
<td>2 (16.7)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>5 (41.7)</td>
<td>6 (54.5)</td>
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</tr>
<tr>
<td>Somewhat Disagree</td>
<td>3 (25)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>0</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Psychospiritual</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>7 (58.3)</td>
<td>7 (63.6)</td>
<td>.674</td>
</tr>
<tr>
<td>Agree</td>
<td>4 (33.3)</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>1 (8.3)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Environmental</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>6 (50)</td>
<td>6 (54.5)</td>
<td>.779</td>
</tr>
<tr>
<td>Agree</td>
<td>4 (33.3)</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>2 (16.7)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Disagree</td>
<td>0</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Sociocultural</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly Agree</td>
<td>4 (33.3)</td>
<td>3 (27.3)</td>
<td>1.115</td>
</tr>
<tr>
<td>Agree</td>
<td>4 (33.3)</td>
<td>4 (36.4)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Agree</td>
<td>2 (16.7)</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Somewhat Disagree</td>
<td>2 (16.7)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>0</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Strongly Disagree</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4.67 (5.00)</td>
<td>.888</td>
<td></td>
</tr>
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</table>

Table 9

Descriptive Statistics for Family Satisfaction
### Family Satisfaction Questions

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>Mean Score</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>How <strong>comfortable</strong> were you in getting care from the PANDA Care Team?</td>
<td>10</td>
<td>4.90</td>
<td>5.00</td>
<td>.316</td>
</tr>
<tr>
<td>5 = Very comfortable</td>
<td>9 (90)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 = Comfortable</td>
<td>1 (10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How helpful was the PANDA CARE TEAM to you in helping your child to be as comfortable as possible by managing the symptoms and other stresses of your child's transplant?</td>
<td>10</td>
<td>4.80</td>
<td>5.00</td>
<td>.422</td>
</tr>
<tr>
<td>5 = Very helpful</td>
<td>8 (80)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 = Helpful</td>
<td>2 (20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How helpful was the PANDA CARE TEAM in <strong>improving your access</strong> to services at Children's National?</td>
<td>10</td>
<td>4.60</td>
<td>5.00</td>
<td>.699</td>
</tr>
<tr>
<td>5 = Very helpful</td>
<td>7 (70)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 = Helpful</td>
<td>2 (20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 = Neutral</td>
<td>1 (10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How <strong>important</strong> is it to you that Children's National offers the services of the PANDA CARE TEAM?</td>
<td>10</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>5 = Very important</td>
<td>10 (100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How likely are you to <strong>recommend</strong> the PANDA CARE TEAM to others?</td>
<td>10</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>5 = Very likely</td>
<td>10 (100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How did your experience with the PANDA CARE TEAM influence your <strong>likelihood to recommend Children's National</strong> to others?</td>
<td>10</td>
<td>4.70</td>
<td>5.00</td>
<td>.483</td>
</tr>
<tr>
<td>5 = Very likely</td>
<td>7 (70)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 = Likely</td>
<td>3 (30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall <strong>Total Satisfaction</strong> Scores (Total possible score = 30)</td>
<td>10</td>
<td>29.00</td>
<td>30.00</td>
<td>1.333</td>
</tr>
<tr>
<td>Actual scores:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 (100% satisfaction)</td>
<td>6 (60)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 (93% satisfaction)</td>
<td>2 (20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27 (90% satisfaction)</td>
<td>2 (20)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#Possible scores from 1 (Very uncomfortable/unhelpful/unimportant, unlikely) to 5 (Very comfortable/helpful/important/likely)

---

Table 10

Descriptive Statistics for Provider Satisfaction
Table 11

Differences in satisfaction across types of HSCT providers

<table>
<thead>
<tr>
<th>Provider Satisfaction Question</th>
<th>N (%)</th>
<th>Mean Score</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How comfortable</strong> were you with referring patients and families to the PANDA CARE TEAM <strong>prior</strong> to the implementation of this study?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending MD</td>
<td>3 (18.7)</td>
<td>4.67</td>
<td>5.00</td>
<td>.577</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (6.3)</td>
<td>4.00</td>
<td>4.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (18.7)</td>
<td>3.67</td>
<td>4.00</td>
<td>1.53</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>8 (50.0)</td>
<td>3.00</td>
<td>3.00</td>
<td>.756</td>
</tr>
<tr>
<td>Social Work</td>
<td>1 (6.3)</td>
<td>3.00</td>
<td>3.00</td>
<td>.000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>16 (80)</td>
<td><strong>3.50</strong></td>
<td><strong>3.50</strong></td>
<td><strong>1.03</strong></td>
</tr>
<tr>
<td><strong>How helpful was the PANDA CARE TEAM to you in helping patients/families to be as comfortable as possible by managing the symptoms and other stressors</strong> during this transplant admission?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending MD</td>
<td>3 (17.6)</td>
<td>4.67</td>
<td>5.00</td>
<td>.577</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (5.9)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (17.6)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>9 (52.9)</td>
<td>3.67</td>
<td>4.00</td>
<td>.707</td>
</tr>
<tr>
<td>Social Work</td>
<td>1 (5.9)</td>
<td>4.00</td>
<td>4.00</td>
<td>.000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>17 (85)</td>
<td><strong>4.24</strong></td>
<td><strong>4.00</strong></td>
<td><strong>.831</strong></td>
</tr>
<tr>
<td><strong>How helpful was the PANDA CARE TEAM in improving your access to services for your patients?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending MD</td>
<td>3 (17.6)</td>
<td>4.67</td>
<td>5.00</td>
<td>.577</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (5.9)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (17.6)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>10 (58.8)</td>
<td>3.20</td>
<td>3.00</td>
<td>1.14</td>
</tr>
<tr>
<td>Social Work</td>
<td>0</td>
<td>Missing</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>17 (85)</td>
<td><strong>3.88</strong></td>
<td><strong>4.00</strong></td>
<td><strong>1.22</strong></td>
</tr>
<tr>
<td><strong>How important is it to you that Children’s National offers the services of the PANDA CARE TEAM?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending MD</td>
<td>3 (15.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (15.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>12 (60.0)</td>
<td>4.67</td>
<td>5.00</td>
<td>.492</td>
</tr>
<tr>
<td>Social Work</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>20 (100)</td>
<td><strong>4.80</strong></td>
<td><strong>5.00</strong></td>
<td><strong>.410</strong></td>
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<tr>
<td><strong>How likely are you to recommend the PANDA CARE TEAM to other patients and families?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending MD</td>
<td>3 (15.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (15.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>12 (60.0)</td>
<td>4.33</td>
<td>4.00</td>
<td>.651</td>
</tr>
<tr>
<td>Social Work</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>20 (100)</td>
<td><strong>4.60</strong></td>
<td><strong>5.00</strong></td>
<td><strong>.598</strong></td>
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**Overall Total Satisfaction** Scores

<table>
<thead>
<tr>
<th>Provider Satisfaction Question</th>
<th>N (%)</th>
<th>Mean Score</th>
<th>Median</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attending MD</td>
<td>3 (15.0)</td>
<td>4.83</td>
<td>4.75</td>
<td>.144</td>
</tr>
<tr>
<td>Fellow</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>PA/NP</td>
<td>3 (15.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td>Staff Nurse</td>
<td>12 (60.0)</td>
<td>4.04</td>
<td>4.00</td>
<td>.468</td>
</tr>
<tr>
<td>Social Work</td>
<td>1 (5.0)</td>
<td>5.00</td>
<td>5.00</td>
<td>.000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>20 (100)</td>
<td><strong>4.94</strong></td>
<td><strong>4.50</strong></td>
<td><strong>.581</strong></td>
</tr>
<tr>
<td>Satisfaction Domain</td>
<td>N</td>
<td>$X^2(df)$</td>
<td>$P^#$</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>---</td>
<td>----------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>Comfort with PANDA Care Team referral prior to implementation of study%</td>
<td>16</td>
<td>6.416 (4)</td>
<td>.170</td>
<td></td>
</tr>
<tr>
<td>Managing the symptoms and other stressors during HSCT admission%</td>
<td>17</td>
<td>12.360 (4)</td>
<td>.015</td>
<td></td>
</tr>
<tr>
<td>Improving access to services for patients%</td>
<td>17</td>
<td>9.388 (4)</td>
<td>.025</td>
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</tr>
<tr>
<td>Importance that Children's National offers the services of the PANDA CARE TEAM</td>
<td>20</td>
<td>3.167 (4)</td>
<td>.530</td>
<td></td>
</tr>
<tr>
<td>Likelihood to recommend the PANDA CARE TEAM to other patients and families</td>
<td>20</td>
<td>6.667 (4)</td>
<td>.155</td>
<td></td>
</tr>
<tr>
<td>Overall Total Satisfaction Scores</td>
<td>20</td>
<td>14.773 (4)</td>
<td>.005</td>
<td></td>
</tr>
</tbody>
</table>

#Level of significance defined at .05
%Missing data represents non-response
Figure 1: Original Conceptual Framework for Comfort Theory (Kolcaba, 2007). This figure illustrates the key concepts and contextual variables of the Comfort Theory. Reprinted with permission from Dr. Kolcaba.

Line 4:
Health Care Needs + Nursing Interventions + Intervening Variables → Enhanced Comfort → Health Seeking Behaviors → Institutional Integrity

Line 5:
Comfort Needs of children or adolescent with advanced or high risk cancers or other non-malignant diseases undergoing HSCT + Comfort Interventions + Demographics - Developmental; Gender; Age; Type & stage of cancer diagnosis; Financial or Payer limitations; Lack of pediatric palliative care specialists; Social support → Physical: Psychospiritual; Sociocultural Environmental comfort → Internal: External; Peaceful Death → Family Satisfaction; ↓ ICU stay; ↓ med usage; ↓ LOS; Embracing standards of pediatric palliative care practice
Figure 2: Operationalization of Kolcaba’s Comfort Theory to Children or Adolescents with Life-Limiting Advanced Cancers and their Families (Kolcaba, 1994; Kolcaba, 2003; Kolcaba, 2007; Foster, Lafond, Reggio, & Hinds, 2010). This schematic drawing illustrates the evolution of the conceptual framework of the Comfort Theory to the specified practice population. Boldface text identifies variables of interest. This figure begins with Line 4 which is the conclusion of Kolcaba’s Comfort Theory substructed from the Theory of Human Press and representative of her Conceptual Framework (Kolcaba, 2003).

Appendix I

Overall Evidence Summary

<table>
<thead>
<tr>
<th>Current Practice:</th>
<th>Evidence Based Practice Question:</th>
<th>Level of Evidential Strength</th>
<th>Number of Studies</th>
<th>Summary of Findings</th>
<th>Overall Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric patients with advanced cancer or other non-malignant diseases undergoing hematopoietic stem cell transplant do not have access to palliative care services early in the disease trajectory, thus they have increased comfort needs.</td>
<td>Do children or adolescents with potentially life-limiting advanced or high risk cancers, or other non-malignant diseases undergoing hematopoietic stem cell transplantation and their families achieve enhanced comfort through coordinated consultation and caring interventions from a pediatric palliative care team to promote relief, ease and transcendence of the treatment experience as compared to standard medical and nursing care alone?</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>LEVEL I</td>
<td>Experimental (randomized controlled trial – RCT) or meta analysis of RCTs</td>
<td>2</td>
<td>Common sites of pain were headache, back pain, neck pain, musculoskeletal pain and widespread regional pain; 2 participants c/o visceral pain; Increased incidence of depression; Multiple measures of pain and QOL; Randomized intervention with cognitive behavioral therapy; CBT substantially improved QOL and functional status</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>LEVEL II</td>
<td>Quasi-experimental</td>
<td>0</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEVEL III</td>
<td>Non-experimental or qualitative</td>
<td>30</td>
<td>A wide variety of symptoms are reported in pediatric patients with advanced cancer. The most common symptoms included pain, fatigue, dyspnea, nausea/vomiting, anxiety and weight loss/cachexia, Parents report child was “suffering” and in many cases, interventions were not adequate to relieve symptom distress. HRQOL was dramatically impacted by symptom distress. Perceived suffering of child impacts entire family. Symptom distress and OOL improved with integration of palliative care. Children are able to participate in EOL decision making. There is lack of information regarding the impact of Phase I therapies on symptom distress and HRQOL.</td>
<td>A-B</td>
<td></td>
</tr>
<tr>
<td>LEVEL IV</td>
<td>Opinion of nationally recognized experts based on research evidence.</td>
<td>8</td>
<td>Symptom management is paramount to quality care at end of life for cancer patients. Strong evidence for treatment of pain. Moderate quality of evidence for management of dyspnea and depression</td>
<td>A-B</td>
<td></td>
</tr>
</tbody>
</table>
### Individual Evidence Summary [PROMOTION OF COMFORT THROUGH PALLIATIVE CARE CONSULTATION FOR CHILDREN & ADOLESCENTS UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION] [04/17/11]

<table>
<thead>
<tr>
<th>Author</th>
<th>Date</th>
<th>Evidence Type</th>
<th>Sample &amp; Sample Size</th>
<th>Results/ Recommendations</th>
<th>Limitations</th>
<th>Strength</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2008</td>
<td>Qualitative, descriptive, exploratory design</td>
<td>65 bereaved parents of 52 children</td>
<td>18 distressing symptoms noted by parents; Most frequent included pain, change in behavior, change in appearance, breathing difficulties, weakness and fatigue, and change in heart rate. More symptoms reported in children with brain tumors than other cancers; Extensive lit review with comparison to other studies</td>
<td>Moderate sample size; only inpatient deaths; potential for history &amp; maturation over time since deaths were ~ 1 year earlier</td>
<td>III</td>
<td>A</td>
</tr>
<tr>
<td>2</td>
<td>2009</td>
<td>Descriptive and retrospective chart review</td>
<td>Convenience sample of 15 children</td>
<td>6.5 to 12.7 (+ 5) symptoms identified with &gt; number in inpatients; Common symptoms at baseline with median of 3 new symptoms identified with palliative care consult; Most common symptoms were pain, fatigue, nausea, depression, anxiety, drowsiness, anorexia, constipation, dyspnea, and insomnia.</td>
<td>Small sample; Lack of documentation in medical record of symptoms by HCT</td>
<td>III</td>
<td>B</td>
</tr>
<tr>
<td>3</td>
<td>2000</td>
<td>Qualitative, descriptive, exploratory design</td>
<td>103 bereaved parents of 103 children who died from cancer</td>
<td>Hallmark study quoted in a wide variety of pediatric palliative care literature; 89% of parents felt their child “suffered a lot” from at least one symptom; Pain, fatigue and dyspnea were most common symptoms; Treatment for pain successful in only</td>
<td>Majority of sample Caucasian and female</td>
<td>III</td>
<td></td>
</tr>
<tr>
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<td>27% and for dyspnea only 16%; Parents more likely that physicians to report symptoms by documentation in medical record; 22% of sample had children who died from brain tumor</td>
<td>Only inpatients so less generalizability to childhood cancer population at large; Sample population from France so may not be as applicable to US patients; Small sample size; Large variability of data; Mothers most commonly completed instrument assessments</td>
<td>III A</td>
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<tr>
<td>Speyer E, Herbinet A, Vuillemin A, Chastagner P &amp; Briancon S.</td>
<td>2009</td>
<td>Non-experimental descriptive comparison</td>
<td>28 children with cancer 5 – 18 years of age and their parent(s); Males &gt; Females; 50% in isolation room</td>
<td>Parents had lower estimates of HRQoL than child but differed in measurements at home vs. in hospital; HRQoL rated higher by both at home; When parents feel child is physically weaker, they rate HRQoL lower; Children commonly report fatigue, lethargy, depression and sadness in the hospital but reported feeling “normal” and more energetic at home Parents ratings of HRQoL influence decision making; Inconsistent results compared to other studies using the same instruments</td>
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<tr>
<td>Mannix M M, Feldman J M &amp; Moody K</td>
<td>2008</td>
<td>Non-experimental descriptive study</td>
<td>Pediatric patients with cancer or aplastic anemia ages 13 -21 years; 26% had brain tumor diagnosis</td>
<td>Sample was quite optimistic but had high scores for anxiety; HRQOL scores were high; Scores for pain, nausea, worry, cognitive problems, perceived physical appearance and communication were also well above average; Moderate correlation between optimism and physical health but also with less pain and fewer communication problems</td>
<td>Patients excluded if deemed “too ill” by parent or physician – sample bias; Primary investigator approached patients for enrollment – may lead to bias;</td>
<td>III B</td>
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<tr>
<td>Lavy, V</td>
<td>2007</td>
<td>Qualitative exploratory design</td>
<td>95 children referred for palliative care in Malawi; 77% with HIV, 17% with various cancers. 25% of the cancer patients had brain tumors. Predominance of males (58 vs. 37).</td>
<td>Most common symptoms in patients with cancer were pain, decreased movement, bleeding, difficulty breathing, weight loss, edema, difficulty swallowing and problems urinating. Many symptoms not volunteered initially. Variety of physical, emotional, and social issues uncovered with direct questioning.</td>
<td>No IRB approval although this study was done in Malawi so may not have same regulations. Open ended question format for data collection regarding symptoms. No symptom assessment tool used. Only frequency was assessed, not level of distress. Authors do not acknowledge study limitations.</td>
<td>III</td>
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<tr>
<td>Houlanah K E, Branowicki P A, Mack J W, Dinning C, McCabe M</td>
<td>2006</td>
<td>Non-experimental descriptive design</td>
<td>18 nurses and 8 fellows in large academic pediatric cancer center and all patients with cancer referred for palliative care consultation.</td>
<td>13% of pediatric cancer patients experience escalating symptoms and intractable distress. Most common symptoms were pain, dyspnea and agitation. Symptoms assessed by HCT as well as patients/families. Templates for intervention identified.</td>
<td>No description of number or demographics of patients provided however the focus of this intervention was on the HCT. Methods of evaluation of symptom improvement not provided.</td>
<td>III</td>
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<tr>
<td>Lorenz K, Lynn J, Dy S et al</td>
<td>2006</td>
<td>Systematic Review, peer reviewed</td>
<td>536 articles</td>
<td>5,187 titles originally identified as related to topic but 4,599 excluded after review of abstract, leaving 537 fully reviewed. Further exclusion based upon identified criteria leaving</td>
<td>Largely adult studies so not as applicable to pediatric setting. The reviewers state a limitation of the</td>
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<td></td>
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<td>9</td>
<td>Nitschke R, Meyer W H, Sexauer C L, Parkhurst J B, Foster P &amp; Huszti H</td>
<td>2000</td>
<td>Qualitative exploratory design</td>
<td>73 children between 6 - 21 years</td>
<td>Symptoms of children on Phase I or II clinical trials similar to those who opt for supportive care only but if unexpected response to clinical trial, symptoms were fewer. Hospitalization often required if enrolled in clinical trial. Time at home maximized for those who opted for supportive care.</td>
<td>Symptoms not described but lumped into one category.</td>
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<tr>
<td>10</td>
<td>Levetown M, Barnard M U, Hellsten M B, Byock I R, Carter B S, Conner S R et al</td>
<td>2001</td>
<td>Meta-synthesis</td>
<td>Critical review of 86 articles pertinent to pediatric palliative care.</td>
<td>Approximately 400,000 children are living with life-limiting chronic conditions and 53,000 children die each year. Only ~ 50% of these children receive hospice services. Symptom management is paramount to care. Barriers to effective care are identified. Research in pediatric palliative care is lacking. Evidence base is poor. Continued extrapolation from adult data is unethical. Outcome</td>
<td>Method of review not clearly identified.</td>
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<tr>
<td>Santucci G &amp; Mack JW</td>
<td>2007</td>
<td>Qualitative descriptive study</td>
<td>Pediatric cancer patients</td>
<td>Most common symptoms were 71-100% anorexia and cachexia, 50-57% nausea/vomiting, 39-50% constipation and 21-40% diarrhea. Many times not recognized by HCT and/or interventions are not effective. Management of symptom distress is paramount to QOL.</td>
<td>Symptom assessment restricted to only GI. Method of symptom assessment not described. Sample not described.</td>
<td>III</td>
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<tr>
<td>Qaseem A, Snow V, Shekelle P, Casey D E, Cross J T &amp; Owens D K</td>
<td>2008</td>
<td>Clinical Guidelines Meta-Analysis for Pain evidence Meta-Analysis for collaboration and consultation for EOL care</td>
<td>43 articles for pain management 13 studies for dyspnea 29 studies for collaboration &amp; consultation for EOL care 5 studies for caregiver support</td>
<td>Symptom management is paramount to quality care at end of life for cancer patients. Strong evidence for treatment of pain. Moderate quality of evidence for management of dyspnea and depression.</td>
<td>No information provided on whether the studies reviewed were for adult patients, pediatric patients or a combination. Review restricted to only three symptoms; pain, dyspnea and depression.</td>
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<td>13</td>
<td>Jalmsell L, Kreicbergs U, Onelov E, Steineck G &amp; Hener J I</td>
<td>2006</td>
<td>Non-experimental survey</td>
<td>449 bereaved parents of 363 children who died from cancer</td>
<td>Most common symptoms were fatigue (85%), reduced mobility (76%), pain (73%) and decreased appetite (71%); Moderate to severe distress reported; Children 9 – 15 years of age most affected; No difference of report from mothers vs. fathers; Other symptoms reported included weight loss, sleepiness, nausea and vomiting.</td>
<td>Sample from Sweden so results not as generalizable to US population;</td>
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<td>14</td>
<td>Wolfe J, Hammel J F, Edwards K E, Duncan J, Comeau M, Breyer J, Aldridge S A, Grier H E, Berde C, Dussel V &amp; Weeks J C</td>
<td>2008</td>
<td>Non-experimental Retrospective cohort study – survey and chart review</td>
<td>Parents and medical records of 119 children who died between 1997-2004 compared to 102 children who died between 1990-1997</td>
<td>Hospice referrals occurred more often and earlier; DNR documented earlier; Significantly decreased deaths in ICU; Decreased suffering from pain (19%) and dyspnea (21%); Parents felt more prepared during last month of life and at time of death; No change in report of incidence and degree of suffering from fatigue; Anxiety also reported as improved; Outcomes improved for those who died of treatment complications who also received palliative care consultation.</td>
<td>No discussion of types of therapies or if child was enrolled on Phase I protocol; Child’s perspective not included although the cohort was of deceased patients; Potential selection bias, but this is common in palliative care studies due to vulnerability of population</td>
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<td>15</td>
<td>Pritchard M, Srivastava D K, Okuma J O, Powell</td>
<td>2009</td>
<td>Qualitative Secondary analysis</td>
<td>42 parents of the original cohort of 65</td>
<td>52.4% reported changes that alerted them that death was near; 31% were surprised that child died on a certain time;</td>
<td>Question asked in secondary analysis was not asked in the main study.</td>
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<td>B, Burghen E, West N K, Gattuso J S, Spunt S L, Baker J N, Kane J, Furnan W L &amp; Hinds P S</td>
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<td>parents of children deceased from cancer</td>
<td>day; 16.7% felt the death was prolonged, thus prolonging suffering; Those who reported death as surprising reported fewer symptoms in last week of life; Perception of death experience is varied; Symptoms of concern to parents included changes in breathing, change in behavior, change in appearance and pain; Turning point of care to focus on palliative care occurred as far as 210 days from death;</td>
<td>original study; Many children died at home so unable to link medical record documentation to parents report</td>
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<td>Goldman A, Hewitt M, Collins G S, Childs M &amp; Hain R</td>
<td>2005</td>
<td>Non-experimental Prospective survey</td>
<td>165 children with various cancer diagnoses who had received palliative care</td>
<td>Increasing number of symptoms reported between palliative care referral and death; Common symptoms included pain, weakness, anorexia, nausea/vomiting, constipation, fatigue and weight loss; Symptoms related to underlying disease; More symptoms noted in children with CNS tumors; Survey completed by the child, parent and primary health care provider; Prevalence of 9 – 34 symptoms for CNS tumors, 8 -14 symptoms for solid tumors, and 8 – 9 symptoms for patients with leukemia or lymphomas; Symptoms separated by cancer type</td>
<td>Sample from United Kingdom so may not be as generalizable to US population; No information if patients were on Phase I therapies or receiving other anti-cancer treatments</td>
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<tr>
<td>Wicksell R K, Melin L, Lekander M &amp; Olsson G L</td>
<td>2009</td>
<td>Randomized controlled trial</td>
<td>Convenience sample of 32 consecutive patients referred to pain team for pain</td>
<td>Common sites of pain were headache, back pain, neck pain, musculoskeletal pain and widespread regional pain; 2 participants c/o visceral pain; Increased incidence of depression; Multiple measures of pain and QOL;</td>
<td>More girls (25) than boys (7); Selection bias; Sample from Sweden so may not be generalizable to US population; Small</td>
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<td>Hechler T, Blankenberg M, Freidrichsdorf S J, Garkse D, Hubner B, Menke A, Wamsler C, Wolfe J &amp; Zernikow B</td>
<td>2008</td>
<td>Qualitative Descriptive design</td>
<td>Parents of 48 children who had died from various cancers</td>
<td>Randomized intervention with cognitive behavioral therapy; CBT substantially improved QOL and functional status</td>
<td>sample size; Differences in treatment length for two groups</td>
<td>II</td>
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<tr>
<td>Hinds P S, Brandon J, Allen C, Hiijya N, Newsome R, &amp; Kane J</td>
<td>2007</td>
<td>Systematic Review</td>
<td>26 articles met the inclusion criteria of patient reported outcomes for quality of life in end of life research for pediatric oncology</td>
<td>Most common distressing symptoms were pain, fatigue, loss of appetite and dyspnea per parent report; Loss of appetite and anxiety not treated adequately; 50% received cancer directed therapy at EOL which parents rated as negative feature; Parents perceived their child suffered from symptom distress</td>
<td>Sample from Germany may not be generalizable to US population; Small sample size; Greater number of boys (31) compared to girls (17)</td>
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<td>Tadmor C S, Postovsky S, Elhasid R, Ben Barak A B &amp; Ben Arush M W</td>
<td>2003</td>
<td>Meta-synthesis</td>
<td>Review of available literature concerning quality of life for pediatric oncology patients</td>
<td>95% of parents reported attending meeting with HCT but only 50% reported that they understood the child would not be cured from their disease; This disconnect increases suffering of child by continued aggressive therapies; Relief of pain and anxiety are paramount;</td>
<td>Sample from Israel so may not be generalizable to US population; Methods of evidence review not described; Difficult to assess how many articles were reviewed</td>
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<td>Hinds P S, Drew D, Oakes L L, Fouladi M, Spunt S L, Church C &amp; Furman W L</td>
<td>2005</td>
<td>Qualitative Descriptive design</td>
<td>20 patients, age 10 – 20 years, with various cancer diagnoses, 6 parents of child or adolescent with cancer and 14 pediatric oncologists</td>
<td>Children and adolescents are capable of participating in decision making regarding EOL choices; 19 patients perceived Phase I therapies as making them “sick”; Other themes included “may do good for others”, “won’t cure me/do no good”, “spend more time in hospital”, “getting depressed” and “might buy a little time”; Parents perceived Phase I therapies as “buying a little time”; “being hospitalized”, “prolonging the inevitable”, “getting sick”, and “doing what my child wants”; Decision making affected by relationship with others potential adverse effects, wanting no more</td>
<td>Small sample size but conducted at 2 sites</td>
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<td>Klopfenstein K J, Hutchison C, Clark C, Young D &amp; Ruymann F B</td>
<td>2001</td>
<td>Retrospective chart review</td>
<td>95 patients who died of pediatric cancers in a large academic pediatric cancer center</td>
<td>Most children died at home on hospice care; 12.6% were enrolled on Phase I clinical trials; Patients with leukemias more likely to die of therapy related complications; With each failure therapy, palliative care should be addressed as option for care</td>
<td>No information solicited from parents or health care team; No information provided if patients were on other anti-cancer therapies other than Phase I therapies;</td>
<td>III</td>
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<tr>
<td>Roddenberry A &amp; Renk K</td>
<td>2008</td>
<td>Non-experimental exploratory design</td>
<td>47 mothers, 16 fathers and 19 children (age 8 – 19 yrs) with cancer from 2 large pediatric cancer centers</td>
<td>Multiple measures of cancer specific HRQOL as well as symptom checklist and depression inventory; Parents had symptoms of depression, anxiety and parenting stress and reported ↓ personal QOL; Children self-reported milder degrees of similar symptoms; No significant differences between parents &amp; child reports; Child’s psychological &amp; physical symptoms predicted HRQOL</td>
<td>Small sample size so may not be able to generalize results however correlation analysis showed moderate relationship for mother/child adjusted for sample size; Pilot study</td>
<td>III</td>
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<tr>
<td>Hongo T, Watanabe C, Okada S, Inoue N,</td>
<td>2003</td>
<td>Non-experimental Retrospective</td>
<td>28 deceased pediatric</td>
<td>Most common symptoms included poor appetite, dyspnea, pain, fatigue.</td>
<td>Sample from Japan so may not be generalizable</td>
<td>III</td>
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<td>Author</td>
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<td>Yajima S, Fuji Y &amp; Ohzeki T</td>
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<td>medical record review</td>
<td>oncology patients between 1 – 19 years of age</td>
<td>nausea/vomiting, constipation, and diarrhea; Anxiety was reported in &gt; 50% overall but no anxiety was reported in patients with brain tumors, however changes in level of consciousness was much higher in brain tumor group</td>
<td>to US population; No information given on degree of symptom distress or effectiveness of interventions</td>
<td>B</td>
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<tr>
<td>Woodgate R L, Degner L F &amp; Yanofsky R</td>
<td>2003</td>
<td>Qualitative Exploratory design</td>
<td>39 children with various cancers and their parents and siblings at 3 different pediatric cancer centers</td>
<td>Multiple methods of data collection; Self report scales alone not sufficient for adequate representation of symptom distress; Variety of symptoms experienced but described in terms of child, i.e. “I feel yucky” or “I feel cranky”, instead of traditional symptom terms; Symptoms attached to meaning for child and family which may impact degree of distress</td>
<td>Small sample size; 95% Caucasian sample so not culturally sensitive</td>
<td>III</td>
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<tr>
<td>Jacobsohn, DA</td>
<td>2008</td>
<td>Systematic Review</td>
<td>Review of 6 articles describing incidence and grading of acute GVHD in children undergoing HSCT with a focus on risk factors, treatment and outcome</td>
<td>Acute GVHD is one of the major complications of HCST; Variables such as the type of HSCT, age of the donor and recipient, preparative regimen and complications of HSCT can affect the presence and severity; Review articles are from larger pediatric studies (N = 26-630); HSCT has significant morbidities and risk of mortality so risks &amp; benefits should be carefully considered; Children are at less risk than adults for GVHD but ↑ with non-related, mismatched donors</td>
<td>Varied sample sizes of studies reviewed; No criteria described for method of review; Some studies were non-US samples so data may not be generalizable</td>
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<td>Mayer DK, Tighouart H, Terrin N, Stewart S, Peterson E, Jeruss S &amp; Parsons SK</td>
<td>2009</td>
<td>Non-experimental</td>
<td>Parental caregivers (N = 161) completed online survey to identify needs and resources of parents whose child underwent HSCT; National survey through BMT InfoNet</td>
<td>Most cited resource for information was the HSCT team (87.7%), books and other print materials (83.1%), and the Internet (81.5%); 17% reported major problem in finding resources and services; 37% reported some problems; 32% reported problems getting information from HSCT team about care.; 79.9% identified managing the emotional and social impact of the transplant on their child, post-transplant and follow-up care, practical strategies for caregiving, maintaining the family, and taking care of themselves during this first year</td>
<td>5 focus groups held for instrument development; Convenience sample = 27 from pilot testing + 136 from national survey but from 231 sites; No protection from multiple entries; 86.7% mothers and 96.2% Caucasian so may not be generalizable; Bias of responders; Did not explore why resources were not used</td>
<td>III</td>
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<td>Wilson K, Mazhur W, Rojas-Cooley T, De Rosa V, &amp; Van Cleve L</td>
<td>2011</td>
<td>Case studies</td>
<td>N = 3; pediatric patients with advanced cancer; 2 of which underwent HSCT</td>
<td>Used open-ended interview as well as more well established assessment tools including MSAS, Peds QL, Child Depression Inventory, Revised Children's Manifest Anxiety Scale, CTC, Lansky Performance Scale, and Spirituality QOL inventory; Used trained interviewer Reported multiple symptoms with moderate to severe distress; Patient used only pharmacological interventions; Reported feelings of anger and sadness; Being alone a stressor; Mixed responses about reliance on faith traditions as source of comfort; Multiple complications during HSCT; Verbal about fears of death; Common issues – need to feel sense of control, social isolation, &amp; positive value on “the little things” to make</td>
<td>Very small sample size; 2 of case studies were Latino background so may be difficult to generalize to other settings; All children interviewed in hospital; Used well established and valid instruments</td>
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<td>Pritchard M, Burghen EA, Gattuso JS, West NK, Gajjar P, Srivastava DK, Spunt SL, Baker JN, Kane JR, Furman WL, &amp; Hinds PS</td>
<td>2010</td>
<td>Qualitative study – Descriptive, exploratory</td>
<td>N = 48 mothers and N = 4 fathers of 52 patients</td>
<td>Telephone interviews 6 – 10 months after child's death; 109 distressing symptoms identified, however, not all concerning to parent; 19 symptoms identified as most concerning to parents; Symptoms of most concern related to apparent unrelieved suffering of the child, changes in child perceived to be negative, &amp; if child less engaged with parent; Symptoms not of concern related to duration of symptoms, newness of symptom, and child's apparent lack of distress; Single most significant factor in parental distress is unrelieved suffering of the child and their feeling of helplessness; Education of illness and symptoms ↓ parental distress</td>
<td>Recall bias since time elapsed from active illness experience; One site but large cancer center; Multiple types of disease; Some parents in initial cohort not asked about symptoms not of concern so difficult to make comparisons across the sample</td>
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<td>Ullrich CK, Dussel V, Hilden JM, Sheaffer JW, Moore CL, Berde CB, &amp; Wolfe J</td>
<td>2010</td>
<td>Retrospective cross-sectional study</td>
<td>N = 141 parents</td>
<td>96% of children with advanced cancers experience fatigue; 56% reported suffering as a result of fatigue; Fatigue correlated with other symptoms of pain, dyspnea, anorexia, nausea/vomiting, diarrhea, anxiety, sadness or fear; Children with less experienced physicians had greater reports of suffering from fatigue; Only</td>
<td>Parental report, not self report; Two study sites; Primarily Caucasian (93%); Diffuse diseases; Retrospective study; Cross-sectional study shows relationship but not causality; Potential</td>
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<td>Poder U, Ljungman G, &amp; Von Essen L</td>
<td>2010</td>
<td>Prospective, longitudinal study; Descriptive, exploratory</td>
<td>N = 214 parents (107 mothers and 107 fathers)</td>
<td>13% of children received fatigue directed treatments and of those, only 25% had successful treatment; Co-morbidity of pain or dyspnea increased likelihood of being treated for fatigue</td>
<td>recall bias; Unidimensional instrument;</td>
<td>III</td>
</tr>
<tr>
<td>Vatne TM, Slaugher L, &amp; Ruland CM</td>
<td>2010</td>
<td>Qualitative - Descriptive exploratory</td>
<td>N = 14 Matched healthy controls (n=8) with children with cancer (n=6), age 7-12 years</td>
<td>Most children (90% in cancer group &amp; 96% in control group) understood the definition of a symptom but ~ 25% in cancer group and 17% in control group could not explain when they might experience that symptom; 63% in cancer group and 73% in control could explain cause of symptom; Children with cancer had more synonyms for names of symptoms and were able to identify intensity of symptoms more than control; Child's understanding of a symptom should be</td>
<td>Small sample size; Study done in Norway so may not be generalizable to US childhood cancer population</td>
<td>III</td>
</tr>
<tr>
<td>Author</td>
<td>Date</td>
<td>Evidence Type</td>
<td>Sample &amp; Sample Size</td>
<td>Results/ Recommendations</td>
<td>Limitations</td>
<td>Strength</td>
</tr>
<tr>
<td>--------</td>
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<td>----------</td>
</tr>
<tr>
<td>Baggott C, Dodd M, Kennedy C, Marina N, &amp; Miaskowski C</td>
<td>2009</td>
<td>Systemic Review</td>
<td>9 studies reviewed that met strict inclusion criteria which was well described, the main criteria being the presence of multiple symptoms captured on 1 of 5 known and valid instruments</td>
<td>Instruments included MSAS (10-18 and 7-12), Life Situation Scale, Therapy Related Symptom Checklist, and structured interviews; Variability across instruments in prevalence, intensity and distress of symptoms; Symptoms were characterized across studies by prevalence, severity and level of distress; Symptom assessment must be done in a consistent manner with regard to timing to avoid recall bias; Need further research on the trajectory of symptoms; Need further research on the impact of symptoms and QOL &amp; functional status – current data sparse</td>
<td>Only reviewed studies where multiple symptoms were addressed; Small number of articles reviewed however there was strict inclusion and exclusion criteria; Only 3 studies done in the US so generalizability is limited</td>
<td>IV</td>
</tr>
<tr>
<td>Ohta H, Hashii Y, Yoshida H, Kusuki S, Tokimasa S, Yoneda A, Fukuzawa M, Inoue M, Hara J, Kusafuka T, &amp; Ozono K</td>
<td>2011</td>
<td>Case report</td>
<td>N = 1, case report of a child with RMS undergoing HSCT</td>
<td>Poor prognosis patient with relapse referred for high dose chemotherapy with HCST; Symptoms included Gr II GVHD of skin, and no other major toxicity</td>
<td>Case study from Japan so less generalizable; Lack of evidence on symptom experience including distress during HCST</td>
<td>IV</td>
</tr>
<tr>
<td>Jaing TR, Huang IA, Chen SH, Yang CP, Liang DC, &amp; Hung IJ</td>
<td>2011</td>
<td>Case reports</td>
<td>N = 5 patients undergoing cord blood transplants for aplastic anemia</td>
<td>All patients with relapsed or refractory AA; GVHD developed in 4/5 patients; Also reported were viral and bacterial infections (2/5), sepsis (1/5), pneumonia (1/5), and failure to engraft (1/5)</td>
<td>Small sample size</td>
<td>IV</td>
</tr>
<tr>
<td>Author</td>
<td>Date</td>
<td>Evidence Type</td>
<td>Sample &amp; Sample Size</td>
<td>Results/ Recommendations</td>
<td>Limitations</td>
<td>RATING</td>
</tr>
<tr>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Maltezou HC, Kafetzis DA, Abisaid D, Mantzouranis EC, Chan KW, &amp; Rolston KVI</td>
<td>2000</td>
<td>Retrospective chart review</td>
<td>N = 96 HSCT over 4 year period</td>
<td>70 episodes of viral infection; Most common were CMV, Varicella, and herpes simplex; 10% of patients died as a direct result of infection; Viral infection linked to GVHD and pre-HSCT neutropenia; Need antiviral prophylaxis during and following HSCT; Viral illness manifest with a host of symptoms including pneumonia, cough, sore throat, URI, diarrhea, and rash; Highest case fatality rate was with CMV (4/5); Majority occur during 1st 100 days</td>
<td>Single institution study; Included multiple diseases and multiple HSCT sources</td>
<td>III</td>
</tr>
<tr>
<td>Rawlinson NJ, Fung B, Gross TG, Termuhlen AM, Skeens M, Garee A, Soni S, Pietryga D, &amp; Bajwa RJS</td>
<td>2011</td>
<td>Case study</td>
<td>N = 1 child with Aplastic Anemia</td>
<td>Case study of a pediatric patient with AA who underwent matched sibling donor HSCT; Suffered fungemia and multiple organ failure leading to death; Normal organ function pre-transplant; Other symptoms include fever, pancytopenia requiring transfusions, mucositis, fluid retention, hypertension, pain, abdominal distention and hepatomegaly</td>
<td>Single case study so results not generalizable</td>
<td>IV</td>
</tr>
<tr>
<td>Gassas A, Raiman J, White, L, Schechter T, Clarke J, &amp; Doyle J</td>
<td>2011</td>
<td>Retrospective chart review</td>
<td>N = 42 Hurlers = 23 Osteopertrosis = 8 X-ALD = 6 Other = 7</td>
<td>60 – 80% overall survival; 72 – 100% ambulatory; 71 – 100% attending regular school; Need continued multidisciplinary follow-up; Parents felt like child had meaningful life with less progression of symptoms following HSCT; Skills improve over time</td>
<td>Single institution study</td>
<td>III</td>
</tr>
<tr>
<td>Author</td>
<td>Date</td>
<td>Evidence Type</td>
<td>Sample &amp; Sample Size</td>
<td>Results/ Recommendations</td>
<td>Limitations</td>
<td>RATING</td>
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<tr>
<td>Brandt J, Dietrich S, Meissner J, Neben K, Ho AD, &amp; Witzens-Harig M</td>
<td>2010</td>
<td>Secondary analysis of data from RCT</td>
<td>N = 98 patients with Hodgkin Lymphoma; Majority of sample was adults but ~1/3 young adults (21-25y)</td>
<td>Patients randomized on treatment protocol to either conventional chemotherapy or high dose chemo with autologous HSCT; Also compared to general population; Median 11 year follow-up; Questionnaires mailed to participants with 64% response rate; HSCT group had reduced QOL; Investigators conclude that QOL is an important consideration in planning treatment protocols</td>
<td>Single institution study; Study done in Germany with adults so results may not be generalizable; Median follow-up is 11 years so current therapies may be significantly different so may not be generalizable to current HSCT methods;</td>
<td>I</td>
</tr>
<tr>
<td>Tomlinson D, Bartels U, Gammon J, Hinds PS, Volpe J, Bouffet E, Regier DA, Baruchel S, Greenberg M, Barrera M, Llewellyn-Thomas H, &amp; Sung L</td>
<td>2011</td>
<td>Qualitative, Descriptive</td>
<td>77 parents and 128 health care professionals</td>
<td>Important factors influencing the decision between therapeutic options were child QOL and survival time among both parents and health care professionals. Hope was particularly important to parents. Parents chose chemotherapy (42/77, 54.5%) compared with health care professionals (20/128, 15.6%; p &lt; 0.0001). The opinions of the physician and child significantly influenced the parents’ desire for supportive care; for health care professionals, the opinions of parents and children were significant factors influencing this decision. Compared with health care professionals, parents more strongly support aggressive treatment and rank hope as a more important factor for making decisions about treatment. Understanding the differences between parents and health care professionals in the relative desirability of supportive care alone may aid in communication and improve end-of-life care</td>
<td>Potential for selection bias as only 77 of 114 parents participated; Only one palliative intervention explored (IV chemo); May have different results if oral chemotherapy considered; Did not include probability of cure as attribute in decision making; Did not include QOL in estimate of desire for longer survival time; Proxy measure of child QOL; Majority of HCP's were nurses</td>
<td>III</td>
</tr>
</tbody>
</table>
# Appendix III

## Palliative Care Intervention Study

### Study Participant Log and Demographic Data Collection Tool

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Initials</th>
<th>Age (years/mos)</th>
<th>Diagnosis</th>
<th>Date of Admission</th>
<th>Date of Discharge</th>
<th>Comments (Include type of transplant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
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<tr>
<td>Visit</td>
<td>Date</td>
<td>Provider</td>
<td>Time In</td>
<td>Time Out</td>
<td>Interventions Needed</td>
<td>Offered</td>
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</tbody>
</table>

**NOTE:** If participant not enrolled, please give information on why not.

Appendix IV

Palliative Care Intervention Study 2011
TIME AND INTERVENTION LOG
Subject #: ________
INSTRUCTIONS FOR COMPLETING TIME AND ACTIVITY LOG: Each subject will have a separate log

1. Subject Number – Subject number will be retrieved from the study subject log and entered into this line as a numerical entry, i.e. 001, 002, 003, etc.

2. Visit – Each visit to the patient/family unit will be entered in numerical sequence, i.e. 1, 2, 3, 4, etc. A minimum of 4 visits will be made for each patient/family unit, however if needed, additional visits may be made to meet the needs of the patient/family unit. Each visit must be recorded on the log, including the 4 weekly minimum visits and any additional visits made.

3. Date – The date of each visit in mm/dd/yy format will be entered.

4. Provider – The last name of the palliative care provider (i.e. Lafond or Jacobs) will be entered for each visit.

5. Time In – The time each visit begins will be entered using military time, i.e. 0800 or 1245, etc.

6. Time Out – The time each visit ends will be entered using military time, i.e. 0915 or 1430, etc.

7. Interventions Needed – Assessment of interventions needed will be made utilizing the framework of the Pediatric Oncology Palliative and End-of-Life Care Resource © and interventions will be listed by code listed below:

   a. Initial family meeting/assessment = 1
   b. Supportive care counseling = 2
   c. Acupuncture = 3
   d. Advanced Directive = 4
   e. Aromatherapy = 5
   f. Art therapy = 6
   g. Biofeedback = 7
   h. Complementary and Alternative Medicine approaches = 8 (specify)
   i. Dietary modifications = 9
   j. Guided Imagery and/or Relaxation techniques = 10
   k. In house Consults – Social Work = 11a, Pastoral Care = 11b, Pain Team = 11c, Child Life = 11d, Other = 11e (specify)
   l. Hospice referral = 12
   m. Massage therapy = 13
n. Music therapy = 14
o. Non-pharmacological interventions = 15 (specify if not coded in any other intervention)
p. Oxygen = 16
q. Palliative chemotherapy = 17
r. Palliative radiation therapy = 18
s. Pharmacological interventions = 19
t. Psychology/Psychiatry = 20
u. Team meeting = 21
v. Others not otherwise specified = 22 (specify)

8. **Offered or Completed**– The date and time each of the interventions listed in the "Interventions Needed" column is offered to or completed for the patient/family unit will be entered using *mm/dd/yy* and military time format, i.e. 05/01/11, 0930.
PANDA Care Team Family Survey

Patient Initials/Study ID: ______________________
Date: ______________________________________
Interviewer: ________________________________
Relationship of caregiver completing survey: ______________________

Thank you for participating in the Palliative Care Intervention Study as part of your child's admission to Children's National Medical Center for stem cell/bone marrow transplantation.

We would like to find out if the services of the PANDA Care Team were helpful to you and your child so we can continue to improve the care we provide, in ways that are most helpful for the children and families we serve. We would like to ask you a few brief questions about your experience with the PANDA Care Team. This will only take a few minutes and is important for determining if palliative care services should be routinely offered for patients and families.

(1) How comfortable were you getting care from the PANDA CARE TEAM?

<table>
<thead>
<tr>
<th>Very Uncomfortable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Comfortable</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: __________________________________________________________

(2) How helpful was the PANDA CARE TEAM to you in helping your child to be as comfortable as possible by managing the symptoms and other stresses of your child's stem cell transplant?

<table>
<thead>
<tr>
<th>Very Unhelpful</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Helpful</th>
<th>5</th>
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</table>

Comments: _____________________________________________________________________________

(3) How helpful was the PANDA CARE TEAM in improving your access to care at Children's National?

<table>
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<tr>
<th>Very Unhelpful</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Helpful</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: _____________________________________________________________________________

(4) How important is it to you that Children's National offers the services of the PANDA CARE TEAM?

<table>
<thead>
<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Important</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: _____________________________________________________________________________
(5) How likely are you to **recommend** the PANDA CARE TEAM to others?

<table>
<thead>
<tr>
<th>Very Unlikely</th>
<th>1</th>
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<th>3</th>
<th>4</th>
<th>Very Likely</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: ________________________________________________________________________________

(6) How did your experience with the PANDA CARE TEAM **influence your likelihood of recommending** Children's National to others?

<table>
<thead>
<tr>
<th>Greatly Decreased</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Greatly Increased</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: ________________________________________________________________________________

(7) Any **other comments**? What could be done to improve the care you got from the PANDA CARE TEAM?

Thank you so much for your time.

Additional comments and suggestions can be written below or discussed with the person asking you to complete this survey. In addition, you may contact the PANDA Care Team at any time to discuss your experience and offer any suggestions for improvement at (202) 476-5246 or via email to dlafond@childrensnational.org or ssjacobs@childrensnational.org.
PANDA Care Team Provider Survey

Date: ________________________________
Interviewer: ________________________

Type of provider: [ ] Attending physician [ ] Fellow [ ] PA/NP [ ] Staff nurse [ ] Other: _____

Thank you for participating in the Palliative Care Intervention Study for children and adolescents undergoing hematopoietic stem cell transplantation and their families.

We would like to find out if the services of the PANDA Care Team were helpful to you and the patients/families so we can continue to improve the care we provide, in ways that are most helpful for the children and families we serve, as well as the primary health care team. We would like to ask you a few brief questions about your experience with the PANDA Care Team during this study. This will only take a few minutes and is important for determining if palliative care services should be routinely offered for patients and families as part of the care provided during the stem cell transplant experience.

(1) How comfortable were you with referring patients and families to the PANDA CARE TEAM prior to the implementation of this study?

Very Uncomfortable 1 2 3 4 Very Comfortable 5

Comments: _________________________________________________________

(2) How helpful was the PANDA CARE TEAM to you in helping patients/families to be as comfortable as possible by managing the symptoms and other stresses during this transplant admission?

Very Unhelpful 1 2 3 4 Very Helpful 5

Comments: __________________________________________________________________________

(3) How helpful was the PANDA CARE TEAM in improving your access to services for your patients?

Very Unhelpful 1 2 3 4 Very Helpful 5

Comments: __________________________________________________________________________

(4) How important is it to you that Children's National offers the services of the PANDA CARE TEAM?

Important 1 2 3 4 Very Important 5

Comments: __________________________________________________________________________
(5) How likely are you to **recommend** the PANDA CARE TEAM to other patients and families?

<table>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>Very Likely</th>
<th>5</th>
</tr>
</thead>
</table>

Comments: ____________________________________________

(6) Any **other comments**? What could be done to improve the care your patients/families received or communication you got from the PANDA CARE TEAM?

---

*Thank you so much for your time. Additional comments and suggestions can be written below or sent via email to dlafond@childrensnational.org or ssjacobs@childrensnational.org.*
Appendix VII

Palliative Care Consultation in Pediatric Stem Cell Transplant

Date_________________________  Code #_____________
Data collection time point:  (Circle one)  Baseline  Time 1  Time 2

GENERAL COMFORT QUESTIONNAIRE – Parent/Guardian Form

Thank you VERY MUCH for helping me in our study of the concept COMFORT. Below are statements that may describe your child's comfort right now. Six numbers are provided for each question; please circle the number you think most closely matches your feeling about your child's comfort. This is about your child's comfort at the moment you are answering the questions.

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. There are those my child can depend on when he/she needs help</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>2. My child does not want to exercise or play</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>3. My child's condition gets him/her down</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>4. My child feels confident</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>5. My child feels his/her life is worthwhile right now</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>6. My child is inspired by knowing that he/she is loved</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>7. The sounds keep my child from resting</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>8. My child feels no one understands him/her</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>9. My child's pain is difficult for him/her to endure</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>10. My child is unhappy when he/she is alone</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>11. My child does not like it here</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>12. My child is constipated right now</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>13. My child does not feel healthy right now</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>14. My child's room makes him/her feel scared</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
<tr>
<td>15. My child is afraid of what is next</td>
<td>1 2 3 4 5 6</td>
<td></td>
</tr>
</tbody>
</table>

(Continue on back)
16. My child is very tired
1 2 3 4 5 6

17. My child is content
1 2 3 4 5 6

18. This chair (bed) makes my child hurt
1 2 3 4 5 6

19. The views are soothing
1 2 3 4 5 6

20. My child's personal belongings are not here
1 2 3 4 5 6

21. My child feels out of place here
1 2 3 4 5 6

22. My child's friends remember him/her with their cards and phone calls
1 2 3 4 5 6

23. My child needs to be better informed about his/her health
1 2 3 4 5 6

24. My child does not have many choices
1 2 3 4 5 6

25. This room smells bad
1 2 3 4 5 6

26. My child feels peaceful
1 2 3 4 5 6

27. My child is depressed
1 2 3 4 5 6

28. My child has found meaning in his/her life
1 2 3 4 5 6

Please feel free to offer any other comments regarding your child's comfort:
Appendix VIII

Comfort Daisies
(c) Kolicaba 2000

Right now I feel:

- Very bad
  1.
- Sort of bad
  2.
- Sort of good
  3.
- Very good
  4.
Appendix IX

100-mm Visual Analogue Scale

Discomfort Assessment

Please draw a line to indicate what level of discomfort you are experiencing right now.
APPROVAL OF RESEARCH NOTIFICATION

Date: January 27, 2012

To: Michele Michael  
RE: HP-00050810
Type of Submission: Initial Review  
Type of IRB Review: Full Board

Approval for this project is valid from 1/27/2012 to 1/26/2013

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced protocol entitled, “Promotion of Comfort through Early Palliative Care Consultation for Children and Adolescents Undergoing Hematopoietic Stem Cell Transplantation (HSCT): Feasibility of Implementation and Evaluation of a Proposed Practice Change”.

The IRB made the following determinations regarding this submission:

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-00050810 v10-24-2011-1319499878547
Study Schedule
HIPPA Palliative Care Intervention Study
HIPPA for Health Care Providers
Reference List
Comfort Posies
Provider Satisfaction Survey
Short General Comfort Questionnaire - Parent form
Demographic Data Tool
Time and Activity Log
Discomfort Verbal Rating Scale
Family Satisfaction Survey
Children's National IRB Cover Sheet
Appendicies to Children's National IRB Cover sheet
HIPPA Palliative Care
Childrens National IRB Approval Letter
Assent 7-11 years
Consent
Assent Ages 12-17 years

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL.  Investigators are reminded that the IRB must be notified of any changes in the study.  In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring
that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants’ safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond 1/26/2013. You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond 1/26/2013. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.


If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.
Deborah Lafond, MS, PNP-BC, CPON
Principal Investigator
Center for Cancer and Blood Disorders

IRB#: 5183

Title: Promotion of Comfort through Palliative Care Consultation for Children and Adolescents Undergoing Hematopoietic Stem Cell Transplantation (HSCT): Feasibility of Implementation and Evaluation of a Proposed Practice Change

Dear Deborah Lafond, MS, PNP-BC, CPON:

The IRB has reviewed and approved the protocol referenced above for a period of 12 months. The IRB determined that the study meets the criteria for expedited review under category, 45 CFR 46.110 (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. This IRB approval will expire on September 10, 2012.

When enrolling participants all Informed Consent documents, including the information sheet, should be stamped "IRB Approved with the approval dates." The signature of at least one legally authorized representative is required on the consent form. Please convey the IRB’s decision to co-investigators, if applicable.

Please note that it is the Investigator’s responsibility to ensure that the Continuing Review Report is submitted to the IRB in a timely fashion.

Federal Human Subjects Regulations require that the IRB review all active protocols at intervals appropriate to the degree of risk, but not less frequently than once per year. When continuing review of a research protocol does not occur prior to the end of the approval period, IRB approval expires automatically. This protocol will expire on September 10, 2012. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval.

If the IRB approval expires, investigators must cease all research activities including:

1. Recruitment;
2. Screening and enrollment;
3. Intervention and interaction;
4. Follow-up; and data analysis.

The PI is required to inform the IRB immediately of any circumstances or new information which may potentially change the risk/benefit ratio. Please refer to the IRB Policies & Procedures on the OPHS/IRB Website at CNMC IRB/OPHS Intranet Site for information concerning Modification Requests, Adverse Event Reports, and Continuing Review Reports. For further information, please call the Office for the Protection of Human Subjects, 301-565-8470.


Naynesh Kamani, M.D.
IRB Chair