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## Parental perceptions of longitudinal outcomes research

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Parental Perceptions of Longitudinal Outcomes Research

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## Parental Perceptions of Longitudinal Outcomes Research

## Abstract

The purpose of this study was to discover parents' opinions' regarding research and research with their NICU child, and also to ask them to forecast possible facilitators and barriers to longitudinal outcome research (LOR) participation. The parent opinions from this study can be used to aid future study designs, so that the research team and the participants and their families may mutually benefit; by using parent opinions in study designs, the chances LOR success will be enhanced. Through analysis of parents' interviews, several major themes emerged. Parents cited logistical, emotional and life conflicts as both barriers and facilitators to LOR participation. Also, stress was an important variable that affected parental opinions. By establishing a realistic study design utilizing the input of NICU parents, NICU LOR success is a real possibility

## CHAPTER I: THE PROBLEM

### Significance of the Problem

NICU (neonatal intensive care unit) patients are a small, fragile subset of newborns. Their medical conditions are complex and varied, as are the interventions employed to treat them. Unfortunately, some of these conditions and interventions potentially have long term ramifications. Prediction of the occurrence, onset, and severity of these ramifications has not been established. Longitudinal outcome research (LOR) of NICU graduates has the ability to shed light on effects of NICU interventions and conditions for all NICU patients, better predict future disability, and improve NICU care for children and families; it can begin to put the “large uncontrolled experiment” (Lucey et al. 2004, p. 1563) that NICU care is currently, to an end. Since longitudinal studies are difficult, the intention of this research is to act as a building block to designing LOR with NICU graduates. Since LOR success is complicated by recruitment issues and attrition, every opportunity to enhance LOR should be sought. LOR with NICU graduates requires cooperation from NICU parents, thus, their opinions regarding participation should be obtained. By including viewpoints from parents, future researchers will have the opportunity to design studies that will accommodate participants and their particular needs. Through this study, the opinions and motivational factors of NICU parents regarding LOR were obtained. With this knowledge, steps can be taken to design successful LOR with NICU graduates.

Critically ill infants admitted to the NICU are exposed to numerous invasive treatments and procedures to save their lives and optimize their health. Interventions vary depending on disease process and clinical signs and symptoms. For example,

treatment for infants experiencing respiratory distress (a common diagnosis in the NICU) includes NPO (nothing by mouth) status, nasogastric tube placement, chest X-ray, CBC (complete blood count, such as white blood cell count, platelets, and hematocrit), blood cultures, blood gasses, intravenous (IV) line placement, IV fluid, and respiratory support. Respiratory support ranges from minimally invasive interventions, such as nasal canula and oxyhood to moderately invasive such as continuous positive airway pressure (CPAP). Examples of maximally invasive interventions are endotracheal intubation and mechanical ventilation. For infants with low blood sugar, a common problem after birth, interventions include IV placement, central line placement, frequent blood sugars, frequent feedings (either by mouth or nasogastric tube) and possible dextrose boluses to increase blood sugar levels. These interventions are general and common to many NICU patients. More patient specific interventions are utilized for specific patient populations.

NICU patients with specific conditions require specialized treatments to optimize their outcomes such as consultations with various specialties (endocrine, genetics, surgery, gastrointestinal, genitourinary, cardiology and neurology), surgical interventions, occupational therapy, and physical therapy. In spite of many improvements, the procedures and treatments necessary to maintain the lives of these fragile neonates may, in fact, impact the child's health negatively. Whether these negative sequelae may be early or late onset, mild or severe, temporary or permanent, is highly variable. In addition to sequelae from NICU intervention, the disease process itself may also have negative consequences for the infant.

Some adverse effects such as hypotension after morphine administration can be readily identified, while others may not manifest themselves for long periods of time.

Steroid administration has been shown to cause an increased incidence of cerebral palsy, which does not fully manifest until well after NICU discharge (Davis, 2003). Also, prematurely born children have demonstrated learning difficulties at school age (range from 6 years old to 20 years old) when compared with full term peers (Davis, 2003). Outcome studies evaluating NICU graduates doubled in prevalence from 1994 to 1999 however, there are no NICU outcome studies available that examine NICU graduates from birth until young adulthood (Forrest, Shipman, Dougherty, & Miller, 2003). Short term evaluations that examine children from birth through preschool age lack the ability to assess completely ramifications of critical illness in the neonatal period and the NICU interventions on NICU graduates (Davis, 2003). To realize fully the effects of their NICU hospitalization, children must be followed throughout their development into young adulthood (Klassen, Lee, Raina, Chan, Matthew, & Brabyn, 2004).

Before longitudinal outcomes studies with NICU graduates can be designed, careful consideration must be taken. Several factors will potentially complicate NICU LOR: (a) longitudinal studies are fraught with problems related to recruitment, retention, and attrition; (b) parents must actively participate in the consent and procedure; (c) the research team must maintain contact with the parents for follow-up; (d) parents must provide reliable transportation; and (e) parents must be accurate historians to participate in data collection. Parents are a central element in the success of LOR. Their ability to verbalize barriers and facilitators to LOR will maximize the chance of success for NICU follow-up research. The information obtained from this research study serves to provide insight on these important contributing factors.

The vast resources utilized during NICU hospitalization, the costs to families and society, as well as the lack of comprehensive knowledge of NICU patient outcomes supports the need to understand NICU longitudinal outcomes. Unfortunately, long term outcome studies are difficult to accomplish due to several factors including recruitment, retention, and ethical barriers related to including the pediatric population in research studies. Considering these obstacles, great care and consideration must be taken with regards to longitudinal research study designs. Each potential impediment must be addressed, facilitators must be identified, and future researchers must be cognizant of the unique needs of NICU graduates and their families when considering longitudinal outcome study designs. Since there are difficulties inherent to both general longitudinal studies and also to LOR specifically with NICU graduates, study designs must be suited to best meet needs of families and their NICU graduates. This will make a difficult undertaking more feasible.

Other aspects to consider when utilizing parents in research include ethical considerations for vulnerable populations. Since the pediatric population is vulnerable, their presence in research is not as frequent as adults (Korenman, 2004). In addition, parents of pediatric (including neonatal) patients are also considered a vulnerable population (Korenman, 2004; Franck, 2005; Golec, Gibbins, Dunn, & Herbert, 2004). As participation of vulnerable groups in research is necessary, extra consideration must be taken to ensure safe and ethical treatment. A study conducted by Mason and Allmark (2000) demonstrated some concerning aspects of parents' vulnerability in research. The parents in their study were unable to remember the study's purpose, they did not recall their right to withdraw from the study, and that unusual stress related to their child's

illnesses makes valid informed consent more challenging for parents. Parents, similar to any prospective research subject to be consented, must have a complete consent procedure, a method of contacting the principal researcher and a written copy with information related to the research study. As with any research study, NICU graduate longitudinal outcome studies must be carefully considered to ensure the most valid informed consent. Due to additional stressors on NICU parents, extra care must be taken with NICU LOR study procedures to ensure valid informed consent.

In conclusion, NICU graduates are at risk for many negative outcomes as a result of their illness(es) and subsequent interventions. NICU graduates must be followed in LOR to better grasp their outcomes after NICU hospitalization. That being said, designing successful LOR is a daunting task. The many aspects of longitudinal outcomes studies with NICU graduates must be addressed prior to developing a successful study design to minimize obstacles. The major goals of this study are: (a) to elicit the opinions of parents' related to research; (b) to obtain the parents opinions related to research involving their NICU child; and (c) to identify barriers and facilitators to LOR as identified by parents. The parents' responses from this study may be used to guide future LOR designs of NICU graduates. Incorporating study findings into LOR designs may enhance study recruitment and retention.

### Key Concept Definitions

The NICU has many terms not widely used in other areas of healthcare. These Key Concept Definitions are provided to explain these key terms and enhance understanding of the text. The definitions of birth weight, gestational age, surfactant,

inhaled nitric oxide, high frequency oscillatory ventilation, and antenatal steroids were obtained from the Manual of Neonatal Care: Fifth Edition (2004).

*Birth Weight Classification:*

Small for Gestational Age (SGA): birth weight less than the 10<sup>th</sup> percentile

Appropriate for Gestational Age (AGA): birth weight within the 10<sup>th</sup> to the 90<sup>th</sup> percentile

Low Birth Weight (LBW): birth weight less than 2500 grams

Very Low Birth Weight (VLBW): birth weight less than 1500 grams

Extremely Low Birth Weight (ELBW): birth weight less than 1000 grams

Large for Gestational Age (LGA): birth weight greater than the 90<sup>th</sup> percentile

*Gestational Age Differentiation:*

Preterm: An infant born before 37 weeks gestational age.

Term: An infant born between 37 and 41 6/7 weeks gestational age.

Postterm: An infant born after 42 weeks gestational age.

*NICU Graduate:* Any infant who was admitted to the NICU for illness during the first 28 days after birth. They are living infants who have been either discharged from the NICU to either home or another institution.

*Neonate:* An infant during their first twenty-eight days of life.

*Parents:* The legal guardian of an infant, either through genetics or legal custody.

The “parent(s)” are responsible for consenting to research and procedures in the NICU.

*Surfactant:* An exogenous form of an endogenous protein found normally in the lungs.

Preterm infants, as well as others, are frequently deficient in this protein that helps to decrease surface tension in the alveolar spaces.

*High Frequency Oscillatory Ventilation (HFOV):* A ventilation method for infants who fail to improve with other respiratory interventions including, but not limited to, exogenous surfactant and conventional mechanical ventilation. Infants with pneumothorax and pulmonary interstitial emphysema also may benefit from this form of ventilation.

*Inhaled nitric oxide (iNO):* This is an inhaled gas given to infants with persistent pulmonary hypertension. This is a drug which is selective for pulmonary vasculature, and helps to dilate the vessels to improve ventilation.

*Antenatal Steroids:* Steroids given to mothers that have threats of preterm labor. The steroids help to mature preterm lungs prior to delivery.

## CHAPTER II: LITERATURE REVIEW

There are many factors involved in the proposed research. The literature review was done to identify current knowledge of the topic and to bridge the gaps in the content area. The Conceptual Framework for this research proposal, current knowledge of NICU graduate outcomes, current longitudinal outcome studies and ethical issues related to pediatric and neonatal research will be examined.

*Conceptual Framework*

The Theory of Planned Behavior (TPB) was developed by Icek Aizen (2002) from the original Theory of Reasoned Action. The TPB was created to identify control as an important component of both intentions to perform a behavior, as well as performing the behavior. The TPB has three components which help to predict the chance of performing a specific behavior: behavioral beliefs, normative beliefs, and control beliefs. Behavioral beliefs account for the likely outcome of a behavior and its evaluations (attitude toward a behavior). Normative beliefs include the normal expectations of others and the motivations to comply (subjective norm). Control beliefs consider factors which may facilitate or impede performance of a behavior and the perceived power over these factors (perceived behavioral control). Attitude toward a behavior, subjective norm, and perceived behavioral control culminate into factors related to intention to perform a behavior. If these are strongly positive, the TPB postulates that the individual's intention to perform a specific behavior is high (Aizen, 2002).

If intention to perform a behavior is strong, the chance of action (actual behavior) also is strong. Behavior, according to the TPB, is defined in terms of its Target, Action, Context, and Time (TACT). According to Aizen (2002), definition of each of the TACT

components is arbitrary. Generally, the target and context elements refer to defining the action, or behavior, to be performed. The time element is the time frame to perform the action. Additionally, each element of TACT must have compatibility with each other. “The principle of compatibility requires that all other constructs (attitude, subjective norm, perceived behavioral control, and intention) be defined in terms of exactly the same elements” (Aizen, p.2). An example, with regards to the subject of parental perception of longitudinal outcomes research, is as follows: parents consent their NICU graduate children to participate in NICU outcomes research, through the age of young adulthood at a NICU outcome center. The components of TACT include:

Target: NICU longitudinal follow up study

Action: Consent, and or participation

Context: Follow up center

Time: Yearly, through young adulthood

The TPB is an appropriate framework for this research since it involves perceived control, behavior and actions. According to Aizen, measuring beliefs about a specific action allows insight into the underlying thought processes behind a behavior. Applying the TPB to this research, parents’ attitudes toward research with NICU graduates are taken into account and can be used in building the study design. Normative expectations take into account the pressures or responsibilities individuals feel as members of a society. Altruistic motives may be driven by normative expectations and have been identified as a contributing factor for parents to allow their infants’ to participate in research (Morley, Lau, Davis, & Morse, 2004). Control is also important to investigate, because NICU parents often have a perceived and actual loss of control (Ward, 2001).

By exploring parents' views and concerns, and using them to develop appropriate and more suitable study designs, parents' sense of control will increase. This greater sense of control will theoretically increase chances of participating in LOR. The TPB is a behavioral theory which accounts for many of the variables involved in motivation to participate in research and is applicable to this research study.

#### Introduction to the Review of Literature

Many follow up studies involving NICU patients involve ELBW, VLBW, LBW, premature and infants with specific disorders or congenital malformations (such as congenital diaphragmatic hernia). But no longitudinal studies in current literature follow these children into young adulthood. A study with all NICU graduates from birth until adulthood would yield valuable information that may be generalized to other NICU graduates. Currently, few organizations collect large amounts of data on NICU patients. The Vermont Oxford Network (VON) is one example of an organization that collects information only during the NICU patient's hospitalization ([www.VTOxford.org](http://www.VTOxford.org)). The data collected by the VON is collected from NICUs throughout the world. The Network's data collection does not include the long term morbidity and mortality of NICU patients.

Even though pediatric outcomes research published in literature has increased in recent years, Forrest et al. (2003) identified a need for more extensive NICU outcomes research. While some infants are only studied during the immediate period after birth, others are studied until hospital discharge, and yet others are followed until they are older. There is a gap in the literature for longitudinal NICU outcomes lasting until the graduate reaches adulthood. Additionally, Forrest, Shipman, Dougherty, and Miller (2003) believe more attention should be devoted to evaluating care for patients with acute

and chronic conditions and for children with multiple co-existing conditions. NICU graduates can be categorized as both. The following are examples of the body of NICU outcome studies present in the literature. Their findings are representative of current NICU outcome knowledge.

#### NICU Outcomes

Survivability of ELBW infants to discharge during the 1990's was studied by many. Meadow, Lee, Lin, and Lantos (2004) as well as Lucey et al. (2004) represent those in the current NICU outcomes literature. Meadow et al. (2004) state the use of high frequency oscillating ventilator (HFOV), inhaled nitric oxide (iNO), antenatal steroids, and exogenous surfactant increased the survivability of critically ill neonates over the first half of the 1990's (approximately 4% per year), but not during the later half. This study only examined survivability. According to Meadow, the next ethical area for exploration is to accurately predict morbidity among NICU graduates. Similarly, Lucey et al., (2004) examined the immediate survivability of neonates born at extremely low birth weight, and similar to Meadow, data collection ceased at hospital discharge. Lucey et al., examined the data of 4172 NICU patients with a birth weight between 401-500 grams born from 1996 to 2000 using data from the VON (Vermont Oxford Network). Data revealed that only 17% of these infants survived until hospital discharge, and those survivors have a "high rate of serious morbidities while in the NICU" (Lucey et al., 2000, p. 1559). The morbidities consisted of a wide range of diagnoses: abnormal head ultrasound (26%), severe intraventricular hemorrhage (8%), chronic lung disease (74%), and retinopathy of prematurity (89%). All of these diagnoses have varied associated morbidity and mortality. Both studies uncovered valuable morbidities for NICU patients,

but also had limitations. Range of characteristics for the sample was narrow, and these NICU patients were not studied after discharge.

Kilbride, Thorstad, and Daily (2004) examined outcomes of infants greater than 801 grams at birth (n= 25) at preschool age (average of 3.5 years old), and compared them to outcomes of their full term siblings (n=25). Findings include ELBW siblings with smaller head circumferences, lower IQ scores, special education requirement, and lower motor quotients. Similar to Lucey et al. (2004) and Meadow et al. (2004), these outcomes may lead to subsequent morbidities which manifest with advanced age. This study compiled an important body of knowledge that demonstrated morbidity extending into school age.

Davis (2003) reviewed many studies of NICU patients during the 1990's. Unlike the other reviews previously mentioned, Davis reviewed cognitive outcomes of former premature/LBW/ELBW NICU graduates at school age. Outcomes demonstrated that 23% of prematurely born infants have severe disability and another 25% have some lesser degree of disability. The disabilities identified by Davis range from subtle motor, learning and behavioral problems to profound mental retardation, cerebral palsy, seizure disorders, hearing loss and visual impairment. Like the previously mentioned studies, only premature infants and the LBW and ELBW children were included in the sample. This study also demonstrates disability into childhood. By examining these few studies representing current knowledge, it is evident that children treated in the NICU demonstrate morbidities unlike their non-NICU counterparts. These disabilities manifest themselves at different ages and researchers need to study NICU graduates into adulthood to completely comprehend the morbidity and mortality of NICU graduates.

The studies cited are representative of current NICU outcomes studies in the literature. They demonstrate a clear relationship between the need for NICU intervention and residual morbidity at and after NICU discharge. Three scenarios are presented in the literature: (a) research for NICU patients is limited to survivability during the immediate postnatal period; (b) the research examines NICU patients until NICU discharge; or (c) NICU graduates are examined only to school age (approximately age 7) at the latest. Davis (2003), among others, stated that NICU graduates must be followed through school age and after, as even subtle changes may not be seen until late childhood. Therefore, the short time period for follow-up may fail to demonstrate the full spectrum of morbidity NICU graduates experience.

#### Parental Participation in NICU Research

When designing a study with NICU patients as participants or involving parents of a NICU patient, issues of informed consent must be addressed prior to any undertaking. In fact, many authors (Franck, 2005; Golec et al. 2004; & Korenmann, 2004) consider both parents and their infants' vulnerable populations. Additionally, parents are integral components of their child's healthcare team and the child's guardian for research purposes. As a result, informed consent must be carefully planned and presented to parents during a calm and relatively stress-free time to ensure careful thought and thorough understanding of the materials presented.

Mason and Allmark (2000) evaluated the informed consent process of parents for neonatal trial participation. They discovered that only 59 of 200 parents' informed consent was valid. One-hundred forty-one parents had questionable consent in the following areas: competence (n=42), information (n=43), understanding (n=44), and

voluntariness (n=21). Mason and Allmark discovered the majority of problems related to consent for emergency procedures and when the research risk was greater than the risk associated with standard treatment. When examining reasons, the stress of their child's illness was cited in 42 parents' questionable consent. Also, when parents were asked, only 147 of 200 considered their decision to consent voluntary, and only 71% of patients understood their right to withdraw. Parents stated that their experienced burden for research consent would have been alleviated if they understood the role of the IRB at the particular institution (Mason & Allmark). Recognizing the complexity of valid informed consent with NICU parents, researchers should be aware of evidence based approaches with consent procedures (Franck, 2005).

Studies examining parental opinions of research with their infants have been done and there is a considerable body of knowledge regarding parents' motivations for research participation. Hoehn et al. (2005) analyzed unsolicited comments from 34 parents of 24 infants who underwent cardiothoracic surgery. Originally parents were being interviewed to uncover impact of prenatal diagnosis on parental permission for neonatal cardiac surgery however, during the study parents commented freely about research participation. Comments pertaining to neonatal research were unsolicited, but used in a qualitative analysis; they pertained to factors allowing their infant to participate in or not participate in research. Reasons to participate in neonatal research included societal benefit (53%), personal benefit (47%), and no perception of harm (26%). Twelve percent of parents expressed anti-experimental beliefs when discussing motivation for refusing research participation. A major factor noted by parents when deciding whether or not to participate was a perceived risk to the infant (29%). Hoehn et

al. (2005) concluded that altruistic motivation of parents is a motivational factor related to infant participation in neonatal research (53%).

In a research study, Morley et al. (2004) conducted an evaluation of parents' willingness to involve their infants in several studies while hospitalized. Parents were considered eligible if their infant was asked to join two or more studies while in the NICU. Fifty mothers and 42 fathers completed the research survey. The following was found: 93% believed their infant would receive same or better care by participating in research, 96% believed that having an infant in a hospital that conducts research was good (or of no harm), and 94% believed their research participation would benefit future infants. In this group of parents, only 10% of parents did not want to consent to any study. No opinions of longitudinal research were examined in the survey.

Oberle, Singhal, Huber, & Burgess (2000) found similar results to Morley et al. (2004); parents were supportive of neonatal research. Again, no opinions of longitudinal research were discussed. Both of these studies clearly demonstrated parents' willingness to involve their infants in NICU research, however, at this time, parents' willingness to be involved in longitudinal research is not known. When considering the possibility of longitudinal outcome research consent with NICU graduate parents, parental altruism is an important quality to understand and to encourage.

### Barriers to Longitudinal Studies

Recruitment and retention play an important part in longitudinal studies success or failure; and there are many factors associated with recruitment and retention of longitudinal study participants. In this section, several articles discussing adult and pediatric longitudinal studies are presented. Much information regarding parents'

opinions of NICU LOR remains to be discovered. This research study illuminates parents' opinions of NCU LOR.

In the San Diego Study of Children's Activity and Nutrition (SCAN) Frank, Nader, Zive, Broyles, and Brennan (2003) examined children during a 13 year period from preschool age until young adulthood. They accredited their relatively high retention rate (53%) as a combination of several important factors. One factor was frequent contact with participants. This aided researchers to maintain the current addresses and phone numbers of the participants, which facilitated consistent contact and thus easing long term follow up. Frequent contact also included newsletters and annual birthday cards; this reminded participants of their study participation. The staff of SCAN cites their success to other key characteristics of the study staff: ethnic diversity, knowledge of the geographical area where the participants lived, knowledge of community and school activities, maintaining confidentiality of the subject matter, and providing information to participants about future studies. The study was designed to facilitate participation: data collection conducted in the participants' home; families received information of their rights as study participants; and incentives were given to participants for completion of sections of the study. All of these aspects of the study design were considered integral to the high retention rates.

Ryan and Hayman (1996) examined genetic and environmental influences on risk factors for cardiovascular disease by comparing twins during school age, and again during adolescence. A 64% retention rate was attained; the authors believed its success was due largely to the use of a Family Coordinator, a Masters prepared nurse with specialization in child's health as data collector. The authors reported families responded

well to free health screening, timely letters to report findings, the use of home visits for data collection, personalized contact information and developmentally appropriate incentives. Another factor the authors considered important was researchers' sensitivity to family change and crisis. In an effort to give personalized family care, changes important to the family were obtained during visits and considered for implementation during family contact. The Family Coordinator was sensitive to situational stressors and was able to give families valuable information related to the development of their child. And finally, data collection was facilitated by individualizing schedules to each family's special needs; by individualizing schedules the family coordinator was able to enhance data collection.

The next study represents longitudinal follow up with adults. In a study focusing on recruitment and retention, 23 African American adults involved in diabetes research in a rural area in North America were studied. The study used a culturally competent, self-managed dietary intervention. Recruitment and retention was examined. With respect to recruitment and retention figures, 66% (n=23) of eligible participants were recruited, and of that 70% (n=16) of the original sample were retained. The authors considered the following important factors to successful recruitment and retention: culturally competent approaches; caring, trusting relationships; and, incentives and follow-up (Loftin, Anderson, Barnett, Bunn, & Sullivan, 2005). Consistent with previously mentioned studies, Loftin et al. (2005) also cited altruism as a powerful motivation for research participation. Using methods from this study, recruitment and retention of future longitudinal studies may be enhanced, especially with respect to African American families.

In another study focusing on successful recruitment and retention of participation in longitudinal behavioral research (Leonard, Lester, Rotheram-Borus, Mattes, Gwadz, & Ferns, 2003), useful methods were found when examining the high recruitment and retention rate of 84-97% (normally 45-65%) by the UCLA Center for Community Health. The UCLA Center for Community Health completed 8 successful intervention trials involving underserved populations (runaway youth, homeless persons, minority groups). Flexible scheduling, demonstrating interest in the participants life, establishing a relationship, giving the participant a copy of the IRB consent, having anchoring contacts, making a good connection between researcher and participant, and maintaining trust were determined as key components to success. Maximizing rewards associated with participation is also an important motivational factor for research participation over time. Some examples of rewards are interpersonal relationships with skilled study staff, referrals to community agencies, the possible benefits from interventions and the opportunity to contribute to a study which may benefit others.

Loftin et al. (2005) and Leonard et al. (2003) demonstrated methods to increase recruitment and retention. Researchers maintained internal validity by using culturally competent approaches, demonstrating genuine concern for each participant, building trusting relationships with participants, following up with participants, and obtaining useful information for study purposes. Using these findings, study designs for longitudinal outcomes research can be enhanced. Through the use of enhanced designs greater knowledge can be gained pertaining to NICU graduates longitudinal outcomes.

### Summary

NICU outcome studies have increased in the literature but there remains more to be studied. Longitudinal outcome studies are important in the evaluation of health care services, more specifically they are important in the future improvement of NICU care. Maintaining sensitivity towards the stressful situations faced by parents, not only in the hospital, but also at home, will aid in building a trusting relationship with essential members of the research team – the parents. Examples of maintaining sensitivity includes scheduling flexibility, flexible study designs, willingness to accommodate for parents and their child's needs. Since the need for longitudinal outcome studies with former NICU patients has been supported, developing a research design that is most likely to succeed is in the best interest of not only research subjects, but also the researchers.

It is unrealistic to assume that parents will want to automatically participate in NICU LOR; parents have very busy lives, they may have many follow up services for their child or they may wish to forget about their NICU experience. The Theory of Planned Behavior (Aizen, 2002), is an excellent conceptual framework to apply to this study. It considers the behavioral aspect to perform an action. Understanding the motivation of parents may guide researchers to a better study design and promote increased recruitment and retention for longitudinal outcomes research with NICU graduates. The previously highlighted longitudinal studies demonstrate a clear relationship among caring professionals, increased comfort for study participants, individualized plans for data collection, and consistent participation by study participants. By exploring the motivations behind research participation, better studies can be

designed, thus increasing the likelihood of increased recruitment and retention. With increased recruitment and retention the chances of LOR success is enhanced. Through successful LOR, the effects of NICU hospitalization can be better understood. This information is critical to prepare parents and families for their child's outcomes after NICU discharge. Also, understanding NICU outcomes may lead to improvement of NICU care.

## CHAPTER III: METHODOLOGY

### Study Design

The intent of this study was to gain an in-depth understanding of the parents' perceptions of participation in NICU LOR. Parental perception of research involving their children is critical to the success of longitudinal studies: parents are the gate keepers for their children. A qualitative research design was chosen to allow for a thorough exploration of the subject. Interviews of each parent yielded a rich data set, which provided insight into parents' unique perspectives of research participation on behalf of their children. The goal of this exploratory study was to provide conceptual/thematic description that not only surveys, but gains insight into the parental experience and perception of enrolling their NICU graduate into longitudinal research.

### Setting and Sample Selection

Participants were recruited from parents at Massachusetts General Hospital (MGH) NICU, where their children were patients. The setting of the study was a Level 3 NICU at Massachusetts General Hospital, a large urban hospital located in a major metropolitan area in the Northeast region of the country. The NICU is an 18 bed unit. Additionally there is a nine bed Level 2 Special Care Nursery (SCN, separate from the Level 3) and a 4 bed Transitional Care Nursery (TCU, also separate from the Level 3). The hospital also has a well newborn nursery. The sample for this study was derived only from the parents in the NICU. The NICU is an extracorporeal membrane oxygenation (ECMO) center and admissions are accepted from not only the in-house delivery service, but also high risk and referral transport teams servicing outlying hospitals.

Participants were included if they spoke English, were over 18 years old with a child hospitalized in the NICU for greater than 48 hours and with an expected length of stay of at least one week. If the infant was discharged from the hospital prior to the interview, the parent was not considered eligible for participation as it was felt that the phenomena of interest may be different for parents whose children have been discharged. Parental exclusion criteria were as follows: (a) documented cognitive barriers; (b) documented communication barriers; and (c) pervasive mental illness. These criteria served to minimize confounding variables pertaining to responses of the interview discussion.

### Procedures

#### *Data Collection*

The Resource Nurse in the NICU assisted in identifying potential parents that met the inclusion criteria. The NICU Resource Nurse is a staff nurse functioning in a leadership position for the shift, with responsibilities including, but not limited to, staff assignments, attending deliveries, serving as a source of conflict resolution, and triaging infants. After the Resource nurse identified potential participants for the researcher, the researcher asked the bedside nurse responsible for the infants' care if it was a convenient time to approach the parents. If it was deemed an appropriate time, the bedside nurse asked the parent(s) if they may be approached by a researcher. If they assented, the researcher introduced herself to the parent and explained the research study. If they wanted to participate in the study, they completed an informed consent, scheduled the interview, and received the Study Information Sheet for Parents. Enrollment was open

to one or both parents if they chose to participate, however parents were interviewed separately. Timing for the interview was at the parents' convenience.

The interviews were conducted in a conference room away from the bedside but inside the NICU. The only people in the room during the interview were the participant (the parent) and the researcher. Estimated time for each interview was approximately one hour. Interviews for mothers and fathers of the same infant were scheduled as closely as possible to avoid discussion between interviews. The researcher was available after the interviews via telephone and email if any participant had questions or concerns.

The study was approved by the Massachusetts General Hospital (MGH) IRB and the Northeastern University IRB. Data collection consisted of face to face interviews lasting approximately one hour. The interview questions were broad, open-ended, and supplemented with probing questions during the interview to gather a rich data set (Appendix A). The interviews were conducted in a private face to face interview, which was tape recorded. The audio taped interviews were transcribed verbatim and the data coded and analyzed using NVIVO 7, qualitative data analysis software. The Parent Demographic Information Sheet (Appendix C) and Infant Demographic Information Sheet (Appendix B) were used to gather demographic information to describe the study participants.

Consistent with qualitative research methods, data collection continued until saturation was reached. Polit and Beck (2004) define saturation as when the themes and categories in the data become repetitive and redundant, when no new information is attained through further data collection. For the purposes of this study, it was estimated

that 20 interviews yielding approximately 20 hours of data would be necessary to reach saturation.

### *Human Subjects Consideration*

As previously presented, NICU parents are a vulnerable group (Korenman, 2004; Franck, 2005; Golec et al. 2004). Their experiences have not been studied well and stress is an important factor in informed consent decision making during their child's NICU hospitalization (Mason & Allmark, 2000). The following are examples of the researcher's methods to decrease stress and ensure valid informed consent for this research:

*Parents of NICU Infants:* NICU parents experience high levels of stress related to their infant's illness, NICU admission, and hospitalization. To decrease questionable informed consent caused by stress, written information pertaining to the research was provided to the parents. They were provided with contact information for the researcher and parents were given the chance to ask additional questions at any point after the interview. Contact could have been made through a phone call, email, or bedside letter, whichever was more convenient for the mother and/or father.

*Consents:* Consenting parents who met the inclusion criteria were enrolled while at their infant's bedside; mothers and fathers were only approached after permission from their nurse. The parents were asked if the timing was appropriate and the informational sheet was read to them. They were asked if they understood the information presented. They were also asked if they consented to participation and finally they signed the consent form. To reduce instances of questionable informed consent, the researcher read an informational sheet about the study to the parents and gave them a copy of that

informational sheet for later reference. If they had any questions, they were given the researcher's email address and phone number.

*Risks:* Risks were minimal and were related to discussing factors pertained to stressful information about their ill infant. If necessary, participants were reminded of their voluntary participation and their right to withdraw without negative repercussions at any time. The principal researcher was available to any participant who experienced stress related to the study. The LICSW was also available if parents communicated persistent stress after speaking with the researcher.

*Confidentiality:* Information related to the interview discussion was summarized in this report without identifying respondents by name or by their infants' names. Data collected remained confidential and identity was known only to the researcher. Information collected during the study (such as consents, transcription documents, and audiotapes) was kept in a locked box at the researcher's residence. The study information has been maintained in a locked box with the researcher for the time appropriated by the IRB at MGH and Northeastern University. All other data collected during the study has been maintained with the researcher as well. Links between data and specific parents/children were secured by the researcher in a locked box until study completion. Upon completion of the study any information linking names and data will be destroyed by shredding, and audiotapes will be destroyed by crushing. No documents have identifying links between names and data after study completion.

#### Data Analysis

Demographic data from parents served to describe characteristics of participants. Ages and education of the parents were summarized using frequency distributions.

Ethnicity, occupation, marital status, pregnancy history and history of research participation are presented using descriptive statistics. Also, infant demographic data was used to describe infant characteristics and condition: length of time in the NICU, gestational age at birth, birth weight, post conceptual age at time of enrollment and acuity are included. Diagnoses and whether single or multiple births are presented as descriptive statistics later.

Transcripts of the interviews were entered into NVIVO 7, a qualitative data analysis software program. Data analysis began by immersing the researcher in the data via a line by line reading of the interview text. Coding began with identifying concepts and then organizing them into broader themes. These broader themes were matched with interview data and were used to identify similar themes among interviews. This data analysis was done concurrently with the interviewing process to heighten sensitivity to saturation. Additionally, once themes were identified with the organizational help of NVIVO 7, interviews for participants became richer with respect to the quality of data obtained. Once saturation was achieved, the data collection ended. From the data analysis the broad themes emerged. It is from these themes and concepts that the answers to the research questions emerged.

CHAPTER IV: RESULTS

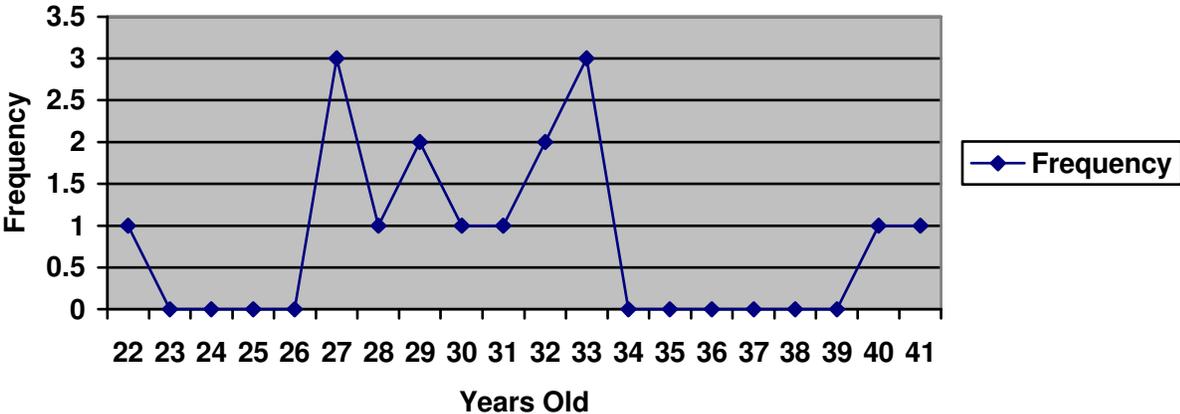
Sample

*Parent Characteristics*

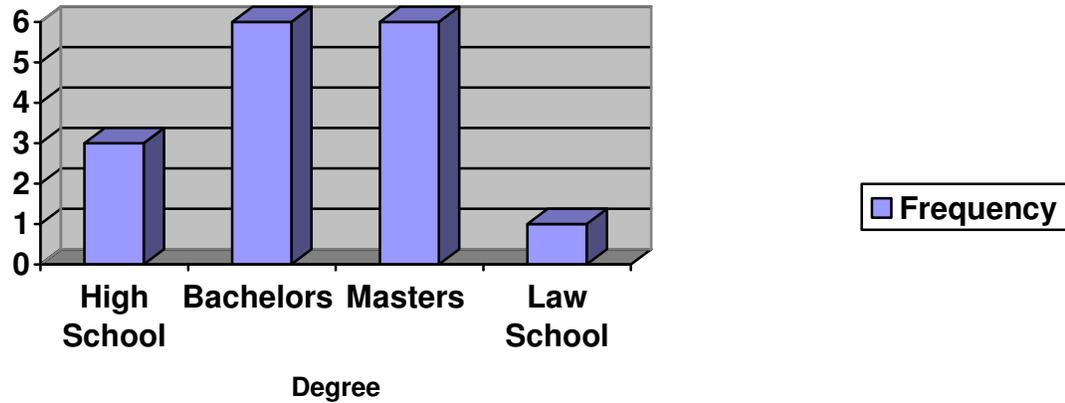
Seventeen parents agreed to participate in the study but sixteen parents completed the data collection process. One parent was consented but not included in data collection because their child was transferred to the level 2 nursery prior to the interview and therefore was ineligible for the study. Although the original estimate of sample size was 20 participants, saturation of data was achieved with 16 participant interviews.

Parent characteristics recorded included age, phone number, ethnicity, occupation, level of education, marital status, pregnancy history and history of research participation (see Appendix C). Of the 16 parents interviewed, 6 were part of a 2 parent dyad which made up 3 couples. Two of the dyads were married. The final couple was co-habiting and engaged to be married.

*Figure 1: Parental Ages*



*Figure 2: Educational Achieved*



The majority of parents were Caucasian and one parent was African American. More mothers (n=12) than fathers (n=4) were interviewed. An array of occupations were reported: homemaker (n=4), management (n=2), office coordinator (n=1), adoption coordinator (n=1), consultant (n=1), power plant technician (n=1), cabinet maker (n=1), graphic designer (n=1), teacher (n=1), customer service director (n=1), business owner (n=1), and attorney (n=1).

Pregnancy history was obtained by verbal reporting from the mothers and fathers. Validation of this information was obtained from the infants' medical record. For 13 of the parents, this NICU baby was their first living child. Among the 3 parents that already had living children, 2 parents had children who were former NICU patients. Per parent report, the older siblings had similar diagnoses, treatments and outcomes during their hospital courses in the NICU. As part of the Parent Information, parents were asked if there was any significant family medical history that was important to share for this research. Most parents chose not to report any significant past family history (n=12). Of those that did, significant medical history included cancer (familial), diabetes (familial),

arthritis (familial), Parkinson's Disease (familial), adenomyosis and endometriosis (maternal), and pregnancy induced hypertension (maternal).

Efforts were made to recruit a heterogeneous sample of mothers and fathers for the study. The parents in this study are representative of the parent population that met inclusion criteria with children in the MGH NICU during the enrollment period. Due to the inclusion criteria, exclusion criteria and convenience sample, the sample is homogeneous. Most of the parents were married mothers, had an education of at least high school level and were gainfully employed. Those without employment were homemakers. This baby was the first child for most parents.

### *Infant Characteristics*

Sixteen participants were interviewed for the study resulting in a total of 14 infants included in the study. The discrepancy between parents and babies is due to several factors: 3 intact couples were interviewed (3 infants for 6 parent respondents), and one mother had twins in the NICU (2 Infant Information sheets). Of note, another infant was one of a twin gestation. Unlike the previously mentioned twins, these twins were separated: one infant was readmitted to the NICU, while the other remained in the Special Care Nursery (SCN). As the twin in SCN was not a NICU patient, no information was collected on that baby.

Infant data included length of time in the NICU, gestational age at birth, birth weight, diagnosis/diagnoses, acuity classification, and singleton or multiple birth (see Appendix B). Length of time in the NICU ranged from 2- 52 days, with an average of 12 days. The youngest gestational age of the infants was 26 5/7 and the oldest gestational age at birth was 41 6/7 weeks. The following definitions classify infant gestational age

and birth weight. These definitions were obtained from Manual of Neonatal Care: Fifth Edition (2004):

*Birth Weight Classification:*

Low Birth Weight (LBW): birth weight less than 2500 grams

Very Low Birth Weight (VLBW): birth weight less than 1500 grams

Extremely Low Birth Weight (ELBW): birth weight less than 1000 grams

*Gestational Age Differentiation:*

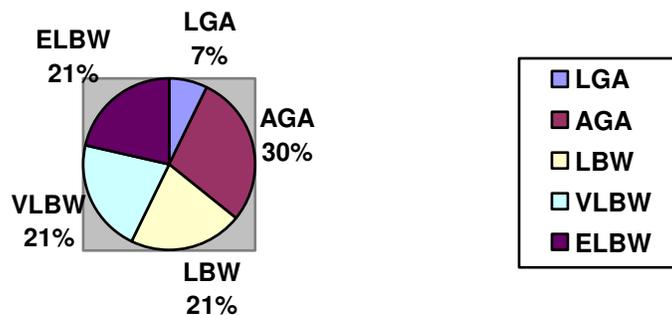
Preterm: An infant born before 37 weeks gestational age.

Term: An infant born between 37 and 41 6/7 weeks gestational age.

Postterm: An infant born after 42 weeks gestational age.

Based on gestational age, the number of premature infants (n=9) was greater than term infants (n=5). The average infant birth weight was 2257 grams (LBW), with a range from 520-4955 grams. Infant weight distributions are presented below.

*Figure 3: Infant weight distributions*



Of note, one baby included in the study was readmitted to the NICU for a complication of prematurity (NEC). This is a twin; the second twin remained in the Special Care Nursery

(SCN). The SCN is a nursery that provides care to neonates at a lower level of acuity than those cared for in the NICU. Since the second twin was in SCN information was not obtained for that infant. This baby's previous time in the NICU was not included in the length of time in the NICU.

The following diagnoses were obtained from the infants' medical record. The diagnoses to follow include initial diagnoses, but may not include all secondary diagnoses discovered during hospitalization. Infant diagnoses in order of most frequent are as follows: prematurity (n=6); respiratory distress (n=5); pneumonia (n=2); patent ductus arteriosus (n=2); pneumothorax (n=1); imperforate anus (n=1); group Beta Streptococcus sepsis (n=1); persistent pulmonary hypertension (n=1); necrotizing enterocolitis (n=1); cystic periventricular leukomalacia and cystic encephalomalacia (n=1); intraventricular hemorrhage (n=1); meconium aspiration syndrome (n=1); narcotic abstinence syndrome (n=1); intrauterine growth restriction (n=1); and, tracheoesophageal fistula with esophageal atresia (n=1). Using the Key Concept Definition of preterm gestation, gestational age at birth that is <37 weeks is preterm. With this sample of infants, however, babies >35 weeks gestation did not have a diagnosis of prematurity in their medical record. In spite of this discrepancy, definitions from Key Concept Definitions were used when describing the infant population.

Hospital administration uses an acuity classification for each baby as a means of assessing nursing care needs. The acuity range in this NICU is from 3 to 6, with 6 being the most critically ill and labor intensive for nursing care purposes. This number is not static: it is re-assessed for each baby by the nursing staff daily. At the time of the

interview, the babies in this study were classified as either 3 (n=2) or 4 (n=12) level of acuity.

### Qualitative Analysis of Interview Findings

The interview guide consisted of 6 questions (Appendix A). Every parent responded to all 6 questions. As previously discussed, the interview questions were meant to initiate discussion, not limit it. During the interview parents were frequently asked to elaborate on responses to stimulate discussion. These elaborations were critical to gain a complete understanding of each parent's viewpoint. In addition to elaborations, some parents chose to share feelings or ideas independent of the interview questions. These were categorized as independent responses. The following section describes the responses for the 6 interview questions, the elaborations, the independent responses that emerged during interviews and also the comparison of intact couple responses.

#### *Previous Experience with Healthcare Research*

As past experiences have an impact on opinions and decision making, the first 2 interview questions sought to gain an understanding of parents' previous experience with healthcare research. The first research question of the interview guide explored parents' previous healthcare research experience. Responses indicate that the majority of parents had no experience with healthcare research (n=13). Several parents had experience with research, but this research was not related to healthcare. Three of the 13 parents had previous non-healthcare research experience; research topics included biotechnical (n=1), developmental health (n=1), special education (n=1). Another mother in this group completed her own unofficial research study to learn how to treat her endometriosis. This research resulted in the formulation of a progesterone cream. This mother was not

included in the group with experience in healthcare research since her research was not an official research study, and the progesterone cream was not formally tested. Three parents did have experience with healthcare research; 2 participated in research during their babies' hospitalization, and one participated prenatally.

#### *Knowledge of Longitudinal Research*

The second question explored parents' knowledge of longitudinal research. Twelve of the parents reported no knowledge of longitudinal research and 4 parents had minimal/basic knowledge of longitudinal research. As the majority of parents had no knowledge of LOR, the following scenario was provided to all parents: their child, a former NICU patient, would be studied until they reached 18 years old if the parents consented. Giving the parents a consistent scenario ensured that responses were based on similar knowledge; little was left for the parents' individual interpretation. The parents were instructed to use this scenario when answering the remaining interview questions.

#### *Stress as a Factor in Decision Making*

NICU parents frequently experience stress during their child's hospitalization. As previously discussed, this stress is an important factor in decision making for NICU parents (Mason & Allmark, 2000). Stress also has been recognized among parents in the PICU (pediatric intensive care unit) and among parents caring for chronically ill children (Garro, Thurman, Kerwin, & Ducette, 2005). Stress symptoms emerged during the parent interviews, and had an impact on parents' responses. These symptoms became especially evident when discussing best timing for LOR consent. Cognitive and emotional symptoms observed by the researcher and supported by the Mayo Clinic's description of stress symptoms during interviews include:

- Memory problems
- Inability to concentrate
- Trouble thinking clearly
- Focusing on the negative
- Impatience
- Feeling overwhelmed
- Indecisiveness
- Trouble thinking clearly
- Anxious
- Restlessness
- Inability to relax

([http://www.mayoclinic.com/health/stress-symptoms/SR00008\\_D](http://www.mayoclinic.com/health/stress-symptoms/SR00008_D))

Physical and behavioral symptoms were not observed during interviews. As a result, stress levels were assessed based on the Mayo Clinic's cognitive and emotional symptoms of stress only. Stress level was assessed by the researcher as either low, moderate, or high. The level determined was by the number or stress symptoms observed or the pervasiveness of the symptoms during the interview. Stress level was assigned to each parent and used in analysis of the interview questions.

#### *Best Timing for LOR Consent*

The 4 remaining questions asked parents to use their understanding of LOR (as previously described). The questions to follow asked parents to share opinions and viewpoints about best timing for consent, frequency of reminders of participation, barriers to participation, and facilitators to participation. The third interview question asked parents about their best consent timing for LOR. Data in Table 1 (below) are results for best timing. The results compare 2 of the 3 responses: now/during hospitalization and after hospitalization. The third grouping of responses for best timing of consent was "non-specific". The results for "non-specific" responses are discussed below as well.

*Table 1: Comparison of parental and infant characteristics and best timing response*

Characteristic	Now/During Hospitalization (n=5)	After Hospitalization (n=9)
Parent stress level	5 low	5 low 4 medium
Length of time in the NICU (average days)	15.6	9.1
Baby's Gestation	5 preterm	4 preterm 5 full term
Birth Weight (average kilograms)	1.4	2.8

Parents that responded best timing would be now or during hospitalization were comprised of both mothers (n=4) and fathers (n=1), and 80% were educated beyond high school. Parents had both no research experience (n=3) and a positive history of research participation (n= 2). Marital status was as follows: 4 married, 1 co-habiting. Parents that responded best timing would be after hospitalization were similar: comprised of both mothers (n=6) and fathers (n=3), 77% had education beyond high school. Marital status for this group: 6 married, 2 co-habiting and 1 single parent. Three of these parents had a history of research participation, while 6 did not. As demonstrated, timing ranged: now/during hospitalization (n=5), not specific (n=2), and after hospitalization (n=9). After parents responded to the interview questions, the interviewer asked them to elaborate. The researcher sought elaboration for 2 reasons: (a) their thought process

could be better understood; and (b) specific time frames could be outlined for definition purposes. If best timing was after discharge, parents fell into one of three categories according to responses: at discharge, a short time after discharge (2 weeks to one month after discharge) and a long time after discharge (6 months to one year after discharge). Time frames were obtained from parents' definitions during elaboration. Best timing responses depended on many factors: parent characteristics, parent stress level, the infants' current state of illness, unknown future factors and more.

Parents were asked to elaborate on their responses to best timing because their responses were essential to understanding their motivation. The following quotes were extrapolated from the interviews of parents that believed best timing was during hospitalization. One mother of a baby born at 36 weeks gestation with a tracheoesophageal fistula and esophageal atresia reflected:

Oh, I think I would be comfortable in the NICU, now; probably because of the situation that we find him in. I don't think I'd have to wait 6 months or a year. I think I would do better if you asked me now, and I would be more willing to say yes because of the incredible care that he has received here. I'd feel like I'd want to give back and would do so more willingly the closer I am to receiving the care.

Another mother of 29 week twins responded:

Um, I would say any time frankly. I don't um, yeah any time. I am open to the conversation now. I think there are other people that would be really stressed out about being here, and my husband and I are, but not so overwhelming that if someone asked me to be in a study I would be like 'I can't even think about it'. So, I am kind of open to those kind [sic] of conversations at any point in time.

Understanding parents' thought processes are important, as they may share the same views as many other NICU parents.

The following responses were obtained from interviews with parents that believed best timing for LOR consent to be after hospitalization. The mother of a preterm baby stated: "I think while you are here you have enough going on, enough to deal with wondering if he is going to be ok. Once you get the all clear and everybody is happy again...". Another mother of a full term baby shared the following:

There is no rhyme or reason to it. I think, I mean for me, I have only been here for a month, so I'd say that other NICU parents that are here for long periods of time, but I feel like there has to be some separation of hospital and home, and then I would imagine a couple of weeks would do that.

The parents that spoke about separation of hospital and home sought to maintain or establish normalcy in their lives. A mother of a full term baby with an imperforate anus elaborated "Um, well when you are at the hospital it's sort of overwhelming. I would say actually probably not until we get home. But not right away, so maybe after a week or two of them being home". No parent said they would refuse to participate in LOR.

Two parents did not fit into either of the previously mentioned categories. One mother did not specify ideal timing; she responded that "anytime" would be adequate. Her stress level was low, her baby was full term, and was being discharged the following day. Her first child was also a full term baby admitted to the NICU after birth. The first child's hospital course was similar to this baby, but the mother was unable to recall the reason for admission.

The other mother in this category was quite different. She readily consented to the interview. During the interview, she was wide-eyed, with rapid and pressured speech, she was in constant motion, and had difficulty focusing on the interview questions: her stress level was assessed as high. Her baby had been in the NICU for 20 days and was premature at birth. The baby's diagnosis included prematurity, cystic periventricular leukomalacia (PVL), and cystic encephalomalacia. During her interview she was unable to answer any question with specificity, citing that she was overwhelmed due to her baby's unknown future and his unknown health status. When asked of timing of reminders prior to appointments, she replied "Um, I don't know. I don't know what is going to happen, so I don't know". When asked what would make LOR easier (facilitators), she asked that parents have the ability to contact researchers regarding when to participate - "I know most mothers here are very overwhelmed and you really don't want take time to talk and sit down with anybody, because you're into your baby and you want to be there at every moment". Her ability to consider the research questions and respond in an organized manner was inhibited by her stress level due to her baby's illness, and (the baby's) unknown outcome. Being aware of this level of stress among parents in the NICU is important when considering approach for LOR consent.

#### *LOR Participation Reminders*

Frequency reminders of LOR participation was the fourth interview question. All parents responded similarly: reminders should occur at the same frequency as reminders for doctor appointments. For example, a notification day prior to the follow-up appointment was adequate.

#### *LOR Barriers*

The fifth interview question explored barriers to LOR participation. Barriers included logistical aspects, emotional aspects, and also life conflicts and Table 2 summarizes the frequency of responses. Logistical aspects refer to details of study. Examples included site distance from home (n=6), frequency of the appointments (n=5), long term commitment of the study (n=5). Emotional aspects to LOR participation included baby's health status (n=6), pain/safety for the baby (n=4), and lack of perceived benefit (n=2). Examples of life conflicts included other children in the family (n=2), multiple medical appointments for the NICU graduate (n=1), parent work conflicts (n=1), and spousal objection (n=1).

*Table 2: Barriers to LOR participation*

Barrier	Frequency (n)
Logistical Aspects	16
Emotional Aspects	12
Life Conflicts	5

Logistical barriers were cited most frequently by parents. Distance was one of the most frequently cited barriers (n=6). Parents who responded in this category either lived outside of Boston currently or would possibly live outside of Boston in the future. These parents were concerned about traveling into the city for appointments. None of the parents that responded as such shared transportation issues that would hinder them from conveniently traveling into the city. Frequency of follow up appointments was another logistical concern for parents. In general, parents believed that a monthly or more than monthly follow up was too frequent and would impact their daily lives. The long term

commitment was a consideration as well. Many parents also were apprehensive about LOR due to the unknown future i.e. moving, other children and even extracurricular activities. For example, a parent of a full term infant stated:

It's probably mainly just scheduling, you know, like the form said there's no foreseen benefit to me, to this, so [sic]. So like 10 years from now, L's got soccer practice it'd be hard to say 'you shouldn't go to soccer practice' so she can go participate you know, just scheduling and busy lives. That, I think is the biggest issue.

Emotional aspects to LOR barriers were also important to the parents. The emotional difficulty related to the baby's health status was reported by 6 parents. Of the parents identifying this as a barrier, 3 were fathers and 3 were mothers. One father of a full term baby shared "I guess if she had some sort of, God forbid, some sort of medical issue that was related to her time in the NICU then that would certainly be kind of emotionally difficult." Thus health status of the baby may be a problem for recruitment and retention of participants. Another father of a preterm baby reflects "might be difficult, if it is a very sick child to have them travel so much. Um, hopefully that won't be our situation". As discussed previously, long term morbidities can frequently impact former NICU patients. A high level of sensitivity toward how these ongoing medical issues affect families must be maintained with LOR. When asked about barriers to LOR, one parent was concerned about pain:

I just think anything too medically invasive. I think she has been pinned and pricked at enough. She's only a couple of weeks old. It just would depend on

what, how we'd look at the information needed to determine what the long term effects would be.

Yet another emotional aspect to LOR was no perceived benefit to the parents or their child by participating in the research. Both of the parents that cited "no perceived benefit" as a barrier to participation were fathers with moderate levels of perceived stress. Their children were quite different, however: one premature baby with NEC and the other was a full term infant with GBS sepsis S/P ECMO.

Life conflicts included other children, spousal objection, work schedule or other appointments for the baby. This category demonstrated significant impact factor for parents. Impact factor is an aspect of data analysis that is unique. While it may not be frequently cited, it is a critical element for some parents. In this case, impact factor is a term taking into account preferences, wants and values of the participant (Gilgun, 2006). For example, one parent said that if their spouse objected to the research they would definitely not participate in the research.

Impact factor was also significant for the following 2 emotional barriers: emotional difficulty related to baby's health status and pain to the baby or safety concerns. The parents who were concerned about the baby's health status and pain were adamant: the parent would not allow the baby to participate in LOR if the child had a poor health status or if the child would be in pain as a result of participation.

#### *LOR Facilitators*

The sixth interview question explored parents' perceived facilitators to LOR. The emotional aspect was not as significant a factor for this question. Similar to barriers,

facilitators of LOR were separated into 3 general groups. Table 3 summarizes the frequency of logistical, emotional and life conflicts associated with LOR facilitators.

*Table 3: Facilitators of LOR Participation*

Facilitator	Frequency (n)
Logistical	27
Emotional	5
Life Conflicts	2

Logistical facilitators represent the majority of facilitators. They included creative study sites, such as home visits (n=4), study site local/not Boston (n=4), flexible time of day (n=9) such as afternoon/evening (n=2), day time (n=2), and weekends (n=5), no visit necessary with data collection via telephone or internet, with other baby appointments (n=2), reimbursement for travel (n=1), and enrollment unique for each family (n=1) .

The parent that identified a unique enrollment procedure was a facilitator was a mother with a high stress level. She said “Yeah, like if people are interested they should be able to call you and say ‘I am interested in the study’ and if they are not they should be polite and say ‘I am not interested’”. This mother repeatedly expressed stress regarding her child’s condition and indicated that she did not want to take time away from her baby. Her stress symptoms would have been an impediment to consenting for research at the time of the interview, therefore unique enrollment procedure would possibly facilitate her involvement in LOR research. If she were expected to conform to standard/inflexible enrollment procedures she may be less likely to allow her child to participate.

Emotional facilitators (n=5), while not as frequently reported, were important to parents. For an example of an emotional facilitator, one father responded that the dependability of the study was important to him. This father lived a long distance from MGH, and he was concerned about the distance of study site from home (if the study site were at MGH). He believed that if the study staff were not prompt it would discourage him from participation. Non-monetary benefit of research was another example of an emotional facilitator. One mother stated “I mean otherwise I just can’t imagine not wanting to, as I said earlier, help with something that might help another baby that goes through something similar to what L did”. In this set of responses, dependability of the study site had the greatest impact.

One example of life conflict facilitators is combination of appointments. One parent responded:

It would be helpful if it were coordinated through his pediatrician. Like if you were going to your pediatrician, you know, how ever often you go to get vaccines and well-being checks, if it were coordinated with that that would be great.

The other example in this cohort is a minimal study time commitment. Minimal time commitment encompasses the study visits per year. Parents believed that the fewer times per year for visits, the easier to participate in NICU LOR. Facilitators for LOR consist of logistical, emotional, and life conflict components. Maximizing these identified facilitators when designing and implementing NICU LOR will enhance its success.

### *Independent Responses*

As stated previously, three independent themes emerged during the interviews. The independent themes included: positive view of research (n=7), desire to maintain normalcy (n=7) and feelings of being overwhelmed (n=4). These independent themes were unrelated to the 6 questions on the interview guide and were extrapolated from anecdotes and comments during the interviews. Positive view of research and desire to maintain normalcy were discussed equally in frequency. Parents that had a positive view of research expressed a desire to “give back”, to repay for the care their child received while in the NICU. Parents of both preterm (n=4) and term infants (n=3) were represented in this group. With respect to positive view of research, one mother of a premature baby stated “I think that when you have a premature baby anything that helps the doctors or the nurses to better help preemies in the future, like her, I’m more than willing to let them do”. Another mother of a full term baby felt similarly:

I’d imagine it wouldn’t just be her – there would be several babies, hundreds of babies that would go through the same kind of path she went through, so are there long term effects of some of the drugs she was given, or of her original condition. Being able to follow her in that way would be able to provide more outlook for someone else who was born with her situation.

These parents wanted to contribute to the body of knowledge that helped/was helping their baby’s during illness.

Desire to maintain normalcy was yet another independent response. As a result of their babies’ NICU hospitalization, parents were unable to have a “normal” birth process: having the baby eat by mouth, room in with the parent(s), and be discharged home with their parent(s). This loss of normalcy was discussed among parents of both premature

(n=4) and full term infants (n=3). The loss of normalcy affected parents in such a way that the parents needed to attain this normalcy before they could consider LOR. Of the parents that stated a desire to maintain normalcy and feeling overwhelmed, the vast majority also believed best timing for consent should be after hospitalization. The parent of a full term infant elaborated:

I mean for me, I have only been here for a month, so I'd say that other NICU parents that are here for long periods of time, but I feel like there has to be some separation of hospital and home, and then I would imagine a couple of weeks would do that.

Having an understanding and appreciation for the subjective experience of parents in the NICU is an important factor in LOR recruitment and retention.

Feeling overwhelmed, the third independent response, was discussed by 4 parents. The parents in this group also had premature (n=3) and full term babies (n=1). Their babies' hospitalization was a significant stressor, causing an inability to even consider participation in LOR. Feeling overwhelmed and experiencing stress has a significant impact on communication, ability to listen, and decision making. The parent of a preterm infant said: "In the beginning I wasn't listening to anything anybody said. I couldn't process anything. Probably would be better to wait until I knew what you were saying to me". Consenting for LOR will be impacted by parental stress. Another parent of a full term baby with pneumonia responded:

Because you are so focused on what's going on right now you don't want to be taking on anything else. You know? Like, I am not planning anything else right

now: my focus is my son and my family. And I am just not going to take anything else on.

One father of twins expressed his stress: “I don’t know, I’m just saying it to be...It’s all new to us. And we have one baby down in the NICU and one over in Special Care, so it’s all just overwhelming right now”. Clearly and understandably parents experience stress in the NICU. Their stress is subjective and maintaining sensitivity to their individual experiences may be critical to LOR success.

These independent themes, while not originally sought after, gave important insight into the parents’ viewpoints and concerns. These viewpoints and concerns are necessary to determine the appropriateness of consent timing, approach, and study design. Additionally, they support the idea that the stress and lasting effects of a child’s hospitalization are subjective to each parent. These lasting effects will have a great impact on LOR success or failure. These independent themes are equally invaluable to future LOR designs as the interview guide responses.

#### *Comparison of Intact Couple Responses*

Researchers face unique challenges when conducting research with children. One aspect of the challenge includes ensuring that parents or legal guardians have the child’s best interests in mind. Additional difficulties may arise when two parents disagree about research participation for their child. In this study, three intact couples participated allowing for comparison of parental attitudes and beliefs about research participation. Comparing the intact couple responses provided a useful illustration of the differing opinions and how these differences may affect LOR recruitment and retention. As

previously discussed, parents were interviewed separately, but within one hour of each other to minimize discussion between interviews.

The first couple was the parents of a full term infant with GBS sepsis S/P ECMO. Their baby was not on ECMO at the time of the interview. Both had medium levels of stress and both preferred consent timing after hospitalization. When asked to elaborate, this mom cited a need to maintain normalcy, while the father had no rationale. Barriers were similar: concern for the long term commitment and logistics. Facilitators for the mother were related to contributing to the body of knowledge for NICU patients, while the father's were of a logistic nature (flexible time for appointments, for example). During their interviews, both parents expressed a desire to maintaining normalcy. The mother repeatedly expressed a positive view of research, while the father did not express a positive or negative view. These parents had different motivations, so attention should be paid to each parents' needs and wishes. These parents had similar and dissimilar responses for the interview questions.

The next couple had a preterm baby with pneumonia. Both parents had low stress levels. The mother believed the best timing for consent was after discharge; she believed the hospital was overwhelming and when home she would be able to be approached for consent. The father believed that timing would be appropriate during hospitalization; he was comfortable with recruitment because the baby's condition was improving. Barriers to LOR included distance from the study site for the mother; distance from study site, health of the child, and long term commitment for the father. Facilitators included appointments on the weekend for the mother, and monetary compensation for travel and

study dependability for the father. Both parents' concerns were logistical. Similar to the previous couple, this pair had both similar and dissimilar responses.

The final couple had a preterm baby diagnosed with an esophageal atresia and tracheoesophageal fistula. While both parents had a low stress level, their best timing for consent differed: the mother preferred consent to be during hospitalization, while the father believed consent should be a long time (one year) after NICU discharge. The mother, when she elaborated, had a positive view of research and a desire to "give back". When the father elaborated, he spoke of a desire to maintain normalcy as reasoning for late consent. Their barriers were slightly different. The father cited spousal objection and pain to the baby as barriers. The mother cited time commitment, baby's health and distance from home as barriers to LOR. Facilitators for the father included understanding the purpose of the research and lack of risks to the baby. Mom's facilitators included home visits or visits coordinated with the routine pediatrician appointments. Modifying study designs to meet the needs and concerns of both parents is essential to recruit and retain for LOR. As demonstrated, intact couples have similar and dissimilar beliefs and motivations. Understanding both parents' point of view is important to the success of LOR

#### Scientific Rigor and Generalizability

According to Seale (1999), in order to attain reliability in qualitative research, ensuring trustworthiness is crucial. In order for the data from parent interviews to prove trustworthy, several aspects must be examined. When potential participants were recruited, differing parent backgrounds (age, race, education, etc.) was sought to contribute to the credibility and generalizability of the study findings. Other factors that

contribute to credibility are correct number of participants and appropriate method of data collection (Sandelowski, 2000). In addition, quotations directly from the transcriptions enhanced credibility. An additional researcher performed a member check: read through the data, evaluated the meaning units and other categories and ensured agreeability. This researcher is a PhD prepared nurse with research experience as well as extensive experience with the NICU population and their families. This validation added to the credibility of the data and its analysis. Another aspect to trustworthy data is that of transferability. Transferability is the extent to which findings can be transferred to other situations (Graneheim, & Lundman, 2003). A wide range of characteristics of participants will enhance transferability, which also adds to credibility (Sandelowski, 2000).

In addition to the data analysis and member check, the researcher maintained a detailed journal throughout the data analysis process. This journal served as a diary of the analysis thought process. It was also used to clarify any decision making after initial data analysis.

The homogenous group of parents limits the generalizability of the data. A more diverse group of parents was sought after, but was not attained due to the limitations of inclusion/exclusion criteria and availability of parents and the researcher during recruitment. The infant characteristics were diverse, with the exception of race. The measure of credibility of the data includes correct number of participants, appropriate data collection and the use of quotes to support analysis. Saturation of the data was reached at 16 parents. Data was collected for infant information, parent information and the interview responses. The methods for data collection were appropriate and quotes

were used to support the analysis. Transferability of this data to other situations is unknown: the parents are not a diverse population, but this is also an infrequently studied group. More research should be done with NICU parents to determine the transferability and credibility, preferably with a diverse parent group. A member check was completed by Margaret Settle RNC, PhD. After reading raw data and the associated conclusions, Margaret Settle concurred with the data analysis. This member check ensured agreeability of the data.

The researcher's journal was effective for cataloguing choices. It was also helpful for the researcher to reflect on emotional decisions during the recruitment of parents. As a staff nurse on this unit, I made several decisions to ensure an appropriate barrier between staff nurse and researcher: (a) I never recruited or discussed the research while working or wearing a uniform, (b) I did not recruit families that I was familiar with, and (c) I did not work and recruit on the same day. In addition, I also avoided approaching families if their baby was acutely ill (i.e. ECMO, HFOV). This may not have been necessary as parents experience stress subjectively, but it was done to minimize harm and stress to the NICU parents. As a result, most parents who were approached did agree to participate in the research.

## CHAPTER V: DISCUSSION

The goal of this research was to gain insight into the opinions of NICU parents regarding research in general and research with their child. Information was sought about parents' knowledge of research, knowledge of longitudinal research, best timing for LOR consent, timing for LOR participation reminders, LOR facilitators, and LOR barriers. The purpose of data collection was to gain a basic understanding of parents' opinions of LOR, as little is known about this topic. Many of the findings from this study, such as altruistic motivation for research, were similar to findings from the literature review. The following section is a discussion of the study results.

The parents that participated in the study were a homogeneous group however, the infants involved in the study were a mix of premature and full term, medical and surgical patients. A discussion of the parent group, infant group and question responses will be explored in this section. Several of the questions had straightforward responses, possibly because of the researcher's manner of questioning, the nature of the question or as a result of the homogeneous group of parents. Such question/responses included Questions 1, 2, and 4 (see Appendix A). The parents that participated in the study typically had no/minimal experience with healthcare research, no/minimal knowledge of LOR and all wanted reminders similar to any routine physician or dentist appointment. Other responses were more complex.

Best timing for consent yielded a rich set of data. Parents that preferred consent during hospitalization tended to be less stressed, with longer lengths of time in the NICU and with babies of smaller birth weight. Parents that believed best timing for consent was after discharge had a higher stress level, with shorter lengths of time in the NICU and

babies of larger birth weights. While the reason for this is unknown, it is possible that parents of full term or near full term babies were not as prepared for NICU hospitalization as parents of premature babies. Parents that believed best timing for consent to be after discharge were more likely to have a full term infant.

Parental responses demonstrate that stress has a global effect on decision making for these NICU parents: parents are able to consider LOR participation once they have achieved normalcy and are no longer overwhelmed. Parents do not want to be reminded of their child's hospitalization until they have coped with it effectively, and NICU LOR may be a reminder for them. Understanding this stress and the understandable need to achieve normalcy is important; LOR consent may need to have different points of consent to maintain sensitivity to each parent's personal stress and coping skills. For example, parents typically had 3 choices for LOR consent: now/during hospitalization, short time after discharge, and a long time after discharge. The data demonstrates that parents of premature infants with longer lengths of time in the NICU are more likely to consent now/during hospitalization. However, this is not absolute. Perhaps future researchers may develop a tool to assess consent readiness. Coping, time to achieve normalcy and methods/factors to achieve normalcy are important aspects of the NICU parents' experience that should be considered as important to LOR designs.

As demonstrated, logistical aspects are not the only consideration for parents. The emotional piece is critical as well; LOR success will require organization of a highly personalized study design that can adapt to each families needs. Parents should play an integral role in the research design. One possibility is to include parents as members of the research team as is seen frequently in participatory research. Parents can then help

researchers design studies that incorporate needs unique to the population enrolled in the protocol. For example, attention should be paid to the health of the NICU graduate and their families. Parents responded that traveling with a sick child would be problematic. Parents also felt that the LOR should not include any harmful/painful procedures, as the child has already been exposed to enough painful stimuli for their relatively young age.

With respect to consent timing, the parents' readiness should be evaluated. Based on the data, timing for consent should be flexible, i.e. consent attempt from the time in the NICU until one year after discharge. Utilizing parent responses, data collection points should be once or twice yearly and some data collection should be done in a flexible and convenient way, such as via mail or email. Employing both independent responses and facilitators, parents and the children should be updated regarding study findings and the purposes for data collection. This may also serve as reminders of research participation. Using this update throughout the study, attrition may be decreased.

Helping families understand that their involvement is critical to data collection and making them feel involved in the study could help enhance retention. Employing another independent response, stress and parents' feelings of being overwhelmed should also be taken into account. Their stress and experiences play a key role in either participating in or not participating in LOR. And while recruitment may be achieved, retention may not. Maintaining sensitivity and communication with the parents is critical to continual LOR success.

Taking identified barriers into consideration, children involved should be in minimal/no emotional and physical discomfort from participating. For example, when

assessing developmental milestones and achievements children with limitations (due to cerebral palsy, long term pulmonary problems, or other problems), data regarding this aspect of their life should be sought from specialists that monitor them for that specific issue. For example, physical therapy notes and assessments should be communicated to the researchers so the children do not have duplicate data collection and exams. This will also decrease time spent participating in the study for the parents and children, accounting for another barrier that these parents identified.

### *Conclusion*

The theoretical framework for this research was the Theory of Planned Behavior (Aizen, 2002). The TPB is a behavioral theory which accounts for many of the variables involved with behavior motivation. When applied to this study, it provides a relevant framework to understand the dynamics involved in decision making. More specifically, it explores the motivations for participating in NICU LOR. By exploring parents' views and concerns, their motivations will be better understood. Through the use of parental motivations for study design development, the chances of parental participation will be enhanced.

As demonstrated, stress has a significant impact on parents in the NICU. Stress and how it impacts families must be understood prior to undertaking LOR research. Perhaps a tool that can assess stress and consent readiness should be made to enhance the chances of recruitment. Each family's experience is subjective and their stress level should not be assumed. In order to achieve recruitment and retention, all of these details should be understood and considered when recruiting participants.

Efforts were made to recruit a diverse group of participants, however after the selection process the group was essentially homogeneous. For future exploration, efforts should be made to recruit a heterogeneous group of parents. Other areas for possible future research include the difference between hypothetical responses of parents while their child is in the NICU and response changes after discharged. This research demonstrates how parents' desire to contribute to research, their need to maintain normalcy, and feelings of being overwhelmed all contribute to their decision making process during their child's' NICU hospitalization. It is unknown how much these factors change after NICU discharge when normalcy is achieved. Due to the many morbidities of NICU graduates, true normalcy may never be achieved. It is also unknown how each of these factors may impact parents' decision making. Understanding these factors and respecting each parents' subjective experience is critical to LOR recruitment and retention.

In summary, NICU graduates are at risk for many negative outcomes as a result of their illness and subsequent interventions. LOR is essential to explore fully the impact of illness immediately after birth and the interventions to improve health. Unfortunately, developing a LOR study design is a daunting task. Many aspects in the design of LOR with NICU graduates must be addressed prior to developing a successful study and to minimize obstacles. The major goals of this study were: (a) to elicit the opinions of parents' related to research, (b) to obtain the parents opinions related to research involving their NICU child, and (c) to identify barriers and facilitators to LOR as identified by parents. These goals were met and surpassed. In addition to gaining a more complete understanding view of the previously mentioned aspects of parents' opinions,

parent interviews also highlighted other pieces of the puzzle. These pieces are as important, if not more, than the previously sought information; these independent responses are invaluable to this research. This researcher has gained a deep appreciation for the opinions of parents related to LOR, which is vital to the ultimate success of LOR with NICU graduates.

This research provided insight into a special group, NICU parents. Their children are exposed to extensive medical and possibly surgical interventions at an early and vulnerable age. The effect of NICU admission on parents is stressful and affects their opinions and understanding of research, as demonstrated in the data analysis. Their involvement in NICU LOR is essential. Therefore, their opinions were sought in a small interview study. These opinions have shed light on the experience of NICU parents, but have also led to more questions. Future research is needed to examine the extent of their experience, and how it impacts decision making regarding research. This information will be important when NICU LOR is being designed. Parents must be involved if LOR is to be successful. Areas for future research include: (a) comparison of parent opinions prior to and after discharge, (b) data collection from a more diverse parent population (possibly multi-site recruitment), and (c) eventual future LOR research with NICU graduates.

## References

- Aizen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes*, 50, 179-211.
- Aizen, I. (2002). *Constructing a TPB Questionnaire: Conceptual and Methodological Considerations*. Retrieved March, 13, 2006, from <http://www.people.umass.edu/aizen/pdf/tpb.measurement.pdf>.
- American Academy of Pediatrics (2005). *Child Health Insurance Status*. Retrieved October 12, 2005 from [www.aap.org/research/factsheet.pdf](http://www.aap.org/research/factsheet.pdf).
- The American Academy of Pediatrics (2005). *Medicaid Reimbursement Reports*. Retrieved October 12, 2005 from [www.aap.org/research/medreimpdf0405/ma.pdf](http://www.aap.org/research/medreimpdf0405/ma.pdf).
- Arford, P. (2004). Working With Human Research Protections. *Journal of Nursing Scholarship*, 36(3), 265-271.
- Barry, A. (2005). How Attrition Impacts the Internal and External Validity of Longitudinal Research. *Journal of School Health*, 75(7), 267-270.
- Boothroyd, R., & Best, K. (2003). Emotional Reactions to Research Participation and To Understanding of Informed Consent Disclosure. *Social Work Research*, 27(4), 242-251.
- Cloherty, J., Stark, A., & Eichenwald, E. (2004). *Manual of Neonatal Care* (5<sup>th</sup> ed.). Philadelphia: Lippincott, Williams & Wilkins.
- Davis, D. (2003). Cognitive Outcomes in School-Age Children Born Prematurely. *Neonatal Network*, 22(4), 27-38.

- Dawson, A., & Spencer, S. (2005). Informing Children and Parents About Research. *Archives of Disease in Childhood*, 90, 233-235.
- Edwards, S. (2005). Research Participation and the Right to Withdraw. *Bioethics*, 19(2), 112-130.
- Ellis, E., Riegel, B., Hamon, M., Carlson, B., Jimenez, S., & Parkington, S. (2001). The Challenges of Conducting Clinical Research: One research Team's Experiences. *Clinical Nurse Specialist*, 15(6), 286-292.
- Forrest, C., Shipman, S., Dougherty, D., & Miller, M. (2003). Outcomes Research in Pediatric Settings: Recent Trends and Future Directions. *Pediatrics*, 111, 171-178.
- Frank, G., Nader, P., Zive, M., Broyles, S., & Brennan, J. (2003). Retaining School Children and Families in Community Research: Lessons From the Study of Children's Activity and Nutrition (SCAN). *Journal of School Health*. 73(2), 51-57.
- Franck, L. (2005). Research with Newborn Participants: Doing the Right Research And Doing it Right. *Journal of Gerontology and Neonatal Nursing*, 19, 177-186.
- Garro, A., Thurman, SK., Kerwin ME., & Ducette, JP. (2005). Parent/caregiver stress during pediatric hospitalization for chronic feeding problems. *Journal of Pediatric Nursing: Nursing care for Children and Families*. 20(4), 268-75.
- Gilgun, JF. (2006). End Notes: The four cornerstones of qualitative research. *Qualitative Health Research*, 16 (3), 436-443.
- Golafshani, N. (2003). Understanding Reliability and Validity in Qualitative Research. *The Qualitative Report*, 8(4), 597-607.

- Golec, L., Gibbins, S., Dunn, M., & Herbert, P. (2004). State of the Art Informed Consent in the NICU Setting: An Ethically Optimal Model for Research Solicitation. *Journal of Gerontology*, 24, 783-791.
- Graneheim, U., & Lundman, B. (2004). Qualitative content analysis in nursing Research: concepts, procedures, and measures to achieve trustworthiness. *Nurse Education Today*, 24, 105-112.
- Hoehn, K., Wernovsky, G., Rychik, J., Gaynor, J., Spray, T., Freudtner, C., & Nelson, R. (2005). What Factors are Important to Parents Making Decisions About Neonatal Research. *Archives of Diseases in Childhood*, 90, F267-F269.
- Horbar, J., Rogowski, J., Plsek, P., Delmore, P., Edwards, W., Hocker, J., Kantak, A., Lewallen, P., Lewis, W., Lewit, E., McCarroll, C., Mjuscje, D., Payne, N., Shiono, P., Soll, R., Leahy, K., & Carpenter, J. (2001). Collaborative Quality Improvement for Neonatal Intensive Care. *Pediatrics*, 107(1), 14-22.
- Kanner, S., Langerman, S., & Grey, M. (2002). Ethical Considerations for a Child's Participation in Research. *Journal for Specialists in Pediatric Nursing*, 9 (1), 15-23.
- Kassam-Adams, N., & Newman, E. (2005). Child and Parent Reactions to Participation in Clinical Research. *General Hospital Psychiatry*, 27, 29-35.
- Kavanaugh, K., Moro, T., Savage, T., & Mehendale, R. (2006). *Enacting a Theory of Caring to Recruit and Retain Vulnerable Participants for Sensitive Research*. *Research in Nursing & Health*, 29, 244-252.
- Kilbride, H., Thorstad, K., & Daily, D. (2004). Preschool Outcome of Less Than 801-Gram Preterm Infants Compared With Full-Term Siblings. *Pediatrics*,

113(4), 742-747.

Klassen, A., Lee, S., Raina, P., Chan, H., Matthew, D., & Brabyn, D. (2004). Health Status and Health-Related Quality of Life in a Population-Based Sample of Neonatal Intensive Care Unit Graduates. *Pediatrics*, 113(3), 594-600.

Korenman, S. (2004). Research in Children: Assessing Risks and Benefits. *Pediatric Research*, 56(2), 165-166.

Leonard, N., Lester, P., Rotheram-Borus, M., Mattes, K., Gwadz, M., & Ferns, B. (2003). Successful Recruitment and Retention of Participation in Longitudinal Behavioral Research. *AIDS Education and Prevention*, 15(3), 269-281.

Loftin, W., Barnett, S., Bunn, P., & Sullivan P. (2005). Recruitment and Retention of Rural African Americans in Diabetes Research: Lessons Learned. *The Diabetes Educator*, 251(9), 1-11. Retrieved January 30, 2006, from <http://0-tde.sagepub.com.ilsprod.lib.neu.edu/cgi/content/full/31/2/251>.

Lorenz, J. (2001). The Outcome of Extreme Prematurity. *Seminars in Perinatology*, 25(5), 348-359.

Lorenz, J., Paneth, N., Jetton, J., Ouden, L., & Tyson, J. (2001). Comparison of Management Strategies for Extreme Prematurity in New Jersey and the Netherlands: Outcomes and Resource Expenditure. *Pediatrics*, 105 (6), 1269-1274.

Lucey, J., Rowan, C., Shiono, P., Wilkinson, A., Kilpatrick, S., Payne, N., Horbar, J., Carpenter, J., Rogowski, J., & Soll, R. (2004). Fetal Infants: The Fate of 4172 Infants with Birth Weights of 401-500 Grams-The Vermont Oxford Network Experience (1996-2000). *Pediatrics*, 113(6), 1559-1566.

- Mason, S. & Allmark, P. (2000). Obtaining Informed Consent to Neonatal Randomized Controlled Trials: Interviews with Parents and Clinicians in the Euricon Study. *Lancet*, 356, 2045-51. Retrieved October 17, 2005, from CINHAL Database.
- Mayo Clinic (2007, February 20). *Stress Symptoms: Effects on your body, feelings and behavior*. Retrieved January 14, 2008, from ([http://www.mayoclinic.com/health/stress-symptoms/SR00008\\_D](http://www.mayoclinic.com/health/stress-symptoms/SR00008_D))
- Meadow, W., Lee, G., Lin, K., & Lantos, J. (2004). Changes in Mortality for Extremely Low Birth Weight Infants in the 1990s: Implications for Treatment Decisions and Resource Use. *Pediatrics*, 113(5), 1223-1229.
- Melnyk, B., Gillis, L., Feinstein, N., Crean, H., Johnson, J., Fairbanks, E., Small, L., Rubenstein, J., Slota, M., & Corbo-Richert, B. (2004). Creating Opportunities for Parent Empowerment: Program Effects on the Mental Health/Coping Outcomes of Critically Ill Young Children and Their Mothers. *Pediatrics*, 113(6), 597-607).
- Minden, K., Niewerth, M., Listing, J., Bierdermann, T., Bollow, M., Schontube, M., & Zink, A. (2002). Long-Term Outcome in Patients with Juvenile Idiopathic Arthritis. *Arthritis & Rheumatism*, 46(9), 2392-2401.
- 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, F225-F228.
- Nield, T., Langenbacher, D., Poulsen, M., Platzker, A. (2000). Neurodevelopmental outcomes at 3.5 years of age in children treated with extracorporeal life support:

- Relationship to primary diagnosis. *The Journal of Pediatrics*, 136(3), 338-344.
- Oberle, K., Singhal, N., Huber, J., Burgess, E. (2000). Development Of An Instrument to Investigate Parents' Perceptions of Research with Newborn Babies. *Nursing Ethics*, 7(4), 327-338.
- Polit, D., & Beck, C. (2004). *Nursing Research: Principles an Methods* (7<sup>th</sup> ed.). Philadelphia: Lippincott Williams & Wilkins.
- Ritchie, S. (2002). Primary Care of the Premature Infant Discharged From the Neonatal Intensive Care Unit. *Journal of Maternal/Child Nursing*, 27(2), 76-85.
- Ryan, E., & Hayman, L. (1996). The Role of the Family Coordinator in Longitudinal Research: Strategies to Recruit and Retain Families. *Journal of Family Nursing*. 2(3), 325-335.
- Sandelowski, M. (1986). The problem of rigor in qualitative research. *Advances in Nursing Science*, 8(3), 27-37.
- Sandelowski, M. (1995). Focus on Qualitative Methods: Sample Size in Qualitative Research. *Research in Nursing & Health*, 18, 179-183.
- Sandelowski, M. (2000). Focus on Research Methods: Whatever Happened to Qualitative Description. *Research in Nursing and Health*, 23, 334-340.
- Sandelowski, M., & Barroso, J. (2003). Classifying the Findings in Qualitative Studies. *Qualitative Health Research*, 13(7), 905-923.
- Sandelowski, M., & Barroso, J. (2003). Writing the Proposal for a Qualitative Research Methodology Project. *Qualitative Health Research*, 13(6), 781-820.

- Seale, C. (1999). Quality in Quantitative Research. *Qualitative Inquiry*, 5(4), 465-478.
- Smeltzer, S., & Bare, B. (1992). *Bruner and Suddarth's Textbook of Medical Surgical Nursing*. Philadelphia: J.B. Lippincott Company.
- Snethen, J., Broome, M., Knall, K., Deatrick, J., & Angst, D. (2006). Family Patterns of Decision-Making in Pediatric Clinical Trials. *Research in Nursing & Health*, 29, 223-232.
- Taylor, H., Klein, N., Minich, N., Hack, M. (2001). Long-Term Family Outcomes For Children with Very Low Birth Weights. *Archives of Pediatrics and Adolescent Medicine*, 155(2), 155-161.
- The Vermont Oxford Network. (2005). *A Network of Neonatal Professionals*. Retrieved October 18, 2005 from [www.vtoxford.org](http://www.vtoxford.org)
- Thomas, K. (2005). Safety When Infants and Parents are Research Subjects. *Journal of Perinatology and Neonatal Nursing*, 19(1), 52-58.
- Ward, K. (2001). Perceived Needs of Parents of Critically Ill Infants in a Neonatal Intensive Care Unit (NICU). *Pediatric Nursing*, 27(3), 281-285.
- Whittemore, R., Chase, S., & Mandle, C. (2001). Pearls, Pith, and Provocation: Validity in Qualitative Research. *Qualitative Health Research*, 11(4), 522-537.
- Whittle, A., Shah, S., Wilfond, B., Gensler, G., & Wendler, D. (2004). Institutional Review Board Practices Regarding Assent in Pediatric Research. *Pediatrics*, 113(6), 1747-1752.

## APPENDIX

## Appendix A: Interview Guide

The interview will begin with some broad open ended questions that are intended to facilitate a discussion of the topic. There will be facilitating questions to guide the discussion. Questions include:

1. What has been your experience with healthcare research?
2. What do you know about longitudinal research?
3. If you were to be asked to be involved in longitudinal research after your child was discharged from the NICU, when would be the best time to be asked?
4. If you were invited to participate in research (or your child was), how often would you need to be reminded of your involvement in the research?
5. If you were to allow your child to be involved in longitudinal studies, what factors would make it hard for you?
6. What would make participation in longitudinal outcome studies easier?

Parents will be encouraged to dialogue with the researcher through probing questions to gain the best understanding of parents' perceptions.

Appendix B: Parental Perceptions of Longitudinal Outcomes Research

Infant Information

Name:

Date:

Date of Birth:

Date of NICU admission:

Length of time in NICU:

Gestational Age at birth:

Birthweight:

Diagnosis/Diagnoses:

Post Conceptual Age at Enrollment:

Anticipated Length of Stay:

Current Acuity Classification:

Singleton or Multiple Birth

Appendix C: Parental Perceptions of Longitudinal Outcomes Research

Demographic Information for Parents

Name:

Age:

Address:

Phone Number:

Ethnicity:

Occupation:

Level of Education:

Marital Status:

Pregnancy History:

    First pregnancy, first child:

    Previous pregnancy, first child:

    Previous pregnancy, other children:

    Ages:

If applicable, have you had other children in the NICU?

Do you, or your family, have any significant medical history?

History of research participation?

## Appendix D: Parental Perceptions of Longitudinal Outcomes Research

## Informational Sheet for Parents

Thank you for taking the time to consider this research. I would like to invite you to discuss your opinions about research in an interview. I want to understand your perceptions related to your child and research involving your child. While I will ask some questions, you will also help guide the discussion. To be able to focus on our discussion, I will tape record our discussion. I will only play the tape recordings outside of the NICU, and the tapes will be destroyed after the study is finished. I will use the tape recordings to better understand our discussion. Responses from the session will be confidential, and only used for research purposes.

While your involvement is appreciated, your participation is voluntary. If you choose not to participate it will not change the care you or your child receive while in the NICU, or after. Also, if you decide to withdraw from the study, you may do so at any time. Although the stress and discomfort from this research should be minimal, each person's experiences are different; if you feel upset about the research subject anytime during this research or after, please either contact myself, or the licensed social worker in the NICU.

The Institutional Review Boards (IRB), a committee that examines and approves research, at both Massachusetts General Hospital and Northeastern University has found this research to be safe. If at any point you find this research study to be harmful or upsetting you can stop participation, and/or contact the IRB board at Massachusetts General Hospital or Northeastern University.

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