Evaluating Quality of Death at the End of Life in Neonates in the NICU

Dissertation

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Abstract

End-of-life (EOL) care for neonates admitted to the Neonatal Intensive Care Unit (NICU) is understudied and practice varies widely across centers and providers. We just do not have a clear understanding of those physiologic processes and other factors that can impact the quality of a neonatal death in the NICU. By not paying close attention to, and then not appropriately treating the symptoms the critically ill neonate expresses as death approaches, we may very well be depriving these infants and their families the opportunity for the “good” death one might hope for an infant.

This dissertation work includes a proposed new model for evaluating the quality of a neonatal death that, with testing, will hopefully provide insight and guidance for clinicians who must coordinate care of parent and child at the end of life. Several characteristics and relationships need to be further evaluated, however this new framework will offer a good approach until more definitive knowledge is discovered. Next, an exploratory study is presented examining how dying neonates are currently being cared for in the NICU. Finally, discussion unfolds regarding several methodological issues encountered in EOL care research that makes it incredibly difficult to study this important topic. There is much room for improvement in our understanding so that we may deliver the absolute best end-of-life care possible for these special babies.
Dedication

This work is dedicated to all babies who have died in a neonatal intensive care unit. May your death not be in vain but instead provide us with the knowledge necessary to ensure every future infant who must return to heaven before life has really begun will experience end-of-life care that is comfortable, peaceful and completely absent of pain.

And, to my mom, Arlea, who died after an unexpected illness during the final stages of the writing of this dissertation. She was my biggest cheerleader and wanted nothing more than to see me complete this work and achieve my goal.

I love you and miss you, mom…forever.
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Many times I prayed for God to lead me in another direction with my research interest, ANY other direction. Every time I hit a stumbling block, another door would open bringing further support and encouragement. I willingly follow wherever He may lead me next on this incredible path.

Matt, my husband, has been my rock, keeping me grounded and focused on the important things in my life, while pushing me forward to greater accomplishments. My children, Ava and Ayden, are my pride, joy, love, life and inspiration. My parents, Guy and Arlea Burford, have loved and encouraged me all my life, no matter where my experiences have taken me. Jim and Mary-Jayne Fortney have given of themselves routinely in support of my advanced education. I love immensely these special people.

I am forever grateful to my advisor, Dr. Deb Steward. She went places in the literature I know she would have rather not traveled and acknowledged the importance of my passion for improved end-of-life care for neonates. I must also thank Dr. Vicki Von Sadovszky and Dr. Pamela Salsberry for their time, comments and commitment to my education during the candidacy and dissertation phases.

I am indebted to the babies and nurses who were my subjects. It is my hope I will honor them while continuing to advocate for improved end-of-life care for future neonates who will unfortunately succumb to their illnesses way before their time.

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Figure 1 is reprinted from The Lancet, v. 351, supplement 2, Emanuel, EJ & Emanuel, LL, The promise of a good death, SII21 – SII29, May 1998, with permission from Elsevier.
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Chapter 1: Introduction

Death is inevitable for some neonates in the neonatal intensive care unit (NICU). Advances in the management of high-risk deliveries have significantly contributed to an increase in the numbers of neonates confronting prematurity, congenital anomalies, or other syndromes who survive the initial delivery resuscitation, and are admitted to the NICU. Once in the NICU, the management of these neonates is focused on stabilization and survival, however for many neonates it becomes apparent that, despite all of the tremendous technical capabilities available to manage neonatal illness, treatment becomes futile and death is inevitable. The majority of deaths in the NICU are attributed to withdrawal of life-sustaining treatment (Abe, Catlin, & Mihara, 2001; Verhagen, et al., 2010). Once the decision is made to withdraw or withhold treatment, the emphasis must turn to managing the end-of-life (EOL) process.

Dying neonates deserve a good death. Whether these neonates are currently experiencing a good death is unknown. However, there is compelling evidence that the majority of dying neonates are not medicated for pain during the dying process (Abe et al., 2001). Experts in area of neonatology have advocated for the importance of a good death (Walden et al., 2001). The Institute of Medicine defines a good death as one that is “free from avoidable distress and suffering for patients, families and caregivers; in general accord with patients’ and families’ wishes; and reasonably consistent with...
clinical, cultural and ethical standards” (IOM, 2003). However, we have not been able to consistently provide dying neonates with a good death because we have yet to identify the signs and symptoms they exhibit during the dying process nor do we know if nursing interventions for a dying neonate should be different from illness management. Currently, management of the end-of-life process is guided by the philosophy of individual NICUs. Further, protocols that can allow neonates to experience a good death are widely needed as batteries of tests and other procedures commonly utilized during the dying phase very likely only increase suffering and prolong death.

Many have called for increased attention toward the study of end-of-life care. Since 1997, the National Institute for Nursing Research (NINR) has been the lead institute at the National Institutes of Health (NIH) for end-of-life research. NINR is focusing on physical and psychological symptom management, communication, ethics and clinical decision-making, caregiver support, and care delivery issues” (NINR Strategic Plan, October 2011) and includes research to improve care for dying children and their families. Further, the Institute of Medicine (IOM) report (2003), entitled, “When Children Die: Improving Palliative and End of Life Care for Children and Their Families,” outlined the importance of caring for dying children and their families, including neonates.

Unfortunately, EOL care for neonates in the NICU has received very little attention from a research perspective. Empirical evidence is lacking that characterizes the signs and symptoms that the dying neonate exhibits, as well as the treatment strategies that are used (Pierucci, Kirby, & Leuthner, 2001). Because of the pre-verbal status of the neonate, communication of symptoms is through behavioral and physiologic cues. Thus,
accurate interpretation of the cues is required by the caregiver in order to intervene. This is a major problem in identifying illness or injury in neonates (Selekman & Malloy, 1995). There is much room for error.

Many factors impact the recognition of symptoms, including the effectiveness of the cues exhibited by the neonate; the capacity of the caregiver to interpret the cues correctly; and the caregiver’s knowledge of normal neurodevelopment and pathophysiology, as well as their experience and intuition (Selekman & Malloy, 1995). Accurate evaluation of the dying neonate can be further hindered because the neonate might exhibit few obvious cues (Walden, Sudia-Robinson, & Carrier, 2001) and one sign may be indicative of any number of symptoms the neonate might be experiencing. The “signs” become the empirical indicators of the “symptoms.”

**Specific Aims**

The purpose of this project was to determine the signs and symptoms commonly exhibited by the neonate during the dying process and the management strategies used by caregivers. The following **specific aims** were addressed:

1. To characterize the physical and behavioral signs and symptoms exhibited by the neonate at the end of life.

2. To identify the treatment strategies used to manage physical and behavioral signs and symptoms exhibited by the neonate at the end of life.

**Background and Significance**

There has been increased interest among pediatric experts in relation to palliative
care and the dying child. However, little attention has been given to the dying neonate from a research perspective and yet this specific group of children constitutes the highest percentages of deaths for any age-group in pediatric institutions (McCallum, Byrne, & Bruera, 2000). In a 2002 study, 42% of the 13,761 pediatric deaths reported to the National Association of Children’s Hospitals and Related Institutions Data Consortium for the years 1991, 1994, and 1997 were of neonates (Feudtner et al., 2002). Further, of those deaths, 32% were related to prematurity and newborn disorders and 66% had received mechanical ventilation. This is further supported by McCallum and colleagues (2000) who found that 53% of the deaths in their pediatric institution were attributed to neonatal deaths. Not included above are the numbers of deaths that occur in NICUs in a delivery hospital. This rate is even higher for preterm neonates. Unfortunately, it is clear that neonates do die. It is imperative that research studies are carried out to identify signs and symptoms exhibited by dying neonates so that clinical guidelines can be developed to effectively manage the end-of-life processes for these neonates (Partridge & Wall, 1997).

Death is always the expected outcome when treatment is withdrawn or withheld from a neonate (McHaffie, Lyon, & Fowlie, 2001; van der Heide, et al., 1998). Anecdotally, we know that neonates often suffer pain and discomfort at the end of life, however we know very little about what constitutes optimal end-of-life care for these neonates. When the only inevitable outcome for a neonate is death, the priority must shift to provide adequate pain relief and comfort measures for the dying neonate. The greatest concern expressed by parents of dying children is that their child will suffer when life support is removed (Meyer, Burns, Griffith, & Truog, 2002). Therefore, providing a good death is critical.
However, at this time, the range of symptoms experienced by neonates during the dying process, as well as the best way to treat those symptoms is simply unknown. A few neonatal palliative care protocols do exist that offer suggestions on managing the death of a neonate, however, there are wide variations in the care measures provided in the clinical setting (Carter, 2004), which offer little direction to health care providers (McHaffie, et al., 2001). The literature shows that babies are being under-medicated during and after withdrawal of treatment (van der Heide, et al., 1998) and that parents are most distressed by the uncertainty of the predicted time until death, as well as the physical signs (e.g. unpleasant noises, color changes, gasping) the infant exhibits while dying (McHaffie, et al., 2001). As the limits to the margin of viability continue to be stretched, research must be undertaken in an effort to discover the best way to care for those neonates who will die as a result of their condition, as well as ease the distress experienced by their parents and care givers.

Two major constructs, the dying process and physical and behavioral symptoms, guided this research study. From these constructs several concepts were hypothesized as being potentially important variables to explore, such as pain, restlessness and agitation, renal status, cardiovascular status, and respiratory status. However, the extent to which physical and behavioral symptoms manifest in these systems during the dying process is unknown.

**Research Design and Methods**

**Research design**
The study is exploratory in nature and utilizes a descriptive design. The purpose was to determine the signs and symptoms exhibited by the dying neonate at the end of life. This study is the first step in identifying pertinent variables for use in future descriptive, as well as interventional studies. The plan was to collect data from two sources; review of medical records and semi-structured face-to-face interviewing of neonatal staff nurses assigned to care for infants who died during the last 24 hours of life. Further, no categories of symptom clusters were determined a priori.

Sample

The ideal sample for the project would have been neonates actively experiencing the dying process. However, direct observation of the dying neonate by a researcher would disrupt the dignity and privacy of the end-of-life experience for the family and neonate and is ill-advised until there is sufficient systematic research to identify relevant variables to observe. Therefore, the sample for this project was comprised of two groups: 1) neonates who had died in the NICU and 2) neonatal staff nurses who had actively cared for those dying neonates during the last 24 hours of life.

The rationale for including neonates who had already died was to extract documented symptoms as well as medical management during the dying process from the medical record. Face-to-face interviewing of the neonatal staff nurses was conducted because reliance on medical record documentation is not the best way to obtain a comprehensive picture of end-of-life symptomatology and management (McCallum et al., 2000; Partridge & Wall, 1997). Neonatal staff nurses are included because in the majority of situations it is the nurse who is at the bedside performing routine observation and assessment (Catlin & Carter, 2002). Parents involved in the end-of-life process with
their child report that nurses were the most involved in their child’s care at the time of death (Meyer et al., 2002). Further, what they have recorded may not be all that they have observed.

Often the format of the medical record dictates the data that can be entered. In the electronic medical record, charting is by exception to what would normally be expected. Drop-down boxes are utilized that give the provider a list of options to choose. If the necessary choice is not listed, it is incumbent upon the provider to write a progress note. There is no room for free-text comments on the documentation flow sheet.

For exploratory, descriptive studies no standard exists for the number of subjects to be recruited, therefore, a power analysis will not be undertaken. A sample size of 40, 20 infants and 20 staff nurses, was the goal.

The following inclusion/exclusion criteria derived from a review of the literature was used for the study.

**Inclusion criteria for the neonates who have died group**

- Admitted to the NICU.
- Died as a result of the withdrawing or the withholding of life-sustaining therapy.

**Exclusion criteria for the neonates who have died group**

- Death as a result of a failed resuscitation.
- Sudden or unexpected death in the NICU.

**Inclusion criteria for the neonatal staff nurse group**

- Actively cared for at the neonate during the last 24 hours of life.
Methods

Medical Record Abstraction

Medical record data of twenty neonates who met the inclusion criteria were reviewed. All data recorded in the chart was accepted regardless of the type of personnel who recorded the data. All appropriate personnel, regardless of level of academic preparation, are trained to use the equipment utilized in the NICU and only certain employees have access to document results in the specific area of the chart. Future studies may limit who can collect data.

The following data were collected: demographic factors, including gestational age, birth weight, length of stay until death, age in days of life at death, diagnosis; ongoing therapy at the time of withdrawal; interventions associated with withdrawal; medications given prior to, during and after withdrawal; and all documented physiologic and behavioral symptoms (Zawistowski & DeVita, 2004; McHugh-Strong & Sanders, 2000) as part of the care and assessment of the neonate.

Five records were reviewed to confirm data availability, usability of the data collection form, appropriateness of the data collection procedures. (Aaronson & Burman, 1994). The form was modified and information was added or deleted depending on the usefulness and availability of the data. Records were reviewed again to ensure that information was being correctly located in the record. This minimized threats to both the validity and reliability of the data by ensuring that no relevant data was being overlooked and no unnecessary information was being gathered.

In this exploratory study, all information was weighted the same and of equal importance.
**Face-to-face semi-structured interviews with neonatal staff nurses**

Neonatal staff nurses who have cared for dying neonates included in the study were contacted within one week of the death to ask the nurse to participate in the project. If the nurse gave informed consent to participate in the study, a semi-structured face-to-face interview was scheduled within the following week. The interview was completed within two weeks of the death. An interview can be an exploratory device to help identify variables and relations, to suggest hypotheses, and to guide other phases of the research (Kerlinger & Lee, 2000).

**Data Management and Statistical Analysis**

Data obtained from the chart review and all demographic information for both infants and nurses were analyzed using descriptive statistics and frequencies. The information gleaned from the face-to-face interviews with the neonatal staff nurses was analyzed using the framework approach. Semi-structured interview questions regarding each neonate’s death were asked, hence, qualitative analysis was the best method to discover the themes associated those questions.

**Summary**

The survival rates of high-risk neonates in the delivery room are increasing. These neonates are admitted to the NICU and initially subjected to life-saving therapy. Unfortunately at some point in the disease trajectory it becomes clear that further treatment is futile and death is inevitable. The treatment focus must then shift from curative to supportive. In current practice, no universal standard of care exists to guide EOL care for the dying neonate.
This study is innovative because it is designed to understand the dying process with a focus on the neonate’s experience. From an extensive review of the literature, it appears this is a novel and needed approach to improve the end-of-life care for neonates. The goal of the project was to gather physiologic and behavioral data that could be used to define a good death for the dying neonate and thus shape guidelines for EOL care.

This chapter was an introduction into the background and significance of an EOL care study in the neonatal population. In subsequent chapters of this dissertation, a new framework for evaluating the quality of a neonatal death developed by this author during doctoral study will be introduced, the results from an exploratory EOL care study will be presented, and finally, methodological issues encountered during the study of EOL care in the NICU will be discussed. Some of the content in these chapters may be redundant. Each of the chapters is meant to stand alone as its own manuscript.
Chapter 2: A New Model to Evaluate the Quality of Neonatal Death

Death is inevitable for some infants in the neonatal intensive care unit (NICU). Advances in the management of high-risk deliveries have significantly contributed to an increase in the numbers of infants confronting prematurity, congenital anomalies, or other syndromes who survive the initial delivery resuscitation, and are admitted to the NICU. Management of these infants focuses on stabilization and survival. However, for some infants, despite the tremendous technical capabilities available, treatment becomes futile and death is inevitable. Infant deaths constitute the highest percentage of deaths for any age-group in pediatric institutions (Brandon, Docherty, & Thorpe, 2007). The estimated infant mortality rate for 2010 is 6.14 deaths per 1,000 live births while the neonatal rate (birth to 28 days of life) is 4.04 deaths (Murphy, Xu, & Kochanek, 2012). Further, 36% of all infant deaths are related to prematurity (Mathews & MacDorman, 2011).

Death is never a desired outcome for a newborn infant, but when the situation becomes futile, a death free of pain and suffering should be the goal. Unfortunately, differences in medical opinion and a lack of evidence-based palliative care protocols as well as limited options for neonatal hospice make a death with pain and suffering a very real outcome for many of these infants.

The concept of a “good death” has been introduced in the palliative care literature (Emanuel & Emanuel, 1998). Dying infants deserve a good death. This is an important
area for further exploration. The causes of death occurring in the NICU are substantially
different from those in other age groups (AAP, 2000). Thus, a good death for an elderly
person may not be the good death one would hope for an infant. Very little is known
about what constitutes a good death for an infant in the NICU. A framework for
evaluating the care an infant receives while dying is desperately needed to ensure that
quality care is given to all infants who will die as a result of neonatal illness. This
discussion introduces a framework that describes components for providing a good death
in the NICU.

The Concept of a Good Death

In the NICU, most deaths are due to withdrawing or withholding medical therapy,
primarily mechanical ventilation (Verhagen et al., 2010). Once parents make the
decision to withdraw or withhold treatment, the emphasis must turn to managing the EOL
process. Thus, providing a good death for these infants should be an important
component of the care they receive.

The Institute of Medicine defines a good death as “one that is free from avoidable
distress and suffering for patients, families and caregivers; in general accord with
patients’ and families’ wishes; and reasonably consistent with clinical, cultural and
ethical standards” (IOM, 2003). Parents make the decision to withdraw life support or
withhold treatment based largely on the desire to end pain and suffering for their infant
and want their infant not to suffer during the dying process (Armentrout, 2009).
Unfortunately, there is often a prolonged period of time between the stoppage of
treatment and death. The dying process can take minutes to days (Armentrout, 2009;
McHaffie, et al, 2001). Parents report being distressed by their infant’s symptoms during
the dying process because they perceive their infant is suffering (McHaffie et al., 2001; Pector, 2004).

The concept of a good death has not been defined for infants. Every death in the NICU is unique and the ethical and moral issues that surround each death are different (Gale & Brooks, 2006). From palliative care protocols that have been published (Catlin & Carter, 2002; Gale & Brooks, 2006) we know that the focus of neonatal EOL care is on providing comfort to the infant while alive and bereavement support to the parents after the infant’s death.

Palliative care protocols do not delineate what the infant will experience during the dying process. These protocols require nurses to observe and treat any indications of suffering. This reactive approach is a direct consequence of the fact that we simply do not know the range of symptoms an infant will experience and if those symptoms vary by a wide variety of factors, including gestational age and disease. To date, research on EOL care in the NICU has focused mostly on those who surround the infant as they are dying. Thus, defining a good death for the infant has been hampered by the lack of research focusing on death from the perspective of the infant.

Emanuel and Emanuel (1998) developed a framework, detailed in Figure 1 that defines a good death.
This framework examines the overall experience and quality of care at the EOL for those individuals who are able, or were once able, to interact with their environment and make decisions about their care at the end of life. Fixed and modifiable characteristics of the individual are depicted and highlight those care-system and larger social network interventions that can support the patient and the family during the dying process.

The Emanuel and Emanuel framework is not directly applicable to infants in the NICU because they do not participate in decision-making surrounding their death. Thus, a new framework, Figure 2, is introduced for evaluating the quality of a neonatal death.
This new framework incorporates appropriate components of Emanuel and Emanuel’s framework, as well as hypotheses based on clinical practice for which no current literature exists (Fortney & Steward, in press). The proposed concepts and relationships will require future testing and revision as indicated by the evidence. In this proposed framework, there are three domains that interact with each other within the context of the individual NICU environment where the infant is admitted and the
different care-system interventions involved in each infant’s unique situation. These domains are infant, parent, and nurse. Each domain affects the dying process and the interaction(s) among these domains may impact the quality of the neonatal death.

The Infant Domain

In the infant domain, there are both fixed and modifiable characteristics. Fixed characteristics include demographics and clinical characteristics of the infant; they do not change. Gestational age influences the acuity of the illness, with a higher morbidity and mortality associated with decreasing gestational age (Fanaroff et al., 2007). In addition, infants born small for gestational age have higher morbidity and mortality than others (Westby Wold, et al., 2009). Gestational age probably influences symptoms during the dying process because of physiologic immaturity. For example, extremely preterm infants respond to painful stimuli but do so much less and differently than more gestationally mature infants (Gibbins et al., 2008). Also, boys tend to be sicker than girls (Morse et al., 2006), even as early as the first week of life (Elsmén, Hansen Pupp, & Hellström-Westas, 2004). Black infants are more likely to require mechanical ventilation and have higher mortality than white infants. However, white boys have a lower survival rate than black boys and all girls. Demographic characteristics are clearly important to an infant’s clinical course and could indirectly influence the dying process.

The clinical status of the infant is usually delineated early. Prognosis is often complicated as each infant’s course is individual and highly influenced by prenatal and postnatal factors. Most admitting diagnoses to the NICU are unique to the neonatal population. Sometimes the specific diagnosis of the infant changes as testing is completed or as the infant ages and remains hospitalized. Additionally, many
complications can affect the neonatal course, such as intraventricular hemorrhage, patent ductus arteriosus, sepsis, and necrotizing enterocolitis, which add to the difficulty in assessing and treating the symptoms infants experience during the dying process. These changes seem to conflict with the term fixed characteristics, but the infant’s diagnosis should remain in this category because even though infants may experience multiple issues during a hospital course, these usually fall under one or two overarching diagnoses that initially caused their admittance to the NICU. Other vital information associated with the clinical characteristics is use of any type of respiratory support/mechanical ventilation, as well as type of nutrition utilized (enteral versus parenteral nutrition). These therapies are usually dictated by standard clinical practice for various diseases.

Thus, the data of interest in defining a good death for an infant include gestational age, birth weight, gender, ethnicity, race, initial diagnosis, complications of illness, mechanical ventilation, and nutritional supplementation. These are important clinical factors in neonatal care and require additional study to understand how they influence the dying process (Drake, Frost, & Collins, 2003). Further, there may well be other fixed infant characteristics that should be considered, such as nativity, live birth order and maternal age, education, marital status and smoking which have been identified as influencing infant morbidity and mortality (Mathews & MacDorman, 2011).

Modifiable characteristics (see Figure 1), are influenced by both individual and system variables. Of the modifiable characteristics identified by Emanuel and Emanuel (1998), only physical symptoms apply to infants. The other characteristics are not age-appropriate. However, depending upon the age of the infant at the time of death, the infant may have formed attachments to family members and/or caregivers and find
comfort in these individuals.

The infant’s modifiable characteristics are both behavioral and physical. We presume we can modify the experience by assessing the infant for symptoms, identifying the origins and then properly treating those symptoms. The ultimate goal is to relieve pain and suffering and ease the infant into a good death.

Emanuel and Emanuel discuss adults’ physical symptoms including pain, fatigue, shortness of breath and anorexia, but concede that we know considerably more about pain than other physical symptoms. This point is woefully true in the neonatal population. We assume that the infant may be experiencing pain during the dying process, but know very little of other symptoms. Parents report physical signs such as unpleasant noises, color changes, and gasping (McHaffie et al., 2001; Pector, 2004). Neonatal palliative care protocols provide some direction, suggesting that caregivers monitor the dying infant for indications of pain, dyspnea, discomfort, agitation, and seizures (Catlin & Carter, 2002; Gale & Brooks, 2006). Unfortunately, what is lacking is the evidence that tells families and caregivers what those indications will look like.

Identifying the infant’s symptoms must be approached in a very different manner from an adult’s symptoms. Because of the pre-verbal status of the infant, communication of symptoms is through both physiologic indicators and behavioral cues. Infants rely on others to accurately interpret their symptoms and advocate for relief. Many factors impact the recognition of symptoms, including the effectiveness of the physiologic indicators and behavioral cues exhibited by the infant; the capacity of the caregiver to interpret these indicators and/or cues correctly; and the caregiver’s knowledge of normal neurodevelopment and pathophysiology, as well as their experience and intuition (Pillai
Riddell & Racine, 2009; Selekman & Malloy, 1995). Some infants might exhibit few obvious cues (Walden, et al., 2001) and one physiologic indicator may indicate any number of symptoms the infant might be experiencing. For example, changes in heart rate from crying can be evidence of pain, agitation, a soiled diaper, hunger or a physical need to be held.

Physical appearance of the infant is driven by behavioral and physiologic cues exhibited by the dying infant, such as agitation, gasping, grimacing, restlessness or any other cue that indicates the infant is uncomfortable. Not included in Emanuel and Emanuel’s framework, this is a crucial component to the evaluation of a good death for an infant.

The Infant Domain of the proposed model focuses on a good death from the infant’s perspective. Critical to a good death from this perspective is recognition and management of symptoms.

The Parent Domain

Whether or not parents perceive that their infant experienced a good death will be the lens through which they will review the events surrounding EOL care for their infant. When families agree to withhold/withdraw treatment they are, in essence, choosing the day that their infant will die (Romesberg, 2007). They have reached a point where they realize that there is nothing else left that can be done (Wocial, 2000). Parents must now refocus their role from that of assisting their infant to survive to assisting their infant die (Chiswick, 2001). Parents will live with this decision for the rest of their lives and may question whether it was the right decision (Janvier, 2009). For parents, multiple factors will impact their perceptions of a good death including family characteristics and
dynamics, socioeconomic status, support structure, understanding of their infant’s situation, life experiences, and their belief system.

Pregnancy is a time where hopes and expectations for the new infant are created as the parents-to-be eagerly await the arrival of their new infant. When precipitating events result in admission of the infant to the NICU, parents confront immense grief as they mourn the loss of the ideal infant they envisioned (Wigert, Johansson, Berg, & Hellström, 2006) and now must integrate this loss while attempting to comprehend the impact of their infant’s illness (Dyer, 2005). In the context of their grief, anxiety and fear of the unknown, parents are expected to process a significant amount of new information and, ultimately, make difficult decisions on behalf of their infant. This responsibility is highly stressful for parents (Carter, Mulder & Darlow, 2007) and makes them feel vulnerable as they must rely on the expertise of NICU staff with whom they have no prior relationship (Dyer, 2005; Meert, Thurston, & Briller, 2005).

Personality, mental health, and responses to stress will play a role in how parents handle the decision-making. For example, a parent’s trait anxiety correlates positively with perception of stress in the NICU and negatively with parent-staff communication (Carter et al., 2007). Further, parents’ perceptions of their infant’s illness do not always correlate with the actual severity of illness (Turner et al., 2007) and interpretation their infant’s pain is influenced by their usual beliefs and approach to pain rather than the infant’s actual pain (Pillai, et al., 2009).

Parents are asked to become knowledgeable about their infant’s condition and make decisions for this infant, whom they are getting to know for the first time amidst all of the chaos. Providing them with complete and honest information allows parents to
understand what is occurring and make informed decisions (Meyer, Ritholz, Burns, & Truog, 2006; Wocial, 2000). This process includes providing parents with information about what to expect and what they might observe and hear when life-sustaining treatment is withdrawn. Lack of knowledge increases parents’ frustration and anger with the situation (Meert et al., 2005). As an infant transitions into EOL care, parents’ knowledge of their infant and the infant’s condition will be at some point along a continuum from no knowledge to fully knowledgeable. Parents’ level of knowledge will influence their perceptions of events surrounding their infant’s death.

Partially affecting parents’ opportunities to get to know their infant is their economic status. Finances (Argus, Dawson, Wong, Morley, & Davis, 2009; Wigert, Bert & Hellström, 2010) and distance (Latva, Lehtonen, Salmelin, & Tamminen, 2007; Wigert et al., 2010) can be barriers to visiting their infant in the NICU. Parents who have limited opportunities to get to know their infant may be at a loss recognizing and interpreting their infant’s cues, which ultimately impacts their ability to understand their infant’s unique situation and advocate for a good death.

Parents have a choice whether to be physically present during the dying process and whether to have physical contact with their infant, especially holding the infant. In one study, mothers reported being distressed when NICU nursing staff told them it was very important for them to hold their infant during the dying process (Lundqvist, Nilstun, & Dykes, 2002). An infant’s physical appearance is stressful to parents in the NICU, especially for those infants born prematurely (Carter, et al., 2007). In the context of EOL care, how an infant looks physically has a major impact on parents’ perception of whether or not their infant is suffering (McHaffie, et al., 2001). Memories of their
infant’s appearance will always remain with the parents (Widger & Picot, 2008). Importantly, parents may be vigilant in observing their infant and look for congruence between what the NICU staff communicated to them and what they observe (Wocial, 2000). Depending upon the age of their infant at the time of transition into EOL care, families may have developed some knowledge of their infant’s unique behavioral responses so that they can recognize when their infant is distressed. One study has reported that mothers whose infants died within the first two weeks of life, found themselves dissociating from their infant (Lundqvist et al., 2002). Most parents of infants in the NICU though believe they can recognize behaviors that indicate when their infant was in pain (Franck, Allen, Cox, & Winter, 2005).

Parents are often also distressed by the amount of time that lapses prior to their infant’s death (McHaffie et al., 2001). Parents believe that death will occur quickly once treatment is discontinued, but the process often takes longer than anticipated. The infant’s care during this time is crucial in influencing how parents will move forward following the infant’s death.

Social support plays an important role in the ease in how parents move through this process. Sources of social support may include the spouse or partner, other family members, friends, families befriended in the NICU, and members of the healthcare team. Perception of spousal or partner support is especially important during this emotional time. Married mothers experience less stress and anxiety in the NICU compared to single mothers (Carter et al., 2007; Zelkowitz, Bardin, & Papageorgiou, 2007). Importantly, single mothers received less support from the infant’s father than mothers who were
married. Married mothers report less anxiety in the NICU environment when satisfied with their relationships with their spouses (Zelkowitz et al., 2007).

The unique design of the NICU environment allows families to get to know each other. Mothers with infants in the NICU reported finding support from other mothers in the same situation because they understood what it meant to have an infant in the NICU (Meert et al., 2005; Wigert et al., 2006). Further, parents report that it is important to them that NICU nurses look after their wellbeing in addition to that of their infant (Brosig, Pierucci, Kupst, & Leuthner, 2007). Along with family and friends, social support provided by other individuals play a role in how parents cope with the EOL process.

Parents rely on their spiritual/religious belief system as a means of coping with their infant’s death as well as a framework for guiding them through the decisions that must be made (Meert et al., 2005; Robinson, Thiel, Backus, & Meyer, 2006). Conflicts between parents and NICU staff on EOL decisions are often the result of the parents’ religious beliefs (Garros, 2003). Thus, NICU staff should understand the parents’ spiritual/religious perspective. Parents reported how comforting it was to them knowing that others, including NICU staff, were praying for them and their infant (Meert et al., 2005). While parents can experience spiritual distress, the positive aspects of their faith sustained them as they coped with their infant’s death (Meyer et al., 2006). Thus, prayer and faith are very important.

The attributes of the Parent Domain provide the window through which parents view and interpret the quality of their infant’s EOL process. In addition, these attributes have a role in how parents themselves will handle the journey before them and how they
will advocate for their infant through this process.

The Nurse Domain

Each care provider is extremely important and valuable to the EOL care process. Parents do report that nurses are the caregivers most often involved in the care of their infant at the EOL (Wocial, 2000); thus the new framework focuses a domain specifically on the nurse. Physicians have overarching responsibility for the care of the infant and this role is placed in the larger context of the NICU environment in which interactions occur.

Because nurses are very involved with infants and parents at the bedside, the process of dying and the subsequent death of an infant has a significant impact on the neonatal nurse (Kain, 2006). Nurses report that the death of an infant is one of the most difficult aspects of their job (Catlin et al., 2001). Nurses also often report a lack of confidence in providing various aspects of EOL care, especially if there is a lack of clarity in their roles and responsibilities (Yam, Rossiter, & Cheung, 2001). Experienced nurses are more likely to be comfortable with EOL care (Chan et al., 2008; Engler et al., 2004). The American Academy of Pediatrics (2004) defines a Level III NICU as a unit capable of caring for the smallest and sickest infants, with highly specialized staff who can provide mechanical ventilation, high frequency mechanical ventilation, major surgical procedures, and extracorporeal membranous oxygenation. Nurses practicing in Level III NICUs are exposed to more occurrences of death and are, thus, more comfortable with providing EOL care (Engler et al., 2004). Experience with EOL care is the best teacher.
Like the parents, nurses also bring to the bedside life experiences and belief systems that influence nursing practice. At times the nurse confronts the dilemma between curative and palliative care (Kain, 2007; Yam et al., 2001). The death of an infant is often seen as an unnatural occurrence and nurses often must adopt their own philosophy about life and death in order to cope (Papadatou, 1997). This philosophy can directly influence the relationship that the nurse has with the parents and the infant. Once a nurse realizes that the infant will not recover and that death is inevitable, performing perceived unnecessary procedures, especially invasive ones, becomes extremely difficult (Yam et al., 2001) and may result in moral distress (Kain, 2007). This internal conflict can result in feelings of anger and resentment towards physicians, parents and others who continue to insist upon providing futile care. In addition, the nurse may question personal and professional values (Catlin et al., 2008). The nurses’ spiritual belief system may underpin the nursing care provided at the EOL. Religious beliefs affect their perceptions of decisions made for EOL care. In a survey, 83% of NICU respondents reported praying for infants and their parents (Bilgen, Topuzoğlu Altuncu, & Özek, 2009). In addition, staff members often relied upon their spiritual beliefs to make sense of the suffering experienced by parents and their infants (Catlin et al., 2001).

Palliative care education, either in a formal degree program or through continuing education, would greatly impact a nurse’s relationship with parents during the dying process. NICU nurses believe that formal education would facilitate them providing effective EOL care (Chan et al., 2008). An important component of palliative care education is how to communicate with grieving parents. Nurses report that they lack the necessary knowledge and skills to comfort grieving parents (Yam et al., 2001).
Courses in undergraduate and graduate nursing programs that focus specifically on EOL care are variable. In a survey of NICU nurses, 63% of the respondents had some formal content as a part of their education (Engler et al., 2004), but only 42% of this group was satisfied with the content.

NICUs fail in offering up-to-date palliative care education to their nurses. Nursing staff should be trained in how to provide optimal EOL care and we hypothesize that nurses who receive palliative care training will be more comfortable providing EOL care to infants and their parents.

To provide effective symptom management, nurses must be able to recognize and interpret the infant’s behavioral and physiologic cues by determining the underlying cause of the infant’s symptoms. Context of the situation may influence the nurse’s interpretations. For example, nurses often disagree on pain assessment (Elias, Guinsburg, Peres, Balda, & dos Santos, 2008), which can affect symptom management. Years of experience with pain assessment increases neonatal nurses’ comfort level with this important assessment skill (Pölkki et al., 2010). Familiarity with the infant also influences the nurse’s perceptions of the symptoms exhibited. Regular opportunities to care for a specific infant will allow the nurse to recognize usual behavioral and physiologic responses to noxious stimuli. One could assume that familiarity will allow the nurse to provide better symptom management during EOL care.

Finally, how a nurse perceives the organization and environment in which he/she practices is also important in enabling the nurse to provide quality EOL care. Nurses report that optimal care for the dying infant happens when all members of the healthcare team provide a consistent approach (Yam et al., 2001). Policies and/or guidelines that
direct palliative care will enable the nurse to provide effective EOL care. Nurses who are from NICUs with bereavement policies in place are more comfortable providing EOL care than nurses from NICUs without such policies (Chan et al., 2008; Engler et al., 2004). Conflicts often arise when the lack of direction from policies creates an environment where all members of the healthcare team do not embrace EOL care (Yam et al., 2001). Nurses who feel empowered by the organization to provide quality EOL care should be able to advocate for the infant and ensure a good death.

**Interaction of the Parent and Nurse Domains**

The interaction of the parent and nurse domains influence symptom management and is partly driven by the physical appearance of the infant. Physical attributes, such as color, breathing pattern, skin condition, and instrumentation associated with various treatment modalities, can impact the parents’ and nurses’ perceptions and influence how the infant’s symptoms are managed. At times, parents and the nurse will agree, while at other times they may disagree about the infant’s physical status and, thus, how to treat the infant’s symptoms. Misperceptions can cause tension and hamper communication during a critical time in the infant’s death trajectory. Caregivers and parents often disagree on the intensity of the infant’s pain (Elias et al., 2008; Franck et al., 2005). Interestingly, the caregivers and parents agreed when there was no indication of pain but as the pain ratings increased from zero, the discrepancy in the pain ratings also widened. This divergence certainly has ramifications for the management of pain symptoms if the caregivers and parents cannot agree on the severity of the pain (Elias et al., 2008). For parents, disagreements with the nurse about their infant’s pain increases stress (Gale, Franck, Kools, & Lynch, 2004).
The NICU and Care-System Interventions

The interactions between the three domains all take place within the NICU. The philosophy of attending physicians in relation to EOL practices will influence how the dying process is managed for both the infant and parents. Uncertainty about symptoms results in variable pharmacologic intervention (Verhagen, Dorscheidt, Engels, Hubben, & Sauer, 2009). A significant number of dying infants receive no pharmacologic intervention to manage symptoms during the dying process. Infants are being undermedicated during and after withdrawal of treatment (Provoost et al., 2006; Verhagen et al., 2009). Caregivers often withhold adequate analgesia or sedation because of the fear of hastening death (Schmitz, Taylor & Anand, 2000). We recommend that pharmacologic management involve relief of all symptoms of discomfort, not just pain (Munson, 2007). Pharmacologic practice during EOL care is an important area requiring further study so that symptom management is effective and suffering is minimized.

Because pain is critically important to parents, the NICU philosophy and policy on pain management are important. A significant number of NICUs employ the use of a specific pain scale, such as the Neonatal Infant Pain Scale (Lawrence, et al., 1993) or the CRIES Instrument (Krechel & Bildner, 1995) to evaluate post-operative or procedure pain. Currently, there is no pain scale specific to EOL care. Most NICU nurses believe they can accurately assess pain without a pain scale and do not find the pain scores useful (Pölkki et al., 2010). Whether a pain scale or the nurse’s own observations are used to assess pain and provide intervention, documentation should be clear. Accurate documentation allows all members of the NICU staff to have a clear picture of an infant’s care needs.
NICU policy also influences parental decision-making and perceptions of the events surrounding their infant’s death. For some NICUs, a multi-disciplinary team brings the parties together to guide and support the parents through necessary decision-making. Some NICUs have formalized Hospice/Palliative Care teams who assist the health care team and parents in caring for the infant during the dying process (Romesberg, 2007). Ultimately, the goal is to develop a plan that parents and health care providers agree will result in the least suffering for the infant and provide a good death. Unfortunately, there are situations where, despite the agreement, members of the health care team deviate from the plan. The result is increased frustration and anger among parents and team members (Chiswick, 2009; Meert et al., 2005). In interviews, bereaved parents reported high distress when NICU staff delayed the planned time for discontinuation of therapies or altered the agreed upon course of action (McHaffie et al., 2001). For parents, this distress lingers.

An important component of the NICU is physical environment and the atmosphere during EOL care. Parents will always remember where their infant died (Brosig et al., 2007; Meert, Briller, Schim, Thurston, 2008). The NICU is the only place where they experienced their infant. Many parents want to be physically close to their infant during the dying process and have ready access to their infant whenever desired (Meert et al.; 2008; Meyer et al., 2006). When interviewed, parents reported the importance of a dignified environment that included attending to their infant’s symptoms, creating opportunities for families to be together, and maintaining a reverent atmosphere (Brosig et al., 2007; Garros, 2003; Meyer et al., 2006). Further, parents value the
opportunity to create memories and to hold their infant without any medical instrumentation in an area that allows for private time (Armentrout, 2009).

Each EOL care situation is unique and there are various care-system interventions that may or may not exist within the context of the NICU environment that could influence the quality of the infant’s death. The variables considered by Emanuel and Emanuel (1998) to be care-system interventions include family and friend, social, medical-provider, and healthcare institution interventions. Emanuel and Emanuel propose two types of social interventions; spiritual/emotional and insurance/government-type programs. These interventions, if present, can indirectly impact the neonatal death experience by influencing the level of support provided to parents.

Parents want honest information (Brosig et al., 2007), guidance through the process of removing life-support, and education about what to expect during the entire process (Munson, 2007). Parents want easy access to members of the health care team and coordination among health care team members (Meyers et al., 2006; Munson, 2007). Parents want an appropriate space that will allow for EOL discussions to occur (Meert et al., 2008). Parents want health care providers with positive attitudes, compassion and empathy. (Meert et al., 2005; Meyer et al., 2006; Wocial, 2000). Compassionate and empathetic behavior allowed parents to perceive that the NICU staff genuinely cared about them and their infant.

One of the most stressful aspects of having an infant in the NICU is alterations in the parental role (Carter, et al., 2007). During EOL care, it is important to parents to have the opportunity to perform normal parenting activities, such as changing their infant’s
diaper. Parents need NICU staff to encourage them to be parents during this time (Armentrout, 2009; Brosig et al., 2007).

NICU policy in relation to visitation is important to parents during EOL. Visiting restrictions may need to be relaxed during EOL for extended family and friends (Armentrout, 2009). Also, the physical space should be able to accommodate the numbers of family and friends who are present to provide support (Meert et al., 2008).

Availability of spiritual support is important in the NICU. Parents appreciate the availability of the hospital chaplain and their family clergy member (Robinson et al., 2006). In addition, parents may need to carry out religious rituals (Garros, 2003).

Conclusion

The proposed framework identifies key variables that are likely required for infants dying in the NICU to experience a good death. This is important because the EOL process for infants in the NICU has received minimal attention. The interaction of these variables will impact the overall experience of the dying process for the infant and influence whether this process will be a positive or negative experience. This research should include parents as they can provide the best view into their infant’s experience. Empirical support of the proposed framework will allow for the discovery of the best strategies to care for dying infants and serve as a guide for the provision of EOL care in the NICU. As a result significant improvement will be made in how infants are cared for at the end of life. Until we understand the dying process for infants in the NICU, it will be extremely difficult to consistently provide a good death.
Chapter 3: Exploring the End-of-Life in High-Risk Neonates in the NICU

In recent years, there has been increasing interest among pediatric experts related to palliative care and the dying child. But, little attention continues to be given to the palliative care needs of the dying neonate, even though infant deaths constitute the highest percentage of deaths for any age-group in pediatric institutions (Brandon, Docherty, & Thorpe, 2007; Ramnarayan, Craig, Petros, & Pierce, 2007). In addition, this does not include the number of deaths that occur in neonatal intensive care units (NICU) housed in delivery hospitals. The estimated infant mortality rate for 2010 is 6.14 deaths per 1,000 live births while the neonatal rate (birth to 28 days of life) is 4.04 deaths (Murphy, et al., 2012). Further, 36% of all infant deaths are related to prematurity (Mathews & MacDorman, 2011). Unfortunately, it is clear that neonates do die. The lack of attention to neonatal palliative care is due, in part, to the lack of research in this area.

Background and Significance

Death is always the expected outcome when life-sustaining treatment is withdrawn or withheld from a neonate (McHaffie, et al., 2001; van der Heide, 1998). In the NICU, the majority of deaths are due to the withholding or withdrawing of treatment (Abe, et al., 2001; Verhagen et al., 2010). Clinical experience tells us that neonates often suffer pain and discomfort at the end of life (EOL), however we know very little about what constitutes optimal EOL care for these neonates. When the only inevitable outcome
for a neonate is death, the priority must shift from curative therapies to providing adequate pain relief and comfort measures for the dying neonate.

When parents make the decision to have life-sustaining therapies discontinued they do so with the hope of ending pain and suffering for their infant. Parents want to know that, when they make this decision, their infant will be pain-free during the dying process (Armentrout, 2009; Coughlin, Hernandez, Richardson, & da Silva, 2007). The greatest concern expressed by parents of dying children is that their child will suffer when life support is removed (Meyer, et al., 2002). This is a critical point since the time between the discontinuing of treatment and death is difficult to predict with death often taking minutes to days to occur (Armentrout, 2009; McHaffie, et al., 2001). Therefore, providing a good death is critical. However, at this time, there is a lack of empirical evidence describing the range of symptoms experienced by neonates during the dying process, as well as the best way to treat those symptoms.

The available neonatal palliative care protocols are based on best clinical practices or the philosophy of an NICU in relation to EOL care and not on scientific evidence. Wide variations in care measures provided in the clinical setting (Carter, 2004) offer little direction to health care providers in managing the EOL process for a neonate and the family (McHaffie, et al., 2001). The lack of direction in providing EOL care results in pharmacologic intervention for pain and other symptoms of distress being less than ideal (Williams, Munson, Zupancic, & Kirpalani, 2008). Researchers have demonstrated that variability exists in the pharmacologic management of symptoms, including pain, during and after the discontinuation of curative treatment neonates (Provoost et al., 2006; Verhagen, et al., 2009). The result is that infants are most likely
being under-medicated during the dying process. Whether this is a function of a lack of recognition of symptoms exhibited by the dying neonate is unknown. Parents do report being distressed by the physical signs (e.g. unpleasant noises, color changes, gasping) their infant exhibits while dying, which leads them to believe their infant is suffering (McHaffie, et al., 2001; Pector, 2004). Thus symptom manifestation is important to parents.

As the limits to the margin of viability continue to be stretched, research must be undertaken in an effort to discover the best way to care for those neonates who will die as a result of their condition, as well as ease the distress experienced by their parents and care givers. Parents are concerned their neonate will suffer once treatment is discontinued. Given the variable amount of time between the cessation of treatment and death, it is important to be sure that the dying process does not result in undue suffering for the neonate. Identifying the signs and symptoms exhibited by dying neonates, as well as the treatment strategies used to treat those signs and symptoms are crucial to developing clinical care guidelines needed to effectively manage EOL processes for these infants.

Purpose

The purpose of this study was to determine the signs and symptoms commonly exhibited by neonates at the end of life, as well as, the management strategies used by caregivers to treat manifested symptoms. This project is designed to understand the dying process with a focus on the neonate’s experience. The main objective was to gather physiologic and behavioral data that can be used to define a good death for the dying neonate and thus shape guidelines for EOL care. This project appears to be the first study
to take an in-depth look at the signs and symptoms exhibited by the dying neonate. The following specific aims were addressed:

1) To characterize the physical and behavioral signs and symptoms exhibited by the neonate at the end of life.

2) To identify the treatment strategies used to manage physical and behavioral signs and symptoms exhibited by the neonate at the end of life.

**Theoretical Framework**

A new framework (see Figure 3) to evaluate the quality of neonatal death, developed by this author during doctoral study, guided the project. This new model describes necessary components for providing a good death in the NICU (Fortney & Steward, *in press*).
The model describes three domains, infant, parents and nurses, which interact with each other in the context of the larger individual NICU environment to which the infant is admitted. Various care-system interventions involved in each infant’s unique situation are also considered. Each domain contains important characteristics that could impact the dying process. The interaction(s) between these domains impact the quality of the neonatal death.
In this study, the infant was the focus. Variables of interest are the demographics and clinical characteristics (fixed infant characteristics) of the infant that do not change. Demographics, such as gestational age, gender, and race have been shown (Fanaroff, et al., 2007; Westby Wold, et al., 2009; Gibbins, et al, 2008; Morse, et al., 2006; and Elsmén, et al., 2004) to be clearly important to infant’s clinical course and may impact how an infant approaches the EOL trajectory.

Further, the infant’s clinical course has a major impact on survival. Neonates can experience many complications. The physical and behavioral symptom manifestations of those problems need to be recognized and treated by the health care provider and are important clinical factors to consider. These are the modifiable infant characteristics that health care providers can impact. We should be able to modify the infant’s death experience by assessing the infant for various symptoms, properly identifying the origins and providing adequate treatment. The ultimate goal is to relieve pain and suffering and ease the infant into a good death. The Infant Domain of the model focuses on a good death from the infant’s perspective, which is incumbent upon recognition and management of symptoms.

Little is known about what neonates experience during the dying process. It can be assumed they may have pain, and parents have reported physical signs such as unpleasant noises, color changes, and gasping (McHaffie et al., 2001; Pector; 2004). Whether neonates routinely experience other symptoms is not known.

Because infants cannot verbalize what they are experiencing, it is up to those caring for them to accurately interpret the symptoms and advocate for treatment. This leaves a lot of room for error because it is dependent upon many factors. The physiologic
and behavioral cues the neonate exhibits must be effective enough to be noticed and the caregiver must then interpret those cues correctly. The experience, education and intuition of the caregiver will influence their ability to make the correct assessments and suggest appropriate treatments. We know that caregivers at all levels receive little education regarding EOL care during their formal training and report they feel inadequately trained to provide EOL care (Yam et al., 2001). Further, some neonates might not give obvious cues (Walden, et al., 2001) and one cue might indicate any number of symptoms. For example, changes in blood pressure could be evidence of pain or discomfort or one of a number physiologic processes occurring in the body related to the illness.

The physical appearance of the infant is also a crucial component to the evaluation of a good death. Appearance is an outward sign of the manifestation of physical and behavioral cues. Agitation, gasping, and grimacing are examples of cues that may indicate the infant is experiencing discomfort.

It is important that the first step in evaluating EOL care for neonates, looks at the experience from the neonate’s perspective. This appears to be the first study to do so.

Methods

This was an exploratory, descriptive study that employed the use of data abstracted from the medical record and semi-structured interviews to address the specific aims. The sample was comprised of 20 neonates whose death resulted from the withdrawal or withholding of treatment.
Sample

The ideal sample for the project would have been neonates actively experiencing the dying process. However, direct observation of the dying neonate by a researcher would disrupt the dignity and privacy of the EOL experience for the family and neonate and is ill-advised until there is sufficient systematic research to identify relevant variables to observe. Therefore, the sample for the project was comprised of two groups: 1) neonates who had died in the NICU and 2) neonatal staff nurses who had actively cared for those dying neonates.

The rationale for including neonates who had already died was to extract documented symptoms as well as medical management during the dying process from the medical record. Face-to-face interviewing of the neonatal staff nurses was conducted because reliance on medical record documentation is not the best way to obtain a comprehensive picture of EOL symptomatology and management (McCallum, et al., 2000; Partridge & Wall, 1997). Neonatal staff nurses are included because in the majority of situations it is the nurse who is at the bedside performing routine observation and assessment (Catlin & Carter, 2002). Parents involved in the EOL process with their child report that nurses were the most involved in their child’s care at the time of death (Meyer et al., 2002).

A convenience sample comprised of neonates whose deaths occurred between August 2007 and October 2010 in a single Mid-Western NICU was utilized. Inclusion criteria included: 1) Admission to the NICU; 2) Death as a result of withdrawing or withholding of life-sustaining treatment. The exclusion criteria included: 1) Death as a
result of failed cardiopulmonary resuscitation; 2) Sudden or unexpected death in the NICU.

The sample for the interviews was comprised of staff nurses who provided care to the neonates during the dying process. Inclusion criteria for the staff nurses included: 1) Willingness to participate in a face-to-face interview; 2) Actively cared for the neonate during the last 24 hours of the infant’s life.

**Data collection**

*Medical Record Abstraction.*

Data describing all symptoms as well as interventions used were abstracted from the medical record of each infant for the 24-hour period prior to the death of the infant. Medical record data was abstracted from the electronic medical record of each of the 20 eligible neonates who died during the study period. Data abstracted from the medical record included demographics, prenatal history, diagnoses, ongoing therapy at time of treatment withdrawal or withholding, pharmacologic and non-pharmacologic interventions associated with treatment withdrawal, time of treatment withdrawal and death, age at time of death, palliative interventions used during EOL care, signs and symptoms exhibited during EOL care, pain scale ratings; parental presence during the EOL process, presence of the hospital chaplain, use of the unit-based palliative care protocol, and involvement of the hospital-based palliative care team.

Five records were reviewed by this author and her advisor to confirm data availability, usability of the data collection form, and appropriateness of the data collection procedure (Aaronson & Burman, 1994). The form was modified and information was added or deleted depending on the usefulness and availability of the
data. Records were reviewed again to ensure that information was being correctly located in the record. This minimized threats to both the validity and reliability of the data by ensuring that no relevant data was being overlooked and no unnecessary information was being gathered. In this exploratory study, all information was weighted the same and of equal importance. Descriptive statistics are used to present the medical record data.

Semi-Structured Interviews.

Face-to-face interviews were held with 15 members of the nursing staff involved in a neonate’s care at the EOL. These nurses cared for 14 of the 20 neonates who had died. The interviews were conducted within two weeks of the neonate’s death. As part of the interview process, nurses were asked to complete a survey that gathered demographic information. The semi-structured interview consisted of 11 questions designed to obtain information related to the neonate’s entry into EOL care, the signs and symptoms observed, treatment strategies used and educational needs of the nurse. Probes were used to obtain additional information (Liamputtong & Ezzy, 2005). All interviews were audio-recorded and then transcribed verbatim. Printed versions of the transcripts were used to facilitate analysis of the interview data.

Interview data were analyzed using the Framework approach (Ritchie, Spencer & O’Connor, 2003). The framework approach was developed in the 1980s at the National Centre for Social Research in the United Kingdom. More recently, the framework approach has been used as a means for analyzing qualitative data in healthcare research because it applies the principles of qualitative analysis to a series of interconnected stages that guide the process (Smith and Firth, 2011). The researcher can explore data in depth while maintaining an audit trail, which enhances the rigor of the analytical process, as
well as credibility of the findings (Ritchie, et al., 2003). The Framework approach involves three comprehensive steps. These included data management, descriptive accounts and explanatory accounts. During data management the researchers become familiar with the data by reading and re-reading the transcripts to identify initial categories or themes that result in the development of a coding matrix. Data are assigned to the themes in the coding matrix (see Figure 4). During the descriptive accounts step, coded data are synthesized resulting in a refinement of the initial themes. Similar themes are brought together and form a coding index (see Figure 5). This coding index was used as a means of organizing the entire data set. The coding index is revised throughout data analysis as new insights emerge from the data. The broader themes are examined for associations between the themes resulting in development of more abstract concepts. In the final step, associations between concepts are identified that are reflective of the interview data and prevent misinterpretation of that data (see Figure 6) (Smith & Firth, 2011).

Results

Demographic data for staff nurses

Staff nurses who participated in the project had been nurses for an average of 6.5 years, and in the NICU specifically for an average of 6.1 years. Years of service in the NICU ranged from half a year to 15 years. All nurses were female and white, non-Hispanic, between the ages of 20 and 45 years. Eighty-seven percent of nurse participants held bachelor’s degrees.

As part of the survey, nurses were asked to rate their comfort level in providing EOL care on a scale of one to five, with 1 being uncomfortable; 2 being slightly
uncomfortable; 3 being neutral; 4 being comfortable; and 5 being very comfortable. Responses were received for each point on the scale. However 73% of the nurses interviewed reported being comfortable to very comfortable in providing EOL care to neonates. Most nurses reported having inadequate EOL care education during nursing school, with almost 30% reporting they did not receive any EOL education in nursing school. Sixty-seven percent of the nurse participants received EOL care instruction intertwined with other courses. Only one nurse said that she had taken a course devoted entirely to the delivery of EOL care. Sixty-six percent of respondents reported they felt the hospital or unit had prepared them well to provide EOL care to neonates and their families. About half of the nurses, 7 of 15 reported having some level of familiarity with the infant and family.

**Demographic Data for Infants**

The convenience sample of infants in the study was comprised of 9 males and 11 females. 55% of the infants were categorized as white, non-Hispanic; while 35% were black, African American. One infant was identified with two or more races, while one other was Native Hawaiian or other Pacific Islander. Forty-five percent of infants were considered moderate preterm with gestational ages between 29 0/7 and 33 6/7 weeks. Only 10% of the sample was comprised of infants considered to be extremely low birth weight (ELBW), weighing less than 1000 grams.

**Medical Record Data**

Infant medical records were reviewed during the last 24 hours of life. Based on circumstances surrounding the infant’s death, infants entered the EOL care trajectory in one of two ways: emergently or planned (see Table 1). Infants who entered EOL care
emergently were those infants who had life-sustaining therapy withdrawn while physiologically failing so that parents could hold their infant free of medical equipment. Infants whose entry into EOL care was planned were those infants who were physiologically stable while receiving life-sustaining therapy. These infants were transitioned into EOL care for quality of life reasons. For these infants, withdrawal of therapy occurred at a predetermined time based on discussions with the parents (Meadow, 2012).

<table>
<thead>
<tr>
<th>Emergent Entry</th>
<th>Planned Entry</th>
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<tbody>
<tr>
<td>Prematurity</td>
<td>Holoprosencephaly</td>
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<tr>
<td>Intestinal perforation, NEC totalis</td>
<td>Birth depression - encephalophathy</td>
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<tr>
<td>Sepsis, septic shock</td>
<td>Hamartoma – hepatorenal failure</td>
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<tr>
<td>Alveolar growth abnormality of lungs</td>
<td>Trisomy 18</td>
</tr>
<tr>
<td>Respiratory distress syndrome</td>
<td>Severe CHARGE syndrome</td>
</tr>
<tr>
<td>Congenital diaphragmatic hernia, pulmonary hemorrhage</td>
<td>Early myoclonic encephalopathy, intractable seizures</td>
</tr>
<tr>
<td>Persistent metabolic acidosis, Persistent hypotension</td>
<td>Chromosome 19 deletion, multiple congenital anomalies</td>
</tr>
<tr>
<td>DIC, IVH, PVL – Devastating CNS injury</td>
<td>Ruptured omphalocele</td>
</tr>
<tr>
<td>ABO incompatibility, porencephalic cyst, triploidy</td>
<td>Complete tracheal rings, bronchomalacia, narrowing of right main bronchus</td>
</tr>
</tbody>
</table>

**Table 1: Medical Diagnoses by EOL Categories**

Ninety-five percent of infants in the study underwent some type of life-sustaining therapy. Only one infant had care completely withheld. A second infant had care withheld after an initial palliation surgery.

It was noted that infant vital signs were maintained at stable levels until the time of treatment withdrawal. Adjustments were made to temporarily increase support to
infants to allow for recovery and reestablishment of baseline vital signs following periods of oxygen desaturation or bradycardia. A decrease in vital signs as infants progressed toward the EOL was not appreciated because documentation of vital signs ended with treatment withdrawal in 100% of the cases.

Time to death was within one hour of treatment withdrawal for 70% of infants, with 40% of those deaths occurring within 30 minutes. The longest time period between treatment withdrawal and time of death was just over 20 hours. The remaining 25% of infants died between 1 and 3 hours of treatment withdrawal.

In every case, there was missing data or a lack of documentation related to the EOL care process. There were also inconsistencies in the amount of detail provided in progress notes or death summaries about what had transpired in the infant’s last minutes of life. Some physicians gave detailed accounts of what the infant experienced and how and why the infant was treated with a particular medication, while others gave just a summary of the pronouncement of death.

Nurses inconsistently documented pain scores. In fact, in 25% of the infants, the last pain score was documented more than 8 hours prior to the withdrawal of support. Another 55% of infants had documented pain scores more than 2 hours prior to withdrawal. Three infants had a score documented within the hour prior to withdrawal, while just one infant had a pain score documented at treatment withdrawal. No pain scores for any infant were documented after treatment withdrawal.

Most infants were medicated at the end of life. Of the 20 cases reviewed, only three infants did not receive some type of medication for pain or sedation before withdrawal, at withdrawal or after withdrawal. The reasons varied. One infant did not
receive medication based on the religious beliefs of the parents. They did not want the medication to cause the infant’s death. Another infant received no medication based on her diagnosis and the belief of the physician that she could not feel pain. The third infant had an established plan to receive medication at treatment withdrawal and throughout the dying process, if needed. The plan had been discussed and agreed upon by the attending physician and the parents. However, he did not receive the medication when a new attending physician started on service and refused to carry out the plan. Eighty-five percent of infants received medication prior to treatment withdrawal; 55% received medication at withdrawal and 60% received medication after withdrawal. The majority of the infants in this study received medication throughout the EOL care process. Most infants already had continuous intravenous medication for pain and sedation related to their condition, infusing at the time of treatment withdrawal and death. Boluses of medication were given as needed for EOL management. Medications utilized for pain were fentanyl and morphine, while versed and ativan were given for sedation. Most medication was given intravenously, however one infant received oral morphine and five infants received aerosolized fentanyl.

Inconsistencies in prescribed drug dosage amounts between patients were noted with some infants receiving full standard doses of medication while others were only given half doses. There was no documentation in the medical record regarding the thought processes of physicians related to prescribing decisions.

Parents were very involved in the care of this sample of infants. Sixteen of the 20 infants were held by their parents as they died. Of the four parents were not present at the
EOL, two of the mothers had been very involved in EOL care decision-making but reported not wanting to watch their infant die.

Further, use of the unit-specific palliative care protocol was not documented for any infant. The hospital-based palliative care team was consulted in only one of the cases.

The most impressive findings from the medical record were: 1) an overall lack of documentation related to the entire EOL care process by both nurses and physicians; 2) inconsistent use of medications at the EOL; and 3) a distinct classification of infants into two unique categories at the EOL.

Interview Data

Nurse participants were asked to describe the neonate for whom they provided EOL care, the situation surrounding the infant’s death, their observations of signs and symptoms the infant experienced at the EOL, therapies used to treat pain and other symptoms exhibited by the infant, and their comfort level in relaying EOL care information to parents. Analysis of the transcripts utilized the Framework approach. Three core concepts emerged from analyses of the interview transcripts. These included:

- Uncertainty
- Discomfort
- Chaos

Uncertainty

Several characteristics of the EOL process were identified by the nurse participants that led to feelings of uncertainty in providing EOL care. These were infant prognosis, time of transition from curative to EOL care, symptom recognition and
treatment, time to death following treatment withdrawal, and lack of knowledge related to
the religious/cultural customs of various populations.

Nurses reported that when infants were admitted to the NICU it was not immediately
clear that EOL care might be needed. One nurse stated,

“We weren’t real sure what his prognosis was going to be.”

The focus for the infants was always on survival. It was often difficult for the care
providers to stop trying further therapies, making the infant’s EOL care trajectory
uncertain. One nurse stated:

“I don’t know who mentioned ECMO first, the fellow or the attending. I
remember thinking, ‘Are you kidding me?’ because we don’t normally use it for
that purpose in the NICU. Sometimes I wonder if we are grasping at straws. Did
they really think they were going to save this child? I mean he was in complete
DIC.”

Another nurse said:

“Nothing the team could do helped her. At the end they were pushing in blood
product after blood product and it was coming out just as fast and she had swelled
so much, she was twice her normal size”

While another nurse remembers:

“We basically coded him all night long. No chest compressions, but lots and lots
of medicine.”

In terms of symptom recognition, a few nurse participants recalled some symptoms
infants had experienced at the EOL, such as pain, gasping, grimacing and color changes.
They were not always certain that infants were exhibiting symptoms in the same way
they were being interpreted, such as in cases where the infant was obtundened and offering
few cues into symptoms being experienced. Often these infants were rated as being
without pain. Nurses expressed uncertainty in knowing if the infant for whom they were
caring was actually experiencing pain or any other symptoms. One nurse reflected:

“She would desat all the time. I don’t know if it was from pain or issues with not being able to breathe.”

Another nurse said:

“I don’t know that he was necessarily pain.”

And another said:

“He never really acted in my mind like he was in pain, but who knows. Even if he had been in pain, I don’t even know if he could have shown it.”

Nurses reported that the EOL trajectory for infants is also hard to predict. It is very
difficult to explain to parents what might happen once treatment is withdrawn and the
infant begins to die. One participant reported:

“I told the parents I didn’t think it would happen immediately; that we should have time to take him from the bedside to the parent room”

Another nurse said:

“The physician told the parents it might take a couple of days; I told the family I thought it would only take a couple of hours.”

Last is the uncertainty of providing culturally competent EOL care for various
populations. Nurses knew that there were special considerations that should be made, but
had little direction in what needed to be done. One nurse recalled:

“The baby was Muslim and the chaplain was never called. I knew they had special funeral customs from past experiences. I called the chaplain and he said he didn’t know anything.”
Discomfort

Of all the events surrounding the death of the infant discussed by the nurse participants, the most overwhelming theme that arose was the discomfort nurses felt with various components of the neonatal EOL care process. Factors that clearly contributed to their discomfort in providing EOL care were lack of formal EOL care education, lack of opportunity to deliver EOL care, lack of resources to help with the provision of EOL care, inconsistency between providers in EOL care delivery, talking with families about EOL care, taking on the role of advocate for the infant, ethical dilemmas related to perceived use or misuse of advanced technology and medications, lack of familiarity with patients and with the EOL care situation in general.

Nurses reported a lack of formal education in relation to EOL care during their nursing education. Some content was provided in orientation classes. Nurses also reported that a lack of opportunity to provide EOL care resulted in feeling uncomfortable when the placed in an EOL situation.

As one nurse said:

“It would be beneficial if they had a class we could take. In orientation you don’t always get the experience (of caring for a dying baby) and by the time it comes around for you to do it on your own, you don’t remember.”

and

“I think we do have a good program, but our unit is so large, you don’t get a dying baby very often and the circumstances are always different the comfort level with it (EOL care) is not very high.”

Nurses acknowledged a lack of availability of EOL care resources from which to draw upon when providing EOL care to an infant. They agreed that the availability of these resources would make them more comfortable with the EOL process. As one nurse said:
“There could be something written out...more than just the bereavement checklist, such as things that are good or not good to say to families.”

Nurse participants reported discomfort with knowing what to say to families, as well as their role as an advocate for the infant and the family at the EOL. One nurse experienced discomfort in talking with families, saying:

“I am always at a loss with things to say to the families. I don’t want to say the wrong thing. So, when in doubt, I just shut my mouth. Because what do say, “Sorry for your loss?”

While another struggled with her role as an advocate:

“There were several times throughout the day when I just wanted to go over to them (parents) and give them permission to ask the team to stop. I don’t know what they would have said. I also didn’t know what was going to happen in the end. Maybe something would have worked, who knows. I wasn’t the doctor, so I kept silent. I was just supportive.”

Nurses are also concerned about the various ethical dilemmas that arise from the use of technology and medications. One nurse was very troubled by having to give certain medications at the EOL:

“Sometimes I feel what we do is euthanasia...It’s hard with the gasping; you don’t want to see that because it seems like they are suffering, but it is hard for me when they order a large bolus of something, to give it.”

Another major concern for nurses was the inconsistency they witnessed in the provision of EOL care between patients and between providers. In one nurse’s account, she relayed that an EOL care plan had been determined earlier in conference with the family, but a new provider coming on duty did not agree to carry out the established plan. This caused considerable distress for the nurse:

“Care was not withdrawn; it was changed. I had a lot of anxiety because I felt we were opening the door to a whole host of symptoms or manifestations of discomfort based on the fact we weren’t doing anything to prevent that. I had no
idea what to tell mom (about the plan being changed). Had the palliative care team been involved, we could have called them and maybe they could have stepped in to do something.”

Familiarity of the nurse with the patient and the family was key to the nurse’s comfort with the EOL care situation. Those nurses who had experience caring for the infant and the family were better prepared to dialogue with parents about the infant’s condition and prognosis, as well as answer questions in order to provide good, comprehensive EOL care. Not having that familiarity lead to discomfort:

“I didn’t know the infant; didn’t know the family. It was not a very good thing. I was very detached.”

A nurse who was familiar with her infant and family had a different response:

“I was her primary nurse. I was very familiar with the infant and her family. There was a plan and I was very comfortable with what we needed to do.”

Finally, nurses also reported a natural discomfort that comes just from being in an EOL care situation:

“No matter what, there is always some level of discomfort, but you just do the best you can.”

**Chaos**

Nurse participants described the milieu of the NICU as chaotic. Factors that make the environment seem chaotic are many providers caring for one infant, the presence of other ‘extra’ staff wanting to observe EOL care, having many tasks to complete that all need to be performed quickly, as well as the uncertainty and magnitude of the situation, especially if it was not expected.
Sometimes having ‘extra’ staff at the bedside can lead to nurses feeling that the situation is chaotic:

“I remember at one point looking up and seeing six respiratory therapists and I am pretty sure we didn’t need six. And the MD had his 16-year-old daughter with him. She was standing at the bedside next to the dad while he is watching his baby die. She was there and all these people were gawking and this poor dad was just standing there. I think we could have handled that better.”

Nurses are focused on getting tasks done and reported not being able to talk much to the parents or observe the baby during this time. Parents often witness the chaos. Nurses said:

“Your adrenalin is going and you are all about task-oriented things; trying to do whatever it is you need to do”

and

“I came in and got report and then was immediately hanging lines. I didn’t get to talk to the parents until like an hour or so later. I knew they had been updated; I could hear the physicians talking to them.”

One nurse was relieved that the parents of her infant had left the unit:

“I felt that we were doing a lot of scrambling. We couldn’t find the (memory) boxes and then there were only like two boxes left in the back. We were scrambling trying to get things done. I mean it was probably good that mom and dad weren’t there. I think it would have made it a lot harder for them to see us scrambling around.”

Often, the critical nature of the infant’s condition combined with ambiguity about the best treatment option lead to varied opinions and confusion surrounding the infant’s care. A nurse recalled:

“Many times during the night I had two different opinions about what to do. I mean at one time I had bicarb in one hand and epi in the other and two different people telling me to give two different meds. It was confusing.”
Discussion

For the majority of high-risk neonates, the initial emphasis of care upon admission to the NICU is on survival. Life-sustaining therapies are initiated and the neonate’s response to therapy is monitored. Unfortunately at some point during the disease trajectory it becomes clear that further treatment is futile and death is inevitable. For these neonates, the treatment focus must then shift from curative to supportive. However, the exact time point when this shift should be made remains uncertain. Even when an infant is admitted with life-limiting conditions, such as trisomy 18 or holoprosencephaly, palliation procedures can be performed to give the infant and parents maximum time together while not increasing the infant’s level of suffering. Death in this instance is postponed and may also make it very difficult to determine when EOL care should begin. Often infants remain in the hospital setting instead of being referred to neonatal hospice.

Infants in this study entered EOL care via two distinct pathways; emergently and planned. Our results are similar to the findings of Verhagen and colleagues (2010) who demonstrated that EOL care is initiated differently for infants based on the trajectory of their illness. Some infants may die despite ongoing acute intensive interventions. These neonates are often obtunded and die very quickly once treatment is withdrawn. Other infants may die after treatment is withdrawn or withheld for “quality of life.” The length of time between withdrawal or withholding of treatment and death can be variable and hard to predict. In the current study, time to death ranged from immediate to just over 20 hours. Seventy percent of the infants died within 60 minutes; 40% of those were within 30 minutes. Our findings are consistent with those of Armentrout (2009) and McHaffie
et al. (2001) who also demonstrated variability in time to death once treatment was withdrawn. The variability in time to death is difficult for parents who assume that, once treatment is discontinued, their infant will die quickly (McHaffie et al., 2001).

Emergent entry into EOL care occurred for those infants who, despite significant interventions, were in a state of physiologic failure but had not reached a point of requiring cardiopulmonary resuscitation. Until the decision was made to discontinue treatment, the focus of interventions was directed towards the infant’s survival. As the nurses described, the environment surrounding this specific group of infants is chaotic since numerous members of the NICU staff are present and multiple interventions are being attempted with the goal of achieving physiologic stability. In addition, nurses were not always in agreement with the medical plan during this time period, believing that further intervention was futile. This contributed to discomfort with the EOL process. Nurses involved in the care of these specific infants expressed frustration at carrying out seemingly futile interventions. These findings are supported by Yam and colleagues (2001) who reported the dilemma nurses confront when asked to perform invasive procedures that they believe are inappropriate based on their perceptions of the infant’s failing medical condition. Researchers have demonstrated that nurses and physicians do not always agree on the likelihood of predicting survival of critically ill neonates (Meadow et al., 2012). Their findings highlight the difficulties in determining the point of time when life-sustaining treatment has become futile (Meadow et al.). The perspectives of nurses and physicians originate from repeated exposure to the various nuances of caring for critically ill infants.
In this study, almost every infant received medication for pain and sedation. Many of the infants, especially those who were acutely ill, were already receiving these medications to manage their illness prior to the decision to discontinue curative treatment. These medications were not specifically prescribed for treatment or management of EOL sequelae. Boluses of these prescribed medications were given at treatment withdrawal. For those infants who had planned withdrawal and no intravenous access, other routes of administration were utilized such as oral and aerosolized medications. Across infants, the numbers of doses and dosage amounts were highly variable. In this study, infants appeared to be well medicated during the dying process. This finding conflicts with previous studies where infants were not well medicated (Garten et al., 2011; Janvier et al., 2011; Verhagen et al., 2009). While our findings demonstrate that pharmacologic intervention was viewed as an important component of EOL care, findings from other studies indicate that discussions need to continue related to the appropriate use of this intervention for infants in the NICU.

An interesting finding is the incongruence between the nurses’ self-rating of their comfort level with EOL care and the amount of discomfort surrounding participation in EOL care. The majority of nurses rated themselves as comfortable or very comfortable providing EOL care and yet discomfort with the entire EOL process was a clear theme throughout most of the interviews. Contributing to their discomfort was a lack of formal education related to EOL care during their nursing education as well as orientation. Nurses report that a lack of education is a barrier to the provision of adequate EOL care (Catlin, 2011). In a survey of neonatal nurses, 63% reported receiving varying amounts of content related to EOL care during their academic preparation; although only 42% of the
nurses were satisfied with the content provided (Engler et al., 2004). Nurses reported that structured educational opportunities would increase their comfort level with EOL care (Chan et al., 2008). Clearly, there is a need for formal education both in academic institutions and in the NICU.

The association between familiarity with the infant and comfort in providing EOL care is important. Nurses who were not familiar with the infant and parents were uncomfortable in providing EOL care since they had no prior interactions. Familiarity with the infant did allow nurses to notice subtle changes in the infant’s status.

The specific aims of this study were to identify the symptoms exhibited by dying infants and the treatment strategies used to manage these symptoms. Unfortunately, addressing these aim proved to be difficult. Several factors contributed to this. The findings of this study indicate that symptom recognition is not the main priority once treatment is stopped. For those infants who entered EOL care emergently, nurses had difficulty recalling observed symptoms because the transition from curative to EOL care was rapid and they were focused on completing necessary tasks. In addition, most infants were obtunded and may not have been physiologically capable of exhibiting symptoms. Observation of symptoms exhibited by infants whose entry into EOL care was planned was hindered by not using parents as informants. In planned entry into EOL care, the parents and infant are placed in a quiet environment away from the NICU staff. Thus, nurses are not in constant observation of the infant. Interestingly, for the few symptoms mentioned, nurses were uncertain as to what they were observing. Lastly, there is a lack of documentation in the medical record related to symptoms, including the use of a pain scale, and non-pharmacologic measures. Of concern is that the available pain scales may
not be appropriate for EOL management. It is possible that an infant could be given a low pain score because they are too ill to mount a response to pain and yet be in pain. This could lead to an infant being under-medicated for pain.

Limitations

There were several limitations to this study. The generalizability of the sample is limited due to the small sample size from one mid-western NICU. Inconsistencies and lack of documentation in the electronic medical record following withdrawal of treatment until the time of death made it difficult, if not impossible, to collect the data of interest. Not all identified nursing staff wanted to be interviewed for this study, so there could be points of view that have yet to be uncovered. Restrictions placed by the institutional review board and the unit made it difficult, at times, for nurses to participate. Further, the nurses had a working relationship with the researcher which may have contributed to their willingness to participate in the study. There is also a lack of parent data. The parents are most often the observers of the infant in the last moments of life because the health care team has backed away.

Recommendations for Future Research

Continued research is necessary if we are to unsure a good death for infants and their parents in the NICU. Future research should examine the unique aspects of entry into EOL care; emergent versus planned. The characteristics of each group appear to be very different and should be considered separately. This will require clearly defined inclusion/exclusion criteria. Parents must be included in any new research efforts on symptom identification at the EOL in the neonatal population. Parents have a vantage point that rarely belongs to another group or individual. They are present for the final
moments of their infant’s life, fully taking in all the infant has to show us. Research is also needed to examine the effectiveness of educational strategies on comfort with EOL care.

**Conclusion**

There is no doubt that infants die in the NICU despite our best efforts. In order for infants to have a good death, their EOL experience must be well managed. Symptom recognition and treatment of those symptoms is a key component. Until the barriers to recognition and treatment of symptoms are reduced, infants may not fully experience the good death hoped for them. Currently, there is a lack of evidence to guide EOL care in the NICU. It is important that research with this unique population of infants and parents occur so that our management of EOL does not continue to be based solely upon clinical experience but rather on strong evidence that will guide practice. As we move forward, it will be important to attempt to understand EOL practices from the infant’s perspective.
<table>
<thead>
<tr>
<th>Transcript # 9</th>
<th>Description</th>
<th>Preliminary Thoughts</th>
<th>Initial Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infant</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;chronic patient&quot;</td>
<td>Initial problem</td>
<td>Babies present with varying problems</td>
<td>Treat appropriately, not always immediately clear that EOL care is needed</td>
</tr>
<tr>
<td>&quot;organs were no longer functioning&quot;</td>
<td>Escalation of problem</td>
<td>Entry into EOL care - when is this evident?</td>
<td>Timing of entry into EOL care</td>
</tr>
<tr>
<td>&quot;absolutely not a candidate for dialysis&quot;</td>
<td>Limits to care</td>
<td>System protocols in place to determine eligibility</td>
<td>Limiting care</td>
</tr>
<tr>
<td>&quot;on continuous morphine; pretty much no reaction to anything&quot;</td>
<td>Pain/sedation</td>
<td>Drugs we use for pain and comfort and appropriate use at the EOL</td>
<td>Appropriate medication use at EOL</td>
</tr>
<tr>
<td>&quot;when we did remove the ventilator, he had what we thought was gasping…”</td>
<td>Infant response</td>
<td>How infants respond; subjective observations by staff</td>
<td>Recognition/treatment of signs</td>
</tr>
<tr>
<td>&quot;fentanyl aerosols…gave it to him when we saw something”</td>
<td>Pain/sedation</td>
<td>Drugs we use for pain and comfort and appropriate use at the EOL</td>
<td>Appropriate medication use at EOL</td>
</tr>
<tr>
<td>&quot;infant was placed in nurse's arms and support was withdrawn&quot;</td>
<td>Nurses role in EOL care</td>
<td>Nurses may or may not understand their role in EOL care; personal intuition takes over during times of uncertainty</td>
<td>Personal intuition/experience as a guide</td>
</tr>
</tbody>
</table>

**Figure 4: An example of the coding matrix**
<table>
<thead>
<tr>
<th>Initial Themes</th>
<th>Initial Categories</th>
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<tbody>
<tr>
<td><strong>Infant</strong></td>
<td></td>
</tr>
<tr>
<td>Uncertainty</td>
<td>*EOL care need not immediately evident vs certain need</td>
</tr>
<tr>
<td></td>
<td>*Different times of Entry into EOL; acute vs planned</td>
</tr>
<tr>
<td></td>
<td>*Recognition and treatment of signs/symptoms</td>
</tr>
<tr>
<td></td>
<td>*EOL trajectory</td>
</tr>
<tr>
<td>Focus on Survival</td>
<td>*Appropriate use of technology</td>
</tr>
<tr>
<td></td>
<td>*All possible interventions utilized</td>
</tr>
<tr>
<td></td>
<td>*Nurses are task-oriented vs observant</td>
</tr>
<tr>
<td>Infant Comfort</td>
<td>*Appropriate use of medications</td>
</tr>
<tr>
<td></td>
<td>*Infant appearance</td>
</tr>
<tr>
<td></td>
<td>*Limiting care</td>
</tr>
<tr>
<td></td>
<td>*Palliative care</td>
</tr>
<tr>
<td></td>
<td>*Withholding care</td>
</tr>
</tbody>
</table>

**Figure 5: An example of the coding index**
<table>
<thead>
<tr>
<th>Initial Themes</th>
<th>Initial Categories</th>
<th>Refined Categories</th>
<th>Final Themes</th>
<th>Core Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainty</td>
<td>*Need not evident vs certain need</td>
<td>Care varies greatly between patients</td>
<td>Best practice unknown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Entry into EOL; acute vs planned</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Recognition of signs/symptoms</td>
<td>Still so much that is unknown</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Treatment of signs/symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Unknown EOL trajectory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focus on Survival</td>
<td>*Appropriate use of technology</td>
<td>EOL care after all interventions are exhausted</td>
<td>Transition to EOL care is uncertain</td>
<td><strong>UNCERTAINTY</strong></td>
</tr>
<tr>
<td></td>
<td>*All possible interventions utilized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Nurses are task-oriented vs observant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant Comfort</td>
<td>*Appropriate use of medications</td>
<td>Goal is for infant to not suffer</td>
<td>Don't know if suffering</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Infant appearance</td>
<td></td>
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<tr>
<td></td>
<td>*Limiting care</td>
<td></td>
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<tr>
<td></td>
<td>*Palliative care</td>
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<tr>
<td></td>
<td>*Withholding care</td>
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</table>

**Figure 6: Defining the core concept of uncertainty**
Chapter 4: Methodological Issues in the Study of Neonatal End-of-Life Care

End of life (EOL) care for infants in the neonatal intensive care unit (NICU) is gaining increasing attention in the literature. This is important since more infants die in the first 28 days of life than during any other period of childhood (Moro, Kavanaugh, Okuno-Jones & VanKleef, et al., 2006). In addition, 28% of premature infants born less than 29 weeks gestation do not survive, with mortality rates increasing as gestational age decreases (Stoll et al., 2010). Moderately preterm (32-33 completed weeks gestation), as well as the late preterm infants (34-36 completed weeks gestation) also die at elevated rates when compared to their term counterparts (Shapiro-Mendoza & Lackritz, 2012). Unfortunately palliative care is rarely offered to dying infants and their parents in the NICU. Since 1997, the National Institute for Nursing Research (NINR) listed EOL care as one of their research priorities. A component of this priority included research to improve care for dying children and their families, which were aligned with the recommendations detailed in the Institute of Medicine (IOM) report, entitled, “When Children Die: Improving Palliative and End of Life Care for Children and Their Families.” This important IOM report outlined the importance of caring for dying children and their families, including neonates. Unfortunately, the changes proposed in the IOM report have not made a significant impact on EOL care in the NICU because
very little research is being directed towards this important, but difficult, aspect of NICU management.

Conducting EOL research in the NICU presents unique challenges that can hinder the ability of the researcher to answer well-defined research questions. While these challenges are most likely confronted by all researchers focused on the EOL, they are magnified because of the perceived vulnerability of infants and parents in the NICU (Tomlinson, et al., 2007; Franck, 2005). These challenges can serve as very difficult barriers to overcome thus limiting the ability of researchers to conduct quality research that will make a difference in how EOL care is provided to infants and their parents in the NICU. In order to provide EOL care that is evidence-based, it is important that barriers to research are identified and strategies developed to overcome these barriers. The purpose of the article is to discuss potential barriers to studying EOL in the NICU.

**Barriers to EOL Research in the NICU**

Given the lack of research related to EOL care in the NICU, every aspect of care requires further study. The results of a survey of neonatologists demonstrates that decisions related to EOL care are based on past experiences and not grounded in research (Feltman, Du, & Leuthner, 2012). The specific barriers encountered by researchers will be the result of the research questions being addressed. These barriers could impact subject recruitment resulting in a sample size that is too small to answer the research questions. Further, these barriers could hinder actual data collection. Six categories of barriers have been identified through research study implementation, as well as review of the literature that impede research on EOL care in the NICU:
Uncertain entry into EOL care

Health care providers

Institutional Review Boards (IRB)

Recruitment of bereaved parents

Lack of documentation of EOL care

Heterogeneity of sample

Uncertain Entry into EOL Care

When infants are admitted to the NICU the focus of care is directed towards facilitating the infants’ survival. In very few situations is the care immediately directed toward EOL. Health care providers in the NICU do agree that EOL care should be initiated upon admission to the NICU for infants with lethal conditions or conditions perceived to be incompatible with life (Catlin, 2011). Infants in the NICU confront a variety of illnesses with the majority of these illnesses being unique to this population. In addition, infants often confront a variety of complications. Researchers continue to focus on determining the origins of many of these illnesses as well as developing the best strategies to manage these illnesses. Included in this research is trying to understand how a specific illness is manifested in various groups of infants, especially those born prematurely. For example, because of physiologic immaturity, the diagnosis of sepsis can present very differently in a premature infant born at 24 weeks gestation when compared to a full-term infant born at 40 weeks gestation (Ohlin, Björkqvist, Montgomery & Schollin, 2010). With an initial emphasis on survival and variability in how an illness
presents, it is difficult to predict when life-sustaining treatment has become futile and there should be a shift towards EOL care. Researchers have demonstrated that, when asked to predict whether a premature infant on mechanical ventilation would survive or die, neonatal nurses and neonatologists were correct only 40% of the time in predicting an infant would die (Meadow et al., 2012).

Infants in the NICU usually enter EOL care in one of four ways: 1) neither withholding or withdrawing care and death occurs while receiving CPR; 2) withholding but not withdrawing care and death occurs while receiving ongoing therapy, but no CPR; 3) withdrawing support while physiologically failing; and 4) withdrawing support while stable on the ventilator for poor neurological prognosis (Meadow, 2012). The majority of deaths in the NICU occur following a withdrawal of treatment and those deaths can be characterized into two groups; stable or unstable (Verhagen, et al, 2010). Unstable infants are those who die due to clinical deterioration despite the use of maximal NICU interventions. Infants who are physiologically stable have care withdrawn because of a poor neurological prognosis (Verhagen, et al, 2010). This distinction is important because their EOL experiences may be very different, including when EOL care is initiated and the length of time to death following treatment withdrawal. For unstable infants, much uncertainty surrounds when care will be deemed futile by both physicians and parents. In most cases, the decision is made very quickly to discontinue treatment and extubate the infant so that the parents can hold the infant during her/his last moments of life. These infants are most often moribund at the time all treatment is stopped and often die very quickly. Infants who are physiologically stable and extubated for quality of life reasons
enter EOL care at a pre-determined time and may take an extended period of time to die (Janvier, et al., 2011).

The timing of an infant’s entry into EOL care is also influenced by the beliefs of the neonatologist and the wishes of the parents. Neonatologists are charged with providing parents with the necessary information to make an informed decision related to their infant’s care as well as giving the medical orders to withhold/withdraw life-sustaining treatment. Determining when life-sustaining treatment has become futile is not easy (Meadow et al., 2012). This can lead to disagreements among neonatologists about whether an infant is dying (Caitlin, 2011). This can become a hindrance to considering EOL care. Parents have to also be ready to agree with the assessment that their infant’s care has become futile. Parents’ readiness or unwillingness to discontinue treatment will influence how their infant enters EOL care (Caitlin, 2011). When parents do not agree with the neonatologist’s suggestion that care is becoming futile, these infants often die despite receiving life-sustaining treatment (Singh, Lantos, & Meadow, 2004).

The difficulty surrounding when entry into EOL care will occur is further supported by the use of mathematical models. Various research groups have attempted to develop or use mathematical models to predict whether a premature infant would die or survive with neurodevelopmental impairment. Researchers in the NICHD Neonatal Research Network found that at birth, the probability of death or neurodevelopmental impairment can be estimated by considering factors such as gender, exposure to antenatal steroids, multiple births, and birth weight, in addition to gestational age (Tyson, et al., 2008). This same group of researchers further refined their model by including information, such as severity of respiratory illness, which becomes available later in the
infant’s clinical course (Ambalavanan et al., 2012). While mathematical models have correctly predicted death for some infants, there are those infants who are misclassified. Boland et al. (2012) demonstrated a significant difference between their prediction model and the actual numbers of deaths in the NICU. For EOL researchers who may have some interest in using a mathematical model to predict death, the model provides no information about when the infant reaches the point that life-sustaining care has become futile. Thus, it is difficult to precisely determine that point in time when entry into EOL care will occur (Caitlin, 2011).

Researchers whose research questions require recruitment of subjects upon the infant’s entry into EOL care will have difficulty identifying when the transition from life-sustaining care to EOL care will occur. The inclusion/exclusion criteria of a study will determine eligibility for a study. How infants enter EOL care may impact eligibility since entry is variable. These are important considerations in the development of EOL care studies with neonates. Research questions should drive the category of infant to be studied and inclusion/exclusion criteria formulated as appropriate.

Health Care Providers

Health care providers can facilitate EOL research by being participants in the research as well as providing access to infants and parents. However, they can also provide barriers to conducting EOL research in the NICU by several mechanisms. These include a lack of education related to EOL care, serving as gatekeepers to infants and parents, an unwillingness to participate in research, and being task-oriented during the dying process. These barriers will limit the enrollment of subjects and hinder data collection efforts.
“Educational preparation for end of life has been inconsistent at best and sometimes neglected within nursing curricula” (American Association of Colleges of Nursing (AACN), 2004). Education related to EOL care is lacking for both nurses and physicians in both formal educational programs as well as hospital-based programs (Gibbins, McCoubrie, & Forbes, 2011; Botwinski, 2010; Ferrell & Coyle, 2002; Schlairet, 2009). This lack of knowledge impacts the comfort level that health care providers have with EOL care. Neonatal nurses and neonatologists have identified a lack of education as an important barrier to providing EOL care (Caitlin, 2011). Research efforts have the potential to be hampered because health care providers have not developed an appreciation for the importance of EOL care and the need to have research conducted in this area.

In the NICU, nurses and, especially, neonatologists serve as gatekeepers between infants and their parents and researchers. It is through these gatekeepers that researchers will gain access to infants and parents. If these gatekeepers balk at the notion of studying aspects of EOL care that involve infants and/or parents, they may prevent access to subjects. Neonatal staff became very protective at the EOL, especially as the infant becomes sicker and closer to death. This protectiveness includes the parents. This can have a significant effect on recruitment of research participants. In EOL research with infants, parents are viewed as the key informants and researchers often seek access to parents. Neonatal staff who deny access to parents believe they are doing so because they have the parents’ best interests in mind. Reasons for their denial include a lack of understanding about the study, the intense emotional situation surrounding the death of an infant, and their own discomfort or reluctance in speaking to parents about EOL
issues, as well as participation in EOL care research. Neonatal staff are concerned that infant and/or parental participation in research will place undue burden on them (Buss & Arnold, 2004; Hinds, et al., 2007; Tomlinson, et al., 2007). However, this paternalistic thinking takes away the opportunity for the parents to make an autonomous and informed decision about their own desire to participate in research (Tomlinson, et al, 2007). Researchers have demonstrated that parents want to make their own decisions related to research participation for themselves as well as their infant (Snowden, Elborne & Garcia, 1999; Burgess, Singhal, Amin, McMillan & Devrome, 2003; Singal, Oberle, Burgess & Huber-Okrainec, 2002; Stenson, Becher & McIntosh, 2004). The reluctance of the neonatal staff to facilitate researcher access to parents and their infants will introduce a source of bias into study findings since only certain categories of parents or infants are being referred (Hinds, Burghen & Pritchard, 2007).

Researchers may have developed research questions that require data based on observations made by the neonatal staff during the EOL process. However, the staff may have limited observations to report. For infants who are unstable and enter EOL care very quickly, the neonatal staff are most likely task-focused on the infant’s care and not necessarily making in-depth observations of the infant or parents. For example, prioritizing of treatment and routine care appears to prevent attention to symptom recognition at the EOL (Willard & Luker, 2006). Thus, they may not be able to accurately provide the data that researchers are seeking. In addition, for infants who are stable and enter EOL care at a planned time, the infant and parents are given privacy away from the neonatal staff so that the staff is not available to make observations. If researchers are interested in observational data, it may be that the parents are in a position
to provide the most accurate data since they become the front-line observers during the final moments of the infant’s life. Even though parents report it is the nurse who is at the bedside more than any other caregiver; at the EOL, it is the parent who becomes the front line observer in those final moments of life. Thus it becomes important to include parents in EOL research.

Researchers may be interested in obtaining the views of neonatal staff in relation to EOL care. This necessitates the staff being willing to participate in research. Researchers may encounter staff who are unwilling to participate in research for various reasons including beliefs about EOL care in the NICU, understanding the relevance of the research study, and time constraints (Tomlinson, et al., 2007; Roxburgh, 2006). Findings from a study focused on staff participation indicate that the staff believe research must be more clinically relevant to their own work and the needs of the profession (Sandberg, Johnson, Robila & Miller, 2002). Specific to EOL care, neonatal staff need to believe that research in this area is important and worth carrying out in order to increase their level of participation (Singhal, Oberle, Darwish & Burgess, 2004; Sandberg, et al., 2002). Researchers may choose to focus on the perceptions of nurses because of their perceived involvement with EOL care. Parents reported that, while the neonatologist was involved, it was the nursing staff who was most visible during EOL care with their infant (Meyer, et al., 2002). Nurses who have a positive view of research are more likely to participate (Bonner & Sando, 2008) but, time is one of the most frequent reasons given by nurses for not participating in research (Jacobson, Warner, Fleming & Schmidt, 2008). As researchers recruit willing participants, consideration must be given to bias in the data as the data may not be reflective of the views of those who were not willing to participate.
Institutional Review Boards

It is the responsibility of Institutional Review Boards (IRB) to protect potentially eligible, as well as, enrolled study participants from research-related risks. As a component, the IRB must consider whether a specific group of subjects is vulnerable and plays an important role in protecting those who cannot look after their own best interests. IRBs have been historically paternalistic in their protection of subjects in bereavement research because of underlying concerns that participation would be intrusive and alarming while increasing stress and suffering to the patient and family (Emanuel, Fairclough, Wolfe & Emanuel, 2004). Paternalism is defined as rejecting research studies that poses potential risk to individuals who are perceived as vulnerable but are competent to decide for themselves (Edwards, Kirchin & Huxtable, 2004). In relation to EOL research in the NICU, IRBs are often paternalistic during the approval process and, even with safeguards in place, have difficulty approving studies (Emanuel et al., 2004; Lee & Kristjanson, 2003). In the case of dying infants and their parents, the perception of vulnerability appears to be magnified (Tomlinson, et al., 2007). Because parents speak for their infant, the paternalism exhibited by the IRB is directed toward protecting bereaved parents, most often during interviews. There is great concern that parents might experience undue stress and emotional turmoil by re-living the dying experience of their infant.

Edwards, et al. (2002) argue that IRBs should not be paternalistic by rejecting studies that may pose risk to people who are competent to decide for themselves about their participation in research. Emanuel, et al (2004) agreed, writing that “IRBs should not preemptively restrict studies with bereaved parents without strong evidence that they
will be stressful or otherwise harmful.” This is important since IRBs have denied access to parents (Snowdon, Elbourne & Garcia, 2004). Undoubtedly, parents are in a vulnerable position when asked to participate in research that explores the end of their infant’s life and there is some risk that accompanies their participation in terms of the emotional burden. However, there is a lack of evidence indicating that parents are incapable of making an informed decision about their participation in research (Hinds, et al, 2007; Ward, 2007).

Based on parental report, the concerns related to increasing the emotional burden may be unfounded. Hinds, et al. (2007) found that the majority of bereaved parents in their studies denied experiencing distress as a result of participating in EOL studies. Further, these researchers reported that, upon review of participation and refusal rates as well as reasons for refusal, parents were able to discern when participation in an EOL study was not in their best interest and were able to decline. Even though interviews can be difficult, parents have reported satisfaction with their participation without negative outcomes. Further, they actually describe the process as being therapeutic (Hynson, Aroni, Bauld & Sawyer, 2006). Parents derive benefit from participating in EOL research. These benefits include feelings of relief in getting emotions out in the open, an opportunity to talk about their infant, and a feeling of altruism that by participating they may be helping others (Michelson, Koogler, Skipton, Sullivan & Frader, 2006; Hynson, et al., 2006; Scott, Valery, Boyle & Bain, 2002; Hoehn, et al., 2005). Participation in research also gives parents the opportunity to better comprehend their own feelings and solidify previously unarticulated ideas.
In order to overcome the potential for paternalistic views preventing IRB approval, it is important when planning EOL research in the NICU to work closely with the IRB to understand their concerns related to conducting research with this vulnerable population and developing strategies to allay these concerns. Open communication with the IRB is critical. It has previously been recommended that the IRB should include at least one professional with expertise in palliative care in their membership (Casarett & Karlawish, 2000). Because the recruitment of parents often triggers IRB concerns, suggestions from parents who have participated in previous research should be incorporated into the research protocol. Parents who have participated in EOL research (Dyregrov, 2004; Hynson, et al., 2006; Michelson, et al., 2006; Cook & Bosley, 1995) highlighted several skills they thought were pertinent to having a good experience with research on this sensitive topic. These include displaying empathy and genuine interest in what the bereaved parent has to tell about their infant, allowing parents to cry and express strong emotions, creating an unhurried interview process, and pairing the right interview questions with the parents’ ability to discuss the issues (Hynson, et al., 2006). Overcoming IRB concerns will allow researchers to address important questions that will improve EOL care provided in the NICU.

**Recruitment of Bereaved Parents**

One of the most important areas to be addressed by EOL research in the NICU is understanding the needs of the dying infant and their parents. This includes understanding what symptoms the infant is experiencing and identifying strategies to prevent or minimize pain and suffering. While observations of the neonatal staff can be informative, parents are in the ideal position to observe their infant’s journey through the
dying process since, in most cases, they are highly involved in their infant’s care and choose to remain at the bedside throughout the dying process. In addition, most parents choose to hold their infant until their infant dies. Thus, parents can be the best informants about the needs of dying infants as well as the needs of the parents themselves.

Researchers encounter several obstacles in recruiting bereaved parents. These include uncertainty of the infant’s prognosis, access to the parents (discussed above), timing of recruitment efforts, how to recruit parents, and data collection methods. As has been discussed, when an infant is admitted to the NICU, the emphasis of care is on the infant’s survival. Determining when an infant’s medical care is becoming futile is difficult to predict (Meadow et al., 2012). Even when this determination has been made by the neonatal staff, parents are not always ready to make the decision to withdraw life-support and initiate EOL care (Caitlin, 2011; Singh et al., 2004). Thus, parents who have not come to acceptance of their infant’s condition cannot be approached to consider research studies.

The timing of recruitment efforts and how to recruit parents are intertwined. A critical question is when to approach parents. Should recruitment occur before the infant dies or should researchers wait a specified period of time before contacting parents? Researchers must be sensitive and recognize that not all parents make their way through the grieving process the same way or in the same length of time. Researchers have shown that parents do not want to be contacted initially after their infant’s death as they are dealing with their emotions and making plans for closure, such as funeral arrangements. Parents would not be inclined to participate in research for several weeks after their infant’s death (Cowles, 1998). One recommendation is that a three-month waiting period
has been recommended as the minimum time that researchers should wait prior to contacting a bereaved parent to participate in a research interview, especially where emotional issues will be discussed (McHaffie, et al., 2001).

Once researchers determine the appropriate time to wait before recruiting parents, the next point to consider is the approach to contacting parents. A study by Hynson et al. (2006) found that parents prefer that initial contact with them be made via letter with a complete description of the research project provided at that time. Parents stated that receiving the letter instead of a phone call as the initial contact enabled them to take adequate time to process their thoughts about participation in a research study, to talk to their partner or family about their feelings, and to prepare for the phone call. Parents also felt that receiving the mailing was the least intrusive means of contacting them about participating in a research study (Hynson, et al., 2006). However, a dilemma arises in determining whether the parents received the mailing. Simply mailing a letter without a follow-up call creates the possibility that a parent who would have participated in the study, but never received the mailing, will be excluded from the study. Researchers must determine how to follow-up with parents after the letter has been mailed. In two studies with bereaved parents, initial contact was via mail but required the parent to opt out of the study within a certain time period either by calling a telephone number (Hynson, et al., 2006) or mailing back a response card (Emanuel, et al., 2004). If the parent did not respond, a follow-up telephone call was placed. This procedure eliminated any question as to whether the parent received the information or their intent to participate. It is not known whether a telephone call to a parent who had somehow not received the letter via the mail would cause undue stress to the parent.
How the data are collected could prove to be an obstacle. The most common methodology used with bereaved parents is interviewing. This allows the researcher to elicit greater insight into the experience of the dying infant. There is always concern that participating in an interview will cause undue burden on the parents by causing emotional turmoil while re-living the death of their infant. However, those persons who have suffered loss report that often others avoid them, seem very uncomfortable talking to them, and/or do not offer much in the way of support because of a fear of upsetting the parent or “ripping open healed wounds” (Dyregrov, 2004). Parents actually want to talk about what they have experienced and need to talk about those experiences in order to move on with their life (Dyregrov, 2004; Woodgate, 2006). Parents have reported that having a person other than family and friends to talk to helped them to explore their full range of emotions without having to burden those closest to them (Dyregrov, 2004). Dyregrov found that 100% of bereaved parents felt their research participation was a positive experience and had to regret about having participated. For parents, an important component of data collection is where the data are to be collected. Parents stated that it was of utmost importance to them to be able to choose the time and location of the interview, with many parents choosing to have the interview conducted in their own home where they felt most comfortable (Hynson, et al., 2006). It has been found to be extremely distressing for parents to return to the hospital or unit where the infant died (McHaffie, et al., 2001). Researchers need to develop a data collection plan that does not cause unnecessary stress for parents. However, if parents want the interview to occur in their home, researchers need a contingency plan that can be activated if the parents experience overwhelming emotions.
Lack of Documentation of EOL Care

Researchers may have developed questions that require abstraction from the infant’s medical record in order to address these questions. Medical record review allows retrospective access to the infant’s data that might not otherwise be obtained. Because of the inherent ethical issues surrounding direct observation of the dying infant by the researcher, the medical record can be a crucial piece of information in conducting EOL research, serving as the record of events, documented by those who are present during the infant’s final moments of life.

The use of medical record data has been criticized for its lack of validity and reliability due to the many problems inherent in the documentation of patient information that was not collected exclusively for the purpose of research (vonKross Krowchuk, et al., 1995; Gearing, et al., 2006; Jansen, et al., 2005; Gilbert, Lowenstein, Koziol-McLain, Barta & Steiner, 1996). One of the most common problems with using medical records in research is that important data may be missing. There are several reasons why information might be missing: the data were never recorded, part of the record is missing, or the entire medical record is missing (vonKross Krowchuk, et al., 1995). The information that is available in the medical record is limited only to the items that were documented (vonKross Krowchuk, et al, 1995). Thus, data on variables of interest may not have been collected and recorded in the medical record. Further, the clinical information included in the medical record consists of both subjective and objective data that can be unreliable and inaccurate. Data obtained by interview, physical examination, and observation are all subjected to the interpretation by the neonatal staff member who is gathering the data. For example, if the staff member does not have sound assessment
skills, important signs or symptoms may never be appreciated and therefore will not be documented in the medical record. When dealing with retrospective data, the researcher is unable to ask the staff member to clarify documentation or complete missing data.

In EOL research with infants, documentation in the medical record may be missing because of the standard of care during the dying process. In anticipation of the moment of death and for the emotional protection of the parents, all monitoring devices are usually turned off when life-sustaining treatment is withdrawn. This provides the parents with the opportunity to hold their infant without the attachment of multiple wires and tubes. Essentially this time point marks the end of routine documentation of basic vital signs and other symptoms the infant may be exhibiting. Thus, documentation may stop when all treatment is stopped. There will be a final notation in the progress notes by the neonatologist, but it may not contain in-depth detail of the events surrounding the infant’s death. Because the accuracy of the medical record is dependent upon various factors, data from the medical record should not be used as the sole source of data (Luck, Peabody, Dresselhaus & Glassman, 2000).

**Heterogeneity of Sample**

The last barrier to conducting EOL research is determining how much variability is desired in the sample. In the NICU, the potential exists to have a sample that may be too heterogeneous to address those research questions which require recruitment of infants. In the NICU, gestational age at birth plays a significant role in the infant’s physiology, how the infant will respond to treatment, and how the infant will exhibit signs and symptoms. The researcher needs to give careful consideration to the inclusion/exclusion criteria. For example, does the researcher want to only recruit infants
in a specified gestational age range (i.e., 24-28 weeks) or does the researcher want to widen range of gestational ages? An important consideration is the role of gestational age in how the variables of interest will be manifested. Many illnesses found in the NICU have an uncertain trajectory that is greatly influenced by gestational age.

**Recommendations**

There are several recommendations to be made for overcoming the barriers to conducting EOL care research in the NICU:

- Future EOL care studies of neonates should look at groups of infants differently. Infants should be separated by their entry into EOL care; emergent or planned, as well as by gestational age, as these differences between groups may be significant.
- Good, open communication must be maintained with IRBs, physicians and nurses to facilitate education and understanding of the importance and need for EOL care research in this vulnerable population.
- IRBs should be consulted early in the planning stages, prior to funding application, to address potential concerns and ensure final study approval.
- Advocate for increased nursing presence at the EOL, as well as continued monitoring of infants during the time between the withdrawal of life-sustaining therapy and death to ensure data is captured and infants are being provided optimal EOL care.
- Advocate for continued education for physicians and nurses regarding EOL care and in-service staff on study variables of interest.
• Include parents in future EOL care research by working with case managers and social workers to identify those parents who might be willing research participants. A counselor or psychologist should also be designated to assist with negative reactions that parents may encounter as a result of their participation in an EOL care research study.

Conclusion

Management of EOL care in the NICU will continue to be based on experience and intuition if researchers do not focus on EOL research. There are many significant barriers to conducting EOL research in the NICU. However, it is important that researchers develop strategies to overcome these barriers. If researchers continue to encounter barriers, studies will be at risk for having samples that are small, biased, and underpowered. The results cannot be generalized to other NICUs and will have limited impact on changing EOL care.
References


Ohlin, A., Björkqvist, M., Montgomery, S., & Schollin, J. (2010). Clinical signs and CRP values associated with blood culture results in neonates evaluated for suspected...


Appendix A: Data Collection Forms
Subject Number___________
DOB___________
Gestational Age___________
Birth Weight___________ kg
Date of Death___________
Time of Death___________
Time of Treatment Withdrawal___________
Age at time of death___________ days
LOS___________ days

Diagnosis__________________________________________________
Perinatal Diagnosis? Yes/No

Ongoing therapy at time of Treatment Withdrawal____________________________________
_____________________________________________________________________________
_____________________________________________________________________________

Interventions associated with Treatment Withdrawal____________________________________
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<th>At Withdrawal</th>
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**Neurological Data**

All recorded data will be collected from 24 hours prior to withdrawal of treatment until time of death.

Pain Level Evaluated? Yes/No

Pain Scale Utilized______________________________

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<td>Pain Score and interventions</td>
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<tr>
<td>Pupillary Reaction: Brisk, Sluggish</td>
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<td>Seizures: Yes/No Lip Smacking Eye Rolling Twitching Grimacing</td>
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<td>Temperature</td>
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<td>Other:</td>
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**Respiratory Data**

All recorded data will be collected from 24 hours prior to withdrawal of treatment until time of death.

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<td>Retractions: (Mild, Moderate or Severe)</td>
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<tr>
<td>Respiratory Parameters Nasal flaring, head bobbing, chest heaving</td>
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</tr>
<tr>
<td>Other:</td>
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</tbody>
</table>
**Cardiovascular Data**

All recorded data will be collected from 24 hours prior to withdrawal of treatment until time of death.

<table>
<thead>
<tr>
<th></th>
<th>Date/ Time</th>
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<th>Date/ Time</th>
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</thead>
<tbody>
<tr>
<td>Heart Rate</td>
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<tr>
<td>(If available)</td>
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<tr>
<td>BP (If Available)</td>
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<tr>
<td>Color: Pink, Pale,</td>
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<tr>
<td>Dusky, Cyanotic</td>
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<tr>
<td>Capillary Refill</td>
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<tr>
<td>&lt; or &gt; 3 seconds</td>
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<td>Other:</td>
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</table>
### Renal Data

All recorded data will be collected from 24 hours prior to withdrawal of treatment until time of death.

<table>
<thead>
<tr>
<th></th>
<th>Date/Time</th>
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<th>Date/Time</th>
<th>Date/Time</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine Output mg/kg/hr</td>
<td></td>
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<tr>
<td>Edema</td>
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<tr>
<td>Skin and mucous membrane integrity</td>
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<tr>
<td>Other:</td>
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</tbody>
</table>
**Other Data**

Parents at the bedside during the dying process? Yes/No

Parents at the bedside at the time of death? Yes/No

Palliative care protocol utilized? Yes/No

Hospital Bereavement Team involved? Yes/No

Hospital chaplain involved? Yes/No

Comments:________________________________________________________
_______________________________________________________________
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_______________________________________________________________


Nurse Demographic Information Data Collection Form

1. How long have you been a registered nurse?______________

2. How long have you been a NICU nurse?____________________

3. What is your educational background (AD, BS, BSN, MS)?_______


5. On a scale of 1 to 5, with 1 being uncomfortable; 2 being slightly uncomfortable; 3 being neutral; 4 being comfortable; and 5 being very comfortable; please rate your comfort level in providing end-of-life care to infants and their families. _______

6. Did your nursing school provide you with instruction in end-of-life care? If so (please circle one choice), a. Was the instruction included in other courses? OR b. Was there a course devoted solely to the provision of end-of-life care?

7. On a scale of 1 to 5, with 1 being not at all prepared; 2 being somewhat prepared; 3 being neutral; 4 being adequately prepared; and 5 being very well prepared; please rate how well you feel your hospital or unit has prepared you to provide end-of-life care to infants and their families. _______
8. Do you feel that you would benefit from having hospital or unit-sponsored education on providing end-of-life care to infants and their families? Yes or No

9. What is your race/ethnicity?

Caucasian_____ African American_____ Hispanic_____ Asian, Pacific Islander_____ Other_______________

10. On a scale of 1 to 5, with 1 being not at all familiar; 2 being somewhat familiar; 3 being neutral; 4 being somewhat familiar; and 5 being very familiar; please rate how familiar you were with the patient for whom you provided end-of-life care. __________
Nurse Interview Schedule - Symptom Identification

1. Please tell me about the infant for whom you provided end-of-life care. (What was the diagnosis, situation surrounding the withdrawing of care?)

2. Can you describe for me what you observed the infant doing as care was being withdrawn? (Signs/Symptoms being exhibited)
   a. Did you think the infant was in pain?, Did you notice any color changes?, Was the infant’s breathing affected? (A wide range of symptoms will be explored here and the nurse will be able to talk freely about what he/she saw the infant experience).
   b. Is there anything else you can tell me about what the infant experienced as care was being withdrawn?

3. Can you tell me what you observed the infant doing at the time of the infant’s death? (Signs/Symptoms being exhibited)
   a. Do you think he/she was in pain?, Did you notice any color changes?, Was his/her breathing affected?
   b. Is there anything else you can tell me about what your infant experienced at the end of life?

4. Of the signs/symptoms that you saw the infant experience: Did you feel you were able to adequately treat and relieve any of the symptoms? How were they treated? Was any medication given? Did you employ any non-pharmacologic techniques?
5. Did you feel comfortable during the end-of-life care process that you knew what the infant was going to experience and that you were able to describe adequately to the parents what they might see?

6. What resources could help you better care for a dying infant and their family (bereavement education, etc)?

7. Is there anything else that you would like to talk about in regard to the end-of-life care that your infant received or what you observed?