Neonatal Nurses' Experiences of Caring for High-Risk Infants Involved in Research

By

Bella Iomdina

A Thesis

Submitted to the Faculty of Graduate Studies
In Partial Fulfillment of the Requirements
For the Degree of

MASTER OF NURSING

Faculty of Nursing
University of Manitoba
Winnipeg, Manitoba
July 2008

ABSTRACT

Although attention has been given to parental attitudes regarding enrollment of their high-risk infants in research, there is a paucity of knowledge in the literature, which investigates nurses' experiences of caring for high-risk infants involved in research. Consequently, there is little understanding of how caring for these infants impacts nursing care. The purpose of this research was to arrive at an increased understanding of neonatal nurses' experiences in caring for high-risk infants involved in research. Attention was given to exploring neonatal intensive care unit (NICU) nurses' perspectives towards neonatal research and the notion of risk to involving high-risk infants in research, their perceived roles and responsibilities with regards to high-risk infants in research, and the impact of research on caring for high-risk infants. This study was built on the research program of the student's supervisor that seeks to increase the knowledge base of the nature of risk in child health research.

An exploratory descriptive study within the qualitative paradigm was used. Seven semi-structured interviews, one focus group interview, and field notes were used to obtain information from seven NICU nurses. All of the qualitative data that emerged was analyzed using the constant comparative data analysis technique. Data analysis revealed that safeguarding their patients, or being a "safety net", was the essence of nurses' experiences of caring for high-risk infants involved in research. The nurses described their main role was the provision of a safe environment, regardless of the infants' involvement in research. Acting as a "safety net" involved the nurses always being on guard and knowledgeable about their patients' care. The following three themes further depicting the safeguarding experience emerged: *feelings within*, *keeping it near and dear*, and *making it safer*. The first theme, *feelings within*, uncovered nurses' mixed emotions when caring for infants involved in research, which ranged from positive feelings to feelings of moral distress. The second theme, *keeping it near and dear*, referred to the uncomfortable feelings and memories that nurses held about situations in which they felt infants enrolled in research had suffered because of their inability of not being able to fully safeguard them. Some of the nurses expressed regretting their choices, such as not speaking up on a patient's behalf, while others described it as a learning process, which eventually contributed to their abilities to safeguard infants. The third theme, *making it safer*, was based on the nurses' enthusiasm about the future of neonatal research. The nurses identified many ways in which child health researchers, bedside nurses, REB members, and parents could minimize the risks of involving high-risk infants in research. This study yielded new insights about how NICU nurses care for high-risk infants involved in research that may be used to improve the protection of high-risk infants in research and ultimately contribute to the quality of care for these infants. Recommendations for nursing practice, education, and research are suggested.

ACKNOWLEDGEMENTS

I would like to express my gratitude to my committee chair, Dr. Roberta Woodgate, Assistant Professor, Faculty of Nursing. Your constant guidance, encouragement, and invaluable suggestions have made this experience enjoyable and further strengthened my love for qualitative research.

Thank you for your support to my committee members: Dr. Marie Edwards, Faculty of Nursing, Dr. Catherine Cronin, Faculty of Medicine, and Doris Sawatsky-Dickson, Clinical Nurse Specialist, Children's Hospital. I appreciate your time and your suggestions for this study, as well as for the future research questions on this topic.

A special thank you to Cosette Taylor-Mendes, Faculty of Nursing, for your help with this project.

To the nurses who participated in this study, thank you for sharing your experiences and thoughts, which were essential to this study.

Thank you to my family, for their constant support.

The researcher was supported by Child Health Graduate Studentship in Nursing and Foundation for Registered Nurses of Manitoba Award.

TABLE OF CONTENTS

CHAPTER I: INTRODUCTION

Introduction

Continuous progress in neonatal medicine would not have been possible without research that involved infants (Taeusch & Ballard, 1998). Neonatal research has contributed to constant progress in technology, as well as various therapies and procedures (Taeusch & Ballard). The importance of inclusion of vulnerable populations, such as infants and children (Purdy, 2004) in research has been continuously gaining recognition in the medical community, based on the principles of fairness, equality, and beneficence (Grodin & Glantz, 1994; McIntosh et al, 2000; Menikoff, 2004). Therefore, it is not only necessary to continue research that involves infants, but unethical not to conduct such research (Franck, 2005; McIntosh et al).

When a high-risk infant is admitted to the neonatal intensive care unit (NICU), it can be a stressful experience, not only for that infant's family, but also for the nurses who are involved in the increasingly complex intensive neonatal care (Hagedorn & Gardner, 1999; Spence et al., 2006). Looking after a high-risk infant who is a participant in research can be an additional source of stress for these nurses, as well as for the parents (Alt-White & Pranulis, 2006; Stenson, Becher, & McIntosh, 2004). Although attention has been given to parental attitudes regarding enrollment of their infant in research (Burgess, Singhal, Amin, McMillan, & Devrome, 2003; Singhal, Oberle, Darwish, & Burgess, 2004; Stenson et al.), there is a paucity of knowledge in the literature, which investigates nurses' experiences of caring for high-risk infants involved in research. Consequently, there is little understanding of how caring for these infants impacts nursing care.

This study generated understanding of the experiences of neonatal nurses who provide care to high-risk infants enrolled in research. This study was built on the research program of the student's supervisor that seeks to increase the knowledge base of the nature of risk in child health research. An exploratory methodology within the qualitative research paradigm was employed to carry out this study. This particular method was used due to the lack of research in this area and the need for in-depth data. Critical to arriving at a detailed and accurate understanding of participants' perspectives is a solid foundation in descriptive theory.

Significance of the Problem

The numbers of high-risk infants, including premature, low birth weight, and infants with congenital anomalies admitted to the NICU have been steadily growing worldwide, due to improving medical care (Canadian Institute for Health Information [CIHI], 2006; CIHI, 2004; Lee et al., 2000; Sankaran et al., 2002). Various studies, which have examined the stresses associated with working in the NICU, found that certain factors may contribute to the complexity of nursing care in the NICU. Nurses working in the NICU may be confronted with ethical issues and dilemmas, which may cause a significant amount of stress (Biel, Eastwood, Muenzen, Greenberg, & Viejo, 1999; Downey, Bengiamin, Heuer, & Juhl, 1995; Ewing & Carter, 2004; Heuer, Bengiamin, Downey, & Imler, 1996; Lussky, 1999; Spence, 1998; Stutts & Schloemann, 2002). Nurses working in the NICU may also be implicated in certain legal issues, related to high-risk infants' care (Dunn, Gies, & Peters, 2005; Hagedorn & Gardner, 1999; Verklan, 2003). Other factors identified in the literature, which have been associated with nursing stress, are emotional stress (Ewing & Carter, 2004; Heuer et al.; Sawatzky, 1996),

increasingly sophisticated technology (Biel et al.; Rosenthal, Schmid, & Black, 1989; Mark, 2002), and staffing and increased workload (Heuer et al.; Lippman & Arnold, 2005; Mulcahy & Betts, 2005).

The nurse's roles in research have been discussed in the literature, however the findings have not pertained specifically to research with infants (Cheng et al, 2000; Di Giulio, 1996; Oberle & Allen, 2006). Several studies were conducted to examine the challenges associated with research involving infants, such as an informed consent (Ballard, Shook, Desai, & Anand, 2004; Golec, Gibbins, Dunn, & Hebert, 2000). There was only one study that has examined attitudes of nurses towards research with newborns (Singhal et al., 2004).

In conclusion, although the stresses associated with working in the NICU have been well documented, the impact on the neonatal nurse's care for an infant involved in research has not been sufficiently investigated. Knowledge of neonatal nurses' experiences in caring for a high-risk infant involved in research and their perceived roles and responsibilities is lacking. The knowledge gleaned from this study will help guide and support nurses as they care for high-risk infants involved in research, and will ultimately improve the protection of high-risk infants in research and contribute to the quality of care for these infants.

Purpose of the Study

The primary purpose of this exploratory study was to arrive at an increased understanding of neonatal nurses' experiences in caring for high-risk infants involved in research. This included exploring and describing neonatal nurses' perspectives and beliefs towards neonatal research and the notion of risk to involving infants in research,

their perceived roles and responsibilities with regards to high-risk infants involved in research, and the impact and challenges of caring for high-risk infants involved in research on nursing care.

Research Questions

This study examined the following research questions:

1. What are the perspectives and beliefs of neonatal nurses about involving high-risk infants in research?
2. What are the perspectives and beliefs of neonatal nurses about the notion of risk to involving high-risk infants in research?
3. What are perceived roles and responsibilities of neonatal nurses who provide care for high-risk infants involved in research?
4. How does caring for high-risk infants involved in research impact on nursing care?
5. What challenges may be experienced by neonatal nurses caring for high-risk infants involved in research?

Assumptions

The assumptions for this exploratory, descriptive study came from the review of the literature and the researcher's professional experience in the field of neonatology.

1) One of the primary assumptions was that research involving infants is necessary to the progress of neonatal care, which includes improvements in technology, various therapies and procedures (Taeusch & Ballard, 1998).
2) Another assumption was that nursing is generally considered a stressful profession (Keane, Ducette, & Adler, 1985). The literature indicated that it is the

case, especially in the intensive care units, where combination of stressors, such as emotional stress, sophisticated technology, and increased workload contribute to the development of burnout.

3) Consequently to the previous assumption, it was assumed that the added responsibility of caring for an infant involved in research can contribute to any of those stressors, leading to job dissatisfaction.
4) It was also assumed that caring for an infant involved in research can positively impact on nursing care, thus leading to increased job satisfaction.

Definitions of Terms

The major constructs of this study, caring, high-risk infant, neonatal nurse, and research were defined as follows:

Caring

Caring refers to the actions directed toward supporting, assisting, and promoting individual's well being, thereby improving a human condition (Leininger, 1988). Caring, from a moral perspective, is an obligation of nurses to relate to patients in a particular way, based on the knowledge of the patient gained through nurse-patient relationships. Therefore, caring is a holistic approach, which includes attending to the health care needs of individual patients with unique life histories and to select or not to select their therapies based on their potential to facilitate the patient's achievement of preferred life goals (Raines, 1993). Furthermore, in the NICU, caring involves not only supporting an infant's health needs, but also providing emotional support to parents and including families in the decision-making process.

High-Risk Infant

For the purposes of this study, a high-risk infant was defined as any infant admitted to the NICU.

Neonatal Nurse

For the purposes of this study, a neonatal nurse was defined as any nurse who is employed at the neonatal intensive care unit.

Research

For the purposes of this study, the term "research" referred to any research directed at understanding and / or improving some dimension of high-risk infant health and health care; research may include a variety of research methods or designs such as clinical trials, survey research, and intervention research and involve a variety of research fields such as biomedicine, psychology, and nursing (Woodgate et al., work in progress).The research may be therapeutic or non-therapeutic.

Chapter Summary

This chapter provided a synopsis of the background and the significance of exploring neonatal nurses' experiences caring for high-risk infants involved in research. A lack of the literature exploring such experiences has been established. With an increasing number of critically ill infants being admitted to NICUs, chances are that more babies will be involved in research. A better understanding of nurses' experiences in such situations will further an awareness of the phenomenon of caring for an infant involved in research. In addition, this awareness may be able to promote a positive atmosphere and collaboration between nurses, other health care professionals, and parents.

The following chapter presents a review of the literature pertaining to the emergence of neonatal care, the complexity of issues surrounding care for high-risk infants, the nurse's role in research, ethical considerations for nurses in research, nurses' attitudes towards caring for a patient involved in research, and neonatal research in the family context.

CHAPTER II: LITERATURE REVIEW

Introduction

This chapter presents a review of the literature contributing to an understanding and awareness of the emergence of neonatal care, and the complexity of issues surrounding care for high-risk infants. Contemporary statistics pertinent to neonatal intensive care, and a historical overview, including highlights of the evolution of neonatal care and the development of neonatal research are presented. In addition, the complexity of care in the neonatal intensive care unit (NICU), encompassing issues such as workload, ethical concerns, and legal issues, is discussed. This is followed by an overview of the nurse's role in research and an examination of ethical considerations for nurses in research. Finally, literature related to nurses' attitudes towards caring for a patient involved in research and neonatal research in the context of family is reviewed.

Neonatal Intensive Care: Statistics

Increasingly sophisticated medical technology in neonatal intensive care has contributed to improving the survival for preterm infants (born before 37 weeks of gestation) and low birth weight infants (infants weighing less than 2,500 grams) (CIHI, 2006). The preterm birth rate in Canada is 7.5 per 100 live births (CIHI, 2006). This is an increase from 1991 when 6.6% of babies were born prematurely (CIHI, 2004). The trend is similar in other countries, such as an increase from 10.6% in 1990 to 12.1% in 2002 in the United States (CIHI, 2004). Preterm birth can put babies at higher risk of immediate and long-term health problems, contributing to 60 to eighty percent of deaths among infants without congenital anomalies (CIHI, 2004). Short-term difficulties associated with prematurity include respiratory distress syndrome and intraventricular hemorrhage;

longer-term health problems include cerebral palsy and other complications (CIHI, 2004). Advances in neonatal care have significantly reduced neonatal mortality rates (Sankaran et al., 2002). In their study of 17 tertiary-level Canadian neonatal intensive care units (NICUs), Sankaran et al. (2002) report that the most prevalent conditions associated with death in the NICU, besides outborn status, were a gestational age of less than 28 weeks (52% of all deaths) and congenital anomalies (34%).

Infants who were born prematurely, infants with low birth weight, or with any other health problems may be admitted to the NICU. In Canada, the admission rate of newborns to NICUs has increased from 12.6% of newborns in 1994-1995 to 14.4% in 2001-2002 (CIHI, 2004). According to the CIHI (2004), 82% of very low birth weight babies (weighing less than 1,500 grams) were admitted to NICU in 2001-2002 and 62% of low birth weight babies spent time in the NICU. A study of 17 Canadian NICUs found that 53% of babies admitted to the NICU weighed less than 2,500 grams, 65% were admitted at less than 38 weeks of gestation, and 20% of term babies treated in the NICU were admitted for congenital anomalies (Lee et al., 2000).

Neonatal Care: Historical Overview

An upsurge of new concepts and technology in neonatology in the past century has led to dramatic changes in neonatal mortality and morbidity (Lussky, 1999). Advanced technologies, the understanding of the pathophysiology of critical illness, and the development of the multidisciplinary team have made this care possible. The advances in neonatal care of the last century have mostly been focused on improving the care of preterm infants (Kenner & McGrath, 2004). The first hospital nursery for premature infants was established in 1893 by Dr. Pierre Budin (Kenner & McGrath).

Prior to 1893, there were no institutions dedicated to the care of infants except foundling homes, where mortality rates were as high as 85% to 95% (Lussky). A decade after Budin pioneered incubator care of premature infants, the first premature nursery in the US, operated by Hess and Lundeen, was opened (MacDonald, Mullett, & Seshia, 2005). In the early 1900s, institutional mortality in the US was 78% for admitted premature infants (Lussky). With improved perinatal management of neonatal sepsis, mortality rates decreased from 90% in the early 1930s to the current 4% to 6%. It was not until the 1950s when special care units for premature and low birth weight infants began to emerge (Mifflin, 2003). Moreover, neonatal critical care medicine as a specialty emerged in the 1960s and has expanded dramatically since (Kenner & McGrath, 2004; Mifflin). The field has made major advances in the areas of infant nutrition, sepsis monitoring, surfactant replacement therapy, prenatal steroids and ventilatory management (Kenner & McGrath; Lassky; MacDonald et al.). Presented are the highlights of the evolution of modern neonatal care from its roots. In addition, emergence of neonatal intensive care and the expansion of neonatal research are reviewed.

Evolution of Neonatal Care

The first isolette that decreased the neonatal death rate to 38% from 66% among infants with birth weights less than 2,000 grams was developed by Tarnier in 1878 (Lussky, 1999). At the end of the 19th century, foundling homes were being replaced with children's hospitals and hospital nurseries began appearing (Lussky). Care for preterm infants in the early 20th century mostly focused on the feedings, specific nursing skills and procedures and infection control which was maintained by limiting access and minimal handling of preterm infants (Kenner & McGrath, 2004). In 1910s, obstetricians

and pediatricians debated on the incubator and prevention of early mortality versus the pediatricians' focus on feeding and the prevention of infection (Lussky). The infant mortality rate then was 99.6 per 1,000 live births (Lussky).

The 1920s and the 1930s are characterized by a mixture of successes and downfalls. While infections in newborns declined due to better hygiene and stricter isolation, there was greater maternal-infant separation and decreased breastfeeding. Interestingly, a spirit of ammonia and a small dose of whiskey were advocated for the management of infant apnea, and oxygen often was administered with a second stimulant, such as brandy (Lussky, 1999).

In the 1940s, antibiotics to treat newborns were on the increase and a 50% survival at 28 days of age was achieved for infants with birth weights under 1,800 grams (Avery, 1998; Lassky, 1999). Unfortunately, in this decade, with technological advances came a significant iatrogenic disease, retrolental fibroplasia (RLF), caused by hyperoxia (Avery; Lussky). RLF was the leading cause of blindness, affecting an estimated 8,000 children in the US (Avery; Lussky).

In the 1950s, the thermal regulation (maintaining body temperature by controlling the thermal environment) was discovered, significantly decreasing low-birth-weight mortality; in addition, surfactant deficiency was described (Lussky, 1999). The term "Premature Nursery" was changed to "Special Care Nursery" and then to "Newborn Intensive Care Unit". These changes reflected the increasing significance of the care of critically ill newborns (Lussky). Infant mortality rates in 1950s decreased from 28 per 1,000 births in the 1940s to 21 per 1,000 births (Lussky).

In the 1960s, neonatology emerged as a specialty due for the most part to certain

technological advances such as the introduction of nasogastric feeding, the development of radiant warmers, and more finite scaling of ventilator settings (Kenner & McGrath, 2004; Mifflin, 2003). In the 1960s, the focus of preterm infant care shifted from temperature control to a more comprehensive and scientific approach to newborn infant care. For instance, initial neonatal ventilators were adapted from adult models and delivered ventilation without continuous positive airway pressure; total parenteral nutrition was first used for infants. Consequently, the terms "neonatology" and "neonatologist" were introduced. Moreover, the development of total parenteral nutrition and the use of central lines for infusions further contributed to neonatology progress (Kenner & McGrath).

Emergence of Neonatal Intensive Care

The establishment of the neonatal intensive care units was prompted by the growing number of critically ill premature infants, who were surviving due to the introduction of continuous positive airway pressure by Gregory and associates in 1971 (Taeusch & Ballard, 1998). This breakthrough in the neonatal care led to the development of special ventilators for newborns. In the 1970s, the invention of oximeters enabled the monitoring of neonates' oxygenation status, followed by routine blood gas monitoring, and noninvasive apnea, heart rate, and blood pressure monitoring (Lussky). In addition, improvements in intravenous therapy, laboratory devices, and monitoring infants' vital signs, contributed to the establishment of intensive care for sick infants (Taeusch & Ballard). This decade witnessed the introduction of routine eye exams, head ultrasounds, and high-risk infant follow-up (Lussky). As a result of these more extensive exams, the mortality rate decreased to 50% for infants with birth weights of 900 grams

and gestational ages of 27 weeks (Lussky). The most significant accomplishment of the 1980s was the administration of surfactant to newborn infants, as this procedure dramatically decreased mortality and morbidity rates (Lussky). The 1990s has been yet another decade of significant accomplishments in the care of very premature infants. Successful treatment of newborns, with gestational ages of 23 to 25 weeks and birth weights of 500 to 750 grams, has been made possible by surfactant replacement therapy, improved perinatal management, new technologies for maintaining temperature, precision micromanagement of fluid delivery, sophisticated nutritional management, and continued improvement in ventilatory management (Lussky).

Expansion of Neonatal Research

All of the above advances in neonatal care would not have been possible without research that involved infants. Basic science, combined with clinical trials, resulted in continuous progress in nutrition, respiratory therapies, diagnostic technologies, and surgical procedures (Taeusch & Ballard, 1998). Clinical trials helped to avoid serious misadventures, such as a trial in the 1950s that found prophylactic antibiotic treatments to cause increased kernicterus (MacDonald et al., 2005).

Newborn care came into the academic setting in the 1910s, through the work of Julius Hess, who established concepts of research in the newborn and became the leading American expert on prematurity (Lussky, 1999). Hess, Chief of Pediatrics at Michael Reese Hospital in Chicago, promoted advances in aseptic techniques, neonatal transport service, and nasal feeding with help of the unit's nursing director, Evelyn Lundeen (Lussky). One of the examples of the earliest form of neonatal nursing research in the beginning of the 20th century was an observation by a nurse, which included the

speculating about a relation between the gestational age and the survival of an infant (Campbell, 1990). During the 1920s and 1930s, neonatal nurses continued to identify important issues in infant care by compiling statistical types of data, such as the causes of death and patients' characteristics (Campbell). While continuing to publish their observational experiences through the 1930s and 1940s, nurses primarily aided doctors in research projects (Campbell).

In the 1950s nurses, in addition to assisting physicians in research, have began conducting their own research, most of which was related to the care of premature infants (Campbell, 1990). In the late 1950s and early 1960s, a series of increasingly sophisticated studies were carried out, with experimental methodology employed, which in turn led to interventions (Campbell). In the 1960s, nursing research started being recognized by attaining significant financial assistance for such studies as Jane Torrance's study of axillary and rectal temperature measurement in premature infants (Campbell). Since the 1950s, topics such as infant pain, mother and premature baby attachment and breastfeeding the premature baby in the intensive care unit have been studied.

In the second half of the 20th century, randomized, prospective, controlled, blinded, clinical trials that evaluated the efficacy and the safety of new interventions began to escalate (Avery, 1998). In the 1960s, declaring neonatal mortality unacceptably high, American Congress significantly increased neonatal research funding by the National Institutes of Health, which led to advances in respiratory support, fluid therapy, assessment of low-birth-weight infants, and temperature regulation (Lussky, 1999). In the 1990s, the development of interinstitutional, randomized, prospective studies and

databases continued (Lussky). To this day, neonatal research, including neonatal research conducted by nurses, continues to flourish.

Recently, the principle of justice has been an important consideration in research ethics when "vulnerable groups", such as infants, are involved (Franck, 2005). If such research is conducted in an ethical manner and if it helps to gain important knowledge about children's conditions, it can be approved (Franck). The Royal College of Paediatrics and Child Health (then the British Paediatric Association) published its first guidelines in 1980; since then, the guidelines have been revised to take into account the advancements in the understanding of children's interests and in the proper regulation of research (McIntosh et al., 2000). Moreover, in 1999, The Royal College of Paediatrics, Child Health declared that it was unethical not to conduct important research on infants (McIntosh et al.).

Complexity of Care in NICU

Nursing work in the neonatal intensive care is becoming increasingly complex, involving responsibilities of constant support and monitoring of high-risk, vulnerable infants (Hagedorn & Gardner, 1999; Spence et al., 2006). Nurses who work in the NICU are faced with multiple issues on a daily basis. The review of relevant literature revealed such complex challenges in NICU as legal issues, ethical issues, and burnout.

Legal Issues

Traditionally, nurses have not been named individually as defendants in malpractice cases. However, nurses are increasingly named as primary and secondary defendants in these cases (Dunn et al., 2005). Neonatal nurses are responsible for providing routine assessments, recognition of the symptoms of complications in the

neonate, resuscitation, and activation of the emergency system *(*Dunn et al.). Common allegations against neonatal nurses can include failure to assess, failure to document properly and failure to obtain informed consent. Failure to assess and treat patients in a timely matter or according to an institution's protocol can result in nurse's liability for complications, if such should arise (Dunn et al.). For example, the failure to treat neonatal hypoglycemia is one of the common claims against neonatal nurses, along with failed resuscitation and medication errors (Dunn et al.; Hagedorn & Gardner, 1999; Verklan, 2003). The medical record is the only legal document that represents a valid record of events (Dunn et al.). Hence, appropriate documentation is extremely important in neonatal settings and should reflect patient's status, assessments, care and procedures provided, and communication with other team members, such as physicians (Dunn et al.).

A combination of factors may result in unfortunate outcomes for neonates. According to Hagedorn and Gardner (1999), to prevent mistakes and subsequent lawsuits, the nurse should take the following steps: to provide an infant with an appropriate level of care or assign a nurse with advanced knowledge for a high-risk situation; to take action when an infant's condition warrants; and to constantly evaluate the care provided, within the nursing code of ethics and the standards of practice and care. In addition, the nurse should follow institutional protocols or advocate for the establishment of such protocols. Finally, open and honest communication with the parents can decrease the risk of liability as well as establish a caring and trustful relationship (Hagedorn & Gardner; Verklan, 2003).

The standard of care is expected to be practiced by all neonatal nurses, regardless of geographical location, and is established by defining what a reasonable and prudent

nurse would do (Verklan, 2003). One of the methods of establishing the standard of care is to adhere to institutional standards (policies, procedures, and protocols) that may offer protection if legal issues arise (Verklan). The standards defining professional nursing practice were developed by the American Nurses Association and have been used by various health organizations (Verklan). For example, the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) have adopted standards defining professional nursing practice and in 2003 published Standards for Professional Nursing Practice in the Care of Women and Newborns (Verklan).

Ethical Issues

The ethical issues confronting nurses working in NICUs are complex and add to the stress of everyday practice. Technological progress, the availability of resources, and parental participation resulted in smaller and sicker infants being admitted to NICUs, and intricate ethical issues emerged (Lussky, 1999; Spence, 1998). Ethical dilemmas, which neonatal nurses may be faced with on a daily basis, can involve such matters as the survival of a neonate with a severe handicap, withdrawal of treatment, and resuscitation of infants with poor prognosis or severe anomalies (Spence). Another common concern in the NICU is saving life in a situation in which the quality of life may be severely compromised (Biel et al., 1999). The integration of the values, beliefs, and practices of the health care professionals involved in the infant's care, with the family's beliefs, values, and hopes for their child can present itself as an ethical dilemma in the care of critically ill infants (Ewing & Carter, 2004). Following is the review of ethical issues in the NICU, such as life-sustaining support, quality of life, and loss of life.

Life-Sustaining Support

Medical technology has made it possible to sustain life almost indefinitely, but prolonging the life of a person should not be done without considering the patient's best interests, pain and suffering (Stutts & Schloemann, 2002). The benefits of prolonging life support include lengthened life, potential for improvement of quality of life, and emotional satisfaction, while the disadvantages of life-sustaining support include pain, permanent disabilities, emotional suffering, and invasive interventions (Stutts & Schloemann). Ethical dilemmas may arise in situations of prolonging life for a patient whose quality of life, from the medical professionals' point of view, will be poor. Such dilemmas may be caused by different perceptions of health care professionals and parents' of the principles of beneficence and non-maleficiance (Stutts & Schloemann). In Stutts and Schloemann's case study, staff viewed the continuation of life support as contradicting such principles because they could not provide a cure or improve the baby's quality of life, while the parents thought that there was a chance of a cure. In addition, religious and cultural beliefs can complicate such situations by making the decisions even harder (Stutts & Schloemann).

Quality of Life

Inappropriate life support, as deemed by the nurses, in the Heuer et al.'s study (1996), linked to poor life quality, is one of the major sources of stress for NICU nurses. In a case study conducted by Stutts and Schloemann (2002), nurses reported feelings of frustration, anger, helplessness, and confusion when having to continue life-sustaining support when there were great concerns about the ongoing and future quality of life. According to nurses in this study, prolonging the baby's life did not do anything "good"

for this baby; the baby endured pain and suffering, which was viewed as prolonging his dying rather than living. As a result, according to Stutts and Schloemann, these nurses experienced a conflict with their commitment to the principles of beneficence and non-maleficence. However, from the family's perspective, continuance of life-sustaining support provided families with the gift of time to develop a relationship with the baby and find meaning for her / his life and death (Stutts & Schloemann).

Loss of Life

Another issue that adds to the stresses experienced by the neonatal nurses is a loss of life. In Downey et al.'s study (1995), NICU nurses reported experiencing a significant amount of stress, leaving them feeling helpless and sorrowful, when infants died. The most common symptoms of grieving, described by nurses in this study, were chronic fatigue, lack of physical exercise, and irritability. Grieving loss is one of the major stressors experienced by NICU nurses, especially if a personal attachment to the infant and the family is formed (Ewing & Carter, 2004).

Burnout

Neonatal nurses are expected to provide an abundance of support, monitoring, and education to infants and their families in the NICU. Performing routine assessments, initiating and performing emergency interventions, recognizing the symptoms of complications in the neonate are just some of the examples of the complex tasks the neonatal nurses are expected to perform. However, despite intensive care nurses' carrying heavy workloads and extensive responsibilities, caring for high-risk patients, facing emergencies and working with advanced technology, they have only limited authority (Bakker, Le Blanc, & Schaufeli, 2005; de Rijk, Le Blanc, Schaufeli, & Jonge, 1998).

According to Karasek (1979), the combination of high demands with limited control over decisions, can cause stress, both psychological and physical, and eventually lead to burnout. Burnout is defined as the "exhaustion of physical or emotional strength or motivation usually as a result of prolonged stress or frustration" (Merriam-Webster Online Dictionary, 2006). Symptoms such as depression, trouble awakening in the morning, nervousness, anxiety, and insomnia can characterize the consequences of burnout on the job combining high demands and low job decision latitudes (Karasek). Other indicators of burnout may be fatigue, apathy and irritability, and are familiar to many nurses (Lippman & Arnold, 2005). Various studies have confirmed that sicker patients, chronic under-staffing, and longer hours are taking their toll and result in an increase in burnout (Lippman & Arnold). Factors contributing to the NICU nurses burnout, including emotional stress, technology, inadequate staffing, and increased workload are discussed next.

Emotional Stress

The nursing care of a critically ill infant can cause profound emotional stress (Heuer et al., 1996; Kain, 2007; Nathaniel, 2006). Feelings of purposelessness or hopelessness can affect nurses' wellbeing, cause substantial stress, and negatively impact on their job performance (Heuer et al.). Unnecessary life support was identified as one of the major stressors for NICU nurses and nurses who worked in the adult intensive care units (Elpern, Covert, & Kleinpell, 2005; Heuer et al.; Sawatzky, 1996), as well as nurses who worked in the neonatal intensive care units (Kain). Unnecessary prolongation of life is a stressor which is generally perceived as out of nurses' control, but rather within the control of physicians (Sawatzky). According to Karasek's (1979) model of high demands versus limited control over decisions, experiencing a stressful situation that the nurse

perceives out of her / his control can cause significant stress, both emotional and physical, and possibly lead to burnout.

Ewing and Carter (2004) state that one of the main workplace stressors identified by NICU nurses was dealing with grief, loss, and bereavement. Ewing and Carter describe two types of loss: work loss and personal loss. Work loss is anticipated and consequently more easily adjusted to as part of a job. Personal loss arises from the formation of a personal attachment and is experienced when the caregiver develops an awareness of the infant or family on a personal level. Another example of a personal loss occurs when the infant has an extended hospitalization, thus allowing for the nurse to get to know the infant. Although potentially a patient's death may be experienced more intensely as a personal loss, it still results from the work routine, and as a result, it may not be fully acknowledged, and may remain unresolved (Ewing & Carter). This work-place loss could be defined as disenfranchised grief (Ewing & Carter).

Moral Distress

Experiencing moral distress is another potential source of burnout for NICU nurses. Nurses experience moral distress when their own moral values and ethical beliefs come into conflict with the events and institutional policies in their workplace (Nathaniel, 2006). Moral distress in neonatal nursing was once described as 'moral unrest', which was experienced by nurses while providing futile aggressive care to sick infants (Thornton, 1984, cited in Kain, 2007). A literature review conducted by Kain (2007) indicates that although moral distress is widely investigated in other areas of nursing, it is somewhat under-researched in the area of neonatology. The existing research suggests that moral distress is common in neonatal nurses (Kain). Due to immense treatment

developments in the field of neonatology, moral dilemmas such as decisions to initiate or withhold treatment are part of the neonatal intensive care unit health care practitioners' daily functioning (van Zuuren & van Manen, 2006). Bell (2004) and Yam, Rossiter, and Cheung (2001) report that it was the provision of palliative care or withdrawing of life support in the curative setting of NICU that caused the nurses to experience moral distress most often. The nurses in van Zuuren and van Manen's study reinforced that it is the perceived suffering of the newborn that ultimately contributed to the feelings of moral distress. Similarly, highest levels of moral distress were associated with the provision of aggressive care to critical care patients that was seen as futile, or not beneficial (Elpern et al., 2005).

Nurses can experience moral distress demonstrated by both physical, and psychological symptoms, such as fatigue, anxiety, apathy, and sense of meaninglessness (Ewing & Carter, 2004). If moral distress, and its associated symptoms, stays unresolved, it can contribute to significant stress and ultimately lead to burnout (Ewing & Carter; Gutierrez, 2005).

Technology

Another source of stress, which can ultimately lead to burnout, in the NICU is a change in technology. Nurses describe their patients in the NICU as "smaller, sicker babies with more machines" (Biel et al., 1999, p. 288j). Stresses associated with technology and increasingly complicated medical care for babies in the NICU have been reported in the literature since the 1970s (Rosenthal, Schmid, & Black, 1989). The increase in the number of surgical procedures parallels the increase in the procedures for which nurses are responsible, such as the insertion of intravenous catheters (Biel et al.). Other examples of a highly invasive technology are the extracorporeal membrane

oxygenation that is used for infants with respiratory failure and heart transplantation for neonates with hypoplastic left heart syndrome (Kenner, Wright Lott, & Applewhite Flandermeyer, 1998). Higher levels of patient technology have been associated with perceptions of poorer staffing adequacy (Mark, 2002). Eventually, patient acuity and technological demands in the intensive care units can lead to emotional distress, decreased productivity, and burnout (Oehler, Davidson, Starr, & Lee, 1991; Sawatzky, 1996). To help nurses cope with sicker patients and more sophisticated technology, Mark recommends comprehensive unit-based orientation, continuing orientation programs, preceptor programs for new staff, and provision of individualized stress management programs.

Staffing

Inadequate or reduced staffing in the neonatal intensive care units has been acknowledged and reported in the literature (Dunn et al., 2005; Oates & Oates, 1996). Understaffing, as well as emergencies and unnecessary life support, was identified as one of the major stressors for NICU nurses (Heuer et al., 1996). Insufficient staffing can interfere with the safe and optimal care in the intensive care units. Poor staffing can lead to issues such as the failure to assess and document properly (Dunn et al.). Mulcahy and Betts (2005) reported increased stress, absence of teamwork, and low morale in a neonatal unit as a result of inappropriate staffing and increased workload. Mulcahy and Betts described a situation in which an increase in the number of NICU beds was combined with daily nursing shortages and the introduction of mandated nurse to baby ratios of 1:1 to 1:4. These circumstances led the management to pressure neonatal nurses into working overtime, which in turn led to staff exhaustion. However, it is not always sufficient to use patient acuity to determine staffing (Spence et al., 2006). Other factors,

involving high levels of technology, unpredictability of patient care, and organizational factors, such as the organization of the manager and mental stress, are associated with the nurses' perceptions of inadequate staffing (Spence et al.).

Increased Workload

Inadequate staffing naturally leads to increased workload. A study that measured nursing workload in neonatal intensive care (Spence et al., 2006) showed that mental stress was one of the organizational factors that contributed to the workload as perceived by the nurses in NICUs. In this study, mental stress in the perinatal ICU was perceived to be more significant in its impact on the workload than such factors as own work capacity, cooperation with peer nurses, cooperation with doctors, presence of students, and meetings during shift. Several studies demonstrated that nursing workload affects the quality of patient care and safety. Increasing workload affects the quality of nursing care, including the ability to monitor patients safely and complete all related nursing tasks (Dunn et al., 2005). Moreover, mortality in the NICU was directly related to the increased workload caused by inadequate staffing (The UK Neonatal Staffing Study Group, 2002). In addition, such components of care as comfort, support and teaching parents might not get done (Spence et al.). Adding research tasks to that could potentially increase workload.

Nurses' Role in Research

Whether acting in the role of a research nurse or a staff nurse, participating in clinical trials is challenging and requires a variety of skills, knowledge, time and patience. The existing literature indicates that physicians are generally given a role in framing information, while nurses provide ongoing clarifications during research trials (Cheng et al., 2000).

Traditionally, nurses' roles in clinical research are associated with participant recruitment and collection of clinical trial data (Spilsbury, Petherick, Cullum, Nelson, Nixon, & Mason, 2008). A study conducted by Spilsbury et al. revealed that another role is that of a clinical research nurse. This role was being an informal "participant observer". Being a participant observer meant gaining an insight into contextual details of the settings being studied that could potentially affect the trial findings. An example provided by the authors was a research nurse's observation of poor documentation of the phenomenon under investigation by the staff nurses.

Mueller (2001) identified a clinical trial coordinator as one of the nurses' roles in clinical research. In the role of trial coordinators, nurses are responsible for tasks such as following the study protocols (for example monitoring participants for adverse effects) and for communication with the study physicians.

Di Giulio et al. (1996) distinguish several nurses' roles in clinical research, including that of the educator of the patient, direct caregiver, coordinator of care and research, administrator of research resources, participant in the conduct of the study, and ally of the patient. According to Di Giulio et al., the role of educator may be the most challenging role, as providing information could be the foundation upon which the decision to participate in a trial is built. Nurses can educate and inform patients or their families about the details of a trial and any risks or benefits involved. The role of direct caregiver or caring for a patient involved in research is one of the most common tasks of nurses involved in trials. Di Giulio et al. state that staff nurses are frequently responsible for the delivery of treatments and for observing and reporting clinical results; thus, the nurses are expected to be familiar with study protocols, usually provided by the

physicians. The nurse can act as a coordinator of care and research by participating in the communication among multidisciplinary team members, frequently acting as the first contact for the study. In addition, nurses may also be responsible for determining the amount of resources required to provide care in a research setting, such as obtaining equipment (Di Giulio et al.). The role of an ally includes assistance with informed consent, ensuring that the patient understands the information and making an informed choice (Di Giulio et al.). Similarly, this nursing role can be described as a role of patient's advocate. Nurses, acting as patients' advocates, have an obligation to report to the principal investigator or to the institution's research ethics committee their observations, if they perceive that the treatment may harm the patient involved in a trial, or if one treatment is superior to the other (Oberle & Allen, 2006).

Di Giulio et al. (1996) review a few procedures in order to facilitate nurses' role in clinical research and to assist their access to protocol-related information. One method to facilitate nurses' access to a research protocol is to copy the pages of the protocol that are most frequently used and place them in the patient's chart. Another way to improve nurses' knowledge of research their patient is involved in is to develop a fact sheet listing the protocol guidelines to serve as a quick reference guide or to provide in-services; fact sheets were especially advantageous as they made information available at all times. One approach to raise nurses' awareness and access to protocol information, especially recommended by Di Giulio et al., is a nursing summary. In short, a nursing summary would provide nurses with brief and clear information about the study. The information supplied in a nursing summary should provide guidance with the more practical aspects of the research protocol, thus making the implementation of the research protocol easier

and safer. In addition, the creation of the nursing summary could potentially lead to the identification of practical information left unanswered or not sufficient in the main protocol, which in turn might help nurses evaluate their actual workload related to research and its impact on their day-to-day patient care (Di Giulio et al.).

Research: Ethical Considerations for Nurses

Clinical trials are an important part of contemporary medicine as they allow for the development of new treatment strategies and increased medical knowledge in general. Nurses involved in clinical research encounter various ethical issues, whether they are caregivers or research nurses. Ethical issues in a research setting, identified in the literature, include nurses' moral obligations related to methodological issues, and issues related to beneficence / non-maleficence, autonomy, and informed consent (Oberle & Allen, 2006).

Nurses' Moral Obligation Related to Methodological Issues

One of the ethical issues that may arise in a research context is nurses' moral obligations related to methodological issues (Oberle & Allen, 2006). An example of a methodological and ethical issue in placebo trials is the concept of the nurse as a therapeutic tool. The nurse might feel conflicted, being obligated on the one hand to follow the therapeutic protocol and on the other hand feeling the moral obligation to support individuals with health care needs. This could pose a potential problem in that simple nursing actions performed by the nurse researcher or research nurse could enhance the placebo effect and diminish the therapeutic differences (Oberle & Allen).

Beneficence / Non-maleficence and Autonomy

The nurse may feel conflicted in relation to her / his obligations to the study and

obligations to the individual patient (Oberle & Allen, 2006). One concern is related to the concept of clinical equipoise, which can be described as the researcher's genuine uncertainty about whether or not the new treatment is better than the old treatment (Oberle & Allen). At the beginning of a study, nurses can assume equipoise as they do not know about the effects of treatment. However, as the trial proceeds, it is possible that the nurse may begin to observe differences between patients, feeling that the study is depriving some patients of better treatment or possibly causing harm to some patients (Oberle & Allen). In this case, a moral conflict could be nurses' feelings of obligation to the advancement of science, and an obligation to do good and do no harm.

Informed Consent

Since the 1990s, obtaining informed consent has increasingly become one of the most important ethical concepts, making not only health care providers but also consumers aware of the issue (Smith, 2000; Walterspiel, 1990). The Canadian Nurses Association Code of Ethics for Registered Nurses has 'choice' as one of the primary values of nursing (in Oberle & Allen, 2006). In order for true choice to be exercised, one must be fully informed. Therefore, the nurse would be obligated not to recruit until it is clear that the patient fully understood the potential risks and benefits, and the commitments required (Oberle & Allen).

Informed consent is important in letting a patient know about all of the potential benefits, risks, and other details of a trial (Dunn et al., 2005). In any medical trials, informed consent is an absolute necessity and legal responsibility of health care providers or researchers (Dunn et al.). While it is the role of the physician to discuss with patients informed consent, the nurse should document the process of obtaining informed consent

and the patient's understanding. In most situations, parents can give informed consent for treatment of their minor children and infants.

Research Involving Infants

As medicine and technologies evolve into an increasingly sophisticated domain, the accompanying research becomes more daring and involves all population groups, including infants. Although research is crucial in improving quality of life, it can also compromise the lives of those involved in clinical trials. Neonatal nurses play an important role in protecting critically ill babies involved in research. It is generally agreed that research involving newborns is an important aspect in improving care for these babies (Singhal, Oberle, Burgess, & Huber-Okrainec, 2002). There are certain conditions and issues that can only be researched in the newborn population. For example, newborn respiratory distress syndrome (RDS) is unique to the premature newborn. One of the major advances in the therapy of this condition was the administration of exogenous surfactant, the clinical trials of which had to be conducted exclusively in newborn infants (Kauffman, 1994). Another example is retinopathy of prematurity, a condition that primarily affects premature infants weighing less than 1500 grams at birth (Kauffman). However, due to the extreme vulnerability of this population, this specific research can present many issues, some of which are informed consent, risk / benefit ratio, and other ethical concerns (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2003). Those issues are very similar to the ethical considerations for nurses in research discussed above. Somewhat different is an informed consent, which can be particularly challenging in neonatal research.

Informed Consent in Neonatal Research

The review of the literature shows that another important aspect of infants' safety when involved in research is informed consent (Franck, 2005; Thomas, 2005). Infant research subjects are unable to provide informed consent. Therefore, parents are naturally expected to provide consent on behalf of their babies. The parents, providing the informed consent on their babies' behalf, are at their most vulnerable time and potentially the validity of their consent could be challenged. According to Klepatsky and Mahlmeister (1997), informed consent should include the following components: the nature of the procedure, expected benefits, risks and outcomes of the procedure, alternative therapies to the intended procedure as well as their benefits and risks, and the risks of refusing the procedure. However, obtaining consent for a vulnerable participant, such as an infant can be further complicated by asking a parent who might also be vulnerable at the time to provide it (Ballard, Shook, Desai, & Anand, 2004). Hence, obtaining valid proxy consent in this situation can be compromised. To appreciate the extent of the information understood by parents or how well parents were informed, Ballard et al. conducted a study that looked at the validity of informed consent obtained from parents whose babies were involved in the NEOPAIN study. More than half of the parents reported their understanding of the purpose and benefits of the study in which their premature infant was involved, and verbalized their awareness of the voluntary concept of the study. However, only few parents met all of the criteria for giving a truly informed consent, mostly due to their inability to name a specific risk; this could have been due to the time passed since their baby was involved in the original study. The findings are concerning as it does not demonstrate obtaining a valid consent, or at least

not a completely informed consent in some cases. To address this problem, a Canadian research team comprised of various health care professionals, including a nurse, has proposed a recruitment model for parents of babies in the neonatal intensive care unit setting (Golec et al., 2004). The authors argue that their proposed model will help parents to make a truly informed choice when involving their babies in research. The model incorporates such aspects of the recruitment process as informing parents about the research in addition to their rights prior to any solicitation, approaching for one study at a time, minimizing information given, and allowing parents time to decide.

Nurses' Attitudes towards Caring for a Patient Involved in Research

There were a few studies found in the literature that examined nurses' attitudes towards involving their patients in research. A study in which nurses identified their attitudes and beliefs toward clinical trials involving cancer patients revealed the agreement among nurses that research is important in improving the quality of care (Burnett et al., 2001). However, despite nurses' support of clinical trials, they were not necessarily willing to participate as research subjects themselves. In addition, the majority of nurses in this study stated that, unlike nurses, physicians did not always respect patients' wishes. Moreover, the nurses felt that the patients were not always sufficiently informed by physicians (Burnett et al.). There is a lack of literature that describes nurses' experiences caring for infants involved in research, and a lack of research about nurses' views on such research in general. A study that examined attitudes of nurses, among other health-care providers towards research with newborn babies surveyed 50 nurses at a large tertiary care center in western Canada (Singhal et al., 2004). The majority of nurses in the study agreed that babies could and should participate in

research. Seventy six percent of nurses, compared to over 92 % of physicians, agreed that informed consent is required for all forms of research. The majority of nurses indicated a good understanding of the research process (82%). Nurses and physicians, compared to parents in this study, were more likely to believe that research should be conducted for the purposes of benefiting all babies. In responding to hypothetical scenarios, nurses and doctors were more willing to enroll their own babies than were the parents. However, the nurses were less willing than physicians in the study to encourage parents to enroll their infant in a study and less willing to enroll their own babies, hypothetically. Fewer than half of the nurses and 56% of physicians agreed that it was important to involve babies in research with additional risk, with 30% of both groups willing to enroll their infant in a study carrying moderate risk and no direct benefit. Finally, 6.1% of nurses and 3.1% of doctors in this study indicated that they would not involve babies in research because of these infants' inability to provide informed consent. The study concluded with a recommendation to further explore the views of nurses, and to further investigate possible reasons for their somewhat negative attitudes toward research with newborn babies.

Neonatal Research and the Family

Families, previously excluded because they were considered a potential infectious disease risk for the neonate, have become an integral part of the NICU team (Spence, 1998). In the last few decades, parent support groups were developed, fathers obtained "nonvisitor" status, and breastfeeding was encouraged (Spence). It is supported in the literature that nurses believe that parents should be part of the decision-making process and that they require emotional support during their infant's hospital stay (Spence). To be

effective participants, parents need to be fully informed of the issues leading up to decisions made (Spence). Parental attitudes concerning the enrollment of their children or infants in research (their perspectives on the informed consent, their decision-making and attitudes regarding research with infants in general) have been acquiring increasing interest in the research literature (Singhal et al., 2004). A few studies were conducted to examine the perceptions of parents of the quality of informed consent. One study looked at parental perceptions of informed consent in the neonatal intensive care unit (Burgess et al., 2003). Ninety percent of parents in this study reported making an informed decision and 93% of parents thought that they, rather than the doctor, should ultimately decide if a newborn should join a study. Another study surveyed parents who were invited to enroll their babies in a SIDS study (Hayman, Taylor, Peart, Galland, & Sayers, 2001). The majority of the parents who agreed to have their baby in the SIDS study reported the consenting process as satisfactory. The information received by parents as a part of informed consent was perceived as sufficient and clarifications were provided if parents had any questions. These findings were consistent with the results of a study conducted by Stenson et al. (2004). Stenson et al. also looked at parents' perceptions of the effects of their infants being research subjects on their whole experience as NICU parents. The authors found that neonatal research may cause additional stress to parents. Specifically, approximately a quarter of the parents in this study reported that they felt some pressure and experienced increased anxiety. Most parents wanted their permission to be obtained when including their baby in a study. The majority of parents in the study were happy to enroll their baby in research. The same results were reported by Morley, Lau, Davis, and Morse (2005). The authors stated that parents seemed to appreciate the benefits of

participating in research trials, and recognized the potential risks involved, as well. The reasons to enroll their infants in a study, cited by parents, included benefits to society in general and possible personal benefits (Hoehn et al, 2005).

Chapter Summary

The literature review revealed that the neonatal intensive care is a complex discipline that can be rewarding but also very challenging. The studies reviewed were both quantitative and qualitative in nature. While a significant amount of the literature describes the issues and concerns in neonatal care, there was a dearth of literature investigating the concerns surrounding neonatal research, other than the informed consent. The literature focusing on the perceptions of nurses who care for high-risk infants involved in research is particularly scarce. Therefore, this literature review supported the need for a study that would examine the experiences of nurses who work in the neonatal intensive care unit, and having to care for a critically ill infant involved in research. The exploratory approach within the qualitative paradigm ensured the in-depth examination of the nurses' experiences.

The next chapter presents the selected methodology and procedures, including the research design and conceptual framework guiding the study.

CHAPTER III: METHODOLOGY AND PROCEDURES

Introduction

This chapter discusses the selected methodology and procedures essential to conducting the study. The research design is identified and described with the purpose of providing the rationale for the chosen methodology. The guiding framework is presented. The chapter identifies procedures with detail to sampling technique, data collection methods, and data analysis. In addition, ethical considerations and criteria for establishing methodological rigor are presented.

The Research Design

The design, or methodology, selected for this study was exploratory description, within the qualitative paradigm. Commonly, qualitative designs use words, narratives or documents as their data source; qualitative designs are frequently used where little is known about a subject (Gerrish & Lacey, 2006). Moreover, the purpose of a qualitative design is typically exploratory which was consistent with the purpose of this particular study.

Philosophical Underpinnings of Qualitative Research

The understanding of the study of humans can be traced back to the philosophers and scientists of the earlier times. For instance, in addition to Descartes' views of observation as an obsolete ground of science, Kant described perception as an important part of the scientific reality (Speziale & Carpenter, 2007). Kant's ideas, furthered by later philosophers such as Husserl, founded the qualitative paradigm. Qualitative research is based on the notion that answers can be found through the exploration of individuals' realties, experiences, and their attributed meaning of these human life events (Speziale &

Carpenter). Building on the positivist position of the apprehensiveness of reality, the ontology of the qualitative paradigm is the post-positivist viewpoint of the multiple realities shaped by social, cultural, and gender values (Speziale & Carpenter). Qualitative research, furthermore, is based on the notion of a dynamic reality, which is described and understood through meaningful human experiences (Speziale & Carpenter). According to Speziale and Carpenter, "When conducted in the spirit of the philosophy that supports it, qualitative research is rich and rewarding, leaving researchers and consumers with a desire to understand more about the phenomena of interest" (p. 23).

Essentials of Qualitative Research

One of the general characteristics of qualitative research design, which is applicable to various disciplines including nursing, is a belief in multiple realities (Speziale & Carpenter, 2007). Multiple realities, or perspectives, exist due to individuals' different experiences and understandings of life's phenomena. Based on the belief of multiple perspectives, Speziale and Carpenter identify another characteristic of qualitative research, which is a commitment to the participant's viewpoint. One of the means of obtaining the study participants' views, rather than the researcher's perspective, is the use of unstructured or semi-structured interviews with the help of open-ended prompts. Semi-structured interviews were used in this study to obtain information from nurses (see Appendix D). Prompts were used as necessary.

Another common characteristic of qualitative design is the researcher becoming the research instruments (Polit & Beck, 2006). A researcher can take part of the study as the observer, interviewer, or the interpreter; hence, the subjective nature of qualitative research and the understanding that researchers affect what is studied (Speziale &

Carpenter, 2007). The principal investigator in this study was the research instrument, interviewing nurses and interpreting the information.

A merging together of various data collection approaches is another characteristic of qualitative research (Polit & Beck, 2006). For example, interviews, observations, and field notes can be used as a combined source of data collection. Interviews were the main source of data collection in this study. Field notes were used to document any additional observations such as non-verbal communication or researcher's thoughts right after an interview.

Another characteristic of qualitative research is that it requires ongoing analysis of the data in order to determine or adjust subsequent strategies (Polit & Beck, 2006). In this study data analysis and collection occurred concurrently. Finally and in keeping with qualitative research, the study findings were reported in a rich literary style, enriched with participants' quotations and commentaries (Speziale & Carpenter, 2007).

Exploratory Description Method

An exploratory descriptive study is an intense investigation of the meaning of a phenomenon for a group of people, with the purpose of discovering themes and patterns (Parse, 2001). Researchers conducting qualitative descriptive studies explore as much data as possible, to capture all of the elements of an event, and there is always room for the unanticipated (Sandelowski, 2000). The philosophical basis for the qualitative descriptive design is rooted in the general beliefs of naturalistic inquiry, which implies studying something in its natural state, without preselection or manipulation of variables (Sandelowski). The descriptive design provided an opportunity to explore and understand the phenomenon of caring for a high-risk infant involved in research in this cohort of

neonatal nurses. The qualitative design permitted the exploration of not one, but multiple realities of the perceptions and beliefs of neonatal nurses about involving high-risk infants in research and how it impacts on nursing care, based on individual nurses' experiences and interpretations of these events.

Conceptual Framework

Within the descriptive exploratory method, a conceptual framework is used to guide the research study (Parse, 2001). Adopting a framework to guide the study was appropriate because this study was at the level of theory-building and not theory-testing. A guiding framework helped to inform the researcher throughout the entire research process, while at the same time afforded the opportunity for new insights to emerge about the phenomenon under study.

A combination of two different models was utilized to create a guiding framework for this study. First, the theory of caring, has been developed by several distinguished nursing researchers, such as Madeleine Leininger and Jean Watson. Roach's caring theory was developed in the 1980s, and Boykin and Schoenhofer presented the most recent caring theory (McCance, McKenna, & Boore, 1999). While the basic premise of Watson's and Boykin and Schoenhofer's caring theories is that "all humans are caring", Leininger and Roach talk more about caring being the essence of nursing. Specifically, Roach (1984, in McCance et al.) states that caring is not unique *to* nursing but is unique *in* nursing. According to Roach, nurses build on the basis of being caring human beings, through professional development of cognitive, technical, and administrative skills. The main concepts of Roach's theory, or five Cs, will be incorporated in the guiding framework for this study. The five Cs, compassion, competence, confidence, conscience,

and commitment are presented in Table 1. Roach suggests that those five categories are human behaviours within which nurses may express their caring (Roach, 1998).

Table 1. Roach's five Cs.

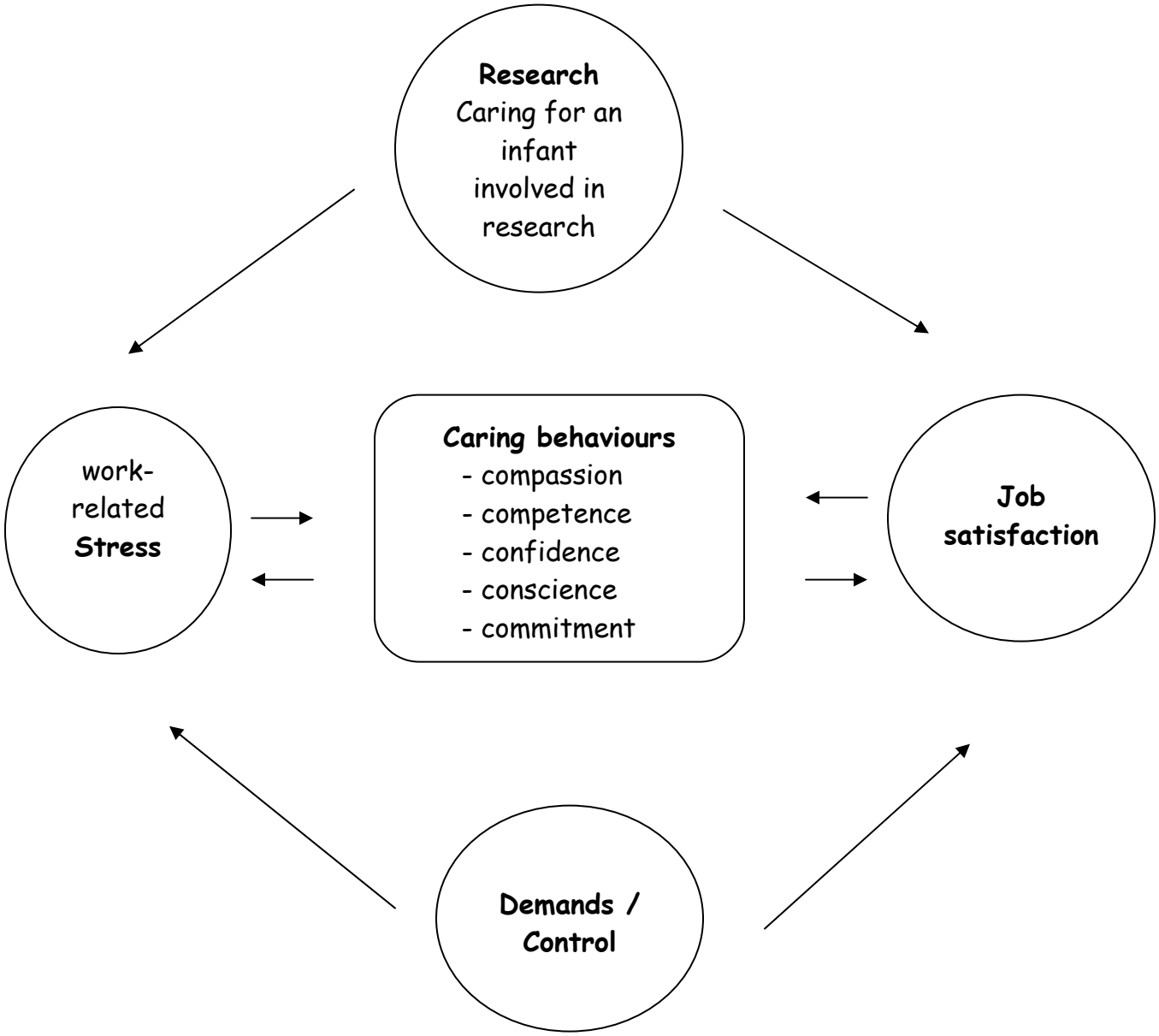
Compassion	A way of living born out of awareness of one's relationship to all living creatures; engendering a response of participation in the experience of another; a sensitivity to the pain and brokenness of the other, a quality of presence which allows one to share with and make room for the other
Competence	The state of having the knowledge, judgment, skills, energy, experience and motivation required to respond adequately to the demands of one's professional responsibility
Confidence	The quality which fosters trusting relationships
Conscience	A state of moral awareness; a compass directing one's behavior according to the moral fitness of things
Commitment	A complex affective response characterized by a convergence between one's desires and one's obligations, and by a deliberate choice to act in accordance with them

The second model that was used for this study is the Karasek's demand – control model (1979). The basic premise of this model is that the combination of high demands with limited control over decisions can cause stress, both psychological and physical, and eventually lead to burnout. Conversely, both high demands and high control result in job satisfaction and general well-being. According to Karasek's model, experiencing a stressful situation that the nurse perceives out of her / his control can cause significant stress, both emotional and physical.

Nurses who work in intensive care units often have demanding workloads and limited control (de Rijk, Le Blanc, Schaufeli, & Jonge, 1998). If a neonatal nurse perceives the research that the infant under his / her care is involved in, as an addition to his / her already heavy workload, and his / her authority as limited, he / she can identify his / her job as challenging or stressful. Consequently, the stress that nurses experience at work can affect their caring capabilities for their patients. For example, one of the major

dimensions of nursing burnout is diminished work related competence (de Rijk et al.). Notably, competence is one of the major attributes of caring, identified in the Roach framework. Other attributes of caring, such as compassion and commitment, can be affected by emotional exhaustion experienced as a result of work related stress. On the other hand, confidence and conscience can be positively impacted if a nurse perceives his / her job as demanding but rewarding and manageable. It was an assumption of this study that working with an infant involved in research can impact on nursing care, negatively or positively. The diagram that depicts the possible links between potentially negative or positive demands, which were created by looking after an infant involved in research and its impact on caring, is presented in Figure 1.

Figure 1. Looking after infants involved in research: how does it affect nursing care?



Procedures

This section of the chapter details the study sample, setting, data collection methods, and data analysis. Additionally, ethical considerations and issues of methodological rigor are discussed.

Sample

Sample selection, sample size, participant access, and sample recruitment are reviewed next.

Sample Selection

A purposeful sampling is used in qualitative descriptive studies, with the goal of obtaining cases considered information-rich for the study purposes (Sandelowski, 2000). The participants for this study were selected on a voluntary basis from the nurses who were employed in a neonatal intensive care unit, and who have had at least two years of experience working with the high-risk infants.

Sample Size

Although a sample of 8-12 participants was planned, the final sample size was determined by the completeness of the data and the ability to achieve theoretical saturation of the phenomenon under study. That is, until: 1) no new or relevant data emerged; 2) theoretical categories were dense; and 3) relationships between categories were well established and validated (Morse & Field, 1995; Strauss & Corbin, 1990).

Participant Access

Participant access was obtained through the Pediatric Research Coordinating Committee and the Research Impact Committee of the Health Sciences Centre (HSC), Winnipeg, Manitoba.

Sample Recruitment

The neonatal nurses were recruited from the neonatal intensive care unit at the Children's Hospital in Winnipeg, Manitoba. This site is one of the two major neonatal intensive care units in the province of Manitoba. A poster describing the study was placed in the staff lounge. Brief in-services were provided during four education days, which all of the staff nurses attended. During the in-services the researcher introduced the study, outlined its purposes, and invited nurses to participate in the investigation. Personal recruitment letters inviting nurses to participate in the study were given to the nurses, together with the informed consent form, and the researcher's contact information. In addition, the information about the study was available through the Children's Hospital child health intranet.

Data Collection

The purpose of data collection in qualitative descriptive studies is typically to discover the basic nature of events or experiences (Sandelowski, 2000). Accordingly, data for this study was collected using semi-structured interviews, which allowed the researcher to explore the topic of interest. A focus group was conducted to validate emerging themes and expand on the findings. In addition, demographic forms and field notes were collected.

Demographic Form

A demographic form (Appendix C) was used to gather data related to participants of this study. Specifically, such variables as their age, gender, and number of years of experience working in the NICU were collected. The form took approximately five minutes to complete.

Interviews

The interview process is a discussion between the researcher and a participant during which open-ended questions are asked and prompts are used. The questions for these interviews derived from the objectives of the study and reflected participants' experiences of caring for an infant involved in research. The open-ended, or semi-structured interviews are one of the most frequently used data collection approaches in qualitative research (Speziale & Carpenter, 2007). Semi-structured interviews, although having predetermined objectives (interview guide), allow the participants to fully describe their experiences and retain flexibility to explore issues that have not been anticipated (Gerrish & Lacey, 2006; Speziale & Carpenter). During the semi-structured interviews, the researcher's function is to encourage participants to freely discuss all of the areas of interest (Polit & Beck, 2006).

Seven nurses participated in this study. One interview was conducted with each nurse, and it lasted approximately forty five minutes to 1.5 hours. The second interview was conducted in one case, and was used to clarify the data collected in the first interview and gave an opportunity for a participant to add any information to his / her previous answers.

Prior to interviewing, it is important to explain to participants that there are no right or wrong answers, that they have the right to stop at any time, and that the interview will be recorded on audiotape, with their permission (Gerrish & Lacey, 2006). The researcher conducted and transcribed all interviews. Please refer to Appendix D for the interview guide.

Focus Group

A focus group interview was conducted, for the purposes of enriching the information gathered from the individual interviews. The advantages of a focus group are its efficiency and an ability to elicit discussion among the participants (Polit & Beck, 2007). To make the focus group interview effective, the participants must share experiences on which the discussion can build (Speziale & Carpenter, 2003). The three nurses that participated in the focus group interview shared many years of experience working with high-risk infants in the same hospital unit. As for the individual interviews, the questions for this interview were derived from the objectives of the study. The focus group interview was open-ended, or semi-structured. It allowed the participants to freely discuss their experiences, with the moderators keeping the discussion within the area of interest.

The discussion lasted one and a half hours. Prior to interviewing, the participants were reminded that there that they had the right to stop at any time, and that the interview would be recorded on audiotape. The group was moderated by the principal investigator and her thesis supervisor. The principal investigator transcribed the interview. Please refer to Appendix E for the focus group interview guide.

Field Notes

Field notes are the notations researchers make to document their observations and their interpretation of those observations (Polit & Beck, 2006; Speziale & Carpenter, 2007). The field notes should be taken as soon as possible after an interview, especially if all of the details during the data collection were not recorded, or in order to remember any important questions or observations (Gerrish & Lacey, 2006). Field notes may be

used to record participants' expressions, changes in position, and other non-verbal communication. These notes can be very important during data analysis, as they can provide validation of particular ideas and help to emphasize emerging themes (Speziale & Carpenter). Polit and Beck identify several categories of field notes: observational, reflective, theoretical, methodologic, and personal notes. Observational notes are objective contextual description of conversations or events. Reflective notes are used to document researcher's personal thoughts and experiences. Theoretical notes are made to possibly interpret and attribute meanings to observations. Methodologic notes can be used as a reminder or an organizer of subsequent data collection. Personal notes may be used for the researcher's own feelings during the study. The researcher kept field notes and reviewed them with her supervisor throughout this study.

Research Setting

The interviews were conducted outside of the Children's Hospital, and the location was determined upon agreement with a participant. The interviews were conducted in a non-disruptive and comfortable environment as much as possible in order to facilitate sharing of research participants' thoughts. The settings were a participant's home or a quiet location within the Health Sciences Centre complex.

Data Analysis

The purpose of data analysis is to organize and extract meaning from the collected data (Polit & Beck, 2006). As with any qualitative research, analysis of data will be carried out concurrently with data collection (Sandelowski, 2000). All interview transcripts and field notes were fully transcribed using a word processing program, checked for accuracy of transcription and printed with wide margins.

All qualitative data emerging from the interviews and field notes was analyzed using the constant comparative data analysis technique. This method was selected as it not only afforded the description of the phenomenon under study, but more importantly resulted in interpretation of data by the development of themes. Key steps of this method included: analyzing the emerging themes and patterns by coding or giving meaning to all units of information; revising previously coded data; and aggregating and clustering codes into categories and/or themes (Strauss & Corbin, 1990; Strauss & Corbin, 1994). Critical to the coding process was making comparisons within and between data sets. Data related to each category and emerging themes was retrieved from the database and linked to other related data. Some examples of organizing the data included arranging the data from most prevalent to least prevalent themes, or description of the same event, or a theme from the perspective of more than one participant. The end result of the data analysis process was the development of the overall essence of the nurses' experiences or meta-theme and its themes and sub-themes. The essence and themes were co-created by the principal investigator and her thesis supervisor.

The demographic data were summarized and described using such descriptive statistics as percentages and averages.

Ethical Considerations

Permission to conduct this study was obtained from the researcher's thesis committee, the University of Manitoba's Education /Nursing Research Ethics Board, the HSC Pediatric Research Coordinating Committee, and the HSC Research Impact Committee. The standards of ethical conduct in research are based on the three primary ethical principles: beneficence, respect for human dignity, and justice (Polit & Beck,

2006). In addition, as a part of these principles, informed consent and confidentiality are important to consider when conducting research (Gerrish & Lacey, 2006; Polit & Beck; Speziale & Carpenter, 2007).

Beneficence

Beneficence is one of the main ethical principles in nursing research. It implies the researcher's responsibility to prevent or minimize harm and to promote good to all research participants (Silva, 1995). During the research, harm or discomfort can be not only physical, but also emotional, social, or financial (Polit & Beck, 2006). Those discomforts can be subtle and should receive close attention. In a qualitative investigation, sensitive topics may surface in the interview. In such a case, the interview may be ended if a participant chooses to do so, and potentially followed up with counseling and referrals (Speziale & Carpenter, 2007).

In this study, the risks and benefits were explained to participants in the consent form. Although no known risks to participants were apparent, there is always a possibility that participants might become emotional. Therefore, caution and sensitivity were exercised when conducting interviews, and debriefing was provided at the end of the interviews. No increased stress was reported by the participants or was apparent to the interviewer. The nurses seemed to have enjoyed the interviews and an opportunity to share their experiences caring for high-risk infants involved in research.

Respect for Human Dignity

The ethical principle of respect for the human dignity of participants includes the right to self-determination and the right to full disclosure (Polit & Beck, 2006). The right to self determination is defined by the American Nurses Association as the right of

research participants to voluntarily decide to participate in a research, to ask and answer any questions, and to withdraw from the study (Silva, 1995). The right to full disclosure is the participant's right to informed consent when the nature of the study, and all of the risks and benefits, are fully disclosed by the researcher (Polit & Beck). In this study, the participants were fully informed of the nature, purposes, risks and benefits in the study's consent form. It was also reinforced verbally prior to interviews.

Justice

The principle of justice includes participants' rights to fair treatment and their right to privacy (Polit & Beck, 2006). The researcher must assure participants that they will be treated with respect and dignity, and that their anonymity and confidentiality will be maintained (Gerrish & Lacey, 2006; Polit & Beck; Speziale & Carpenter, 2007). The principle of justice was sustained by including all of the nurses who were willing to participate, regardless of their age, gender, and years of experience. Due to the nature of data collection in a qualitative research, anonymity might be impossible. The researcher knew the identity of the participants because the interviews were conducted face-to-face. However, access to the participants' names was restricted to the researcher. Codes or pseudonyms were used on all sources of data. All of the data were kept in a secure place. Confidentiality, an assurance that any information disclosed by the participants will not be reported in identifiable manner and will not be accessible to others, was strictly upheld.

Participants were informed of the above-mentioned principles and their maintenance through the informed consent and verbally before the interviews. The

participants were also informed that the results may be published in a scientific journal and presented at a conference.

Informed Consent

According to Polit and Beck (2006), informed consent intends that participants "…have adequate information regarding the research; comprehend the information; and have the power of free choice, enabling them to consent voluntarily to participate in the research or decline participation" (p. 93). The informed consent form included the study purpose, the voluntary nature of participation, potential risks and benefits, and intended participants' time commitment. The consent form is presented in Appendix B.

Methodological Rigor

The establishment of methodological rigor is important for qualitative researchers in order to validate their work. It is also important to note that qualitative or human science objectivity and subjectivity are not mutually exclusive categories. Objectivity in human sciences research means that the researcher remains true to the object (van Manen, 1990). Subjectivity means that the researcher needs to be as perceptive or insightful as he or she can be in order to show the object in its full richness (van Manen). It also implies that while the researcher is perceptive to the object of study in a professional and a personal way, he or she needs to be careful not to become self-indulgent and carried away with the preconceived notions about the phenomenon under study (van Manen). Lincoln and Guba (1985) suggested four criteria to ascertain rigor, or trustworthiness, of qualitative research: credibility, dependability, confirmability, and transferability.

Credibility

Credibility refers to actions, which increase probability that credible or truthful finding will be produced (Polit & Beck, 2006; Speziale & Carpenter, 2007). Findings are considered to be credible when others going through the same or similar experience, as did the research participants, would be able to recognize the interpreted data as their own (Sandelowski, 1986). The researcher, as the composer of the multiple realities derived from the raw data, needs to show that those multiple realities were represented adequately in that the data are credible to the original constructors of the data (Lincoln & Guba, 1985). There are several ways to establish credibility: prolonged engagement, member checking and peer debriefing, and triangulation (Polit & Beck; Speziale & Carpenter).

Prolonged engagement refers to a significant amount of time invested in the collection of data to reach an in-depth understanding of the phenomenon under investigation. The researcher in this study collected the data over one or two interviews, with the participant's permission. After an interview, the researcher asked permission to contact the participant for further clarifications, if needed.

Member checks, as well as peer debriefing are other activities to establish credibility by involving external sources. Member checking refers to the confirming the results or themes' descriptions with the participants, in order for findings to be recognizable as true. Peer debriefing is a review session held with peers who are experienced in either qualitative research or in the topic of interest. In this study, the researcher shared her interpretation with the participants, as necessary, to confirm that the researcher's interpretations were indeed reflective of participant's experience (Lincoln & Guba, 1985). The peer debriefing was attained through meetings and discussions of the

research process and data analysis with the researcher's supervisor, Dr. Roberta Woodgate, who possesses significant experience and expertise in qualitative research in general and in the phenomenon under study in particular. This was done throughout the study and served purposes such as providing opportunities to test working hypotheses; providing opportunities to change or develop new strategies for data collection; and providing the opportunity to vent the researcher's thoughts and feelings throughout the study (Lincoln & Guba).

Triangulation refers to the use of multiple references to collect the data or make conclusions about the data. The researcher of this study interviewed a cohort of neonatal nurses, which was diverse in terms of their experience. The saturation of data from these sources also supported the credibility (Lincoln & Guba, 1985).

Dependability

Consistency of the findings, which is concerned with whether similar findings would result if the study was replicated with similar participants in the similar context (Lincoln & Guba, 1985), and can be defined in terms of dependability. Dependability refers to the stability of data over time and can only be met if the credibility of the findings is achieved (Polit & Beck, 2006; Speziale & Carpenter, 2007). Due to the nature of qualitative research, even though conclusions may not be the same, findings may be comparable (Sandelowski, 1986). The concept of dependability implies trackable variability, or variability that can be traced back to identified sources such as changes in the informant's life situation. In this study, to achieve dependability, the researcher included out of the ordinary or atypical situations in the findings. The researcher also provided a clear decision trail of the research process from beginning to end, which

included the coding procedures and field notes. Another technique to assess data dependability is the inquiry audit (Polit & Beck). It can be done by an external reviewer who will evaluate the data and relevant contextual documents, or, in this study, it was done by the student's supervisor.

Confirmability

Confirmability is a process concerned with the objectivity and relevance of the data (Polit & Beck, 2006). Using quotations and keeping a reflexive journaling are the strategies that can enhance confirmability. Although it has been argued by such scholars as Sandelowski (Speziale & Carpenter, 2007) that only the actual researcher who has conducted the study can confirm the findings, a technique such as an audit trail can be employed to establish both, the dependability and confirmability (Polit & Beck, 2006; Speziale & Carpenter). An audit, which is a recording of matters such as raw data, field notes, and interview transcripts, can be performed by another researcher. In this study it was done by the student's supervisor, Dr. Roberta Woodgate.

Transferability

Transferability can be described as a potential fit of the findings to others in similar situations, or the generalizability of the results (Polit & Beck, 2006; Speziale & Carpenter, 2007). According to Lincoln and Guba (1985), it is important for a researcher to provide a rich descriptive data of the sampling, setting, and design of a research. In this study, thick description was achieved through purposeful sampling. In addition to the detailed description of the sample and setting, thick description in this study also included the context of specific actions or situations; the intentions and meaning behind the actions; and the evolution and development of specific acts (Denzin, 1989).

Chapter Summary

This chapter reviewed the exploratory descriptive design, within the qualitative paradigm, chosen to conduct the study. Exploratory description was selected to gain an increased understanding of neonatal nurses' experiences in caring for high-risk infants involved in research. The guiding framework, combining the theory of care and the demand – control model was presented. The procedures for data collection such as demographic forms, semi-structured interviews, and field notes were reviewed. The process of data analysis was presented. For this research, constant comparative analysis was identified and described. In addition, ethical considerations and criteria for establishing methodological rigor were discussed.

CHAPTER FOUR: FINDINGS

Introduction

This chapter presents the qualitative analysis of the individual interviews, focus group interview, and field notes. A description of the participants is provided. The findings of this study represent the essence of nurses' experiences caring for high-risk infants involved in research and identify the three key themes within these experiences. The essence of nurses' experiences of caring for high-risk infants involved in research was safeguarding a baby. With safeguarding came the nurses' feelings and memories about caring for high-risk infants involved in research, as well as their recommendations to minimize the risks to the infants in the future. Therefore, the themes that emerged were: (1) feelings within, (2) keeping it near and dear, and (3) making it safer. The overall purpose of this study and the research questions related to nurses' experiences, roles and responsibilities, challenges, and their notion of risk involving high-risk infants in research were answered through the essence and the supporting themes.

Description of the Participants

Seven nurses participated in this study. Seven individual interviews and one focus group, which was comprised of three nurses, were conducted. At the time of the interviews all of the participants were employed in the NICU at the Children's Hospital in Winnipeg, Manitoba. The nurses who participated in this study had an age range from 32 to 55 years with mean age of 45 years. Due to confidentiality issues, the gender of nurses who participated in the study will not be specified. At the time of the study, five nurses were married or living common-law, one was single, and one was separated. Five nurses had their own children, the number of whom ranged between two and seven

children. Three participants were employed full-time at the nursery, and four were employed part-time, with the part-time code ranging between 0.3 and 0.8. The number of years that the participants had worked as nurses ranged between six and a half and 36 years with a mean of 22 years. The number of years that the participants worked at the nursery was in a range of 6.5 and 27 years with a mean of 18 years. The nurses reported their highest education obtained at either diploma or at a baccalaureate level. The estimated number of infants involved in research that these nurses had cared for in the last two years, was estimated as anywhere from "several" to "approximately a hundred", with other responses being 5, between 10 and 15, between 12 and 15, and 50 infants. Table 1 presents a summary of participant demographics.

Table 1. *Participant Demographics.*

Characteristic	Number	Percentage
Age		
30-40	1	14
41-50	5	71
51-60	1	14
Marital status		
Single	1	14
Married	5	71
Separated / common-law	1	14
Own children		
Yes	5	71
No	2	29
Code of employment		
Full-time	3	43
Part-time	4	57
Years employed as a nurse		
5-15	1	14
16-25	4	57
26-35	1	14
36-45	1	14
Years employed at the nursery		
5-15	1	14
16-25	5	71
26-35	1	14

Main Findings

The essence of neonatal nurses' experiences looking after high-risk infants involved in research and the themes representing the core of these experiences are presented in this section. In addition, the findings outline the nurses' recommendations minimizing the risks to high-risk infants involved in research.

The Essence of Nurses' Experiences

Safeguarding a baby was the essence of the nurses' experiences of caring for high-risk infants involved in research. The participants described their daily care for all of the infants in the unit as making them vigilant, protective, and wary of the smallest changes in their patients' routines. To the nurses, safeguarding their patients meant ensuring that the infants' world was safe. The nurses reinforced that their main job was to provide as safe an environment as possible, regardless of the infants' involvement in research:

> *"I think the big thing is: you are always looking at what's best for the baby. I don't think that we are looking many times at our workload…you are looking at what's best for the infant. We get so much information about what we need to be doing. So if we are getting conflicting information about you know, don't over handle the baby, well, we got to go in and do this now because he is on a project. Well, that's conflicting information. I always find that just voicing in a calm rational manner your concerns in rounds is a really positive* [strategy to address safety]. *I think that you can't take one hat off* [being a research facilitator and a nurse] *and put the other one on. They are there all the time. You are just looking at what's best for the baby and the family."(#7)*

The participants repeatedly stated that they would provide the "same care" if an infant were not involved in research, reinforcing that essentially their roles and responsibilities would not change. For the nurses in this study, the experience of caring for high-risk infants involved in research was basically the same as "simply providing the best care" for high-risk infants, whether they were enrolled in research or not. To the

nurses, patient care and research were not two separate entities. As a nurse's care is centered around the well being of a baby, research appears to be "invisible" or incorporated in their daily care. As one nurse reiterated, "care and research meld." To the participants, research, care, and treatment seemed inseparable. In other words, the care that would be provided to two babies, one enrolled in a study and another one not, is essentially the same:

> *"The basic care for those 2 children is the same…The way we manage their feedings, their fluids, the way we do vital signs…Only if they become compromised, only if their physical status, and not because they are on a research study, but because they are a premature infant. Something in their status changes, and so they are no longer reacting in a way that we can just sit back and kind of watch them breeze through, we have to take more aggressive steps. But normally we come in and we are assigned to 2 babies and do the things we do. We assess them, we do treatments, such as take their temperature, maybe suction them, listen to their chest, listen to their heart, check their pulses, do a blood pressure, do a blood sugar, depending on what that child needs, it's very similar from child to child, depending on what condition the child has…Our routine care, overall, is not hugely affected."(FG)*

When describing a "typical" day at work, the nurses did not mention research as part of their daily routine. Rather, the nurses listed the typical tasks which they do during their day, such as getting report, going through rounds, examining the baby, and interacting with the parents:

> *"…charting, vital signs, drawing bloodwork, draw blood gases, interacting with other medical staff, would it be physicians, physiotherapy, respiratory therapy, especially with the ventilated babies, collaborating with the other nurses, um…ensuring that to the best of your ability you protect baby's rights and provide proper care, gathering and disseminating information to the parents, supporting the other staff is a big part of the job, in terms of other nurses."(#2)*

Nurses mainly concentrated on the complexity of their care for high-risk infants when describing a "typical" day at work. The care that they normally provide their

patients with is based on such factors as infant's gestational age and their physical condition, not research:

> *"You get report…you might have one very sick baby, you might have two that are not…one can be ventilated, one could be on CPAP, and you start with prioritizing what their care is. With preterm infants we usually "block" the care, so that you could go at a certain time, you do all care and you leave them alone for awhile, because the rest is very important. So, you start doing that and you help out the other module-mates. You might have a baby that has to be fed every 2 hours, you might have every 3 hours. You might have X-rays, ultrasounds, you might have to go to MRI, there are different things that are happening with them…After rounds, there might be some changes in the care that they've decided. Put a line in, take a line out. Um…change how we are feeding a baby, maybe do echocardiogram, head ultrasound. There are all kinds of tests that are needed to be done. You can also help with other patients. If there is a baby that's quite sick, you are expected to help with that, too…" (#7)*

Part of their daily routine also included the nurses' interactions with infants' families. Being able to help parents, by either educating them or helping them to physically take care of their infants, was another example of looking out for their patients' best interests. According to the nurses, caring for a baby in the NICU typically involves caring for their parents as well:

> *"A good day is when…the baby gets better. When the status improves, we are able to wean off the ventilator settings or…depending on how sick the baby is…maybe extubate…A good day would be helping the mom… mom or dad, to do Kangaroo care for the first time. A good day would be getting a baby well established on a breast."(#3)*

When the nurses were specifically asked if caring for an infant involved in research had any impact on their day, either making it a "good" or a "bad" day, the unanimous answer was no; it did not have any effect on the day's outcomes. Rather, factors such as an improvement in the baby's condition and feelings of accomplishment determined if the day was successful or not:

> *"…a good day would be described as if you can leave the unit knowing you've done something good for the baby, you know, I guess the other day I left knowing*

that I did not get a lot accomplished, I guess it technically was a bad day since baby did not get a lot accomplished in terms of medical care…"(#2)

Deterioration, or taking a turn for the worse in a baby's condition, would often determine what kind of a day it was for the nurses interviewed:

"A very, very, very bad day is when a baby dies. That will never be a good day. Even if it's a baby who's been extremely ill and suffering for a very long period of time, it is still a very bad day. And I can say that after all the years that I've worked here it's never gotten easier. So, for me, that's the worst day."(#3)

Overall, the nurses reinforced that the research does not impact on their role of protecting infants. In other words, it does not affect their daily routines, nor does it change their roles and responsibilities to safeguard their patients. When asked if they saw their role as a research facilitator as separate from a nursing role, the nurses reported no significant differences between the two roles:

"I would say both. I know a lot of nurses would say separate, but I guess because I am back at school looking at research all the time, I know there needs to be research and I know that nursing is a huge part of that because we are at the bedside. So, I would say everything that we do is based on research. And everything that we'll do in the future will be based on research, so I think it's doable. I don't think we are one or the other, I think we are both."(#5)

Although many infants are involved in one or more research studies, the nurses stated that their main role of protecting the babies' best interests did not change. The fact that a baby was in a research study did not affect nurses' "liking to care for a baby". The nurses did not feel that just because a baby was involved in research, certain risks were acceptable, or they needed to be less vigilant. The quality of care for these babies remained unaffected by the fact that they were involved in research:

"…when I look after an infant, it does not make an impact whether the baby is on a research study or not. My care is not delivered based on whether the baby is on a research study…it's always the same...if your baby was on a CPAP study, your care would be delivered in the same way: you would suction them and turn them,

and care for them in the same way on CPAP, and do all the CPAP care that's required…" (#4)

However, although the nurses stated that caring for an infant involved in research did not create an additional workload overall, certain studies caused the nurses to distribute their time between their patients unevenly. The nurses explained that, although extra documentation might not have a direct effect on an infant's health status, it might compromise the nursing care of another infant. For example, if a study requires frequent documentation, or recurrent adjustments to the respiratory equipment, it can significantly increase the amount of time spent to care for that infant, at the expense of another infant assigned to them, therefore compromising their safeguarding of that infant:

"I think sometimes when you are in with that baby, it does not, it's when you are finished with that baby and you are in with another one. You are all washed up and then all of a sudden everything rings off and you have to stop everything you are doing here and wash up again and go back over there, if no one is available… and that can happen frequently, maybe three times, so that really interrupts the flow of care, interrupts what you are doing here. And there is a huge chance of contamination, how well you are actually washing your hands, you know…You want it to stop ringing, and you know it's ringing because it's high, and you know if you drop the Oxygen on a ventilator, and it goes too low, then they just plummet down into the 70s, and they react and you bring it back up and they go high again. And we kept track of this. You can be adjusting it like 75 times a day, and that's a lot, a lot of noise, a lot of adjustments, just to keep it within those parameters. So, it can be difficult that way. (#5)

"There are specific Oxygen saturation monitors… in this study, we have to document every time we titrate the FiO2. That's a lot of work for us. Because we titrate the FiO2, it could be every 30 seconds. And to be writing that down every 30 seconds, and then we have another baby… Normally we have two patients, we don't have just one patient for the most part. Honestly, I don't see how I am going to be able to chart every time I titrate FiO2 on my baby… One night we counted: 130 times his alarm on the O2 sat monitor went off in a 12-hour period. I wish there was an easier way of documenting this." (FG)

"Safety net"

The nurses reinforced that in order to safeguard their patients' welfare, they

would have to act as a "safety net". To the nurses, being a "safety net" meant to be always on guard, to be knowledgeable about their patients' care, and about the patients themselves. The nurses described the phenomena of "caring for the children as if their own". Having to care for the babies from the day they were born, watch them to go through their hard courses, and battle for their survival allowed the nurses to get to know their little patients very well. The nurses described their relationship with their patients as "intimate". The nurses explained that due to having a small nurse-patient ratio in the NICU (1:1 or 1:2), they are able to get to know all the babies in the unit and to become familiar with the smallest nuances in their condition. In addition, nurses stay at their patients' bedsides for eight to 12 hours every day, as opposed to other health care professionals who come and go:

> *"For the first week, two weeks these babies, in their isolette, are on their own… So, we are it." (FG)*

All of the nurses interviewed expressed their genuine affection for the babies they had cared for over the years. The nurses reported that they knew when their patients were taking a turn for the better or worse, even if an infant's condition involved the smallest changes. Over the course of weeks and months, the nurses were able to get to know not only their own patients, but most of the babies in the nursery really well. Being thoroughly involved in their patients care allowed the nurses to become the "safety net":

> *"...I had a kid who was having frequent As and Bs. I pulled out the criteria…and there were actually criteria for the number of apneas for this one study. So, I pulled it out and I said: look, this is how many we've had…they ended up tubing the kid. You do have to be aware of the parameters. You have to be the safety net..." (FG)*

To the nurses, safeguarding the infants, or being the "safety net", involved three

components: watching over their patients, advocating for their patients, and looking after the infants' families.

Watching over. The nurses reinforced that a major part of their care for these infants not only included the very highly-skilled physical care, but also involved guarding babies' welfare. The nurses described watching over every aspect of the babies' care, be it their developmental care or their involvement in new therapies. The nurses stated that they felt that they were in a best position to protect the babies' interests, due to their constant presence at the infants' bedside. Because parents might not always be present, especially in the first few weeks, nurses become temporary "guardians" of these babies:

> *"…Nurses are at the bedside, we are the constituent, physicians are not involved in hands-on, they come and go…" (#7)*

The nurses explained that frequently there would be no parents caring for the babies in the first few days or weeks, or that the parents would come in for a short period of time, as opposed to nurses who spend 12 continuous hours at an infant's bedside:

> *"The moms are in the hospital, sick, and dads are scared to death of our unit. Because on a ward, say oncology ward, you have exceptional nurses there, who are incredible advocates…99% of the time a parent would be there, a mom or the dad, and the child in most cases can say "I hurt" and that nurse may have 3 other patients, whereas we have one. When parents do come in, they are so scared witless by this sick infant that they look at us and they take in every single thing that we say. They are often afraid to touch, they don't know what to say, they don't know how to parent…That role is initially stripped right out of their hands." (FG)*

Watching over included closely monitoring the infants, becoming familiar with their conditions and particular needs, and ensuring that their hospital stay is as smooth as possible. The nurses stated that if a certain procedure was not necessary or even harmful, they would try their best to look out for the infants' wellbeing. If a procedure could be postponed to be carried out at a more convenient time for an infant, the nurses ensured

that these arrangements are made. While recognizing the importance of research, nurses evidently put babies' interests first. For example, if getting a blood sample required a heel poke, it would be incorporated into routine bloodwork, if possible. Delaying a blood sample was one of the strategies that the nurses were able to do in order to shield the babies from any possible stress:

> *"If the baby does not have an arterial line and baby needs blood, I am not going to poke that baby just for a research tube. I will wait until TPN bloodwork is drawn, or whatever. I'd like…to save the baby a poke. So, if we are already doing tests, taking some blood for the research study, I am fine with. It's when it's an added step where you have to poke the baby…I like to save the babies' feet. It has to be done, I know. If parents have consented to the research, it has to be done. But I like it to be done when we are already doing it, not a special step for it…So, that has happened, where I am not drawing it till there is other bloodwork."(#5)*

In some situations, the nurses reported being especially watchful over the infants, identifying certain types of research as more "risky". Those situations involved an "extra vulnerable" infant, typically an infant of a low gestational age, a study that would potentially withhold a treatment from an infant, or a study requiring an extra handling of an infant:

> *"Well, personally, if I think that it is inappropriate…if I am doing my blood work anyway type of thing….if I have to poke a baby one more time and I don't think that it is in a baby's best interests, I won't do a second poke to do get a study's blood work. If I can't do it on a first poke, I can't get enough to get both, then I am not going to poke baby again."(FG)*

To the nurses, any extra handling required for a study was deemed devastating, especially for a severely premature infant. In order to safeguard their patients, the nurses carefully watched over them to ensure that the amount of handling was kept at a minimum:

> *"…Any extra handling. Most of our babies are on 'minimal handling". So we go in every 4 hours. So, if we had to go in every half-hour to check their pupils, that would be… Ok, that would not happen, but if they came and said that look, we*

> *really need to get this specimen, and this child is not due to be touched for 3 more hours, I would say I am sorry, my baby is minimal care and I am not going in for that."(FG)*

Advocating. The nurses reported not only watching over the infants' welfare, but also actively advocating for their patients. According to the nurses, in certain situations it was not enough to watch over their patients and adjust their care. Advocating for the infants involved speaking up on their behalf to various specialists, such as physicians, respiratory therapists, and occupational therapists. The nurses saw themselves as being the "ultimate advocates", by always prioritizing the wellbeing of their vulnerable patient population. Regardless of the type of care an infant needed and whether or not the neonate was a study participant, nurses felt that they were in the best position to advocate for their babies' interests. This applied not only to infants under their care, but to any baby admitted to the unit:

> *"It's mainly because we are always there, at the bedside. We are there. We are unrelenting. We poke and poke and poke and poke. And if they say no, no, no* [to a child needing to go off a study]*, we just find somebody else…We, NICU nurses, are the ultimate patient advocates. They ask for us.* [the parents] *will ask if I am there. That's the relationship we have with most parents."(FG)*

It was emphasized that if an infant was enrolled in a study, nurses would advocate to the best of their abilities for this infant's interests. The nurses ensured that participation in a study would not compromise their patient's condition. With the previous experience of looking after infants enrolled in research, nurses described having a "feeling" when it would be disadvantageous for a certain baby to participate in a trial, and would be sure to voice their concerns:

> *"…it is a nurse that has to be the one to say: enough already…"well, we want to put this child on CO2 study…", how many times do we hear that? I don't care what you want, buddy! This baby needs to be taken care of now, I am sorry, I don't mean to sabotage you, but this child needs to be taken care of. And the most*

> *difficulty is working with a doctor who has a special place in his or her heart for their research. That's all he can see." (FG)*

The nurses looked out, not only for their own patient's interest, but also for any other baby's. The nurses stated that, due to their extensive experience with high-risk newborns, they felt that they had the right and responsibility to speak up for the babies who were cared for by more junior nurses:

> *"Any of us that are experienced NICU nurses, we want to do what's best for this baby, we really don't give a damn about a study…Ultimately, if a kid, in this case, is having numerous apneas, I really don't think about the study, I call the doctor and tell "get down here and intubate". If it's a choice between life or death, a study is not even a part of the equation. But if it is a choice between "ok, let's give this child a chance", most definitely a study is very important, but if it's a choice between life or death, absolutely not, study does not even come into vocabulary." (FG)*

The participants stated that if a baby was involved in a study, and a nurse disagreed with a certain aspect of a study or its potential effect on a baby, they would most definitely speak to a physician or to a study's principal investigator. For example, if an infant were having numerous respiratory and cardiac difficulties, the nurses would make an active effort to locate and inform an investigator. At the end of the day, it is always the infant's safety, which took priority above anything else:

> *"…I will make every effort to get them* [samples]*, but I have made the choice also to say that I am not going to poke that baby again, so it was hard enough to get a sample of blood that we needed for him. And I am not going to bruise his heels again to get another sample, I will have to try with another blood work."(#1)*

Looking after families. Safeguarding the infants included looking after their families' interests as well. The participants reinforced that making families, which are most often the infants' parents, as comfortable as possible was an important part of the infants' overall wellbeing. The participants described some strategies that they implemented in order to safeguard the families of the infants involved in research. One of

the strategies included a delay in approaching parents about participation in a research study or taking a different approach to introduce a study to parents. If the nurses felt that asking a parent to consent to their infant participating in a research study was not appropriate at the time, they would either postpone approaching the family, or proceed with caution:

> *"Parents not being ready…you can kind of just get a feel for them not being ready. If a baby is very fragile and you kind of know that baby will not survive the first 24 hours of its life…I tend not to overwhelm the parents with meeting whole bunch of people that… Yeah, sometimes I'd make a decision to postpone, if there is a crisis and the baby is unstable and you know, the parents are just having to deal with fragile little life before them, I don't ask them to participate in any studies."(#4)*

> *"just by being the bed-side nurse, you know, I can see that parents' emotional state, then I think that there is sometimes… I make an active decision not to approach them about it* [participating in a study]*, because of their stress level…(#1)*

Ensuring that the parents fully understand the informed consent was another strategy that the nurses would implement to minimize the risks of involving infants in research. The nurses stated that they would either explain the study to the parents in a "simpler" language, or that they would encourage the parents to speak to the study investigators and ask as many questions as they need to fully understand the study:

> *"I'll tell them. We take the baby into the room with mom and dad before we leave the hospital. The doctor talks for 5 minutes. They leave, I pretend to leave something behind and I go back and[*ask*]: did you understand? He is a really good doctor but sometimes hard to understand." (FG)*

> *"Feel free to ask as many questions as you want, about this study and how it is going to affect the care of your baby. Whether it means more blood work….And go back to the physicians. Just because now you have decided what you want to go with the study, if you decide anywhere along the line that you are not comfortable or you want more information, we can always get the study physicians back…I make sure that it's an informed consent that they really do understand what they are consenting to and how it affects their baby." (FG)*

Themes

The data that transpired from neonatal nurses' discussions of their experiences looking after high-risk infants involved in research revealed three themes. The themes emerged were "feelings within", "keeping it near and dear", and "making it safer". The three themes further describe the essence of the nurses' experiences, which is safeguarding the baby.

Feelings Within

Further adding to our understanding of the nurses' safeguarding experience is the theme outlining the nurses' feelings. The feelings that the nurses experienced were related to their experiences safeguarding the high-risk infants involved in research. Depending on how their ability to safeguard those infants was affected, the nurses experienced positive, as well as negative feelings about the research.

The participants reported having experienced mixed emotions when caring for an infant involved in research, which ranged from positive feelings to feelings of moral distress. The nurses also described feelings of uncertainty, or feelings of being unsure about certain aspects of research involving infants. The nurses' feelings reflected their perception of how they viewed the risk of involving high-risk infants in research. The nurses also described what they liked the least and the most about research. In addition, the nurses identified the worst, in their opinion, procedures that could be done to a baby involved in research.

Positive feelings. Despite having mixed opinions about involving high-risk infants in research, nurses identified positive feelings about involving infants in research. Those

feelings reflected nurses' general appreciation for research as means to achieve medical progress, especially needed in a relatively young field, such as neonatology:

> *"I think that research is very important. I think that neonatology is a fairly dynamic field of medicine so we need to have research so we know what is best for the babies and to learn from the things that we are seeing. I support the research in the nursery…" (#4)*

> *"…there is risk in any research. And, it has to be done. We are saving babies that even 5 years ago would not have survived. And that's all based on research. It seems that everything we do, we do evidence-based, it seems to be the key word now. Everything that the doctors do or order is based on research. So, if we did not have research, we could be doing something completely opposite or the worst thing for the baby." (#5)*

The nurses associated their positive feelings about research involving infants with their experiences with gradual improvements in high-risk newborn care over the years, mostly in the past few decades:

> *"...Nineteen years ago you'd never see the small babies you see now. Like right now, in terms of patients, 19 years ago a one kilo baby was a small baby, now we are dealing with 500-700 gram babies. We are seeing better outcomes for the babies because of a better technology. Modes of ventilation have changed…The introduction of artificial surfactant has greatly reduced our long-term babies, in terms of BPD."(#2)*

When asked what they liked the best about research, common answers were learning the results and seeing the vast improvements in treatments, therapies, and preventative measures:

> *"Learning results. Finding out…Sometimes it's years and years… down the line, it…I remember when I first started, when the artificial surfactant was first introduced, and it was a big huge study and today we know that that's one of the reasons why we are able to help 24-weekers and have a success rate… because of the drugs like that…To hear results, I think, is one of the greatest rewards that come from doing a study."(#1)*

> *" Well, I just like the whole premise of research and what come out of it, like what we'll see long-term and the results…Like BLES, for example, just the advent of that was so revolutionary. So, it sort of neat to be involved and stuff, sort of cutting edge, so I quite enjoy it." (#6)*

The nurses appreciated research not only for bringing the immediate advantages to high-risk infants' care, such as the survival at an earlier gestational age, but also for the long-term developmental advantages:

> *"I like the best the positive changes that have happened because of it, babies do so much better now. We are getting them off the ventilators so much quicker and that decreases risks incredibly. So it means that instead of , and I'll quote, "saving a child", and by that I mean blind, visual defects, extremely impaired, possibly being able to walk only with assistance or maybe unable to walk, profound CP, to now a child who has really pretty good lungs, may need glasses but is able to see, is able to walk, and just considerably better. So, that's the really good thing about it."(#3)*

> *"I think that when you look at it from a global perspective, research has certainly made a lot of advancements and a lot of improved treatments, positive outcomes for infants. By positive outcomes, I mean their growth and development…I think a lot of it we don't see until they actually start school. Being able to function at school, socially and educationally they are able to meet milestones; those are positive outcomes to me. Some of the research that we are doing now, like how we protect a child from bleeds in their brain, how we protect the lungs, the eyes, the ears, the hearing, all of these things are done so the outcomes will be improved. Sometimes we don't know what the outcome will be until they are 6 years old and they start school. The research, when you look at it in that way, we are actually trying to take a positive role and make sure they improve outcomes, so that they can be functioning members of society…"(#7)*

Feeling moral distress. When the nurses' ability to safeguard the infants, due to their participation in research, was compromised, they experienced feelings of moral distress. The nurses associated feelings of moral distress with situations in which they were starting to question the ethical aspects of research, and subsequently experiencing uncomfortable feelings. Most often the study involved a battle between feeling that research is crucial to the future babies' survival and health benefits and needs to be done, and feeling that the study puts the present infant participants through extra hardship:

> *"I can't think of a specific baby but I can think of a few studies where I thought: this is ridiculous. This child needs to be on Aminophylline…the CO2 study. We had CO2 monitor and there was a mystery tank. Basically, we were seeing if*

blowing CO2 via nasal prongs worked as well as Aminophylline. So these kids were blown possibly air in their nostrils, and Aminophylline withheld." (FG)

When recalling a study that would stand out in their mind or that was "really bad", or a study that caused a significant amount of distress to them, the nurses provided examples that included studies involving twins, studies involving microprems, studies involving a critically ill infant, studies where infants were "waiting" for the treatment, such as an intubation or a medication, and studies causing more harm to an infant than the usual treatment would. Other examples of studies that caused moral distress to the nurses included an infant whose maximum potential was not reached because of an involvement in a study, an infant involved in multiple trials, an infant of a family who have experienced multiple losses, research involving extra invasive procedures, and a research study that would significantly increase nurses' workload.

Studies involving twins. The nurses felt bothered with involving twins in a study that would deliberately "split them up", assigning one treatment to one twin and another treatment to the other twin. As one nurse put, potentially a study could "set them up so one would do well and one would not":

"… One of the things that I find difficult is…I forget which study it was, because it was a few years ago, but they randomized twins, so one was randomized to the study and the other was not. I had some problems with that, cause one was and the other one was not involved. That was difficult for me."(#7)

"I think that one with the twins…do you treat them as one baby or two babies so the one could be randomized and one could not. So that, I have trouble with that. If you are enrolling twins, do you enroll them sort of so both get it or both don't? Do you separate them and make them two subjects or they are considered one subject? I have had difficulty with that. I think it's not fair to put that pressure onto parents. And do they understand what we mean by randomized / not randomized, and in some cases, and we know this from doing the Surfactant study, we could tell which kid…even though everything was closed off, you could tell which kid got it, because you saw an improvement, so that was quite obvious. So, would you give one twin that and then the other one would not get it and have

> *a terrible course and one would do well. That I had trouble with. The study was many years ago…" (#7)*

Studies involving "microprems". The nurses felt that most risky situations occurred when research involved a severely premature infant, or a "microprem". One of the examples included a study that would require blood samples from a microprem, or an infant of a very low birth weight. The nurses felt that those infants were at especially high risk of various complications, such as needing blood transfusions, if involved in a study that requires blood samples:

> *"Um…on a tiny prem, drawing extra blood may mean he needs a transfusion down the road. Those… those are the biggest risks that I see." (#1)*

The nurses reported being especially frustrated with types of studies in which a very small baby would be put on a form of respiratory support that nurses felt was not the best for the baby at the time. Some of the nurses said that those studies were the hardest, because they seemed "like there was always a battle". One of the nurses explained that this battle was between the fact that studies have to be done and feelings of distress when an infant is not doing well on a study:

> *"So that was very frustrating when that baby "won" the CPAP and is doing awful on it. So…I found that study hard because it almost…you'd see the baby work a lot harder than it should. I'd say a lot of nurses had problems with that study…It was hard because sometimes you knew that the course that this baby was getting was not the best for this baby, but because…it was randomized…you look at this little baby and go, you know what, this baby needs a tube, to heck with this study."(#5)*

> *"And it just seemed like a fight… it was when you had this LITTLE, you know, 1100-grammers that they wanted to put on CPAP, they are setting them up to fail…yes, studies have to be done but also we have to look at the baby that's in front of us at that particular time, and if it fails and it's out of the study, let's move on, give the baby a tube."(#5)*

Some of the nurses thought that perhaps, the most vulnerable infants, the microprems, should not be involved in research, especially research that requires invasive procedures. Other nurses stated that if those infants are involved in a research study, the study should carry the miniscule risks. In other words, if it is possible, bigger and healthier infants should be involved in research. One nurse used a metaphor to illustrate this point:

> *"If you want to put that into something a little bit more simple: if you are just learning how to start intravenous and you are unskilled, if you are a grad nurse, you are not going to start by trying an IV on a baby who has minimal IV access; you are going to start on a baby that has got good veins and very visible veins and don't need an IV instantly, but a child that you can try a poke on, and it definitely will be uncomfortable for the baby, but it's not as much of a risk as doing it on child with minimal veins."(FG)*

Critically ill infant. A critically ill infant was defined as a high-risk infant who is having actual serious health problems, as opposed to a high-risk infant who is facing potential difficulties. The nurses felt that the family could be too easily overwhelmed if they were asked to participate in a research study when their baby was already having numerous health problems:

> *"If it was going to be a palliative child, if the child had…was critically ill, had had a resuscitation, had horrible insult to the brain, so now we are looking at a grade 4 bilateral IVH that we have not changed treatment on…not the time to look at the study on that child only because it won't make a difference, except making it possibly more difficult for the parents, it's one more thing to approach them with. My years of experience show me that they are not going to be ready for. They don't need to be asked something else, they are dealing with a dying child."(#3)*

Waiting for the treatment. Waiting for the "right" treatment, the nurses explained, was morally hard because sometimes they felt that the study's course of care was not the best, or even "wrong" for the particular infant, but because the baby was in a study and he or she was randomized to be in the treatment, there was nothing they could do except to care

for the baby and wait until criteria was met to pull the baby off a study. Nurses described experiencing an emotional battle while "waiting" for the criteria to be met:

> *"…I would say some of the research, like that last CPAP / trigger pressure one, um…it's almost about numbers, they want to be the smallest baby on CPAP that never gets intubated. It's kind of…let this going to be the baby where you know that the baby is going to fail and gets worse whereas if we intubated and gave bless and did all that, the baby would most likely be a whole lot better. But they are just trying to maintain, keep him in, as long as…As I said before, there is that fine line…ok, the baby's failed, let's move on. They are just trying to keep the baby…you know, it's hard to get these babies' parents to consent. Once they get the baby, they are trying to keep him as long as possible, that's frustrating, when you know that the best treatment is not what the baby is getting."(#5)*

The nurses reported that, in such situations, they frequently experienced feelings of helplessness, because they suspected that an infant was "dealt the wrong card". Some of the nurses reported questioning their skills, especially if an infant's health worsened due to their involvement in a research study, and required frequent adjustments of their respiratory support:

> *"The most stressful one for me was the ventilation, where they were going from being ventilated, intubated to TRPA, which was the CPAP… all of a sudden extubated this 27-weeker, put him on CPAP and we are going: whoa! CPAP works, but you've got to have your own respiratory drive, and the TRPA will give you some, with the back up of 15-20…I thought that sometimes the back up rate was a little low, it should have been 25. There was a lot more alarms. And I know when they give reasoning why it makes perfect sense, because of lung damage…I did not think it was high risk, but it was risky, because we've always kept them ventilated for a while. And a lot of them failed, they did not last on TRPA. So was there something that we were doing…they were not doing at other centers and were having success? Was there something in a way we were doing it? And since you are at the bedside, that's a lot of pressure…is the mask on right…" (#7)*

> *"…I have seen them almost just "wreck" a child…how can I say that…say there is a child that is going on…needs to be intubated because he is having apnea and Dr. so and so is running a study and Dr. so and so does not agree with this study and wants to start Aminophylline: "I don't care let's just do it"…" (FG)*

<u>More harm or risk than the usual standard care.</u> The nurses stated that if a research study involved any additional, even slight risks to an infant, they would feel uncomfortable,

having to look after this infant. Even minimal risk was compared to "gamble", and as one nurse put it, no infant who is already high-risk should be subjected to any additional risk:

> *"In any case where there would be more harm or risk to the child than the usual standard care. That's when I feel bothered by having a child involved in research. If there is no harm done to the child as a result of the study, it does not bother me at all. And I think research is great, but it is only when no harm is done to them."(#6)*

> *"…everything we do is based on research, but it's the risk of research that sometimes is hard. It's for the future babies. But it's hard when you are looking after that baby, when you know it's not the right care for that infant. That's what's hard. It's when you are looking for that baby, that's hard."(#5)*

> *"…getting back to a clinical trial, the risks are sometimes greater, because maybe they got the one that maybe was not the right form for them. And so their risk is now increased. Whereas if it was not on a study, that baby would have come in, got a tube, got BLES, everything is fine. But no, because they got consent and they are on research study, we are not going to do the tube, we are going to do this form. So, there is higher risk in that, because maybe for this baby research ways is not the best treatment for that infant."(#5)*

In some situations, drawing blood for research purposes was identified as putting a baby at risk for a future blood transfusion, making nurses feel that a research study was setting these babies up for future difficulties:

> *"There is sometimes…parents don't want blood transfusion, but yet we are taking blood because we have to, and they want another tube of blood for research. Well, you know, parents don't want a blood transfusion. Do we really…does this baby really have to be on this research study, maybe this is not the best baby to be on there. Because another tube is more blood loss."(#5)*

> *"We are getting more and more Jehovah witnesses in out unit. And it makes our job harder. Cause you know, everything is based on blood levels…those 500-grammers can get anywhere to four to 7 blood transfusions by the time they are ready to go home. So far, this baby is doing all right, but at some point…at some point it's going to get very messy."(#5)*

Maximum potential was not reached. Enrollment of a baby in a randomized controlled clinical study which would involve an actual treatment and a placebo left some nurses with mixed feelings, saying that those studies were important for the future, but might be

putting the infants enrolled in the studies at risk of not reaching their full potential. One nurse described this kind of situation as having "an ethical battle":

> *"Clinical trials are a huge risk, and I know that. And their results will help future babies...It's when you are in the moment and you see that little baby struggle. That's when I find it very difficult. When you know that that treatment is not right for that baby. But you know, also in the back of your head, that this guy's struggle may benefit future babies or change the way we do things. It's just hard to keep that all in your head when you are seeing little babies struggle."(#5)*

> *"I guess the way I look at it…for the most part, we are not putting them at extra risk. The plan of care that we might normally assume on these kids might be altered slightly, but I don't see it as necessarily harming them or putting them at additional risk. I just see it as maybe changing it slightly. The CPAP, the ventilation thing…maybe, I think with that one maybe babies were exposed to um…I don't know if risk is the right word, but just not maybe be able to do potentially as well as they could have done, if we had chosen the ventilation method, but…if that's risk, I am not really sure. I don't think that some of the kids maybe met their potential because of the fact that they were randomized to the control group. That was one of the few studies that I've been involved in that I felt, you know, maybe it was not the full potential for the child."(#6)*

In some cases, nurses felt that perhaps a child did not do as well as she or he could have done, had they not been on a research study. Although there was no evidence of an actual harm being done or caused by the study's treatment, nurses could not help but ask themselves "what if"…

> *"…perhaps…like in a case of the child maybe that is not put into the right ventilation group, that I would like them to be put, that I think they would do better in…perhaps harm was not done to them, but they still might have succeeded in the alternate group if we had chosen to put them in that group, rather than being randomized to the other group. I just don't think that maximum potential of the child perhaps was reached as well."(#6)*

An infant involved in multiple trials. Nurses considered it "too confusing or conflicting" when infants were enrolled in more than a few studies. "How many is too many" remained a question:

> *"…how many studies can baby be on? Sometimes you see that this child is on fair number of studies, and you want…I don't think that we have a set rule about that… how many studies can you be on at one time?"(#7)*

> *"I remember one in particular, we thought that the baby was enrolled in too many studies…the parents would not say no to anything…there was an interpreter, but there is a difference having an interpreter that speaks their language and an interpreter with medical background that can kind of phrase it for them in their language, especially if English is not their first language. We thought that the baby was enrolled in quite a few studies and we are going: the parents would not say no…" (#7)*

A family who have experienced multiple losses. The nurses firmly believed that a family with a history of infertility or who had experienced losing children on more than one occasion should be approached more carefully or, in some cases, should remain "hands-off" to the research investigators:

> *"And when you look at…this is the first child of a couple who have been trying many, many, many years, you got to kind of look at obstetrical history. If this mother has already lost 5 children, this is their first live child, maybe this particular person was not the best to involve in research, and once she said no, back off…"(#5)*

> *"I would be bothered…I would not want probably my patient to be involved in research if it was perhaps a family who have experienced multiple deaths…and to use their first child that's living… perhaps they've lost three, 4, 5 children, whatever, which is not uncommon in our unit. And then, this is perhaps their fifth child and they've lost four, and when we are asking this mom and dad whether this child can be involved in a research project, that bothers me a little. I guess I hate to burden these parents with even more than just the stress of this little one…I have mixed emotions then…Although we still have to offer it to the family and we still mention it, if there is a study that we need to mention it, I still mention it. But I still have some reservations about it."(#6)*

Extra invasive procedures. Some of the nurses described feelings of frustration and reported feeling bad when having to look after a premature or a sick infant who required extra invasive procedures because of a research study. When asked what the most invasive procedures were, the nurses replied that invasive included any procedures that would compromise an infant's skin integrity, such as a heel poke or applying a urine

collection bag. The nurses stressed that such procedures, taken for granted with term infants, could pose devastating effects for a preterm infant:

> *"Just something extremely invasive I think would be…A painful invasive procedure that would be number one…for a microprem… That could be so horribly invasive…They may get stressed out after we wash their eyes. Even bigger babies could be extremely sensitive and have a very immature neurological system and be intolerant to even minimal touch."(FG)*

One of the most common procedures that were identified by nurses as invasive was a poke to collect a blood sample:

> *"Oh…*[it makes me] *angry, because you know, we poke these babies frequently, sometimes once or twice a day, or depending on how sick the baby is. And to take a blood sample without anything else, just for a research study…I know it has to be done, but there are different ways that it could be done, like not by itself, to save baby a poke."* (#5)

Another common invasive procedure was collecting a urine sample. A urine sample was deemed invasive for its potential to break a skin barrier, especially on a premature infant:

> *"…the really bad thing…the thing that bothers me is just if there is extra bloodwork on the small babies, so just one very select group… I'd say, 99 % of the time, no problem. That 1 % when it affects very, very small population of babies...the micros, the little ones, yeah, it bothers me." (#3)*

Feeling uncertain. In some situations, nurses described feeling uncertain or not definite about what they felt in regards to the studies that parents were asked to enroll their infants in. Those situations were described as not necessarily stressful but confusing to nurses: they felt that they were supportive of a research study, yet felt conflicted about some aspects of it. The situations like these were not necessarily viewed as risky, but would leave nurses wondering about the ethical aspects of a study. An example of such a situation would be when a low-income family is invited to participate in a study and an incentive is offered. Although a study might not be as "high risk" as some other studies,

being offered an incentive would still be considered conflicting, bringing up questions such as: is this family participating because they cannot afford certain things otherwise? Is it ethical not to offer them incentives?

> *"They would get an access to a breastpump. And the study was…blood and urine and weights and lengths and stuff like that…But if they signed on to it, they got a breastpump. Which was helpful for them. But sometimes I feel conflicted about that. Just because you don't have money to buy a breastpump, and you'll have to go on a study to get it."(#7)*

> *"…I think that there are some* [families] *that are just hands-off. And should we be signing up parents that don't have as much money as other parents so they can get free stuff by going to a research study, is that a reason? I sit on the fence on that one. I think it's a positive that they get this stuff, and if this is the only way, but then I…we kind of twist their arm a bit too. Just the way we approach that, as well."(#7)*

Another example of feeling uncertain about a situation involved caring for an overwhelmed family or a family not coping well with a birth of a high-risk infant. The nurses expressed feeling unsure and at odds about approaching such families in regards to involving their infant in a research study. To compensate for their uncertainty the nurses stressed the importance of approaching families in a gentle manner by "treading carefully" and always leaving parents with a guilt-free way out of the research:

> *"…I think of the families, like I think that the families have enough to deal with, you know, that they don't have to, you know, spend any time talking to…I don't think that they are able to comprehend at that time the details of a study, or actually what they are even agreeing to, you know, I don't think that that would be an informed consent, to have their baby involved, because I think emotionally they are just too fragile. That's what I think, I don't know."(#4)*

> *"I think you have to ask them, but you have to make it very clear that at any time they can say no, it's not a good time, I can't concentrate now…And it won't affect how the baby is treated and all, I think those are important things. But I do believe that they need to be asked, or you'd never get…You need to ask many people to be enrolled in a study. Usually after we've gone through a few things, I'll ask…And just ask them about if they are interested in it and they might have some questions about it and I will give information and say: you can read this or you can ask or I can get*

somebody in to talk to you. And I usually stress that at any time they can say no to this."(#7)

The nurses also felt uncertain about enrolling a family whose English was not proficient enough, as it would be unclear if they could fully understand the informed consent and what they would be agreeing to when consenting to involving their baby in research. The nurses felt that it was important to include these families in research, yet, at the same time, it would be unethical if a family did not have a full understanding of what a study involved. In addition, some of the nurses felt that sometimes the new immigrant families could feel intimidated and obligated to agree to a study:

"We had a family that just immigrated here and they would have said yes to anything. Anything that you ask them. Is that fair? Because they were from a country that was war-torn and they came to Canada, and the health care… everything was free, and they did have an interpreter with them, but if you ask them for anything, they would do it, because they are here and they are fearful, they still have that fear factor and they do consider a physician an authority figure. So we said: is that fair to ask them to do this because we are not giving them time to adjust to being here and to having a baby in an NICU…"(#7)

Keeping it Near and Dear

Despite being more comfortable with research in general, nurses reported that they would never feel comfortable nor would they ever forget the babies who they thought had suffered because of their involvement in research. Some memories were especially powerful, having to do with the situations when the nurses were not always able to protect their patients to the degree that they would have liked. Some of the nurses expressed regretting their choices, such as not speaking up on a patient's behalf, while others described it as a learning process, which eventually contributes to their abilities to safeguard the infants. The nurses also outlined the changes that have happened in the last two decades that have positively impacted the safety of the infant participants.

Ultimately, by remembering the sensitive situations when they were not able to fully safeguard their patients, the nurses reinforced that they will use these experiences to protect their future patients. The nurses focused on minimizing future risks to infants involved in research by remembering their past experiences and learning from them:

> *"I will always remember that. I will always look at the next baby and try to prevent that from happening…In this case, it was a very bad choice. But that is not the norm. Unfortunately, completely unrelated to studies, we have made bad choices…I hold them near and dear. I want to learn from them and never let them happen again."(FG)*

> *"…We had twins that were poorly managed because they were extubated too quickly and did not fair off. If we used traditional treatment…but there is no proof of that. But anybody who worked in neonatology knows that we could have managed these kids better. That was disturbing. I see these kids in a follow up clinic…We could all pick our patients…We do remember them. Some of this was many years ago and we still remember the kids. But that's not the norm…To me, it's not something I could learn to live with." (FG)*

Regretting choices. Nurses recalled a few studies, most of which involved randomized control trials, which had, in their opinion, left the newborn participants with less than optimal choice. The nurses felt that, although a study was approved and there were "criteria" for when a participant could have come off a study, perhaps it was not the best choice of treatment for the baby, or that the baby should have come off the study sooner. The nurses stressed that such studies were rare and that a baby would have never been left to experience many "near death" episodes:

> *"I know that there was talk with this Theophylline study… a lot of people believed that the babies that were experiencing bradys and apneas… there was some discussion after the fact, you know, this baby actually should be taken off the study and put on Theophylline because people believed that baby with increased number of apneas and bradys was probably not getting Theophylline, so maybe at that point… But I think there was criteria…I can't really remember all of the details of the study… and the CPAP study as well…some people believed that the babies that were extubated, the smaller ones should go on a trigger-assisted CPAP and if they were put on a regular CPAP that they were maybe a little bit more at risk for having apneas. Those were just discussions amongst nurses about*

what's appropriate or what we think is going on, we don't know for sure, but… (#4)

However, despite such studies being "approved", the nurses felt that they should have said or done something at the time a study was conducted because, in their opinion, the babies were doing worse by participating in a study. Nurses described feelings of moral regret when recalling these studies, wishing that they have said or done something to perhaps improve the outcomes for these infants:

"I remember baby P. He just got the wrong envelope. He would have lived. So that's the most distressing for us when we KNOW that he would have been better off…We know if they have had BLES or whatever, this child would probably be…But you wish sometimes that you could say something. Especially after you've been doing that a while."(FG)

"You see ok, child A, you know what happened with child A. So that's when it's probably the most difficult, to sit back and [not say anything]*..." (FG)*

While in some instances, the nurses wished that they would have spoken up on behalf of an infant, other times they wished that an infant would have just come off a study, although admitting that sometimes a study does not have a good population and cannot afford to lose participants:

" And I remember a conference where Dr. P. was speaking regarding breastfeeding…and it was hind milk feeds and splitting milk up so that the child got just hindmilk, high concentration of fat; and they had identical twin boys that were born at 24 weeks. One got this end of a study, where he was getting the hindmilk feeds and the other one got regular breastmilk and the difference in weight was [huge] *and she actually just stepped out of a box and had to take that one child off the study, because she thought it was so unethical, watching the one microprem getting it and the other one getting in trouble…I mean they had a huge population, they did that over 500 babies. They had a very good population and we often don't have…unable to step out of the box like that… You need the numbers, right?"(FG)*

Positive changes. Remembering their past experiences, the participants reported seeing a trend of research involving high-risk infants becoming safer over the years:

> *"I think it's much more safe, for sure. Considerably more safe. I think some of the research that was done years ago and I think research is good because it teaches us things…I think it's been ethical for many, many, many years. I think we've just kind of were more on a riskier kind of mind years ago. I think we took more chances."(#3)*

When discussing their past and present experiences with research, the nurses reported positive changes in research over the last two decades, which have ultimately contributed to minimizing the risks to the infants involved in research. These changes include the dramatically increased number of research studies and stricter REB guidelines. The nurses described child health researchers becoming more professional when it came to involving high-risk infants in research, ultimately creating less "risky" situations. The nurses reported becoming more familiar and accepting of research, as well as feeling more comfortable with research due to the number of research studies happening in the unit:

> *"Considerably more research. We are frequently hearing about different studies being done. We are part of many studies. Now, there are many research projects that we are all much more comfortable with it, so, it's not like we are as afraid or as uptight about it, so we just accept it: "Yeah, ok, we are doing this research project, we need to get these babies enrolled and we are just much more comfortable with it."(#3)*

The nurses noted that not only has the research involving infants became more "safe" medically, but the researchers have also gotten better at addressing parental concerns about involving, or choosing not to involve, their infants in research:

> *"For the first 10 or 15 years, I don't really recall that much research, except for maybe the whole Exosurf thing. But in the last 10-15 years, when I hear doctors talk about research, I think every year they get better and better at it. And they sort of trouble shoot what they know parents are really worried about. I think they are getting better and better at dealing with it...I have seen an improvement over the last decade, decade and a half. With how parents are treated. We always like to make sure parents realize that just because you refuse a study, does not mean that your child is not going to get good care. Some families might think: oh, dear, if I don't put my child in this study, they are not going to give my child proper*

> *care. But the physicians and the nurses reiterate the fact that that won't affect your baby's plan of care…" (#6)*

Making it Safer

Despite having negative feelings about some situations, the participants felt passionate about the future of neonatal research. The nurses' role of being the ultimate advocates and their desire to safeguard their patients to the best of their abilities prompted the recommendations on how to minimize the risks of involving infants in research. The participants proposed useful suggestions on how to make research involving high-risk infants safer. The nurses identified many ways in which child health researchers, bedside nurses, REB members, and parents could minimize the risks of involving high-risk infants in research. In addition, advice was given to the research nurses who do not work in the NICU, but are involved in research with high-risk infant population. Recommendations were also made on how to "make life easier" for the parents, infants, and nurses.

Recommendations to parents. Some of the nurses stated that they would be openly supportive of the research studies and encourage parents to participate in studies that would benefit their infants or the future babies:

> *"I'd tell them that we use research…a lot of advancements that we are using now on their infant have come through research, have come through the multi-centered trials or multi-country trials and it's been proven that this type of treatment is far superior to what we were doing in the past. At any time when we think that infants are at risk and they are on a project, we pull them off of it…" (#7)*

Nurses reinforced however, that the parents must be comfortable about their decision to involve their baby in research:

> *"I would encourage them to participate if they are feeling comfortable with it. I would, again, reassure them that no harm will be brought to their baby. That*

research is an important part of medicine and that they are playing a role, making things different or better for future babies. I would talk about it in a positive way, even if I did not agree with the study, I would give them the opportunity to participate."(#4)

At the same time, the nurses stated that they would always reassure parents that it is entirely their decision to enroll their baby in research. The nurses stated that they would reinforce to parents the fact that any decision would not change the care that the baby is receiving:

"...and at no time feel that you are pressured into anything. Don't feel that if you say no, it's going to be a bad thing. I do feel that parents still have that feeling that they are disappointing us or going against what we want. We tell them that that does not change anything that goes on with an infant at all. No matter what your answer is, yes or no, we accept that, it's your decision, we'll try and give you as much information as you need to make the right decision for you." (#7)

The nurses also mentioned that parents should read the study and consent form carefully and have all of their questions answered in order to make an informed decision which is right for their family:

"I would encourage them… to speak up. I always encourage parents to get a notebook and write your questions down and use it…" (#7)

One nurse said that ultimately the parents should go with their "gut instinct":

"The parents? Um…well, I would advise them, number one, to…listen to the person talking to them about research to get the consent, um…to…if they don't understand everything right away, don't sign, but find out some information first. And ask question, ask questions. And my advice would be if you don't feel comfortable with research, don't sign the consent. Or, if you feel you are being coerced, don't sign the consent either. Go with your gut instinct. If you don't think this for your baby, I mean, don't do it. Or, if you think it is for your baby, do it." (#2)

Some of the nurses, however, felt that it was safer not to give parents any advice, preferring to stay neutral. These nurses stated that it was not their place to give the parents any advice. Other than letting the parents know that the quality of care for their

baby would not change, these nurse felt that they could not decide for the parents to enroll their infant in research or not:

> *"No, I don't feel that's what's my place…If a parent has specific questions, I would direct them to the…whoever is in charge of a study, whether it be a doctor, or a study nurse…, but I don't feel that it is my place to encourage them one way or another…other than to assure the parents that the baby's care would not change, whether they refuse to be involved with a study or not…um…that's where I feel that my obligation ends…is that I let them know that there is a study and that someone wants to speak with them, and then whatever they decide, that nothing would change for their baby."(#1)*

> *"*[when parents ask me] *what would you do if it was your baby, I always just say: I can't tell you, unless I was in your situation. I try to stay absolutely neutral. I think that most of us do try to stay hopefully neutral." (#6)*

Recommendations to the child health researchers. Recommendations to the child health researchers, given by the participants, included presenting the parents with a simple yet comprehensive informed consent form, listening to the parents and to their wishes, not "bombarding" parents with multiple studies at once, and keeping in mind nurses' workload. The nurses suggested performing as minimally invasive tests as possible, keeping in mind the fragility of high-risk infants, especially "microprems", for whom simple touch or skin contact, such as attachment of a urine collection bag, can be very invasive and cause significant stress. In addition, the nurses suggested having an NICU nurse participating in the REB committee meetings, in order to optimize the decisions made in regards to research involving high-risk infants.

Informed consent. To the participants, keeping informed consent simple for the parents was seen as very important. The researchers were encouraged to make sure that parents were making a truly informed decision when agreeing to enroll their babies in research. In order to do this objective, the nurses advised to write an informed consent form in lay language and having parents reiterate it back to a researcher:

> *"I think when our parents come in, they are literally deer in headlights. They will sign anything that physician presents to them that they think is going to save their baby's life. And so it needs to be…a little bit shorter and sweeter, so they can really comprehend it. And telling the person about something and having them sign it, to me is not informed consent. They have to be able to tell you what it is you are actually doing. I like them to understand how the study is going to impact their child, what's going to be required, what kind of handling, what things need to be done…" (FG)*

Listen to the parents. According to the nurses, the communication with the parents is the key to a healthy approach for research recruitment. The researchers were advised to listen to the parents and their concerns. Paying close attention to the parents' wishes, and not pursuing their agenda exclusively, would produce an unbiased approach. As one nurse stated: "it's not about you, it's about this little baby…":

> *"Watch what you say, listen to the parents. And if they say no, then they say no. If they say yes, then great. But you are not going to get everyone to say yes to your research. That's just a fact of life. Not everybody wants to be involved in research and if they've made it clear that they don't want to be in research, then back off." (#5)*

Some of the nurses felt that once the parents said "no", they should not be approached about the same study again. If the parents said "no" to all of the research, especially on more than one occasion, these parents should not be approached at all. The participants stressed that if getting consent requires that the parents feel guilty about not consenting, "it is not the right way to go about enrolling infants in a study":

> *"If the parents say no, and you've given them all the reasons why…and they still say no, then back off. It's hard when they say no and the doctors are still kind of jam and jam and jam. It's like, you know what? Don't bully these parents into giving consent. That's hard to see. Because you know what, they've already said no, move on.…I know, I've interrupted, in two particular instances, I've interrupted and said you know what, the parents have said no, it's time to back off." (#5)*

It was recommended to ensure that there is constant communication between the

bedside nurses and researchers in regards to the parents' previous responses to the research participation. An infant's chart should clearly indicate if the parents have already said no to the research so that they would not be approached repeatedly:

> *"… if they've made it clear that they don't want to be involved in research, maybe flag it at chart because so many people come wanting this baby to be on this and on this research and this research. So, the mom has said: I don't want my baby on research, then mark it…"not willing to be a part of research studies", so then these research nurses and doctors don't come, do their spiel, and the mother says no all the time. So then she feels bombarded, and the researchers are wasting their time."(#5)*

Limit number of studies. The nurses stated that sometimes there appears to be a constant flow of research trials, and they reported feeling "bombarded" with the studies. As one nurse stated, it makes some nurses "cynical" when they hear about yet another study starting on their unit. The nurses admitted that in the last few years there have been "so many studies", it would have been hard to remember all of them, and some nurses have somewhat of a blurred vision of the past studies. Due to the number of studies that are proposed and carried out, some of the studies are conducted at the same time. Child health researchers were encouraged to limit approaching parents about studies which are run simultaneously, to avoid having a lot "thrown at them":

> *"As far as child health researchers, I guess I would always say: try to coordinate their projects, as in, if there are several different researchers who want to do research. So, maybe…, pace themselves, i.e., don't all of them be doing them over the same few months…So, I guess I would say coordination…I know that's not always possible because if you want to do a research project in a certain time period…Sort of a little bit of coordination so the parents are not blitzed with multi-research projects at one time... In the last couple of years it just seems that there have been a lot* [studies going on at the same time]*."(#6)*

> *"To find out, first of all, how many projects they are on. If they've been asked 4 or 5 times about different projects and they keep saying no, they are probably going to say no to you. Also, find out a good time...Sometimes there is a narrow window of opportunity when they can talk to parents."(#7)*

Remember that our babies are fragile. To minimize the risks to their vulnerable patients, child health researchers were advised to keep the amount and number of samples required for a study to a minimum, due to the extreme fragility the NICU population. Some of the suggestions were to combine obtaining the research samples with routine bloodwork, so invasive procedures are not done for the purposes of research only, and to determine the absolutely smallest amount of sample material, such as blood, required for a study:

> *"…really to just always be aware how fragile these babies are…I can really only comment on these kids, just always being aware of how fragile they are, and making sure that… that you get enough but not too much. That breastfeeding study that I can't remember lots about...we were doing specimens like every other day, and that's way too much…like blood, urine, stool, it was a lot, it was a lot of specimens that they needed, and so it was: in. touch, poke, stick on a urine bag, stick on this bag, pull that off the skin, just way too much handling. They* [infants] *don't need that. So, I know that the data needs to be obtained, but I think it's…you need to keep it just so it is a sufficient amount and not super, super frequent."(#3)*

Make nurses' work easier. When making a decision to conduct a study, the researchers should consider if their proposed study is realistic. The amount of added work should not compromise the safety of care for the infants:

> *"Um…consider the workload…if it's going to be really an extra workload..." (#2)*

Once a project is underway, it would be helpful to have information about the study readily available to all of the nurses, either by means of holding a workshop or having written information available on the unit:

> *"Make sure that night staff knows what's going on… so we don't feel neglected… just to make sure that there is written information available to people who were not available to attend in-service on days…"(#1)*

The nurses stressed that, while they did not mind performing extra tasks and spending more time on their patient's care for a research study, making the results known

once a study is completed would be greatly appreciated. Knowing the results and how it could impact their care for their future patients was very important to the nurses:

> *"I think I would ask them when the study is completed and they have all their data and they collect their findings, that they inform the nurses and let us know at the bedside…or somehow, whether it's in a newsletter…in regards to such and such study, this is what we discovered, thank you, and they'd let us know in very simple, kind of understandable, terms what the impact of the data, that we helped to collect, means in the care of these premature babies. So, either nursing rounds or research rounds or something…You feel like you are collecting data but you never find out what it all means. And then we practice changes in the nursery and they'll say it's because of the study we did. Well, ok, can you tell us about that? So the evidence is there but let us know what the evidence is..." (#4)*

The nurses made the following specific suggestions to make a nurse's life easier. To minimize the time spent documenting for a study, it was suggested that very simple forms, such as tick sheets, should be available to chart for each study. Having laminated sheets with specific guidelines, available at each baby's bedside, would serve as a reminder of a study. In addition, having a sheet where nurses can put their comments and suggestions would be also helpful.

<u>Include an NICU nurse in the REB committee meetings</u>. Including a nurse who is familiar with the NICU population was seen as extremely beneficial to the committees, when deliberating on the studies that involve high-risk infants. The participants stated that inclusion of an experienced NICU nurse would mean minimizing the risks to the infants in research by making the researchers more sensitive to the high-risk infants' needs:

> *"No, probably not* [no nurses involved in decision-making]. *It's probably strictly physician-directed, hey? Because I think any nurse* [familiar with NICU] *once she / he heard that* [referring to a study] *would say that that's ridiculous."(FG)*

Recommendations to research nurses. Nurses identified certain recommendations to the research nurses who are involved in the NICU studies. The suggestions included

hiring a research nurse that is familiar with the workplace or at least having that nurse spend some time in the unit to become more knowledgeable about the specific population of the unit:

> *"Don't you find often that when there is a research nurse, what she is actually doing, what we see as her role is coming around to pick up specimens and in-putting data? It's not anybody that really knows our unit."(FG)*

> *"…the only contact that research nurse has with us and the patient is the secretions. The stool in the fridge."(FG)*

> *"We see her in-putting data and we see her collecting specimens, but whether she says look you guys, what are you doing? I don't see that as being her role in this… I don't think that they really utilize her the way they need to. They could send a mail courier to pick up the same thing. That's not putting her down at all, it's not. I think that she could be far better utilized."(FG)*

It was suggested that a research nurse could talk to the bedside nurses and use their concerns and advice for the future studies. It was reinforced that a research nurse, who is familiar with issues of bedside nurses who look after high-risk infants involved in research, could contribute to minimizing the risks posed to those infants:

> *"Because the research nurse would be thinking: ok, this is what I have to get. And that's her job. I have to get a stool specimen, .7 in a CBC tube, I have to get this, this, and this. I have to get it on Mondays and Wednesdays. And they come up and: where are my samples? Well, honey…let me tell ya…For some reason, I am looking after 3 kids today. I have not stopped running. On the bottom of my list is getting poop for you. No disrespect, but it's true." (FG)*

It was suggested that a research nurse could be used as a bridge between the bedside nurses and the primary investigators. Spending time on the unit and talking to the bedside nurses would make a research nurse more aware of the specificities of the high-risk infants' care and become aware of the difficulties with a study, if there are any. It was mentioned by the participants that a research nurse should also inform the bedside nurses of a study's progress:

> *"I think she should have more input. I think that she should spend time on the unit, see…At the bedside. Talk to the bedside nurse. Explain what's going on with this project, just a little bit of input… They have little feet like this. Would you know how big a child's foot is if you actually have not seen it, at small gestation? Would you have any idea how fragile they were? Would you have any idea what things could be done to make it a little bit easier? And how about a child who is having blood sugar problems? His little heels look like hamburgers. So, the idea of poking a child for a study or having to poke again to get enough for a study…If a research nurse was actually seeing some of these things, then maybe they would come with other ways that would be a little bit better."(FG)*

Voicing the bedside nurses' concerns and addressing existing issues by bringing it up to the study's investigators could greatly add to the role of a research nurse, and ultimately, benefit the babies involved in research. The nurses felt that a research nurse could help to fill the void that is sometimes formed between the tasks that have to be done for the research and the reality of the negative effects that these tasks could have on their fragile patients:

> *"…take back what she's seen at the bedside to the researchers and say: look, some of these babies are absolutely fragile. Do we absolutely have to do bloodwork twice a week or can we not do bloodwork once a week? Do we have to have .7 in a tube or can we get away with .3 or .4? What can we do to minimize the blood loss? Because .3 is nothing to you and I, at all. But collective .3s on a baby that weighs under 600 g, which most likely would not be on a study, so let's say between 500 to a 1000, say closer to a 1000, that child might get on a study…"(FG)*

> *"They could be so much better utilized. There are other things that they could bring to the table…An example that could explain it a little bit better. Sometimes when we get a baby whose family is a Jehovah witness and we want to do minimal bloodletting. We get away with sending less blood. One would think, why can't we do that with every baby…If a research nurse was more familiar with our population and the difficulties in getting blood, maybe then they would be able to negotiate with the lab: what can we get away with? Negotiate. Look, we don't have enough to do this. What can you give me honey, what can you do for me? What tests can you do with this amount?"(FG)*

Recommendations to the research board members. In the interviews, the ethics committee was described as a "watchdog". The nurses seemed to put a great deal of trust

in ethics committees and relied on those committees to make sure that high-risk infants involved in research studies were safe:

> *"...when you read over what the ethics board does, they make it difficult, well, in a good way, they have positive recommendations...I think that ethics board is really a positive thing. And they are like a watchdog. And I don't think they would let projects just go willy-nilly and forge ahead: oh yeah, this looks ok, they really take it quite seriously."(#7)*

The nurses stated that as long as there is sufficient documentation that shows the decision-making process which supports the validity of a study, they trusted the committees to make the right decisions:

> *"We have a very strong, active ethics committee. And any study has to go through rigid ethics... that would be reviewed by ethics committee. And I think for myself...that makes me think that there would not be any study that would be detrimental, they would not allow that."(#1)*

> *"...I mean, the ethics board and review board is versed in ethics far more than I am, in terms of research...I put a lot of faith in the ethics committees at the hospitals to screen out studies that are bad, so, you know, that's what they are there for."(#2)*

The recommendations that the nurses did give to the REB committee members included becoming familiar with the neonatal intensive care area and developing their understanding of the "fragility" of the NICU population:

> *"...from what I understand... a lot of these boards, they don't have really a clue to what really goes on in an NICU...I think it would be a good idea if there was at least one participant on board that was knowledgeable about the whole NICU experience. So that they would have an insight as to goings on in NICU, and so that any proposal that came to them, they would just be a little more savvy about them, and, perhaps, get different ideas or whatever and make a research proposal a better one."(#6)*

> *"... I don't think that they are actually coming to nurseries and take a look at some of the babies that we are caring for or if they actually are aware of how fragile these little infants are, that they are not just little mini adults, that they can't tolerate a whole bunch of stuff."(#4)*

Another suggestion to the REB committee members was to keep in mind that all

of the studies which have been approved to involve high-risk infants, must strive to yield significant results. It was important to the nurses to know that the hard work they put in, when looking after high-risk infants involved in research, and more importantly the potential or actual risks that the infants encountered, yielded significant results:

> *"…we always need to be extremely careful, how fragile these babies are, and so when they are looking at whether or not they are saying yes, you can go ahead and do this study, we consider it ethical, we give our stamp of approval for you to do this study… that they are aware that… not to keep the sampling to a minimum so that it's still sufficient to get… so they can do the analysis…there is no sense in doing any research if you don't have a significant population, if you don't have the data coming in, then it's just…to me, it's just…insufficient data that won't help you." (#3)*

Some of the nurses admitted that they knew little about the work and decision-making of the REB committees and expressed a desire to learn more about it. Workshops or in-services, which bring a light to the nature of such committees' work, were deemed to be beneficial for nurses:

> *"I'd like to know who is on the ethics committee, there is sort of that hierarchy, they are like up there in a hospital, you don't really know who they are. Maybe some in-servicing on how they come to their decision, whether they will agree to this project or not…when they usually start a research project, they tell us that they've got a permission from the ethics committee and then we read it over. And usually the doctor that's involved would come and talk to us about what they want, what they are looking for, what the outcomes are going to be…"(#7)*

> *"I am not sure who sits on the ethics board for neonatal studies, if it's neonatologists or…who they are. I think sometimes it would be nice if we saw who these people are that help make decisions on these little microprems or involve these little microprems in studies. Whether that makes a difference or not, I am not sure. If they are people that have never stepped foot in a nursery, or they have no idea how small some of these babies are, maybe they'd think twice on…no, I think they would probably, no, maybe they would not, I don't know…I don't know if they've seen a premature baby, I don't know if they've seen what a unit looks like, I don't know what kind of background these people have, if they are all adult-based."(#4)*

Recommendations to neonatal nurses. Advice to their fellow colleagues ranged from keeping an open mind and being receptive to research to advocating on behalf of their little patients. Bedside nurses were also encouraged to get to know research staff and freely address their own concerns that may arise throughout the course of research, to the more experienced nurses or to the researchers.

Guard the babies. The nurses encouraged their colleagues to always protect their patients' well-being. Keeping the babies safe seemed their priority. Minimizing handling or minimizing the amount of blood taken for a test were some of the examples of how to minimize the risks posed by the research:

> *"I think just the least… really coordinating how much stuff is done and I mean sampling above all of it… keeping that as low as you can, but sufficient so that you can analyze it, so you can see what's going on, so that would probably be my biggest… Be aware how fragile these babies are cause they are, so, really keeping testing to a minimum but making sure it's sufficient so that can get the information so that the changes can happen." (#3)*

Advocate. The nurses reiterated the importance of being an advocate for their patients. Being unrelenting, always trying to find ways to look out for their patients' interests is what defined their role as an advocate. "Find another physician if you can't get through to this one" or "bring it up during rounds" were some of the advices. To the participants, the nurses who are the best advocates are the nurses who are the most knowledgeable about the research which their patient is involved in:

> *"Well, read the study. Know what's involved in it. Ask questions, educate yourself. And if you feel it's not in best interests of you patient, I mean just express that opinion." (#2)*

Bedside nurses were encouraged to not only advocate on babies' behalf but also to seek help from a senior nurse if they were not sure or afraid to advocate on their own. The participants admitted that being able to speak up comes with experience:

> *"…we do work at a teaching research hospital, so it's always a part of our work life…be supportive, but yet still remain a patient advocate, still look out for what's best for the baby, but support research when you can, when no additional risk or harm to the child. Now, I know, it will probably take years of nursing practice. It is tough for "early" nurses to achieve that balance: what should I advocate for… I should not be poking this baby 6 times for bloodwork… But even if you are unsure, just maybe go to a nurse that's more senior, get advice from her, just remain a strong patient advocate, but yet support research and furthering of bettering the care we give to these little ones." (#6)*

Be receptive to research. The participants said that the importance of conducting research to the progress of medicine and to the future of high-risk infants has to be recognized by all nurses. The nurses wanted their colleagues to keep in mind that their practice must be evidence- or research-based. Recognizing that evidence-based practice is a relatively new aspect of nursing care, bedside nurses were encouraged to "keep up" with current research, be tolerant of the multiple studies conducted in the unit, and to educate themselves by reading current literature:

> *"… if we don't do research we might be harming babies. So, yes, sometimes when you are having a busy day and you've got this research aspect of your job to do, that yeah, it may suck at that point, but it is very important to do. And I think…the younger ones are more tolerant, because we've all been in school and we've all done research for school, so we kind of know, whereas if you have the ones closer to retirement, they want no part of research, absolutely no part in research studies… And the older ones are just…forget it, I am not going to do it…they are just stuck in their ways…this is how I am going to do it…I guess they call it "ICU" personalities…it's a battle…Just read the journal. Even if you are not going to read the whole thing, read the conclusion, just read… what we did 25 years ago, may have be the worst thing that we've done…It's just…sometimes it is so frustrating when you are getting report from these nurses and you know…Oh, my goodness, just read the journal."(#5)*

According to the nurses, being receptive and supportive of research involves getting to know the research staff well and approach them with any concerns about the research. Communication was considered to be a significant factor in the success of minimizing the risks to infants involved in research:

> *"Get to know who the researchers are and if you have any questions, call them. Don't get frustrated with what you are doing. If things are not…if you are supposed to be doing now that's just not working, just call them and tell them what's going on…the nurse, because we are at the bedside, we are there all the time, we know how many studies is he going to be on and what this is going to be like, and what we are doing with this, just voice these at rounds, bring them up at that time. Keep in touch with them." (#7)*

Types of regulations pertaining to high-risk infants in research. When discussing additional rules or regulations pertaining to involvement of high-risk infants in research, the participants' answers ranged from "no additional regulations are necessary" to the necessity of "translating" the informed consent forms into lay language, and to taking the gestational age of infants involved in research into consideration. Additionally, while keeping babies safe was number one priority, the significance of including all populations in research was mentioned. Finally, nurses reinforced, again, that it would be beneficial to know the results of the studies that their patients participated in.

Minimize the risks. The nurses reinforced that the most important aspect was to keep all babies safe, and make sure that the parents knew that, regardless of their decision to participate, their babies would be safe and well-cared for. To the participants, "keeping babies safe" included strictly following the studies' criteria and keeping invasive procedures to a bare minimum:

> *"Regulations…invasive to only get done when we are already doing invasive." (#5)*

> *"I think they should have certain criteria on when this baby comes off the research study, sometimes I think they push it too far. And sometimes it makes the course a little bit high-risk for the infant, whereas if we took him off sooner, they would have had a better course. Just make sure that the baby's health is not at risk. You have to test certain things and you have to research certain things. But sometimes risk…they should look at risk and well being of the infant. And if the infant is not doing well in a research study, then it comes off. When sometimes they kind of wait a little bit longer than they should…It's almost like doctors are trying…it took so long to get consent that they want to protect their participants*

> *as much as they can, where they are maybe not protecting it, making it worse, and that's hard…It's a battle between nurses and doctors. It's a battle anyways, then you add research into it, just makes it that much harder."(#5)*

Include all populations in research. Many nurses expressed concern about certain risks to infants in research and shared concern about the need for the regulations to be on guard to minimize the risks of including infants in research. However, some of the nurses elucidated to the fact that it was important to keep conducting studies which involve high-risk infants and, in fact, unethical *not* to include high-risk infants in research:

> *"…I think sometimes too, with research, the risk is NOT involving some people in it as well; you know that the outcome might be bad and this might be a chance for them to get some help, as well. It's an access to medications or care that they just don't have… with high-risk infants, there is always an issue of the risk/benefit: is there a benefit or would we do more harm to this child by putting them on a study?"(#7)*

The nurses explicated that without conducting research that involves high-risk infants, there would be no benefit to the high-risk infants in the long run:

> *"And you hear of studies that they would have liked to have done, but the risk factor was too high. Some infants born at a certain gestational age, say 25-26 weeks, we know they might have a very difficult outcome…And that's big, especially with their brain or their lungs. So, that's given a lot of thought. Yes, it would be a good project, but if you can't sign anybody up for it, and you think that the risk factor is too high, you can't go ahead and do it. We don't know how we get that information and you can only do so many animal research before you actually have to apply it to the humans. There are different ways of looking at it."(#7)*

Make it easier for the parents. The participants maintained that making an informed consent form simple, limiting the number of concurrent studies that parents are invited to participate in, and approaching parents gently, would all ensure families' easy transitions to the world of research and allow them to make the best decision for their infants.

Informed consent is an integral part of the parent – researcher relationship and it assures that the parents clearly understand what a study involves. According to the

nurses, parent – researcher communication is only successful when the parents can understand all of the language and content of the informed consent form:

> *"Well, the informed consent. Understandable consent…you know, there is not a lot of medical language, so whenever the parents are given the consent, that they are able to understand in a very basic level what they are getting involved with." (#4)*

The nurses added that not only the written informed consent, but also verbal communication about the research, between the parents and the physicians or study investigators, should be kept to the use of simple terminology and generally be adapted to the parents' "levels":

> *" Um… that someone is available to answer their questions in a basic…often they find some of the research doctors that come by, they speak way above the heads of the parents; the parents really have no idea what they are talking about…Often, I like being at the bedside when the research doctors are talking to the parents, so that you can reinforce after he leaves, you can reinforce to the parents what you've heard him say. Often they might have questions like 'what did he mean by that', and you can…They are just basically everyday people who are overwhelmed with the situation and they don't know a lot of the lingo and terminology that's being used, so…Lay language-way. So, those are really important. People don't know what a double blind study versus…different kinds of data…I don't even know that as a nurse working in the nursery."(#4)*

The participants felt that not only the number of studies, which the parents are approached about, should be limited, but also the way with which the parents are approached should be geared towards "a no-guilt-approach":

> *"…They've said no, they don't want the baby involved in the study. Enough. Cause the mother is almost in tears, cause now she feels guilty. Because now mom is holding back the tears, now it's almost she feels guilty that her baby is not going to be involved, you can almost see that she is almost on the verge of saying yes, she should not be saying yes. Her first response was no…that's no way of getting consent to be enrolled in a study."(#5)*

<u>Take gestational age into consideration</u>. The researchers, as well as ethics board members should take the gestational age of an infant participating in a study into account, by being

not just simply aware of it, but also understanding the risks associated with each week that an infant is born before its due date:

> *"…you could do more sampling on a baby that was close to term than you could on a baby that was under 36 weeks and you would see less decompensation on a baby that was closer to term versus the baby that is preterm. You would see quicker healing from a heel poke on a baby who is closer to term versus preterm, and* [better] *maintaining the skin integrity on a perineum with a urine bag being put on a closer to term, just because they are less fragile. And that's even including a child with congenital heart defect, maybe very fragile, but they are far less fragile than the smaller babies. So, gestation makes a huge difference…" (#3)*

> *"The types of regulations…say it should be dependent on um…the gestational age. As a child matures, their tolerance for handling improves and increases. As a child matures, the skin becomes less fragile, more tolerant. The small babies… different things happen at different gestations, so, say, um…retinopathy is less likely to happen in a baby greater than 36 weeks gestation versus the baby that is 28 weeks gestation…their skin is better, they are more tolerant."(#3)*

Make results available. Making the results available was important to the participants. Knowing what came of the studies made them feel as though their work was appreciated. The nurse felt that having the results available would also reinforce the necessity of the research:

> *"And just regulations that…nice to know what some of the results are. I don't know whose job it would to keep the nurses informed, maybe we can get an update on our education days, cause on our unit we have scheduled education days, twice a year. Maybe our clinical teacher should update us on each study at those times. I think that people would be more interested in participating in the studies, show more active interest in research if they knew what the results were…and how it impacts the care that we deliver."(#4)*

> *"There are a lot of research projects and sometimes you do feel a little overwhelmed cause there is never a stop… there is always more and more coming and…now that we've got into evidence-based practice, there is a lot of nursing research and RTs are doing research and the doctors are doing research, it seems that a lot of people doing research and we do get some feedback from our clinical nurse specialist, preliminary results of what they find. So, hearing the results* [would be] *a positive too. Then you feel that you've contributed in a way. Otherwise you just feel like a drone doing the work."(#7)*

Chapter Summary

Chapter four presented this study's findings. The participants of the study were described. A description of the essence of the neonatal nurses' experiences caring for high-risk infants involved in research was presented. The essence of these experiences was safeguarding patients, minimizing the risks to infants being involved in research. This was followed by the presentation of the three themes which further supported this essence. First theme, *feelings within*, talked about the positive and negative feelings that reflected the nurses' perceptions of the risks of involving infants in research. The second theme, *keeping it near and dear*, reflected the nurses' past experiences of caring for the infants involved in research and learning from it. The third theme, *making it safer*, presented the nurses' recommendations to parents, health care professionals, and researchers on how to minimize the risks associated with involving infants in research. Next chapter will present a discussion of the findings in view of relevant existing literature, and outline the implications of the study for nursing education, practice, and research. In addition, strengths and limitations will be reviewed.

CHAPTER FIVE: DISCUSSION OF FINDINGS

Introduction

Chapter five presents a discussion of the findings. The essence of neonatal nurses' experiences and the themes supporting the essence were identified through the analysis of the participants' interviews and a focus group. These research findings are compared to previous research studies and are discussed in light of these studies. The applicability of a combination of the Theory of Caring and the Demand-Control Model as the conceptual framework is described. Strengths and limitations of the study are presented. This chapter concludes with a discussion of the implications of the study for nursing practice, education, and research.

The Theory of Caring and the Demand-Control Model in Light of Study Findings

This qualitative study was guided by a combination of two theories: the theory of caring (Roach, 1989) and the demand-control model (Karasek, 1979). Chapter two described these theoretical frameworks and the possible links between the main concepts in these two frameworks and nurses' experiences. It was helpful to the data analysis and interpretation to understand how demand and control over their job situations can affect nurses caring for the high-risk infants involved in research. It was felt that for more senior, experienced nurses, who had participated in this study, experience played a significant role in guiding their caring abilities. The experience affected their abilities to control certain work-related demands. The balance of control and demands seemingly affected their caring behaviours: compassion, competence, confidence, conscience, and commitment. The extent of experience working in the critical care setting might affect the nurses' abilities to balance work demands and their control over these demands. The

interviews with nurses provided descriptions that enriched understanding of these experiences. These descriptions are discussed under the main concepts of both theories.

The main postulate of Roach's theory is that caring is not unique *to* nursing but is unique *in* nursing. Gradually, through their professional development, nurses are able to build on their caring nature. The five human behaviours or Cs within which nurses may express their caring are: compassion, competence, confidence, conscience, and commitment. The basic premise of Karasek's demand-control model is that, depending on the perceived control over a situation, added demands at work can either lead to work-related stress or job satisfaction. An analysis of the two theories led to the proposition that the demand-control balance has the potential to influence the behaviour of nurses, or five C behaviours.

Compassion

Compassion is described by Roach as sensitivity to the painful experiences of other human beings. Compassion is often considered a main attribute of caring. This behaviour was evident in the nurses' passionate descriptions of their efforts to protect infants from situations that were deemed as "less safe" in research. Nurses felt that they were in control when they provided compassionate care. Making an infant as comfortable as possible for a procedure or talking to the parents and explaining a procedure was the compassionate care within their control. Being able to provide the most compassionate care possible to the infants and their parents diminished the stressful effects of having to do additional tasks for the infants involved in research.

However, there were situations which made the nurses uncomfortable or caused them moral distress. These situations involved caring for an infant involved in a study

which perhaps did not impose an optimal treatment for the infant. It was evident from some of the nurses' accounts that they perceived these kinds of situations as not being under their control. Thus, they felt distress, which can potentially lead to burnout.

Competence

Competence is the state of having the knowledge, judgment, and skills required for the demands of one's professional responsibility (McCance, McKenna, & Boore, 1999). All of the nurses who participated in this study had many years of professional experience working in neonatal intensive care units. Moreover, most of the nurses in this study had decades of experience looking after high-risk neonates. Although all of the nurses interviewed for this study were competent in their care for high-risk infants, some of the nurses expressed their concern with not always knowing all of the details of a study involving their patients, or not knowing "how the ethics committees are operated". The nurses reinforced that knowing the details of a study, or the decision making process, is important. Not having all of the information could potentially lead nurses to feel as though they are not in total control, which could lead to feelings of dissatisfaction with their work, and ultimately to burnout.

Confidence

Confidence is the quality which fosters trusting relationships (McCance et al., 1999). From the interviews, it was evident that the nurses were able to establish trusting relationships with the parents of their infant patients, as well as the physicians involved in the study. The nurses did not appear to lack confidence. The nurses reported that they would not hesitate to approach a physician if they had a concern about a study. This finding, in fact, could be due to the tremendous experience the nurses possessed, and due

to the development of what one nurse described as “the critical care nurse personality”. The “critical care personality” in nursing is often characterized by assertive traits (Levine, Wilson, & Guido, 1988), as well as by superb communication skills and knowledge (Monterosso, Kristjanson, Sly, Mulcahy, Holland, Grimwood, & White, 2005). The added demands of caring for an infant involved in research did not seem to affect nurses’ confidence.

Conscience

Described as a state of moral awareness, conscience is a compass directing one’s behavior according to their moral standards (McCance et al., 1999). This behavior was another of the “5 Cs” categories that did cause a certain amount of stress for the nurses. The nurses admitted that, as one nurse said, “it was hard” to watch the infants going through certain studies, mostly because a study was approved and research “has to be done”. The demands of having to care for infants involved in the studies that were deemed “not as safe” and the inability to control the circumstances can potentially cause stress. In fact, feelings of moral distress were reported by some of the nurses. The nurses reflected on those unsafe experiences as the ones that they will never forget.

Commitment

Most of the nurses in this study agreed that research can sometimes be an additional source of stress, adding to their already heavy workload. When nurses did perceive that looking after infants involved in research added to their workload, they admitted that their commitment to carrying out the tasks necessary for the research was affected. Some of the nurses said that on a busy day, getting a sample for a study was “the last thing” on their mind. In other words, the nurses’ commitment to caring for their

patients and their safety would take a priority over their commitment to the research study.

Research Findings

The Essence of Nurses' Experiences

The essence of nurses' experiences of caring for high-risk infants involved in research was the safety of their patients involved in research. In other words, when looking after high-risk infants involved in research, the nurses felt that their priority was to protect their patients, by advocating for optimal care. According to Erlen (2006), when it comes to vulnerable patients, "nurses need to safeguard their patients and act as their advocates" (p. 136). Much of the literature concur that NICU nurses are in the best position to look out for their patients' best interests (Hendricks-Munoz & Prendergast, 2007; Griffin, 2001). In Singhal et al.'s (2004) study nurses were less likely than physicians to agree with research involving infants if there were risks present.

The Safety Net

The nurses described themselves as a "safety net", which guarded their patients' welfare and acted as their advocates. The nurses described themselves as being unrelenting, vigilant, and protective. This finding is consistent with the literature in that nurses are described as nurturing and protective (Turner, Tomlinson, & Harbaugh, 1990) and vigilant, ensuring that their PICU patients receive the best quality care (Harbaugh, Tomlinson, & Kirschbaum, 2004). The literature further supports the finding that the nurses' role is to ensure patient safety and advocate on behalf of the patient (Griffiths, 2006; Oberle & Allen, 2006). To the nurses in this study, being the "safety net" included

not only watching over their patients and advocating for their patients, but also looking after the infants' families.

Watching over. The nurses stated that they felt that they were in a best position to protect the babies' interests by the virtue of being their "first parents". The nurses explained that frequently there is no continuous presence of the parents at the infants' bedsides, especially in the first few weeks. If the parents are there, the nurses stated, they are often scared, or too stressed to become responsible enough to make the best decisions for their infants. The literature confirms that being a parent in the NICU is a major stressor for the parents (Bell, 1997; Dudek-Shriber, 2004; Franck, Cox, Allen, & Winter, 2005; Griffin, 2001; Miles, Funk, & Kasper, 1991; Miles, Funk, & Carlson, 1993; Pohlman, 2005; Raeside, 1997). Thus, it is not surprising then that the NICU nurses might need to guard the infant patients.

Advocating. The nurses described themselves as the ultimate advocates for their patients. The participants of this study reported that if they felt that a certain procedure was not necessary or even harmful, they would speak up in order to guard the infant against harm or risk. If a procedure could be postponed to be carried out at a more convenient time for an infant, the nurses made sure that this would be the case. According to Erlen (2006), nurses are in the best position to speak up for their patients, especially when the patients are vulnerable.

Nurses' role of that being a patient advocate has been well supported by the literature (Thacker, 2008; Gosselin-Acomb, Schneider, Clough, & Veenstra, 2007; Oberle & Allen, 2006; Spence, 1998). All of the nurse participants in this study indicated that if they felt that the infants were at a direct health risk, such as an unacceptable

number of apnea and bradycardia episodes, they would "relentlessly" approach as many physicians as needed to get a baby off a research study. Spence states that the NICU nurses often do describe themselves as patient advocates. In fact, ninety-two per cent of the nurses in Spence's study reported themselves always to be advocates for the infants under their care. The nurses in this study stated that, due to their extensive expertise and experience with high-risk newborns, they felt that they had the right and responsibility to speak up not only for the infants under their care, but also for the infants cared for by more junior nurses.

Several nurses speculated that it is their assertive personality which plays a role in their ability to advocate. The fact that experience plays a key role in the NICU nurse's ability to advocate for the patients is supported in the literature (Berseth, Kenny, & Durand, 1984; Chally, 1992; Monterosso et al, 2005; Penticuff, 1989). In a study conducted by Spence (1998), sixty percent of the nurses listed knowledge and empathy, 43 percent mentioned assertiveness and communication skills, and 31 percent cited experience in neonatal nursing as necessary characteristics in order to be effective advocates for their patients. It was mentioned earlier that one of the nurses in this study referred to "the critical care nurse personality". To illustrate this further, the nurses in this study reiterated that when they were concerned about an aspect of a study, they would contact a study physician. However, if they had a "problem" with one physician, they would go to another one, as one nurse put it, "hunting them down". Therefore, it seems that the nurses' personalities can shape their ability to adequately advocate for their patients.

Looking after families. The participants identified multiple strategies to protect infants involved in research. Besides watching over their patients and advocating on their behalf, one of the ways in which the nurses ensured their patients' safety was ensuring that the parents have made an unbiased decision or have given an informed consent. These findings are consistent with the literature on infant safety in research, which identified such important aspects of safety of the infants involved in research as informed consent (Franck, 2005; Klepatsky & Mahlmeister, 1997; Thomas, 2005) and providing information to parents (Cheng et al, 2000). The nurses felt that it was particularly important to look out for infants' best interests in the environment of neonatal intensive care because of the adjustment period for the parents, therefore making nurses "substitute" parents. This finding is well supported in the literature, which describes the parents' difficulties adjusting to having a child in intensive care. The fathers, as well as, the mothers are reported to need this adjustment process (Wigert, Hellstrom, & Berg, 2008).

The nurses' role of being the "safety net" is evident in all three themes. The findings from each theme are discussed and compared to the similar findings from the literature.

Themes

The three themes supporting the essence of nurses' experiences caring for high-risk infants involved in research will be discussed in this section. These themes were: "feelings within", "keeping it near and dear", and "keeping it safe".

Feelings Within

This theme reflected the nurses' feelings about research involving high-risk infants, in relation to their view of risk involved in such research. These feelings ranged from being happy and supportive of the research to feeling moral distress.

Positive feelings experienced by the nurses when caring for high-risk infants involved in research included positive feelings toward research in general, recognizing its contribution to new treatments, and its benefit for the future patients. The literature consistently shows the consensus among nurses that research is important in improving the quality of care (Burnett et al, 2001; Singhal et al., 2004). The nurses in this study seemed especially appreciative of how much the research and development of new treatments and therapies has helped gestationally younger and sicker infants to survive with better outcomes.

Common to all of the nurses' accounts was their agreement that infants should participate in research, mostly to improve life for infants in the future. This finding is reflective of previous research studies looking at nurses' attitudes towards research involving infants as well as adult patients (Burnett et al, 2001; Singhal et al., 2004)**.** Similar to the results from the Singhal et al.'s study (2004), the nurses in this study agreed that it was important to involve infants in research with some additional risk, such as getting an extra poke or being extubated. The nurses stated that it was important because it will facilitate advancements in care for high-risk infants in the future. The literature reports similar parental views on involving infants in research. Morley et al.'s study (2005) results revealed that 93 percent of parents thought that their baby would get

the same or better care in a study. Most of the parents in that study (94 percent) believed that their baby's participation would improve care of future babies.

In certain situations, the nurses described feeling distressed. Nathaniel (2006) defines moral distress as moral pain affecting the mind, the body, or relationships which result from a patient care situation. In these situations, the nurse is aware of a moral problem, acknowledges moral responsibility, and makes a moral judgment about the correct action. However, as a result of real or perceived constraints, the nurse participates, either by act or omission, in a manner he or she perceives to be morally wrong. Moral dilemmas and decisional problems are not uncommon experiences in the discipline of neonatology (van Zuuren & van Manen, 2006). Pendry (2007) states that any of the following may contribute to feelings of moral distress: lack of time, institutional policies, or internal constraints resulting from nurses' belief system. Based on the nurses' replies, this study found that neonatal nurses experienced such feelings of discomfort or distress in situations when, for some reason, parents' consent to a study was biased, or when infants were not doing as well as they could have if they had not been enrolled in a study. One of the most common "perceived constraints" in those morally distressing situations was the approval of the studies that the infants were enrolled in, therefore making the nurses feel at the time that if a study was approved, it was safe for the infant.

The literature reports that a nurse can experience tension when his / her role as a bed-side nurse gets blurred with that of a research facilitator (Spilsbury et al., 2007). In this study, some nurses reported feeling conflicted when observing an infant experiencing negative health effects as a result of treatment assigned by a study. The conflict was

caused by knowing that research is important and on the other hand, feeling that they are responsible for their patient's well-being.

Not much evidence has been found in the literature on the nurses' feelings and experiences in caring for high-risk infants involved in research. However, the literature describes certain situations which can cause feelings of moral distress in the nurses involved in critical care and also feelings of moral distress in the nurses looking after patients involved in research in general. Moral distress is a significant problem in nursing, and is relatively common in neonatology as well as in any other field of nursing (Nathaniel, 2006; van Zuuren & van Manen, 2006; Pendry, 2007). It was identified in the literature review that the following circumstances can cause nurses working in the intensive care units to experience moral distress: continuing aggressive treatment when a patient is critically ill (Elpern, Covert, & Kleinpell, 2005; McClendon & Buckner, 2007; Hamric & Blackhall, 2007), caring for infants and children who would not otherwise be alive were it not for the advances of modern technology (Mekechuk, 2006), dealing with a dying infant (Gale & Brooks, 2006).

In neonatology, moral dilemmas often concern decisions regarding initiating or withholding treatment just after birth, and, in the following days or weeks, with regard to initiating, withholding, continuing or withdrawing treatment (van Zuuren & van Manen, 2006). The literature also informs of moral dilemmas that neonatal nurses report when infants are involved in research (van Zuuren & van Manen, 2006; Spence, 1998). In a study that examined the involvement of neonatal nurses in ethical issues, about 50 percent of the nurses reported that they saw an ethical dilemma when infants were involved in research (Spence, 1998). In general, the nurses in Spence's study experienced

feelings of moral distress when they believed that their patients were not receiving optimal care. In this present study, moral distress related to research was reported by the nurses in situations such as when an infant was enrolled in a clinical randomized trial and got the treatment that the nurses thought was "the wrong one" (CPAP instead of intubation). Another example of situations causing distress for the nurses was in those instances when a treatment could impose future harm such as when an infant was enrolled in a study requiring a blood sample, which could potentially lead to a future complication of a blood transfusion. Similarly, for the nurses in van Zuuren and van Manen's study (2006) the core dilemma was related to the potential for future harm. Nurses reported that the greatest dilemma had "to do with the handicaps induce with our treatment" (p.343). The nurses in that study felt that even if the treatment in the long run had the potential to better the infants' conditions, the short-term effects of suffering and a possible future harm outweigh potential future benefits. Overall, the work to date along with the findings from this present study suggest that neonatal nurses believe that unless the risks of being involved in a study are minimal, the potential benefits for the future infants are not worth imposing the harm on the infants in the present.

According to Erlen (2001), moral distress has become a pervasive problem, mostly due to nurses seeing themselves as ineffective advocates for their patients. Erlen ascribes this ineffectiveness to the shortage of nurses and as a result, nurses not having enough time to devote to the optimal care of their patients. In this study, nurses also experienced moral distress, caused by their inability to advocate for what they thought was the right treatment for the infants involved in research. Although the nurses did not indicate that being short-staffed affected their ability to advocate, Nathaniel (2006) and

Sundin-Huard and Fahy (1999) explain that moral distress leads to burnout and burnout leads to the shortage of nurses. Nursing shortage, in turn, leads to increased incidents of moral distress. Moral distress may contribute to the nursing shortage - an evident self-perpetuating downward spiral. Sense of powerlessness, inadequacy of staffing, and level of expertise were essential factors in experiences of moral distress in Sundin-Huard and Fahy's study. Moral distress was caused by nurses' inability to effectively advocate for a vulnerable patient. In this study, the parallel could be drawn between moral distress and a sense of powerlessness, as the nurses described being torn between "the research needs to be done" and "but it is so hard to see babies in here and now", perhaps not meeting their potential in the long run, or simply having extra procedures.

Hamric (2000) also identified powerlessness as a major contributing factor to nurses' feelings of moral distress. Hamric was wondering whether physicians and other health care providers are also experiencing moral distress, possibly relating it to the increasing advances in medicine. Hamric cites a late physician, William Bartholome, who claimed that moral distress is a common problem in nurses, among other health care professionals who are involved in care for vulnerable humans and have little power to interfere when their treatment appears "wrong".

Hamric (2000) identified factors contributing to moral distress, including nurses' perceptions of inadequate informed consent and the inability to advocate for their patient due to physician power. This is consistent with this study's findings in that some of the nurses also experienced feelings of being distressed, especially when they did not advocate for their patients. However, it was not necessarily because of a physicians

power, but because a study has been approved by the ethics committee and consented to by the parents.

Keeping it Near and Dear

"Keeping it near and dear" referred to remembering certain situations that caused the nurses in this study to feel moral distress. The nurses stated that they will always remember those situations, or the infants involved in them, and feelings that accompanied these experiences.

Research has contributed to significant improvements in the care of high-risk infants (van Zuuren & van Manen, 2006). While the results of research have contributed to the positive feelings about the research reported by the nurses, inadvertently it also contributed to instances of moral distress. Spiraling technology, among other factors, has contributed to an atmosphere in which nurses are faced with morally challenging situations (Nathaniel, 2006; van Zuuren & van Manen). Having experienced moral distress and moral regret in the situations when infants under their care were involved in research, the nurses reported that they would never feel comfortable nor would they ever forget the babies that they thought had suffered because of the research that they were involved in. Hamric (2000) and Nathaniel elucidate to the fact that many nurses vividly remember the situations in which they experienced moral distress years after the occurrence.

Nathaniel (2006) stated that nurses can remember the situations which caused them moral distress vividly, for years after the fact, if not for a lifetime. With images deep in their mind, Nathaniel's respondents said that they can still see the environment in which the situation took place, with such details as patients' names, ages, diagnoses,

faces, and locations of the patients' beds. Indeed, this study's participants reported that they could still remember their patients' names and their bed numbers, especially in the circumstances when the babies were randomized to the "wrong" treatment.

For nurses in Nathaniel's study (2006), telling their stories emerged as integral to the process of reflecting. Interestingly enough, the nurses in this study were, like the nurses in the study conducted by Nathaniel, mature and highly experienced. Perhaps, these are the nurses who went through memorable enough experiences and felt the need to "reckon" or to tell their stories. According to Nathaniel, nurses can still struggle with the conflict between doing what they thought was morally right and following the order many years later.

According to Nathaniel (2006), many nurses who experienced severe moral distress no longer work at the bed-side or do not work in the same place. All of the nurses in this study still worked in the intensive care unit at the time of the interviews. This fact could speak to their dedication, as well as their ability to learn from the past, and to optimize their future patients' care. The nurses stated that they regret those situations, but that they want to learn from them in order to prevent the same mistakes from happening again. Similarly, Nathaniel suggests that nurses' ability to move on depends on their ability to examine the past situations which caused the distress and how they might avoid similar situations in the future.

Making it Safe

The participants identified many means by which the safety of high-risk infants involved in research may be improved. These included recommendations to the parents, to the child health researchers, recommendations to the research nurses, and to the

bedside nurses. In addition, the nurses identified the regulations that should be in place when high-risk infants are involved in research. These recommendations are compared to the recommendations from the literature.

Recommendations to parents. Recommendations to the parents included reading the study thoroughly and going with their "gut instinct". In addition, the nurses stated that they would support the parents regardless of their decision to participate in a study or not. This finding is consistent with the literature describing nurses' beliefs that parents should be part of the decision making process and that they require emotional support (Spence, 1998), as well as the literature that reinforces parents' wishes to participate in research and a need to have freedom to make their own, informed, choice (Burgess et al., 2003; Hayman, Taylor, Peart, Gallard, & Sayers, 2001; Morley et al., 2005).

Recommendations to the child health researchers and to the REB members. The nurses' recommendations to the child health researchers and to the ethics board members included ensuring an ongoing, open communication with the parents, making an informed consent form simple and easy for the parents to read, limiting the number of research studies that the parents are approached to participate in simultaneously, and minimizing the risks for the infants involved. In addition, the nurses recommended that the researchers take nursing workload into consideration when proposing a study and involving bed-side nurses in the research ethics board committee meetings. The recommendations related to types of regulations pertaining to high-risk infants in research involved some similar points, such as to minimize the risks to the newborn participants and to make it easier for the parents. Consequently, the nurses advocate for stronger working relationships and greater communication between key stakeholders.

The notion of vulnerability and the need to minimize the risks for the infants involved in research is emphasized by the British Association of Perinatal Medicine (cited in McKechnie & Gill, 2006) framework for good practice. The Association highlights two key points: two-way clear communication with the parents and accurate documentation, which is critical to consent for neonatal research. Hoehn et al. (2005) concur that addressing parental concerns or "listening" to parents could help to enroll the babies in research. Hoehn et al state that focusing on parental concerns, such as benefits and risks for their infant, could enhance the parental permission process for parents of critically ill neonates. The nurses in this study reported that many times they had to proceed "with caution" when approaching the parents about a study that their infant could potentially be enrolled in, due to the well-known fact that being a parent of a baby in the NICU is a stressful experience. These findings are consistent with the literature, in that the practitioners must utilize a gentle approach when requesting consent from the parents. Manson (2007) stated that getting an informed consent from NICU parents is problematic because the parents are vulnerable, and may experience guilt whether they enroll their baby in research or not.

Singhal et al. (2002) reinforce that the physicians involved in conduct of newborn research must be alert to the possibility of undue parental influence, based on the fact that some parents might enroll their newborn in a study involving a risky procedure that would not benefit their baby. Burgess et al. (2003), aiming to understand parental perceptions of the process of recruitment and enrolment for research in the NICU, revealed that 90 percent of parents felt that they had made informed decisions, and 93 percent were against the option that a doctor decides if the newborn should be enrolled

into a study, rather than the parent. Morley et al. (2005) and Stenson et al. (2004) also reported that the majority of the parents in their studies wanted to be involved in the decision about their baby joining a study.

The participants of this study recommended limiting the number of studies that the parents were asked to participate in, in light of their experiences with parents who were already stressed out by having a sick baby in the NICU. Burgess et al. (2003) reported that 38 percent of parents in their study found that recruitment did add "stress to an already stressful situation"; in addition, most of the parents in that study had been requested to enrol their newborn into more than one trial. On average, parents in that study thought that they would be comfortable with enrolment into two studies. Morley, Lau et al. (2005) found that 22 percent of parents in their study were worried about the number of studies they were approached about. Ward Platt (2005) stated that although it is usually not a problem to ask the parents to participate in a few studies that are in progress simultaneously, this topic should be investigated further, as it may cause ethical concerns.

Making sure that parents are giving a truly informed consent was critical to the nurses' views of the notion of risk of involving high-risk infants in research. The importance of informed consent has been widely acknowledged in the literature (Dunn et al., 2005; McKechnie & Gill, 2006; Smith, 2000; Walterspeil, 1990). The findings of this study coincide with the recommendations made by McKechnie and Gill, for improvements to the consent process. The authors recommend providing the parents with information sheets that are easy to read and comprehend. The influence of socioeconomic status highlights the need to assess the autonomy of parents. The way in which

information is given needs to take into account parental abilities, because some parents might not be able to understand all of the information, or might not be able to read at all. In addition, Morley et al. (2005) reported that when asked how the process could be improved, parents suggested that information be made available before delivery.

The finding that there is a need to include the NICU nurses in the ethics committees is consistent with the literature. According to Franck (2005), neonatal nurses have played an important role in identifying topics of priority for research in the NICU setting. Franck stated that the advantages of neonatal nurses' roles in research are their participation in setting the research priorities and their involvement in the scientific review and critique of research submitted to research ethics committees.

Recommendations to the research nurses. The first recommendation to the research nurses was to become more familiar with the workplace. The nurses in this study felt that if the research nurses knew more about the specifics of high-risk infants' care, it would be beneficial to their conduct or research. It would increase research nurses' understanding of the risks to infants, associated with procedures that are done for research studies. In addition, it would enable the research nurses to become a bridge in communication between the bedside nurses, with their input for the current and future studies, and the study investigators. Interestingly, the literature identified similar concerns, but coming from the clinical research nurses. The research nurses reported lack of communication and lack of cooperation from the staff nurses (Hill & MacArthur, 2006; Spilsbury et al., 2007). It appears that perhaps the opposing findings could be addressed by improving open, two-way communication between the research and bedside nurses.

Recommendations to the neonatal nurses. The nurses' recommendations to their colleagues included being receptive to research, becoming familiar with study protocols, approaching research personnel with any concerns, and advocating on behalf of their patients. The roles of educating the parents, communicating with the study investigators, and advocating on the babies' and parents' behalf are consistent with the roles ascribed to the nurses who care for patients involved in research (Cheng et al, 2000; Di Giulio et al, 1996; Oberle & Allen, 2006). In this study, the identified barriers to successfully utilize research at work included nurses not being completely familiar with research methods and nurses being "stuck in their ways". Similarly, Winters et al. (2007) named such barriers to using research as lack of knowledge of research methods and lack of time to look up information.

Strengths and Limitations

Overall, this study is important as it provides new insights into the invaluable experiences of very experienced and passionate nurses caring for high-risk infants involved in research. Except for Singhal et al.'s (2004) study that focused on nurses', among other health care providers' attitudes towards involvement of newborns in research, there have been no other studies that described and analyzed nurses' experiences. Features of the research design that helped to contribute to the in-depth findings are discussed in this section. Limitations are also discussed.

An exploratory description was an appropriate methodology for this study. An exploratory descriptive study is an intense investigation of the meaning of a phenomenon for a group of people (Parse, 2001). Therefore, this design was conducive to exploring an under-researched phenomenon of nurses' experiences of caring for high-risk infants

involved in research. A qualitative descriptive design allowed for the examination of the topic, capturing not only the expected elements of the phenomena, but also some unanticipated themes (Sandelowski, 2000).

Another strength of this study was the small sample size. A small sample size in certain qualitative design studies is acceptable and even welcomed, in order to elucidate the richness of the individual experience, with many examples of small sample size studies being present in the literature (Woodgate, 2000). The nurses for this study were selected by the purposive sampling technique; the strength of purposive sampling is in selecting information-rich cases. The intent of such technique is not to generalize, but to arrive at an in-depth understanding of an under investigation phenomenon (Patton, 1990; Sandelowski, 1995). According to Woodgate, it is necessary to narrow the sample criteria by focusing on the lived experience of the participants, accessing their personal accounts. The two criteria of the sample in this study were nurses' employment in the NICU, and at least two years of experience working with neonates.

Additionally, a strength of this study was the site of sample recruitment. Being a major tertiary health centre in Winnipeg, Children's Hospital's NICU is a site where many research studies that involve high-risk infants are conducted. Therefore, the nurses who work there typically have an abundance of experience looking after high-risk infants involved in research.

Another strength of the study was the use of open-ended interviews as they afforded the nurses to share their stories about caring for infants in research. A focus group was conducted in addition to the individual interviews. Wong (2008) states that a focus group discussion's objective is to give the researcher an increased understanding of

the participants' perspective on the topic in discussion. An advantage of a focus group is the interaction among group members. Indeed, conducting a focus group for this study allowed for the participants to interact with one another, exchange ideas and comments about each other's experiences. Wong states that a focus group should not be so large as to preclude adequate participation by most members. The focus group in this study consisted of three highly experienced nurses. Wong states that in fact, smaller groups are preferred when the participants have an intensive experience to share about the topic, which was the case in this study.

Limitations of this study mainly are associated with the sample. Specifically, this study could be strengthened by collecting the views of the parents and health care professionals, other than nurses, that are involved in the care of the high-risk infants involved in research. The addition of newer nursing graduates would have provided more depth to representation in the sample and would have strengthened the study; a focus group comprised of more junior nurses, or a mixture of junior and senior nurses would enrich the study's findings as well. Furthermore, longitudinal data collection would have been beneficial to this study. Following up on the results of the first interview, the nurses could have been interviewed several more times, thus strengthening and re-affirming the findings of this study.

Being a novice researcher, the principal investigator lacked certain experience in interviewing skills, perhaps somewhat limiting the data collected. However, this limitation was compensated for with the suggestions and directions given by the thesis supervisor after each interview, and with her guidance during the focus group interview.

Recommendations

This section presents recommendations arising from this study results. These recommendations are divided among the areas of nursing practice, nursing education, and nursing research.

Nursing Practice

Several implications for nursing practice emerged from the results of this study. These implications would provide guidance for nurses, as well as other health care professionals, such as physicians, respiratory therapists, and child health researchers, on how to minimize the risks that are involved in conducting research with high-risk infants.

First, nurses working with high-risk infants involved in research must be aware that such research presents some risks. The risks could involve direct harm to the infants, or it could involve traumatizing the parents or nurses themselves. Nurses should be aware of these risks and try to minimize them. For example, nurses should always know the criteria for the study in which their patient is involved. Child health researchers should always ensure easy access to these criteria for the nurses. The nurses also encouraged their colleagues to voice their concerns, or at least to ask for help from a more experienced nurse. Erlen (2001) supports this recommendation, commenting that young nurses, in particular, would benefit from finding a mentor who can offer guidance and support. A more experienced nurse is a perfect example of a mentor.

The risks to conducting research on high-risk infants involves certain risks to the nurses themselves, such as experiencing negative feelings or feelings of moral distress. Hamric (2000) suggests that physicians need to acknowledge and respect nurses' feelings of moral distress. Perhaps, ethics rounds could be utilized to discuss and analyze these

kinds of feelings. Erlen (2001) suggests facilitating a dialogue among the staff to address moral distress. In addition to verbally discussing their experiences, nurses can bring up their concerns through the communication books, suggestion boxes, and scheduled unit meetings. Nathaniel (2006) states that a moral reckoning, or reflecting and sharing experiences can help nurses to deal with troubling events; even a simple discussion of an event over a coffee break can help nurses to sort out their feelings. Therefore, all nurses should be encouraged to speak about their experiences, whenever they get an opportunity.

Hamric (2000) brings up the important point that sometimes moral distress can be caused by a lack of knowledge about a certain treatment. In a case like this, the distress could be avoided by a clear communication between those who are involved in patient care and those who are involved in decision-making. For example, as some of the nurses in this study suggested, a clear description of a study and its criteria, inclusion as well as exclusion, should be always posted by a patient's bedside. Some of the nurses in this study, who work primarily night shifts, indicated that it is particularly important to them to have a clear and easily accessible description of research studies in which their patients are involved, due to the fact that most in-services on research conducted in the unit happen during the day.

The nurses in this study admitted that although initially the parents may be overwhelmed with their infant's care and the decisions, such as the inclusion of their infant in a study, they are still ultimately the decision-makers. The nurses indicated that they, as well as other members of the health care team, should support parents in their role of decision maker, and ensure that adequate information about the research is

provided to the parents. Catlin (2007) concurs that such information must be accurate, understandable, and include risks and benefits that the parents should be able to weigh.

Finally, the study findings demonstrated the need for all nurses to be more accepting of research. Some of the recommendations made by the participants included keeping up with current research by reading journals, being more flexible, and maintaining positive attitudes towards research in the nursery.

Nursing Education

Implications for nursing education include the need for students to understand the importance of including parents into the decision making and advocating on their patient's behalf. It is important for students to understand that, not only a mother but also her partner, need to be included in the decision making, and to encourage both parents to play an active role in discussions related to inclusion of their neonate in research.

The results of this study showed that not all nurses have sufficient training in research methods. In light of increasing practice of evidence-based nursing, inclusion of research methods in nursing curriculum is of utmost importance. It is pivotal for the nurses, who had not had sufficient training in research methods, to be offered some courses or workshops on research methods. In addition, the nurses indicated their lack of knowledge in regards to the functioning of the research ethics board committees. Therefore, it would be important to perhaps organize workshops that describe the work of an REB committee.

Nursing Research

The findings of this study demonstrated that neonatal nurses' input is essential when implementing studies that involve high-risk infants. Collaboration of various health

care providers, including physicians and the NICU nurses, is necessary to minimize the risks to high-risk infants involved in research.

Finally, further studies are needed to explore nurses', other health care professionals', and parents' perceptions on how to minimize the risks to high-risk infants involved in research. A larger sample size, a different sample, a sample drawn from multiple locations, is necessary to confirm these findings and to investigate whether the themes repeat; results might identify additional themes and areas on which nurses should focus when caring for high-risk infants involved in research.

Chapter Summary

In conclusion, this chapter provided a discussion of the study's findings. The essence of nurses' experiences and four themes supporting the essence were discussed. The discussion of the research findings identified nurses' concerns and proposed strategies with regards to minimizing the risks of involving high-risk infants in research. Methodological strengths and limitations of the study were presented. This study contributed to an increased understanding of neonatal nurses' experiences of caring for high-risk infants involved in research. More specifically, the study identified certain risks that are involved in research with high-risk infants. Recommendations were made for nursing practice, education, and future research.

REFERENCES

Alt-White, A. & Pranulis, M. (2006). Addressing nurses' ethical concerns about research in critical care settings. *Nursing Administration Quarterly, 30*(1), 67-75.

Bakker, A., Le Blanc, P., & Schaufeli, W. (2005). Burnout contagion among intensive care nurses. *Journal of Advanced Nursing, 51*(3), 276-287.

Ballard, H., Shook, L., Desai, N., & Anand, K. (2004). Neonatal research and the validity of informed consent obtained in the perinatal period. *Journal of Perinatology, 24*, 409-415.

Bell, S. (2004). The pharmacology of palliative care. *Neonatal Network, 23*, 61–64.

Berseth, C., Kenny, J., & Durand, R. (1984). Newborn ethical dilemmas: Intensive care and intermediate care nursing attitudes. *Critical Care Medicine, 12*(6), 508- 511.

Biel, M., Eastwood, J-A., Muenzen, P., Greenberg, S., & Viejo, A. (1999). Evolving trends in critical care nursing practices: Results of a certification role delineation study. *American Journal of Critical Care, 8*(5), 285-290.

Burgess, E., Singhal, N., Amin, H., McMillan, D., & Devrome, H. (2003). Consent for clinical research in the neonatal intensive care unit: A retrospective survey and a prospective study. *Archives of Disease in Childhood Fetal and Neonatal Edition, 88*(4), F280-F286.

Burnett, C., Koczwara, B., Pixley, L., Blumenson, L., Hwang, Y., & Meropol, N. (2001). Nurses' attitudes toward clinical trials at a comprehensive cancer centre. *Oncology Nursing Forum, 28*(7), 1187-1192.

Campbell, L. (1990). The not-so-ancient history of neonatal research. *Neonatal Network*, *9*(3), 82-84.

Canadian Institute for Health Information (2004). Giving birth in Canada: A regional profile. Ottawa, Ontario: Author.

Canadian Institute for Health Information (2006). Giving birth in Canada: The costs. Ottawa, Ontario: Author.

Catlin, A. (2007). Commentary on NANN Position Statement 3015. NICU Nurse Involvement in Ethical Decisions (Treatment of Critically Ill Newborns). *Advances in Neonatal Care, 7*(5), 269.

Chally, P. (1992). Moral decision making in neonatal intensive care. *Journal of Obstetric, Gynecologic, and Neonatal Nursing, 21*(6), 475 -482.

Cheng, J., Hitt, J., Koczwara, B., Schulman, K., Burnett, C., Gaskin, D., Roeland, J., & Meropol, N. (2000). The impact of quality of life on patient expectations regarding phase 1 clinical trials. *Journal of Clinical Oncology, 18*(2), 421-428.

de Rijk, A., Le Blanc, P., Schaufeli, W., & Jonge, J. (1998). Active coping and need for control as moderators of the job demand-control model: Effects on burnout. *Journal of Occupational and Organizational Psychology, 71*, 1-18.

Di Giulio, P., Arrigo, C., Gall, H., Molin, C., Nieweg, R., & Strohbucker, B. (1996). Expanding the role of the nurse in clinical trials: The nursing summaries. *Cancer Nursing, 19*(5), 343-347.

Downey, V., Bengiamin, M., Heuer, L., & Juhl, N. (1995). Dying babies and associated stress in NICU nurses. *Neonatal Network, 14*(1), 41-46.

Dudek-Shriber, L. (2004). Parent stress in the neonatal intensive care unit and the influence of parent and infant characteristics. *The American Journal of Occupational Therapy, 58*(5), 509 -520.

Dunn, P., Gies, M., & Peters, M. (2005). Perinatal litigation and related nursing issues. *Clinics in Perinatology, 32*(1), 277-290.

Elpern, E., Covert, B., & Kleinpell, R. (2005). Moral distress of staff nurses in a medical intensive care unit. *American Journal of Critical Care, 14*(6), 523-530.

Erlen, J. (2001). Moral distress: A pervasive problem. *Orthopedic Nursing, 20*(2), 76 -80.

Ewing, A. & Carter, B. (2004). Once again, Vanderbilt NICU in Nashville leads the way in nurses' emotional support. *Pediatric Nursing, 30*(6), 471-472.

Franck, L. (2005). Research with newborn participants: Doing the right research and doing it right. *Journal of Perinatal & Neonatal Nursing, 19*(2), 177-186.

Franck, L., Cox, S., Allen, A., & Winter, I. (2005). Measuring neonatal intensive care unit-related parental stress. *Journal of Advanced Nursing, 49*(6), 608 -615.

Gale, G. & Brooks, A. (2006). Family teaching toolbox. A parents' guide to palliative care. *Advances in Neonatal Care, 6*(1), 54 -55.

Gerrish, K. & Lacey, A. (2006). *The research process in nursing* (5th ed.). Malden, MA: Blackwell Publishing Ltd.

Golec, L., Gibbins, S., Dunn, M., & Hebert, P. (2004). Informed consent in the NICU setting: An ethically optimal model for research solicitation. *Journal of Perinatology, 24*, 783-791.

Gosselin-Acomb, T., Schneider, S., Clough, R., & Veenstra, B. (2007). Nursing advocacy in North Carolina. *Oncology Nursing Forum, 34*(5), 1070 -1074.

Griffin, T. (2001). Parental visits and infant care: Understanding parents' needs. *Neonatal Network, 20*(1), 65.

Griffiths, P. (2006). Being a research participant: The nurse's ethical and legal rights.

British Journal of Nursing, 15(7), 386 -390.

Grodin, M. & Glantz, L. (Eds.) (1994). *Children as research subjects: Science, ethics and law*. New York, NY: Oxford University Press.

Gutierrez, K. (2005). Critical care nurses perceptions of and responses to moral distress. *Dimensions of Critical Care Nursing, 24*(5), 229–241.

Hagedorn, M. & Gardner, S. (1999). Legal issues in neonatal nursing: Considerations for staff nurses and advanced practice nurses. *JOGNN, 28*(3), 320-330.

Hamric, A. (2000). Moral distress in everyday ethics. *Nursing Outlook, 48*(5), 199 -201.

Hamric, A. & Blackhall, L. (2007). Nurse-physician perspectives on the care of dying patients in intensive care units: collaboration, moral distress, and ethical climate. *Critical Care Medicine, 35*(2), 422 -429.

Harbaugh, B., Tomlinson, P., & Kirschbaum, M. (2004). Parents' perceptions of nurses' caregiving behaviors in the pediatric intensive care unit. *Issues in Comprehensive Pediatric Nursing, 27*(3), 163 -178.

Hayman, R., Taylor, B., Peart, N., Galland, B., & Sayers, R. (2001). Participation in research: Informed consent, motivation and influence. *Journal of Paediatrics and Child Health, 37*(1), 51-54.

Hendricks-Munoz, K. & Prendergast, C. (2007). Barriers to provision of developmental care in the neonatal intensive care unit: neonatal nursing perceptions. *American Journal of Perinatology, 24*(2), 71 -77.

Heuer, L., Bengiamin, M., Downey, V., & Imler, N. (1996). Neonatal intensive care nurse stressors: An American study. *British Journal of Nursing, 5*(18), 1126-1130.

Hill, G. & MacArthur, J. (2006). Professional issues associated with the role of the research nurse. *Nursing Standard, 20*(39), 41 -47.

Hoehn, K., Wernovsky, G., Rychik, J., Gaynor, J., Spray, T., Feudtner, C., & Nelson, R. (2005). What factors are important to parents making decisions about neonatal research? *Archives of Disease in Childhood Fetal and Neonatal Edition, 90*(3), F267-F269.

Kain, V. (2007). Moral distress and providing care to dying babies in neonatal nursing. *International Journal of Palliative Nursing, 13*(5), 243 -248.

Karasek, R. (1979). Job demands, job decision latitude, and mental strain: implications for job design. *Administrative Science Quarterly, 24*, 285-308.

Kauffman, R. (1994). Scientific issues in biomedical research with children. In *Children as Research Subjects: Science, Ethics, and Law*. Grodin, M. and Glantz, L. (Eds.) New York, NY: Oxford University Press.

Keane, A., Ducette, J. & Adler, D. (1985). Stress in ICU and non-ICU nurses. *Nursing Research, 34*(4), 231-236.

Kenner, C. & McGrath, J. (2004). *Developmental care of newborns & infants: A guide for health professionals.* Philadelphia, PA: Mosby

Kenner, C., Wright Lott, J., & Applewhite Flandermeyer, A. (1998). *Comprehensive neonatal nursing: A physiologic perspective.* Philadelphia, PA: W.B. Saunders Company.

Klepatsky, A. & Mahlmeister, L. (1997). Consent and informed consent in perinatal and neonatal settings. *Journal of Perinatal and Neonatal Nursing, 11*(1), 34-52.

Lee, S., McMillan, D., Ohlsson, A., Pendray, M., Synnes, A., Whyte, R., Chien, L., &

Sale, J. (2000). Variations in practice and outcomes in the Canadian NICU network: 1996-1997. *Pediatrics, 106*(5), 1070-1079.

Leininger, M. (1988). Leininger's theory of nursing: Cultural care diversity and universality. *Nursing Science Quarterly, 1*(4),152-160.

Levine, C., Wilson, S., & Guido, G. (1988). Personality factors of critical care nurses. *Heart and Lung, 17*(4), 392-398.

Lincoln, Y. & Guba, E. (1985). *Naturalistic inquiry*. Thousand Oaks, CA: Sage Publications.

Lippman, H. & Arnold, L. (2005). Banish burnout! *RN, 68*(8), 61-2, 64, 66.

Lussky, R. (1999). A century of neonatal medicine. *Minnesota Medicine, 82*(12), 48-54.

MacDonald, M., Mullett, M., & Seshia, M. (2005) (Eds.). *Avery's neonatology: Pathophysiology and management of the newborn* (6th Ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

Manson, N. (2007). *Rethinking informed consent in bioethics*. Cambridge; New York: Cambridge University Press.

Mark, B. (2002). What explains nurses' perceptions of staffing adequacy? *Journal of Nursing Administration, 32*(5), 234-241.

McCance, T., McKenna, H., & Boore, J. (1999). Caring: Theoretical perspectives of relevance to nursing. *Journal of Advanced Nursing, 30*(6), 1388-1395.

McClendon, H. & Buckner, E. (2007). Distressing situations in the intensive care unit: A descriptive study of nurses' responses. *Dimensions of Critical Care Nursing, 26*(5), 199 -206.

McIntosh, N., Bates, P., Brykczynska, G., Dunstan, G., Goldman, A., Harvey, D., et al.

(2000). Guidelines for the ethical conduct of medical research involving children. Royal College of Paediatrics, Child Health: Ethics Advisory Committee. *Archives of Disease in Childhood, 82*(2), 177-182.

McKechnie, L. & Gill, A. (2006). Consent for neonatal research. *Archives of Disease in Childhood: Fetal and Neonatal Edition, 91*(5), F374 -376.

Mekechuk, J. (2006). Moral distress in the pediatric intensive care unit: the impact on pediatric nurses. *International Journal of Health Care Quality Assurance Incorporating Leadership in Health Services, 19*(4-5), i –vi.

Menikoff, J. (2004). The involuntary research subject. *Cambridge Quarterly of Healthcare Ethics, 13*(4), 338-345.

Merriam-Webster Online Dictionary. Retrieved on September 1, 2006 from http://www.m-w.com

Mifflin, P. (2003). *Saving very premature babies: Key ethical issues*. Philadelphia, PA: Elsevier Science Ltd.

Miles, M., Funk, S., & Kasper, M. (1991). The neonatal intensive care unit environment: sources of stress for parents. *AACN Clinical Issues, 2*(2), 346 -354.

Miles, Funk, & Carlson, (1993). Parental Stressor Scale: neonatal intensive care unit. *Nursing Research, 42*(3), 148 -152.

Monterosso, L., Kristjanson, L., Sly, P., Mulcahy, M., Holland, B., Grimwood, S., et al. (2005). The role of the neonatal intensive care nurse in decision-making: advocacy, involvement in ethical decisions and communication. *International Journal of Nursing Practice, 11*(3), 108 -117.

Morley, C., Lau, R., Davis, P., & Morse, C. (2005). What do parents think about

enrolling their premature babies in several research studies? *Archives of Disease in Childhood Fetal and Neonatal Edition, 90*(3), F225-F228.

Morse, J. & Field, P. (1995). *Qualitative research methods for health professionals* (2nd ed.). Thousand Oaks: Sage Publications.

Mueller, M. (2001). From delegation to specialization: Nurses and clinical trial co-ordination. *Nursing Inquiry, 8*(3), 182–190.

Mulcahy, C. & Betts, I. (2005). Transforming culture: An exploration of unit culture and nursing retention within a neonatal unit. *Journal of Nursing Management, 13*(6):519-523.

Nathaniel, A. (2006). Moral reckoning in nursing. *Western Journal of Nursing Research, 28*(4), 419 -438.

Oates, P. & Oates, R. (1996). Stress and work relationships in the neonatal intensive care unit: Are they worse than in the wards? *Journal of Pediatric and Child Health, 32*(1), 57-59.

Oberle, K. & Allen, M. (2006). Ethical considerations for nurses in clinical trials. *Nursing Ethics, 13*(2), 180-186.

Oehler, J., Davidson, M., Starr, L., & Lee, D. (1991). Burnout, job stress, anxiety, and perceived social support in neonatal nurses. *Heart and Lung, 20*(5), 500-505.

Parse, R. (2001). *Qualitative inquiry: The path of sciencing*. Sudbury, MA: Jones and Bartlett Publishers.

Patton, M. (1990). *Qualitative evaluation and research methods*. Newbury Park, CA: Sage.

Pendry, P. (2007). Moral distress: Recognizing it to retain nurses. *Nursing Economics,*

25(4), 217 -221.

Penticuff, J. (1989). Infant suffering and nurse advocacy in neonatal intensive care. The *Nursing Clinics of North America, 24*(4), 987 -997.

Pohlman, S. (2005). The primacy of work and fathering preterm infants: Findings from an interpretive phenomenological study. *Advances in Neonatal Care, 5*(4), 204 - 216.

Polit, D. & Beck, C. (2006). *Nursing research: Methods, appraisal, and utilization* (6th ed.). Philadelphia, PE: Lippincott Williams & Wilkins.

Purdy, I. (2004). Vulnerable: a concept analysis. *Nursing Forum. 39*(4), 25-33.

Raeside, L. (1997). Perceptions of environmental stressors in the neonatal unit. *British Journal of Nursing, 6*(16), 914 -6, 918, 920.

Raines, D. (1993). Deciding what to do when the patient can't speak: a preliminary analysis of an ethnographic study of professional nurses in the neonatal intensive care unit. *Neonatal Network, 12*(6), 43 -48.

Roach, M. (1998). Caring ontology: Ethics and the call of suffering. *International Journal for Human Caring, 2*(2), 30-34.

Rosenthal, S., Schmid, K., & Black, M. (1989). Stress and coping in a NICU. *Research in Nursing and Health, 12*(4), 257-265.

Sandelowski, M. (1986). The problem of rigor in qualitative research. *Advances in Nursing Science, 8*(3), 27-37.

Sandelowski, M. (2000). Whatever happened to qualitative description? *Research in Nursing & Health, 23*(4), 334-340.

Sandelowski, M. (1995). Sample size in qualitative research. *Research in Nursing &*

Health, 18(2), 179-183.

Sankaran, K., Chien, L-Y., Walker, R., Seshia, M., Ohlsson, A., Lee, S., & the Canadian Neonatal Network (2002). Variations in mortality rates among Canadian neonatal intensive care units. *Canadian Medical Association Journal, 166*(2), 173-178.

Sawatzky, J.-A. (1996). Stress in critical care nurses: Actual and perceived. *Heart and Lung, 25*(5), 409-417.

Silva, M. (1995). *Ethical guidelines in the conduct and implementation of nursing research*. Washington, DC: American Nurses Pub.

Singhal, N., Oberle, K., Burgess, E., & Huber-Okrainec, J. (2002). Parents' perceptions of research with newborns. *Journal of Perinatology, 22*, 57-63.

Singhal, N., Oberle, K., Darwish, A. & Burgess, E. (2004). Attitudes of health-care providers towards research with newborn babies. *Journal of Perinatology, 24*, 775-782.

Skarsgard, E., Blair, G., & Lee, S. (2003). Toward evidence-based best practices in neonatal surgical care-I: The Canadian NICU network. *Journal of Pediatric Surgery, 38*(5), 672-677.

Smith, R. (2000). Babies and consent: Yet another NHS scandal. *BMJ, 320*(7245), 1285-1286.

Spence, K. (1998) Ethical issues for neonatal nurses. *Nursing Ethics, 5*(3), 206-217.

Spence, K., Tarnow-Mordi, W., Duncan, G., Jayasuryia, N., Elliott, J., King, J., et al. F. (2006). Measuring nursing workload in neonatal intensive care. *Journal of Nursing Management, 14*, 227-234.

Speziale, H. & Carpenter, D. (2007). *Qualitative research in nursing: Advancing the*

humanistic imperative (4th ed.). Philadelphia, PE: Lippincott Williams & Wilkins.

Spilsbury, K., Petherick, E., Cullum, N., Nelson, A., Nixon, J., & Mason, S. (2008). The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing, 17*(4), 549–557.

Stenson, B., Becher, J-C., & McIntosh, N. (2004). Neonatal research: The parental perspective. *Archives of Disease in Childhood: Fetal and Neonatal Edition, 89*(4), F321-F324.

Strauss, A. & Corbin, J. (1990). *Basics of qualitative research: Grounded theory procedures and techniques.* Newbury Park, CA: Sage.

Strauss, A., & Corbin, J. (1994). Grounded theory: An overview. In N. Denzin & Y. Lincoln (eds.), *Handbook of Qualitative Research* (pp. 273-285). Thousand Oaks, CA: Sage.

Stutts, A. & Schloemann, J. (2002). Life-sustaining support: Ethical, cultural, and spiritual conflicts. Part I: Family support-a neonatal case study. *Neonatal Network, 21*(3), 23-29.

Sundin-Huard, D. & Fahy, K. (1999) Moral distress, advocacy and burnout: theorizing the relationships. *International Journal of Nursing Practice, 5*(1), 8 -13.

Taeusch, H. & Ballard, R. (1998). *Avery's diseases of the newborn* (7th Ed.). Philadelphia, PA: W.B. Saunders Company.

Thacker, K. (2008). Nurses' advocacy behaviors in end-of-life nursing care. *Nursing Ethics, 15*(2), 174 -185.

The UK Neonatal Staffing Study Group (2002). Patient volume, staffing, and workload in

relation to risk-adjusted outcomes in a random stratified sample of UK neonatal intensive care units: a prospective evaluation. *The Lancet, 359*(9301), 99-107.

Thomas, K. (2005). Safety: When infants and parents are research subjects. *Journal of Perinatal & Neonatal Nursing, 19*(1), 52-58.

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2003). Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. Ottawa, Canada: MRCC, NSERCC, SSHRCC.

Turner, M., Tomlinson, P., & Harbaugh, B. (1990). Parental uncertainty in critical care hospitalization of children. *Maternal-Child Nursing Journal, 19*(1), 45 -62.

Walterspiel, J. (1990). Informed consent: Influence on patient selection among critically ill premature infants. *Pediatrics, 85*(1), 119-121.

Ward Platt, M. (2005). Participation in multiple neonatal research studies. *Archives of Disease in Childhood: Fetal and Neonatal Edition, 90*(3), F191.

Wigert, H., Hellstrom, A., & Berg, M. (2008). Conditions for parents' participation in the care of their child in neonatal intensive care - a field study. *BMC Pediatrics, 8*, 3.

Winters, C., Lee, H., Besel, J., Strand, A., Echeverri, R., Jorgensen, K., et al. (2007). Access to and use of research by rural nurses. *Rural and Remote Health, 7*(3), 758.

Wong, L. (2008). Focus group discussion: A tool for health and medical research. *Singapore Medical Journal, 49*(3), 256 -260.

Woodgate, R. (2000). Part I: An introduction to conducting qualitative research in children with cancer. *Journal of Pediatric Oncology Nursing, 17*(4), 192 -206

Woodgate, R., Dean, R., Edwards, M. Shapiro, C., Grant, K., & Cham, B. (Work in progress). Perceptions and assessment of the risks to involving children in research: Perspectives of research ethics board members, child health researchers, and families. Canadian Institute of Health Research - RFA for Empirical and Conceptual Research on Ethical, Legal and Social Issues in Studies Involving Pregnant Women and Children.

van Manen, M. (1990). *Researching lived experience: Human science for an action sensitive pedagogy*. London, ON: The Althouse Press.

van Zuuren & van Manen (2006). Moral dilemmas in neonatology as experienced by health care practitioners: A qualitative approach. *Medicine, Health Care, and Philosophy, 9*(3), 339-347.

Verklan, M. (2003). Malpractice and the neonatal intensive-care nurse. *JOGNN, 33*(1), 116-123.

Yam, B., Rossiter, J., & Cheung, K. (2001). Caring for dying infants: Experiences of neonatal intensive care nurses in Hong Kong. *Journal of Clinical Nursing 10*(5), 651-659.

Appendix A

RECRUITMENT LETTER

Dear Nursing Colleague,

My name is Bella Iomdina. I am a registered nurse with six years of experience in the obstetrics, gynecology, and neonatology field. I am also a graduate student in the Master of Nursing program at the University of Manitoba. I am undertaking a thesis as partial fulfillment of the requirements of the Graduate Program.

The purpose of this research is to arrive at an increased understanding of neonatal nurses' experiences in caring for high-risk infants involved in research. The study will focus on neonatal nurses' perspectives and beliefs towards neonatal research and the notion of risk to involving high-risk infants in research, their perceived roles and responsibilities with regards to high-risk infants in research, and the impact and challenges of caring for high-risk infants involved in research on nursing care. This study builds on the research program of the student's supervisor who seeks to increase the knowledge base of the nature of risk in child health research. Dr. Roberta Woodgate of the Faculty of Nursing at the University of Manitoba is supervising this research study. Dr. Marie Edwards (Assistant Professor, Faculty of Nursing), Dr. Catherine Cronin (Professor of Paediatrics and Child Health, University of Manitoba) and Doris Sawatsky-Dickson (Clinical Nurse Specialist, Children's Hospital, NICU) are the other three members of my committee.

You were selected as this study participant because you are currently working in the neonatal intensive care unit at Children's Hospital and have at least 2 years of experience in caring for high-risk infants. Your participation will be a valuable contribution to this study. It is my desire, as a result of this research, to generate better understanding of the experiences of neonatal nurses who provide care to high-risk infants enrolled in research.

This study has been approved by the University of Manitoba Education / Nursing Research Ethics Board, the HSC Pediatric Research Coordinating Committee, and the HSC Research Impact Committee.

The study will involve completing a basic demographic form, which will take approximately 10 minutes to complete. You will be asked to participate in to participate in either one or two interviews and /or a focus group discussion, in which you will be asked to discuss your experiences and perceptions towards caring for a baby who is involved in research. Each interview will last approximately from 45 minutes to 1.5 hours. A focus group discussion will last approximately from one to two hours. The time and place will be chosen at your convenience. I will be conducting the interviews. My thesis supervisor, Dr. Roberta Woodgate, and I will be facilitating the focus group. After each interview and a focus group discussion I will also be writing field notes describing nonverbal behaviours, communication processes, rapport, interview context, and any procedural problems that may have transpired during the interviews or a focus group discussion.

The interviews and a focus group discussion will be audio tape-recorded, transcribed, and used as data.

Your answers will be kept completely confidential and only I, the principal investigator, will know your identity. The records of this study will be kept in privacy. In any report of this study, if published, the researcher will not include any information that will identify you. Only the researcher will have access to the records, which will be kept in a locked file.

Your participation in this study is strictly voluntary. Your participation in the study will not affect your employment. The information received from you will not be shared with your employer. If you decide to participate and decide to withdraw later, you are free to do so at any time. If you wish, you can ask to stop the interview at any point, or refuse to answer any questions if you consider them stressful.

If you are interested in participating in this study and / or have comments or questions, please contact me at xxx-xxxx (home) or email umiomdi0@cc.umanitoba.ca. You may also contact my supervisor, Dr. Roberta Woodgate, at 474-8338.

Thank you in advance for your participation,

Sincerely,

Bella Iomdina, RN, BN, RLC, IBCLC

Appendix B

CONSENT FORM

Research Project Title:	Neonatal Nurses' Experiences of Caring for a High-Risk Infant Involved in Research
Study's Researcher:	Bella Iomdina Phone: xxx-xxxx
Supervisor / Committee Chair:	Dr. Roberta Woodgate Phone: 474-8338 Assistant Professor Faculty of Nursing, University of Manitoba
Committee members:	Dr. Marie Edwards (Faculty of Nursing, University of Manitoba) Dr. Catherine Cronin (Faculty of Medicine, University of Manitoba) Doris Sawatsky-Dickson (Clinical Nurse Specialist, Children's Hospital, Winnipeg)

I, _____, agree to participate in the above study. I understand that the purpose of the study is to arrive at an increased understanding of neonatal nurses' experiences in caring for high-risk infants involved in research. I understand that the study will focus on exploring and describing neonatal nurses' perspectives and beliefs towards neonatal research and the notion of risk to involving high-risk infants in research, their perceived roles and responsibilities with regards to high-risk infants in research, and the impact and challenges of caring for high-risk infants involved in research on nursing care. I understand that the study is being done by Bella Iomdina, a registered nurse and a student in the Master of Nursing program at the University of Manitoba, for her thesis. Dr. Roberta Woodgate of the Faculty of Nursing, University of Manitoba is supervising this research study. Dr. Marie Edwards, Dr. Catherine Cronin, and Doris Sawatsky-Dickson are the other three members of Bella's thesis committee.

I understand that nurses currently working in the neonatal intensive care unit in Children's Hospital and who have at least 2 years of experience in caring for high-risk infants are being asked to participate. I understand that if I participate in the study, I will be asked to complete a basic demographic form and to participate in either one or both options:

1. One or two interviews, carried out by Bella. Taking part in the interviews means that I will be asked to discuss my experiences and perceptions towards caring for a baby who is involved in research. Each interview will last approximately from 45 minutes to 1.5 hours, and the time and place will be chosen at my convenience. The interviews will be audio tape-recorded, transcribed, and used as data.

2. Focus group discussion in which I will be asked my experiences and perceptions towards caring for a baby who is involved in research. The focus group discussion will last approximately from one to two hours, and the time and place will be chosen at my convenience. Bella and her supervisor, Dr. Roberta Woodgate, will be facilitating the focus group. The discussion will be audio tape-recorded, transcribed, and used as data.

I understand that after each interview Bella will also be writing field notes describing nonverbal behaviours, communication processes, rapport, interview context, and any procedural problems that may transpired during the interviews.

I understand that my participation in this study is strictly voluntary. I understand that my participation in the study will not affect my employment and that the information received from me will not be shared with my employer. If I decide to be interviewed, I can withdraw from the study at any time, ask to stop the interview at any point, or refuse to answer any question.

I understand that there are no known risks to me taking part in this study. I understand that this study will result in better understanding of the nature of risk in child health research.

I understand that my answers will be kept completely confidential. I understand that my name will be replaced with a code number so that no one will be able to identify me. I also understand that only Bella and Dr. Roberta Woodgate will read the interviews.

I understand that the results of this study will be written up for Bella's thesis, and it may be presented at a health conference or published in a health journal. I understand that in any report of this study the researcher will not include any information that will identify me; only the researcher will have access to the records, which will be kept in a locked file and destroyed seven years following completion of the study.

My signature on this form indicates that I have understood to my satisfaction the information regarding participation in the research project and agree to participate. I understand that I can ask for clarification or new information regarding the study throughout my participation. I understand that I may contact Bella Iomdina at xxx-xxxx if I have any concerns, questions, or need additional information. I may also contact Bella's supervisor, Dr. Roberta Woodgate at 474-8338.

I understand that this research has been approved by the University of Manitoba Education / Nursing Research Ethics Board, the HSC Pediatric Research Coordinating Committee, and the HSC Research Impact Committee. If I have any concerns or complains about this project, I may contact any of the above-named individuals or the Human Ethics office at 474-7122.

I understand that in recognition of my time commitment, I am offered a meal and a gift certificate for a Manicure / French Manicure or $10 Tim Hortons gift certificate. I understand that for my participation in a focus group, I will be provided with a meal and a gift certificate for a Manicure / French Manicure or $20 Tim Hortons gift certificate. I will also be reimbursed for parking costs that I may incur because of the interview(s) / focus group.

For an interview:
I would like a gift certificate for a Manicure _____or
French Manicure _____or
$10 Tim Hortons _____or
For a focus group:
I would like a gift certificate for a Manicure _____or
French Manicure _____or
$20 Tim Hortons _____or

Signature of Researcher _____

Participant's Signature _____

Date _____

I would like a summary report of the findings:
Yes _____
No _____
Please mail the report to:
Name _____
Mailing Address _____

Appendix C

DEMOGRAPHIC FORM

1. What is your age? ____
2. Are you

   Female ____

   Male ____
3. What is your current marital status?

   Single ____

   Married / Common-law ____

   Separated ____

   Divorced ____

   Widowed ____
4. Do you have children of your own?

   No ____

   Yes ____, if yes, how many ____
5. Is your employment at the nursery

   Full-time ____

   Part-time ____, if part-time, what is your code ____
6. How many years have you worked as a nurse? ____
7. How many years have you worked at the nursery? ____
8. What is your highest degree obtained? _____
9. Have you taken any additional research training workshops / courses?

If yes, which workshops or courses?

_____

10. In the last 2 years, how many infants have you looked after, that were involved in research? ____

Appendix D

INTERVIEW GUIDE

Introduction to the interview: I would like to learn more about what it is like to care for a high-risk infant involved in research. I would like you to share your experiences providing care to high-risk infants enrolled in research. The questions that I will ask pertain to your perspectives and beliefs towards neonatal research, your perceived roles and responsibilities with regards to these infants, and the impact of caring for high-risk infants involved in research on care that you provide. In addition, I would also like to discuss your concerns related to proving care for an infant. If at any time you want to stop the interview or do not feel comfortable answering a question or do not understand a question, please let me know. **(Probes will be asked only if necessary.)**

1. Could you please tell me about your experience in working in the neonatal intensive care unit (NICU)?

   Probes:
   - How long have you been working with high-risk infants?
   - What is a typical day of work like for you?
   - What type of care do you provide?
   - How has it changed since you started working in the NICU?
   - Can you describe to me a "good" day at work? Can you describe to me a "bad" day at work?

2. Could you please provide me with some examples of research studies that high-risk infants under your care have been involved in?

   Probes:
   - For each study ask: What was the study about? What aspects of the study were the most stressful / risky? How long was the study?
   - How has research involving infants changed since you started working in NICU?

3. What are your thoughts regarding research in general and the notion of risk involved in research?

   Probes:
   - Probe re: what risk means to you? How do you define the concept of risk?

4. What are your thoughts in general to involving high-risk infants in research and to the risk of involving such infants in research?

Probes:

- In what context do you consider it is appropriate or inappropriate to involve high-risk infants in research? In what context do you consider it is appropriate or inappropriate to involve critically ill infants in research?
- Should some infants be considered to be more vulnerable in research than others? Please explain. What makes an infant vulnerable? Define vulnerable.
- Should critically ill infants be treated differently when participating in research and if yes, please tell me how they should be treated? Should they be treated differently when compared to high-risk infants? Please explain.
- Could you please tell me about how you view the whole notion of risk in research when high-risk infants are involved? Do you find that it depends on the type of research? Please explain.
- When infants are involved in research what do you perceive are the potential risks for them?
- How do you go about determining the type and degree of risks in research that involve infants?
- What conditions do you feel contribute to increasing the degree of risk in a research study that involves high-risk infants?
- Does the degree of risk depend on the type of study to be conducted (e.g., clinical trials versus survey research, therapeutic versus non-therapeutic)? Please explain.
- Can you please tell me the types of procedures that you feel are acceptable to do on high-risk infants for the purposes of research?
- How do you feel the risks in research for infants differ to the risks that infants may encounter when undergoing a health treatment?

5. Please read this:
   In the Tri- Council Policy Statement Ethical Conduct for Research Involving Humans much emphasis is placed on minimal risk. The Tri- Council Policy describes minimal risk as: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk (p. 1.5).
   What are your thoughts about this statement in general, and when applied to research involving high-risk infants?

6. How does looking after high-risk infants involved in research affect your nursing care?

Probes:

- How different is it caring for infants involved in research compared to that of caring for infants not involved in research? Could you please provide some examples (care scenarios)?
- Do you approach infants differently who are involved in research? Please explain.

- How does care change when infants are involved in research? Do you find that it depends on the type of research? Please explain.
- What do you perceive your role and responsibilities to be when you provide care for high-risk infants involved in research?
- Can you please tell me about the challenges that you have experienced when caring for high-risk infants involved in research?
- Is there anything about research / facilitating research that makes you uncomfortable? Please explain.
- What are your typical concerns for an infant under your care who is involved in research?
- What are the things that you like best about caring for infants in research?
- What are the things that you like least about caring for infants in research?
- How has your experience in caring for infants in research changed over the years?

7. How do you go about determining the type and degree of risks in research that involve high-risk infants?

Probes:

- Could you walk me through the steps by providing examples from your own experience in providing care to high-risk infants involved in research?
- Could you give me an example where you felt there was *no* risk for the infant, and where there *was* some level of risk for the infant?
- What standards do you use in assessing what is minimal risk and what is more than minimal risk?
- What factors influence your perceptions and assessment of risk?
- Can you tell me about those times when you had difficulty in determining the degree of risk?
- In those situations, what is it that makes it more difficult in determining the degree of risk? What things do you do to help you in such situations?

8. Could you please provide me with any examples of research that you were involved in or that you are aware of that you thought the level of risk was more than minimal risk for the infants?

Probes:

- What was it about this study (studies) that you felt put the infants at greater risk?
- What features / aspects of a research protocol make the study more likely to be labeled as more than minimal risk? (e.g. type of design, procedures involved, length of study).

9. What advice or recommendations would you give to neonatal nurses caring for high-risk infants involved in research?

Probes:

- Probe re: advice about how to provide care for infants, ways to protect infants, how to deal with potential risks, etc.

10. What advice or recommendations would you give to parents about involving their infant in research?

    Probes:

    - Probe re: advice about what type of information they need to know in order to make an informed decision, how it may impact care, what questions to ask researchers, nurses, and physicians, etc.

11. What advice or recommendations would you give to child health researchers about involving infants in research?

    Probes:

    - Probe re: advice about the ways to protect infants, what to avoid, how to deal with potential risks, how to approach parents, what advice to give to parents, etc.

12. What advice or recommendations would you give to research ethics board members about involving infants in research?

    Probes:

    - Probe re: advice about the ways to protect infants, what to avoid, how to deal with potential risks, how to approach parents, what advice to give to parents, advice how to assist researchers, etc.

13. Overall what type of regulations should be in place when conducting research in high-risk infants?

14. Is there anything else you would like to add that is important for me to know?

Appendix E

FOCUS GROUP INTERVIEW GUIDE

Introduction to the interview: I would like to learn more about what it is like to care for a high-risk infant involved in research. I would like you to share your experiences providing care to high-risk infants enrolled in research. The questions that I will ask pertain to your perspectives and beliefs towards neonatal research, your perceived roles and responsibilities with regards to these infants, and the impact of caring for high-risk infants involved in research on care that you provide. In addition, I would also like to discuss your concerns related to proving care for an infant. If at any time you want to stop the interview or do not feel comfortable answering a question or do not understand a question, please let me know. **(Probes will be asked only if necessary.)**

1. Could you please tell me about your experience in working in the neonatal intensive care unit (NICU)?

Probes:

- How long have you been working with high-risk infants?
- What is a typical day of work like for you?
- What type of care do you provide?
- How has it changed since you started working in the NICU?
- Can you describe to me a "good" day at work? Can you describe to me a "bad" day at work?

2. Could you please provide me with some examples of research studies that high-risk infants under your care have been involved in?

Probes:

- For each study ask: What was the study about? What aspects of the study were the most stressful / risky? How long was the study?
- How has research involving infants changed since you started working in NICU?
- Have you ever looked after children involved in research that you thought was inappropriate? Can you provide me with examples? How did it make you feel?

3. What are your thoughts regarding research in general and the notion of risk involved in research?

Probes:

- Have you had any experience with research that was really bad? An incident that stands in your mind?

4. What are your thoughts in general to involving high-risk infants in research and to the risk of involving such infants in research?

   Probes:
   - In what context do you consider it is appropriate or inappropriate to involve high-risk infants in research? In what context do you consider it is appropriate or inappropriate to involve critically ill infants in research?
   - Should some infants be considered to be more vulnerable in research than others? Please explain. What makes an infant vulnerable?
   - Should critically ill infants be treated differently when participating in research and if yes, please tell me how they should be treated? Should they be treated differently when compared to high-risk infants? Please explain.
   - Could you please tell me about how you view the whole notion of risk in research when high-risk infants are involved? Do you find that it depends on the type of research? Please explain.
   - When infants are involved in research what do you perceive are the potential risks for them?
   - How do you go about determining the type and degree of risks in research that involve infants?
   - What conditions do you feel contribute to increasing the degree of risk in a research study that involves high-risk infants?
   - Does the degree of risk depend on the type of study to be conducted (e.g., clinical trials versus survey research, therapeutic versus non-therapeutic)? Please explain.
   - Can you please tell me the types of procedures that you feel are acceptable to do on high-risk infants for the purposes of research?

5. How do you go about determining the type and degree of risks in research that involve high-risk infants?

Probes:
- Could you walk me through the steps by providing examples from your own experience in providing care to high-risk infants involved in research?
- Could you give me an example where you felt there was *no* risk for the infant, and where there *was* some level of risk for the infant?
- What standards do you use in assessing what is minimal risk and what is more than minimal risk?
- What factors influence your perceptions and assessment of risk?
- Can you tell me about those times when you had difficulty in determining the degree of risk?
- In those situations, what is it that makes it more difficult in determining the degree of risk? What things do you do to help you in such situations?

6. Could you please provide me with any examples of research that you were involved in or that you are aware of that you thought the level of risk was more than minimal risk for the infants?

Probes:
- What was it about this study (studies) that you felt put the infants at greater risk?
- What features / aspects of a research protocol make the study more likely to be labeled as more than minimal risk? (e.g. type of design, procedures involved, length of study).

7. If you had to make top 10 list, what would be the worst procedure, for research?

8. Please read this:

In the Tri- Council Policy Statement Ethical Conduct for Research Involving Humans much emphasis is placed on minimal risk. The Tri- Council Policy describes minimal risk as: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk (p. 1.5).

What are your thoughts about this statement in general, and when applied to research involving high-risk infants?

9. How does looking after high-risk infants involved in research affect your nursing care?

Probes:
- How different is it caring for infants involved in research compared to that of caring for infants not involved in research? Could you please provide some examples (care scenarios)? If you have two babies, one with research study, one without the research study, do you go about it differently?
- Do you approach infants differently who are involved in research? Please explain.
- How does care change when infants are involved in research? Do you find that it depends on the type of research? Please explain.
- What do you perceive your role and responsibilities to be when you provide care for high-risk infants involved in research?
- Can you please tell me about the challenges that you have experienced when caring for high-risk infants involved in research?
- Is there anything about research / facilitating research that makes you uncomfortable? Please explain.

- What are your typical concerns for an infant under your care who is involved in research?
- What are the things that you like best about caring for infants in research?
- What are the things that you like least about caring for infants in research?
- How has your experience in caring for infants in research changed over the years?

7. What advice or recommendations would you give to neonatal nurses caring for high-risk infants involved in research?

Probes:

- Probe re: advice about how to provide care for infants, ways to protect infants, how to deal with potential risks, etc.

8. What advice or recommendations would you give to parents about involving their infant in research?

Probes:

- Probe re: advice about what type of information they need to know in order to make an informed decision, how it may impact care, what questions to ask researchers, nurses, and physicians, etc.

9. What advice or recommendations would you give to child health researchers about involving infants in research?

Probes:

- Probe re: advice about the ways to protect infants, what to avoid, how to deal with potential risks, how to approach parents, what advice to give to parents, etc.

10. What advice or recommendations would you give to research ethics board members about involving infants in research?

Probes:

- Probe re: advice about the ways to protect infants, what to avoid, how to deal with potential risks, how to approach parents, what advice to give to parents, advice how to assist researchers, etc.

11. What advice or recommendations would you give to the research nurses?

Probes:

- Probe re: how should a research nurse be utilized?

12. What would make your life / parents' life / infants' life easier when it comes to looking after babies involved in research?

13. Overall what type of regulations should be in place when conducting research in high-risk infants?

14. Is there anything else you would like to add that is important for us to know?

Appendix F
RECRUITMENT POSTER

INVITATION
TO PARTICIPATE IN A RESEARCH STUDY

Research Project Title:

Neonatal Nurses' Experiences of Caring for a High-Risk Infant Involved in Research

WHAT IS THIS STUDY ABOUT? Nurses will be asked about their views and experiences about involving high-risk infants in research. The study will help us to better understand your experiences in caring for high-risk infants involved in research, your concerns and the impact on your nursing care.

Nurses (with at least 2 years of experience)!
If you would like to participate and share your experiences about high-risk infants in research or want more information please call Bella Iomdina @ xxx-xxxx

This study is being conducted by Bella Iomdina under supervision of Dr. Roberta Woodgate
Faculty of Nursing, University of Manitoba