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PARENT PERCEPTIONS OF PATIENT SAFETY CULTURE IN THE NEONATAL INTENSIVE CARE UNIT

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PARENT PERCEPTIONS OF PATIENT SAFETY CULTURE IN THE
NEONATAL INTENSIVE CARE UNIT

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

SCHOOL OF NURSING

BY

MADELENE J. OTTOSEN, MSN, RN

MAY, 2015

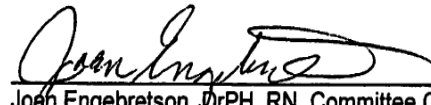
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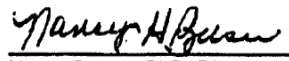
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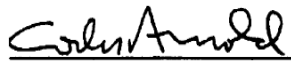
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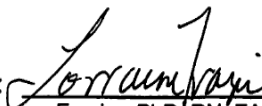
I am submitting a dissertation written by Madelene J. Ottosen and entitled "Parent Perceptions of Safety Culture in the Neonatal Intensive Care Unit. I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.


Joan Engebretson, DrPH, RN, Committee Chair

We have read this dissertation and recommend its acceptance:


Nancy Busen, PhD, RN


Cody Arnold, MD, MPH, MS

Accepted: 
Lorraine Frazier, PhD, RN, FAHA, FAAN
Dean for the School of Nursing

Acknowledgements

I am eternally grateful for the blessings of the Lord God who made it possible for me to carry out this work and to whom I devote my efforts.

I would like to acknowledge the immeasurable sacrifice and support of my family. My husband Doug Ottosen and daughter Jessica Jewell–Elliott inspired me at every step of this journey through their relentless love and encouragement. I am also grateful for the gift of my precious daughter Marissa Ottosen, born prematurely and cared for in the Memorial Hermann–TMC NICU. Being her mom blessed me with many lessons that I will cherish for a lifetime including compassionate insight into the lives of neonatal parents. I am also grateful for the acceptance, love and encouragement of my parents who always believed in me so I could believe in myself. To my dad, Virgil, I am thankful for instilling in me the commitment and desire of serving others. To my mom, Margaret, I am grateful for teaching me what it means to be a dedicated nurse and a strong woman who never gives up.

To my work colleagues at the UT–MH Center for Healthcare Quality and Safety, I am thankful for their support and mentorship in making it possible for me to conduct this project. I am indebted to Dr. Jason Etchegaray for his mentorship in refining this research project and his supportive collaboration in obtaining grant funding from AHRQ to carry out this work. I am also humbled by the generous support and mentorship I received from Dr. Eric Thomas for believing in my abilities and shepherding me into the world of patient safety. Eric, Jason and all my work colleagues provided the professional environment where I could flourish and see my dreams become reality.

My ability to carry out this work would not have been possible without the outstanding guidance and intellectual engagement I received from the doctoral faculty and my colleagues at the UT Health School of Nursing. With every class, paper, discussion and

semester, each professor and classmate was integral to my professional development as a researcher, teacher and colleague. Yet above all, I am most grateful for the gift of my advisor and mentor Dr. Joan Engebretson whose passion for nursing, inquiry and qualitative methodologies instilled in me a new passion for discovery. She patiently listened, gently guided, passionately encouraged and confidently inspired me to weave the thoughtful stories and observations of neonatal parents into a tapestry of shared roles and partnerships aimed at improving neonatal patient safety. Her extraordinary mentorship is both a model and challenge for me to emulate.

To the NICU clinicians and staff who give so tirelessly of themselves and who are such great examples of what it means to care, I am truly thankful for allowing me to be a part of your team.

To the parents of the NICU who selflessly shared their precious time and stories to make things better for all babies and parents in the NICU, I am humbled by your strength, courage and unconditional love.

Abstract

Madelene Ottosen, MSN, RN

Parent Perceptions of Patient Safety Culture in the Neonatal Intensive Care Unit

May 2015

Background: Understanding and promoting a positive culture of patient safety within neonatal intensive care units (NICU) has been shown to decrease threats to patient safety. Parents are an integral part of the NICU culture, yet little is known about how they perceive patient safety and what role they would find meaningful and appropriate for engaging in safety promotion activities in the NICU. Therefore the purpose of this study was to determine how neonatal parents conceptualize patient safety and their role within the Neonatal Intensive Care Unit (NICU).

Methods: Using an ethnographic qualitative approach, semi-structured interviews and field observations of parent interactions within the NICU were conducted from January to November 2014. A purposive sample of twenty-two neonatal parents from a large tertiary NICU was selected for interviews. Data were initially coded according to parent perceptions from interview transcriptions and observed parent interactions. A content analysis of the coded data revealed themes relevant to the study aims. Exemplars of these themes were verified as congruent with the analysis through peer debriefing.

Results: A model of parent involvement in NICU patient safety was developed. To neonatal parents, safe care was evidenced by the presence, intention and respect of clinicians and staff in their actions. Patient safety was characterized by adherence to security and infection control procedures, interactions with their baby, and effective communication with parents. Parents saw their role as advocate, caregiver, decision-maker, learner and guardian in partnership with clinicians to promote safe care.

Conclusions: This model of parent involvement could inform practice and further research about patient safety in the NICU. Parents provided valuable insight impacting the assessment and further study of NICU safety culture. Promoting a culture of partnership between clinician and parents was integral to parents engaging in actions to promote safe care for their infants.

TABLE OF CONTENTS

APPROVAL PAGE	ii
ACKNOWLEDGEMENTS	iii
ABSTRACT	v
SUMMARY OF STUDY.....	1
PROPOSAL	2
Specific Aims	2
Research Strategy	4
Significance	4
Innovation	7
Approach	8
Preliminary Data	8
Design	9
Data Collection	11
Protection of Human Subjects.....	16
Literature Cited.....	19
MANUSCRIPT.....	25
Ottosen MJ, Engebretson J, Etchegaray JM, Busen N, Arnold C, & Thomas EJ	
Parent Perceptions of Patient Safety Culture in the Neonatal Intensive Care Unit	
Literature Cited.....	55
Appendixes.....	59
A. Committee for the Protection of Human Subjects Approval	59
B. Memorial Hermann Health System Approval.....	61
C. Individual Parent Informed Consent Form.....	63
D. Group Informed Consent Form.....	68
E. Interview Guide.....	73
F. Group Interview Flyer.....	77

G. Demographic Data Collection Form.....	79
H. Qualitative Codebook.....	82
CURRICULUM VITAE	84

SUMMARY OF THE STUDY

Patients and families are at the center of care and have important perspectives about what they see occurring surrounding their healthcare, yet organizations do not routinely collect such perspectives from patients/families. The goal of this dissertation project was to learn how parents of NICU infants perceive patient safety issues in the NICU environment and navigate as part of the NICU safety culture. This study incorporated a medically applied ethnographic qualitative approach to explore the experience and perspectives of parents about aspects of safety culture in the NICU. The dissertation is comprised of two sections, 1) the research proposal and 2) a first manuscript of key findings. The proposal outlines two specific aims: 1) to determine how NICU parents conceptualize various aspects of safety culture, such as patient safety, communication and teamwork and 2) to identify the role of neonatal parents as patient safety advocates and determine their relationship with caregivers in contributing to patient safety efforts within the NICU. The project remained on schedule with IRB approval and pilot work completed by May 2014, (Appendices A – G). Recruitment and parent interviews took longer than anticipated. Interviews were completed in November 2015 and analysis completed in January with peer debriefing following in February 2015.

The manuscript includes results for both aims of the project, accomplished through content analysis of the coded data. Codes used for analysis are included in Appendix H. Themes reflecting the stated aims were described and supported by parent quotations and observations. These results led to the development of a conceptual model depicting the relationship of parent-clinician partnerships in the development of parental roles in promoting safe care in the NICU. The results are clinically relevant for neonatal practitioners in developing strategies for engaging neonatal parents as partners to improve patient safety. Future research ideas are also included in the manuscript.

PROPOSAL

Specific Aims

In 1998, the Institute of Medicine (IOM) reported over 98,000 people die annually due to medical errors across US hospitals (America & Medicine, 2001). While healthcare organizations have focused efforts, resources and processes to improve the safety of healthcare delivery, recent reports indicate that trends in adverse events are not improving (Shojania & Thomas, 2013). Neonates are particularly vulnerable to medical errors with reported rates as high as 74 events per every 100 patients (Sharek et al., 2006). One key aim for healthcare improvement and prevention of harm to patients cited by the Joint Commission Center for Transforming Healthcare is to improve the culture of safety within the organization. A culture of safety is represented by the “shared knowledge, attitudes, perceptions, behaviors and beliefs of individuals and groups that determine the commitment, style and proficiency of an organization’s health and safety management” ((Sexton et al., 2006). The term “climate” is used over culture to readily describe the group perceptions without assuming the ability to capture all aspects of culture (Sexton et al., 2006). To understand the culture/climate of safety within any organization, we often focus our attention solely on the views of the clinicians and staff members within the healthcare team/s. However, patients and families constitute an integral component to this safety culture landscape and their views should be considered.

A changing paradigm is evolving within the healthcare system to involve patients and families as partners, not just recipients of healthcare (Conway, J et al., 2006). Studies have shown that patients are aware of problems when they receive healthcare and thus are asked to take on active roles to improve safety such as speaking up about when they have concerns of care (Davis, Jacklin, Sevdalis, & Vincent, 2007; Mazor, Goff, Dodd, Velten, & Walsh, 2010). Often parents and family members can provide valuable information about how factors such as communication, coordination, and collaboration

which impact the care of their children (Mazor et al., 2010). These factors represent integral components in establishing a culture of safety and are essential for hospital leadership to ascertain. In a review of studies about patient and family perceptions of safety, a lack of communication was often defined by them as a “medical error” (Kooienga & Stewart, 2011; Mazor et al., 2010; Rathert, Brandt, & Williams, 2012). Missed, poor and insufficient communication was interpreted as a “breakdown in care”, even if medical treatment was not altered (Kooienga & Stewart, 2011). Lucian Leape and other patient safety experts contend that active engagement of patients and families in all aspects of healthcare delivery especially listening to their stories is essential to learning and transforming healthcare organizations (Leape et al., 2009). Understanding the perceptions of safety held by the patients and families is an important aspect of engagement critical to improving care and patient outcomes. However true understanding of perceptions must be obtained within the context of the unique and complex culture with which these patients and families experience a healthcare (Halligan & Zecevic, 2011).

The complexity of the neonatal intensive care environment is unique and can pose threats to patient safety (Raju, Suresh, & Higgins, 2011; Samra, McGrath, & Rollins, 2011). Parents of neonates are in desperate need of communication to make the right decisions for their newborns (Ricciardelli, R, 2012) but struggle with feelings of anxiety, stress, depression, confusion, difficulty coping and sometimes hide behind feelings of uncertainty (Ricciardelli, R, 2012; Weiss, Goldlust, & Vaucher, 2010). Parents and caregivers exhibit different values and beliefs in the care of infants in the NICU (Latour, Hazelzet, Duivenvoorden, & Goudoever, 2010) creating a challenge for parents to engage as partners on the healthcare team. By gaining a better understanding of what and how parents experience communication and teamwork in the NICU, we can identify appropriate strategies to involve them as partners in care. Learning what parents think about patient safety will provide a basis to help us understand how to engage parents in safety

promotion activities that they find meaningful and appropriate. The Agency for Healthcare Research and Quality (AHRQ) recently identified that a major gap exists in understanding of how patients and families want to engage in patient safety and cited the need for patient and family input in developing effective ways for assessing safety (Maurer, Dardess, Carman, Frazier, & Smeeding, 2012). Therefore the need for this study is both timely and necessary to advancing the patient safety research agenda. The purpose of the study is to better understand parents' experiences and how they construct their role within a culture of patient safety in the caring for their infants in the NICU. The specific aims of the study are to:

Aim 1: Determine how parents conceptualize patient safety, communication and teamwork, within the NICU culture, and

Aim 2: Identify the role of neonatal parents as patient safety advocates and determine their relationship with caregivers in contributing to patient safety efforts within the NICU.

Research Strategy

Significance

One of the key aims for healthcare improvement as defined by the IOM was to promote a patient-centered approach to care (Kohn, Corrigan, & Donaldson, 2000). Patient-centeredness is exemplified through compassion, empathy and responsiveness to the needs, values and expressed preferences of the individual patient (Kohn et al., 2000). Inherent within actualizing this model of care, is embracing a respectful understanding of the individual values, preferences and expressed needs of our patients. Achieving respectful understanding requires an open dialogue, a respectful exchange between provider and patient to forge a relationship of shared decision-making (Hovey et al., 2011). The Institute for Healthcare Improvement identifies the core concepts of family–

centered care as dignity and respect; information sharing; collaboration and participation (Conway, et al., 2006). In its seminal report, the IOM recommended patients and families be involved at all levels of the healthcare continuum as decision-making members to improve care (America & Medicine, 2001). An explosion of activity has evolved since that time, in an effort to actualize this recommendation into reality. Families are included in hospital rounds, alerting rapid response teams and in resuscitations (Gerdik et al., 2010; Schleien, Brandwein, & Stasiuk, 2013). Incorporating family-centered care in patient safety initiatives has been more difficult to implement given the tremendous culture shift required (Carman et al., 2013) to make interventions successful. Federal agencies such as Center for Medicare and Medicaid created programs like “Partnership for Patients” to highlight the need for healthcare organizations to incorporate patient and family-centered initiatives into their measures of quality and safety. Recommendations to hospitals outline the need to promote patient involvement through the development of tools, listening to patients and engaging patients and families to make a difference in their care.

Over the last several years, more neonatal clinical groups have published results of their safety incidents owing to a greater view for the type and complexity of neonatal safety events (Raju, Suresh, & Higgins 2011). Neonatal errors involve, but are not exclusive to, nosocomial infections, infiltration of intravenous catheters, accidental extubations, intracranial hemorrhage, medication errors and misidentification (Raju et al., 2011; Samra et al., 2011). Experts cite multiple opportunities to improve the scope of these problems through teamwork and leadership training, improved processes for order entry and use of reliable tools to measure safety culture (Raju et al., 2011; Samra et al., 2011). Healthcare researchers have developed and provided evidence for the reliability and validity of several tools to measure safety culture, including the Hospital Survey on Patient Safety Culture (Sorra & Dyer, 2010), Safety Attitudes Questionnaire (SAQ) (Sexton et al., 2006) and the Modified Stanford Instrument (Singer et al., 2003). A strength of these tools is that

they measure safety culture from the perspective of healthcare providers and others working for the healthcare organization; a limitation is that patient and/or family perceptions of safety culture are not measured. In order to truly evaluate a culture of safety, all the members of the healthcare team need to be incorporated which includes patients and families. Patient safety culture is well described as having dimensions or subcultures involving leadership, teamwork, communication, evidenced-based, learning, just, and patient-centered (Sammer, Lykens, Singh, Mains, & Lackan, 2010). We do not know if patients and families define or understand the culture of patient safety in the same way nor if their views of the neonatal environment are the same as their healthcare providers. Currently measures of patient and family experience attempt to identify how well the nurses and physicians listened to parents, explained things and treated them with courtesy (Piper, 2011). However it is unclear if these measures of patient experience give an accurate view of how patients perceive the neonatal culture especially with regards to patient safety or patient/family-centeredness. It is known that the NICU represents a highly specialized environment with a complex and unique culture of healthcare delivery (Profit et al., 2012). Parents have a desire to be involved in the care of their infants but are often unsure how to be effective in the neonatal environment (Ricciardelli, R, 2012). A true partnership with parents in the NICU should be rooted in listening to their concerns, valuing their observations and involving them in learning about the teamwork and safety culture/climate of the unit.

There are potential barriers to parent and family involvement in safety. Parents experience feelings of vulnerability, lack of knowledge and concern over confronting caregivers about errors (Mazor et al., 2010). They cite interpersonal barriers when actively involved in safety efforts such as the difficulty communicating with a caregiver or lack of caregiver support to accept information shared by the patient. Lastly, cultural barriers such as lack of organizational support, paternalism, physician adversity and negative

attitudes among caregivers preclude patients from involvement in safety initiatives (Davis et al., 2007). Recognizing these barriers within the neonatal environment could help us understand how parent–provider communication impacts the experience of the parents and families to fully participate as partners in caring for their neonates.

Innovation

This study is innovative in three ways. First, understanding how parents conceptualize their role within the complex culture of the neonatal environment has not been fully explored. Studies examining parent perceptions of their “first moments” in the neonatal intensive care (Arnold, et al, 2013) or how they view their presence on rounds (Grzyb, Coe, Rühland, & Dow, 2014) provide helpful insights about their perspectives of specific components within the neonatal experience. Through interviews, I will obtain a broader overview of how parents conceptualize their role as advocates for their infant’s care. Through field observations, I will observe the behaviors and reactions of these parents as they interact with providers and clinicians in caring for their infants. I will also observe how providers and clinicians interact with parents being interviewed to explore if the parent perceptions are congruent with these observed experiences. Second, the culture of the neonatal intensive care has not been described from the collective perspectives of a diverse group of parents who are experiencing the same culture and who are typical within this population. I will explore perspectives from both fathers and mothers of the same child, parents of varying ages, ethnicity, parity and length of time in the NICU and parents with varying degrees of interaction with the neonatal staff. Thirdly, through a combination of group and individual interviews and field observations I will explore how parents perceive issues of patient safety within their experience of the NICU environment. I will explore what they understand, how they interpret, what is important to them and what recommendations for change they have for improving the quality of care within the neonatal intensive care. Ultimately, this qualitative study will provide valuable

information to clinicians about what parents understand about safety, what they want to report and what roles they are willing to assume as members of the healthcare team in improving the culture of patient safety.

Approach

Preliminary Data. In the fall of 2013, I conducted a pilot study to explore the feasibility of carrying out a qualitative study of neonatal parents to obtain their perceptions of safety within the NICU environment. I obtained information from field observations and consultations with clinical and methodological experts which supported several changes in sampling and methods of data collection. NICU clinicians suggested to me that parents would be too distracted days before discharge for them to give thoughtful feedback about the events and issues of the NICU. They recommended that I interview parents when their infants had been in the NICU at least 3 weeks and were hemodynamically stable, most often classified as level II. Experts also cautioned me in using the term “safety” as it might be difficult for parents to understand. I should consider introducing the topic with a clear connection to the efforts hospitals undergo to improve the care of patients. I conducted a pilot interview with a parent of neonatal twins, one infant had been discharged and one infant was still in the NICU. Even with a clear introduction of the context of the term safety at the outset of the interview, it took several attempts at reframing questions with examples of patient safety related concepts before he was able to address specific issues. He shared his primary area of frustration was with caregivers “trusting” him enough to provide factual information about his infants condition. For him, the information he received from physicians was not detailed enough to really understand what was going on. He took it upon himself to read medical journals on the internet to learn more about his infants’ conditions. He estimated it took about three weeks to “prove to them” that he was capable of understanding the details of his infants’ medical issues before he felt the communication with providers improved. I will continue to explore the

parents' issues of communication with caregivers, their ability to have questions answered and the methods parents use to learn about their infants conditions in future interviews.

Field observations done during the pilot period were helpful to me to gain comfort as an observer and to witness the complexity of what parents observe in the NICU. The staff became more comfortable with my observations as I spent more time in the NICU and when I was wearing less formal attire like a sweater and slacks versus a suit. My ability to interact with them informally greatly increased their willingness to share insights about their interactions with parents and the culture of the unit. As I was conducting field observations, I witnessed the happy departure of a family taking home one of their twins from the NICU. I had observed these parents while in the NICU on several occasions during field observations and recognized their attentive interaction with their infants. Upon interviewing these parents, these observations were helpful to me in establishing a rapport and understanding some of the experiences they described in the interview. I recognized the added value of interviewing parents whom I had observed in the NICU and of carefully recording the infant's bed number and initials with the field notes to aid in tracking the parents over time. Amid the NICU lies a complex array of equipment and personnel supporting the care to a wide variety of infants and conditions. I observed many differences in the way parents interact with their infants and the staff within the NICU signaling that differences in parent perceptions may exist. These initial field observations further solidify the need to more fully explore how parents conceptualize their role within this highly intense and complex environment.

Design. Using a qualitative medical ethnographic approach, I will identify the perspectives of parents with neonates in the NICU to determine how the neonatal intensive care culture shapes their views and practices related to patient safety.

Ethnography involves the study of culture or the beliefs, values, behaviors and language of

a group of people to understand, from their perspective (emic), how they construct meaning to the cultural norms and behaviors within an environment (Green & Thorogood, 2013; Mayan, 2009). This method of study is particularly important in understanding the relationship between differing “cultural systems” of clinicians and patients (Chrisman & Johnson, 1990). Stemming from its anthropologic roots, ethnographic data is typically obtained from observations of the participants, formal and informal interviews and examination of artifacts within the cultural setting (Mayan, 2009; Miller, 1999). A purposive sampling of informants and observations are used to obtain a perspective representative of the breadth and depth of the cultural norms, environment and participant characteristics (Mayan, 2009; Richards & Morse, 2007). Medical ethnography combines the use of these anthropologic methods to understand the how clinical interactions shape the cultural landscape within a medical environment (Engebretson, 2011). To accomplish the study aims I will: (1) conduct field observations to observe the interactions parents have with the people, environment, and ethos of the NICU culture and (2) conduct individual and group semi-structured interviews with NICU parents to gain an understanding of their individual and collective perceptions of patient safety.

Setting and Sample. The study will be conducted within an 80-bed level III–IV NICU housed in a large academic hospital in a metropolitan medical center complex in the southern United States. The informants for the interviews will be parents of infants hospitalized at least 3 weeks in NICU, considered to be in a stable condition or at a level II and who speak English. A purposive sample of typical cases of NICU parents will be selected from observations and referrals by the NICU staff and charge nurses of eligible parents. Purposive case sampling is a preferred method of qualitative sampling in ethnographic studies to get variation in the perceptions of parents typical to the NICU, thereby increasing the credibility of the findings (Kuzel, 1999). Informant selection will include parents eliciting a diversity of the backgrounds and experiences of typical parents

in the NICU. Parents who are highly vocal in their interactions with providers and those who are less vocal yet interested in sharing their views will be invited to participate. Types of variation in parent selection include first time parents, those with other children, those transferred from another NICU, length of hospitalization, the gestational age of the infant upon admission, age/ethnicity of the parent and admitting diagnosis of the infant. Parents who have had other infants admitted to the NICU, who are less present in the NICU or those expressing problems in the care of their infant will be interviewed as potential contrast cases. Either parent is eligible for participation. Both parents may participate if desired and be interviewed simultaneously, counting as one interview or separately if that is their preference. To ensure parents have familiarity with the NICU environment, parents selected will be those participating in regular visitation, at least several hours weekly, with their infants. I will continue to interview parent informants until there is redundancy in the thematic content and saturation in the depth and breadth of the topics discussed. Based on other qualitative studies consisting of in-depth interviews, saturation is estimated to occur with approximately 20–25 participants (Kuzel, 1999).

Data Collection

Field observation method. I will conduct field observations to examine the interpersonal aspects of the NICU culture experienced by parents. Observations within the field or environment of study often accompany interviews to obtain a fuller understanding of the culture (Crabtree & Miller, 1999). My field observations will include patient rounds, general parent to provider interactions, waiting room interactions and other opportunities to witness how parents interact and communicate with the NICU staff and providers who represent its culture. My observations will occur prior to and in concert with interview period. I will conduct regular weekly visits in the NICU to become an expected rather than unexpected observer in the NICU. Observation data will include

communication and teamwork behaviors exhibited such as sharing information, inquiry, assertion, and vigilance (Thomas, Sexton, Lasky, Helmreich, Crandell & Tyson, 2006). I will also note nonverbal communication, word choices, number and role of those present and the environmental variables observed during the communication. Field notes of observations of the parents interacting with the caregivers will contribute to a complete understanding of the communication and teamwork occurring in the unit. Data collected from observations will allow for a richer understanding of “how behavior unfolds” rather than depending solely on a retrospective view of incidents from informants during the interviews (Kvale & Brinkmann, 2009). These observations will provide a focus to the interviews about particular aspects of parent interactions to capture the breadth and depth of what they experience. Observations will take place throughout the 10 pods which make up the NICU. All observations will be recorded as individual word documents by date for coding.

Interview method. I will also conduct qualitative ethnographic interviews with parents of neonates to determine how the neonatal intensive care culture shapes the views and practices of parents related to their roles as parents and their perceptions of patient safety (Crabtree & Miller, 1999). My interviews will be semi-structured used to address the themes and topics of interest in an informal or conversation-style dialogue with parents in the NICU. I will conduct both individual and group interviews with neonatal parents. Discussing patient safety with neonatal parents is a new and unexplored area. Therefore my group interviews will be done as an early measure to provide a focus of the domains and dimensions of parent attitudes and perspectives within the neonatal environment (Richards & Morse, 2007). Group interviews also offer participants the opportunity to engage in more open and interactive discussions (Kvale & Brinkmann, 2009) which may allow for more comfortable exploration of difficult topics and identify parents who could offer substantive information for an individual interview. Group

interviews of neonatal parents will be conducted with five to six neonatal parents in each group. The group interviews will take place in a larger conference room adjacent to the neonatal unit where parents can come and go without notice by the staff. Parents who meet the inclusion criteria will be recruited through personal invitation by the researcher to consider joining a group interview. Besides myself, the group interviews will be conducted with the assistance of an experienced qualitative researcher or one additional researcher to assist with taking written notes of interactions and conversant order. After the group interviews are complete, individual interviews will follow exploring the topics uncovered by the groups in more depth and drawing upon the unique experiences of informants in understanding the NICU safety culture. The individual interviews will take place in a quiet conference room located within the NICU by me and will be tape recorded.

I will conduct both group and individual interviews as a conversation with informants using a semi-structured guide (see Appendix 1 and 2). The fluidity and flexibility in a semi-structured interview allows researchers to uncover and explore themes which might be unexpected yet important to an understanding of the parent's experience and inherent in the emergent nature within the qualitative research design (Spradley, 1980). While an interview guide will be used, additional questions may be added throughout the interviewing phase to explore unexpected or emergent themes. The entire interview process is part of an iterative approach to ground the key findings and incorporate new issues as the interviews progress (Kvale & Brinkmann, 2009). Interviews will begin with open-ended questions asking parents to describe their overall experience in the NICU. Informants will be asked to discuss four major themes which will be highlighted in the interview guide as "grand tour" (Spradley, 1980) items and will focus on parent perceptions of 1) members of the NICU team, 2) communication with the team, 3) their involvement as parents, and 4) safety in the NICU (see Appendix 1). More specific information related to patient safety, components of safety, their desired role in patient

safety activities, and their desired role as a partner of the healthcare team will be addressed as “mini tour” (Spradley, 1980) or probe items. I will structure the interview to discuss specific issues of patient safety but will allow for clarification and probing of issues that may develop during an interview. The interview questions will be “thematic” to obtain knowledge from the informants and “dynamic” to maintain a relationship with the informants (Kvale & Brinkmann, 2009).

During the interviews, I will verify accounts or points voiced by the informant to ensure I have accurately interpreted their views. As the interviewer, I will record notes during the interview of additional questions or of probes to address with the informant. The interview is an iterative process allowing for additional relevant patient safety concepts or issues raised by parents to be added to subsequent interviews. With IRB and informant permission, if a particularly relevant issue is raised after completion of some interviews, I will go back to those previously interviewed informants to clarify or address significant points. Given previous experiences with conducting interviews with patients, I expect the interview to take about sixty to ninety minutes to complete. Each parent will receive a \$50 gift card after participating in an interview. All interviews will be tape recorded and transcribed into a word document for coding.

The researcher is an integral tool in the research methods of an ethnographic study. In medical ethnography, the interrelationships between patient and caregiver are important constructs in understanding the culture of a health care environment, so too is the interrelationship between the subcultures of the researcher to the healthcare environment of study (Kleinman, 1980). The researcher should maintain a “cross-cultural” vantage point outside the culture to adequately study the behaviors and beliefs of a group (Kleinman, 1980, pg 26). My experience as a nurse in intensive care prepares me to understand the mechanics of this highly intensive environment. Yet my inexperience

working in neonatal intensive care reduces the risk of interjecting my cultural biases when analyzing the neonatal culture as described by and observed through the parents.

Sample size and data analysis. Based on other qualitative studies consisting of in-depth interviews, saturation is estimated to occur in 20–25 participants (Kuzel, 1999). Field observations will also continue until redundant themes are identified. The notes of the field observations are coded in the same fashion as the interview data. Emergent themes which arise from the observations will be recorded as such in the analysis and confirmed through either formal or informal interviews with the informants. Each interview will be assessed after it is conducted for an overall assessment of thematic content. Saturation is reached once the thematic concepts revealed in the interviews become repetitive through agreement of this investigator and her advisor and the issues are well described.

Interviews and field notes will be analyzed by this investigator and will be ongoing with data collection. The software program, Atlas ti software, Berlin v. 7, will be used for managing the data. Analysis involves organizing, connecting and corroborating or legitimating the data in an iterative process that culminates in an accurate representation in the accounts of the informants (Mason, J, 2002). All tape recorded interviews will be transcribed into a word document by a transcription specialist. The transcriptions of interviews will be loaded into Atlas ti and coded by this investigator. Codes are “short phrases or words which assign summative, salient, essence–capturing and/or evocative attributes for a portion of language–based or visual data” (Saldana, 2012). A codebook or master list of codes will be developed by this investigator based on concepts relevant to answer the research question and on emerging concepts revealed through analysis. As with other aspects of qualitative design, the codebook is an iterative tool allowing for additions or changes in the coding schema. As each interview is reviewed, new codes

which surface will be discussed with select members of the team. Once the interviews are coded, interviews can be organized into “families” or subgroups to facilitate examination of themes across the data. Queries of the codes within and across groups can be compared to examine differences or similarities further illuminating the patterns and themes identified and described within the data.

Rigor. Multiple data sources, ie, fieldwork, individual and group interviews will provide a method of triangulation in analyzing the data to ensure the emergent themes are accurately supported by the data as they are derived from a more than one source (Crabtree & Miller, 1999). Additionally behaviors observed in field observations can be verified in interviews with parents to ensure my interpretation accurately reflects what was perceived by the parents. A peer debriefing will be facilitated by my advisor Dr. Engebretson with 2 to 3 other qualitative researchers to review the results for congruency. The purpose of this debriefing is to assure that the more abstracted findings are supported by the data.

Limitations/potential difficulties. One limitation to this study is that I will not be able to interview parents who speak Spanish or other languages. This will pose a limitation as to the understanding of how language and cultural variables impact patient safety perceptions of parents from differing ethnicities or who are not able to converse in English.

Protection of Human Subjects

Consent. Parents of infants preparing to be discharged from the NICU will be approached to participate in the interview in a purposive fashion. Parents will be given a copy of the consent document to take home and read or they may agree to be interviewed on the same day. On the interview day, we will meet them to review the consent outlining

the purpose, methods, risks and benefits. If they agree to proceed, we will obtain their signature and provide them a copy of the consent.

Risks. The risks are minimal however it is possible that some parents may experience some discomfort discussing issues surrounding their experience or baby's status in the NICU while undergoing the interviews. Parents may reveal safety concerns about their infant or care in the NICU which should be reported. If this occurs, parents will be asked to share their concerns with the Nurse Manager or Patient Relations in the NICU.

Protections against risks. Prior to conducting the interviews we will identify a contact person used by the NICU to counsel parents who are struggling with emotional issues surrounding the birth or ICU experience. If a parent appears or describes feeling sad or uncomfortable during or after the interview, we will contact the hospital support person with the parent's permission or contact someone of their choosing to talk with. All parents will be assured that the study is voluntary and they can choose not to answer any question. All identifiable information provided by the parent such as names or dates will be redacted from the interviews but kept in the interviewer's notes. None of the protected health information will be entered into the database except the infant's date of birth, gestational age and diagnosis. The server is located behind zone 100 to maintain security and all persons with access have a UT-assigned ID for access. All field notes and interview notes will be kept in a locked cabinet in the office of the investigator until they can be transcribed and added to the Atlas ti database.

Potential benefits. Parents are not likely to receive any benefit to participating except the knowledge gained that it may help better define ways to improve interactions with caregivers and parents in the NICU. It is possible that some parents may find it helpful to talk to someone about their experience. At the time of the interview, the consent

process will be conducted and the consent form signed. Parents will be provided a \$50 gift card to thank them for their time and a \$10 parking pass.

Importance of the knowledge. Findings of parent preferences and beliefs about safety will provide a grounded approach for future strategies to improve parent involvement in patient safety and for the development of a reliable and valid measure of neonatal safety culture through the voice of the parents. Organizations striving to involve parents and families as partners in learning about their safety culture will have an instrument to assess and target the best family-centered approach for improvement.

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[com.ezproxyhost.library.tmc.edu/books/about/Patients_and_Healers_in_the_Context_of_C.html?id=w-7h-sBx9BQC](https://books-google-com.ezproxyhost.library.tmc.edu/books/about/Patients_and_Healers_in_the_Context_of_C.html?id=w-7h-sBx9BQC)

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5/25/2015

Madelene J. Ottosen, PhD, RN
University of Texas Health Science Center at Houston School of Nursing
6901 Bertner Avenue
Houston, Texas 77030

Dee Beresford, Editor
Journal of Neonatal Nursing
deeberesford@btinternet.com

Dear Ms. Beresford,

Enclosed you will find an manuscript for consideration to the Journal of Neonatal Nursing entitled, *Parent Perceptions of Patient Safety Culture in the Neonatal Intensive Care (NICU)*. Congruent with the mission of the journal to support the development of practitioners caring for neonates and their families, this manuscript provides clinicians with a basis to understand how to engage neonatal parents in patient safety promotion activities. Using medically applied ethnography, we conducted 22 qualitative interviews with an ethnically diverse population of neonatal parents from a large tertiary NICU and months of field observations of parent interactions in the NICU. Through our analysis, we describe how neonatal parents perceive patient safety in the neonatal intensive care and their role/s in promoting a culture of patient safety. We bring the concepts of this study together into a conceptual model we developed which outlines a parent-clinician partnership in promoting safe care.

This manuscript provides practical information for clinicians to understand strategies for effective communication with parents, how parents perceive clinician interactions with their baby and patient safety behaviors that parents recognize as safe care. Engaging neonatal parents in patient safety initiatives is a timely and innovative component for neonatal practice. Therefore this manuscript would be uniquely suited to your readers.

Thank you in advance for your consideration.

Sincerely,

Madelene Ottosen

Madelene J. Ottosen, PhD, RN
University of Texas Health Science Center at Houston School of Nursing
Madelene.J.Ottosen@uth.tmc.edu

Parent Perceptions of Patient Safety Culture in the Neonatal Intensive Care Unit

Madelene J Ottosen, PhD, MSN, RN¹

¹University of Texas–Memorial Hermann Center for Healthcare Quality and Safety
The University of Texas Medical School at Houston
Houston, Texas

Joan Engebretson, DrPH, AHN–BC, RN, FAAN²

²University of Texas Health Science Center–Houston
School of Nursing, Department of Family Health Nursing
Houston, Texas

Jason Etchegaray, PhD³

³RAND Corporation
Santa Monica, California

Nancy Busen, PhD, RN²

²University of Texas Health Science Center–Houston
School of Nursing, Department of Family Health Nursing
Houston, Texas

Cody Arnold, MD, MS⁴

⁴The University of Texas Medical School at Houston
Department of Neonatology
Houston, Texas

Eric Thomas, MD, MPH¹

¹University of Texas–Memorial Hermann Center for Healthcare Quality and Safety
The University of Texas Medical School at Houston
Houston, Texas

Corresponding Author:

Madelene J. Ottosen, PhD, MSN, RN

UT–MH–Center for Healthcare Quality and Safety

6410 Fannin, 1100.38

Houston, Texas 77059

Madelene.j.ottosen@uth.tmc.edu

This research was supported in part through a grant from the Agency for Healthcare Research and Quality, R03HS022944, Parent perceptions in NICU safety culture: Parent–Centered Safety Culture Tool

Parent Perceptions of Patient Safety Culture in the Neonatal Intensive Care Unit

Background: Understanding and promoting a positive culture of patient safety within neonatal intensive care units (NICU) has shown to decrease threats to patient safety. Parents are an integral part of the NICU culture, yet little is known about how they perceive patient safety and what role they would find meaningful and appropriate for engaging in safety promotion activities in the NICU.

Purpose: The purpose of this study was to determine how neonatal parents conceptualize patient safety within the NICU culture and to identify how they perceive their role as patient safety advocates within the NICU.

Methods: Using an ethnographic qualitative approach, interviews were conducted with a purposive sample of twenty-two neonatal parents, currently and recently discharged from a large tertiary level I NICU. Field observations of parent interactions within the NICU were also conducted. Transcriptions of interviews and field notes were coded within ATLAS ti, v7. A content analysis of the coded data was conducted identifying themes relevant to the study aims.

Results: Parents perceived safe care as clinicians adhered to environmental protections, provided personalized interactions with their baby and maintained effective communications with parents. In partnership with clinicians, parents sought active roles as advocates, caregivers, decision-makers, learners and guardians to promote safe care. A conceptual model was developed depicting clinician-parent partnerships to achieve NICU patient safety

Conclusion: Clinicians can facilitate active partnerships with parents by understanding their perceptions of safe care and supporting their parenting roles to protect their babies.

Key Words: patient safety, neonatal intensive care, parent engagement

Introduction

The unique complexities of the neonatal intensive care environment can pose threats to patient safety (Raju, Suresh, & Higgins, 2011; Samra, McGrath, & Rollins, 2011). Medical error rates in this highly vulnerable population have been reported to be as high as 74 events per every 100 patients (Sharek et al., 2006). Experts cite multiple opportunities to improve the scope of these errors through teamwork and leadership training, improved processes for order entry and use of reliable measures to understand the culture of patient safety (Raju et al., 2011; Samra et al., 2011). Building and measuring a culture of patient safety involves understanding the shared knowledge, attitudes, perceptions, behaviors and beliefs of the individuals and groups within an organization towards health and safety management (Sexton et al., 2006). Key dimensions representing patient safety culture include assessments of teamwork, communication, and patient-centeredness (Sammer, Lykens, Singh, Mains, & Lackan, 2010). These assessments are often obtained solely from the views of clinicians and staff members of the health care team. However within the NICU, parents constitute an integral component to the safety culture landscape, yet their views are often not considered.

A changing paradigm is evolving within the healthcare system to involve patients and families as partners, not just recipients of healthcare (Conway, J et al., 2006). Parents and caregivers exhibit different values and beliefs in the care of infants in the NICU (Latour, Hazelzet, Duivenvoorden, & Goudoever, 2010) creating a challenge for parents to know how to engage as partners with the healthcare team. Studies cite parents often struggle with feelings of anxiety, stress, depression, confusion, difficulty coping and sometimes hide behind feelings of uncertainty (Ricciardelli, 2012; Weiss, Goldlust, & Vaucher, 2010). While parents desire to be involved in the care of their infants, they are often unsure how to be effective in the neonatal environment (Ricciardelli, 2012). By gaining a better understanding of what and how parents experience the culture of the

NICU, providers can identify appropriate strategies to involve them as partners in care. Furthermore targeting what parents think about patient safety will help health care providers understand how to engage them in safety promotion activities that they find meaningful and appropriate. In a recent report about patient engagement, The Agency for Healthcare Research and Quality (AHRQ) identified a major gap in our understanding of how patients and families want to be engaged in patient safety and cited the need for patient and family input in assessing patient safety within our healthcare environments (Maurer, Dardess, Carman, Frazier, & Smeeding, 2012). Therefore, the need to understand how neonatal parents perceive patient safety and how they construct their role within a culture of patient safety in the NICU is both timely and necessary. The aims of this study are to: **Aim 1:** determine how neonatal parents conceptualize patient safety within the NICU culture and **Aim 2:** identify how parents perceive their role as patient safety advocates in contributing to patient safety efforts within the NICU.

Method

Design

Using a qualitative medical ethnographic approach, interviews along with field observations were conducted to understand how the neonatal intensive care culture shapes the views and practices of NICU parents related to patient safety. Ethnography involves the study of culture or the beliefs, values, behaviors and language of a group of people to understand, from their perspective (emic), how they construct meaning to the cultural norms and behaviors within an environment (Green & Thorogood, 2013; Mayan, 2009). The ethnography method is particularly important in understanding the relationship between differing “cultural systems” of clinicians and patients (Chrisman & Johnson, 1990). Stemming from anthropologic roots, ethnographic data is typically obtained from observations of the participants, formal and informal interviews and examination of

artifacts within the cultural setting (Mayan, 2009; Miller, 1999). Medical ethnography combines the use of these anthropologic methods to understand the how clinical interactions shape the cultural landscape within a medical environment (Engebretson, 2011). For this study, field observations were used to examine the interactions of parents with the people and environment of the NICU. Interviews were conducted with individual parents, partner dyads and in small groups (Green and Thorogood, 2013; Mayan, 2009) to obtain a rich perspective of parent views in the NICU.

Setting and Sample

The study was conducted within an 80-bed Level IV NICU, admitting 1200 babies annually and staffed by over 350 specialty clinicians. The NICU is housed in large academic hospital in the southern United States. A purposive sampling of informants and observations was used to obtain a perspective representative of the breadth and depth of the cultural norms, environment and participant characteristics (Mayan, 2009; Richards & Morse, 2007). Informants were parents of infants hospitalized at least 3 weeks in NICU, considered to be in a stable condition and who speak English. Parents were selected during investigator observation periods in the NICU and through referrals by the NICU staff and charge nurses of eligible parents. Prior to asking each parent for participation, the investigator verified with the primary nurse that the parents were not struggling with emotionally difficult situations and were appropriate for an interview. Informants included parents eliciting a diversity of the backgrounds and experiences of typical parents in the NICU. Parents who were highly vocal in their interactions with providers and those less vocal yet interested in sharing their views were invited to participate. Types of variation in parent selection included first time parents, those with other children, those transferred from another NICU, length of hospitalization, the gestational age of the infant upon admission, parent age and ethnicity of the parent. Parents were given the choice to be

interviewed one-on-one, with their partner or in a group of 1 to 2 other parents. To understand the parent views of the NICU culture, parents were selected if they had been present in the NICU at least several hours weekly, with their infants. A group of three parents discharged from the NICU in the last 2 years agreed to participate as a neonatal Parent Advisory Board. They participated in a group interview for this study and provided feedback on the development of the interview guide. Parent informants were enrolled until there was redundancy in the thematic content and saturation in the depth and breadth of the topics discussed. Based on other qualitative studies consisting of in-depth interviews, saturation was estimated to occur with 20–25 participants (Kuzel, 1999).

Data Collection

Field observations were conducted to examine the interpersonal aspects of the NICU culture experienced by parents. In using ethnography, observations within the field or environment of study often accompany interviews to obtain a fuller understanding of the culture (Crabtree & Miller, 1999). Observations included patient rounds, general parent to provider interactions, waiting room interactions and other opportunities to witness how parents interact and communicate with the NICU staff and providers who represent its culture. Observations were conducted in concert with the interview period (January to November 2014) over both day and night shifts. As the observer, the investigator conducted regular weekly visits in the NICU to become an expected rather than unexpected observer in the NICU. Observational data included communication and teamwork behaviors such as ways of sharing information, inquiry, assertion, and vigilance as well as nonverbal communication, word choices, number and role of those present and the environmental variables observed during the communication. Observations were recorded through hand written notes and transcribed into individual word documents by date.

Interviews were conducted using a semi-structured interview guide (Appendix 1) developed in consultation with research advisors to address the themes and topics of interest with parents in the NICU. The interview guide was reviewed by a group of three neonatal clinicians (two neonatologists and one neonatal nursing director) to ensure the questions were clinically relevant. The investigator also received feedback on the interview guide from the Parent Advisory Board in the group interview with them. As seen in Appendix 1, the interviews began with open-ended questions asking parents to describe their overall experience in the NICU. Informants were asked to discuss four major themes, highlighted in the interview guide as “grand tour” (Spradley, 1980) items focused on parent perceptions of 1) members of the NICU team, 2) communication with the team, 3) their involvement as parents, and 4) safety in the NICU (see Appendix 1). More specific information related to patient safety, components of safety, their desired role in patient safety activities, and their desired role as a partner of the healthcare team were addressed in “mini tour” (Spradley, 1980) or probe items.

While an interview guide was used, additional questions were added throughout the interviewing phase to explore unexpected or emergent themes. The interview was an iterative process to ground the key findings and incorporate new issues as the interview progressed (Kvale and Brinkmann 2009). During the interviews, the investigator verified accounts or points with the informants to ensure accurate interpretation of their views. As additional relevant patient safety concepts or issues were raised by informants, they were added to subsequent interviews. Interviews were conducted from January to November 2014 and took from thirty to ninety minutes to complete. As informants were identified, they were given a verbal description of the study, a copy of the consent to review at home and asked if they might be interested in participating in the study. Those agreeing were scheduled for an interview. At the time of the interview, each informant received a detailed description of the study and answers to all study questions before signing a consent

document. Each parent participating in the interview received a \$50 gift card to compensate them for their time. All interviews were tape recorded, downloaded to secure password-protected network drive and transcribed by an external transcription service into a word document for coding. Prior to any data collection, the study was reviewed and approved by the University of Texas at Houston Committee for the Protection of Human Subjects.

Knowing that the researcher is an integral tool in the research methods of an ethnographic study, the primary investigator was well suited to lead data collection and analysis for this study. In medical ethnography, the interrelationships between patient and caregiver are important constructs in understanding the culture of a health care environment, so too is the interrelationship between the subcultures of the researcher to the healthcare environment of study (Kleinman, 1980). As described by Kleinman, the researcher should maintain a “cross-cultural” vantage point outside the culture to adequately study the behaviors and beliefs of a group (Kleinman, 1980). With 10 years of experience as a cardiovascular critical care nurse, the investigator was comfortable understanding and maneuvering within the highly intensive environment of the NICU. The investigator also had a 12 years prior experience as the parent of infant in the same NICU.

Data analysis

All transcripts of interviews and field notes were stored into a qualitative software program, Atlas ti software, Berlin v. 7, for analysis. Analysis involved organizing, connecting and corroborating or legitimating the data in an iterative process that culminated in an accurate representation in the accounts of the informants (Mason, J, 2002). Transcripts were analyzed by applying codes to quotations or phrases to represent the meaning being expressed. Codes are “short phrases or words which assign summative, salient, essence-capturing and/or evocative attributes for a portion of

language-based or visual data”(Saldana, 2012). A codebook or master list of codes was developed based on concepts relevant to answer the research question and on emerging concepts revealed through analysis. Codes and representative phrases were reviewed with research advisors as they emerged. As with other aspects of qualitative design, the codebook was an iterative tool allowing for additions or changes in the coding schema. Once the data were coded, the findings were reviewed related to parent roles and perceptions of safety in meetings with advisors to reach consensus on interpreted findings. Results were also presented by the principal investigator in a peer debriefing meeting of four nurse colleagues with neonatal and qualitative experience who reviewed the results for congruency that the findings were supported by the data.

Results

Demographics

Twenty-two parents were interviewed representing the general diversity of parents in the NICU. As seen in Table 1, most of the parent participants classified themselves as African American or Hispanic. A majority of informants were female (82%), married (68%) and were having their first baby (61%). Ages of informants fell into two categories, 45% were between 18 and 30 years of age and 55% between 31 and 45 years of age. Of the 13 interviews conducted, 54% were done face-to-face with one parent, 31% were done face-to-face with both parents together and 15% were done in groups of 2 (in person) or 3 parents (over the phone). The average gestational age of the infants was 27.3 weeks (22–37 weeks) and the average length of stay in the NICU for the infants at the time of the interview was 105 days (21–365 days). All of the infants were admitted to Level IV or III care with a broad range of diagnoses, 27% were multiples. A majority of the parents (77%) visited their infant > 6 days per weeks. Six of the informants delivered their baby in

another facility before being transferred to the study site NICU and of those parents, three of their babies received care in another NICU.

Table 1		
<i>Demographics of Parent Informants</i>		
<u>Category</u>	<u>#</u>	<u>% (n=22)</u>
Gender		
Female	18	82%
Male	4	18%
Marital Status		
Married	15	68%
Single	7	32%
Age		
18–30 years of age	10	45%
31–45 years of age	12	55%
Race		
African American	9	41%
Hispanic	6	27%
Caucasian	3	14%
Asian/Islander	2	9%
Other	2	9%
Parity of Mom (*n=18)		
1 live birth	11	61%*
2 live births	7	38%*
4 live births	1	.10%*
Infant's Gestational Age at Birth		
(avg. weeks) (range in weeks)	27.3	22–37
Infant's Length of Stay in NICU at Interview		
(avg. days) (range in days)	105	21–365

The results of the data will be presented to address each of the primary aims of the study to 1) understand parent perceptions of patient safety in the NICU and 2) describe the roles of parents in promoting patient safety. As an additional finding a conceptual model of parent–clinician partnership linking the parents' perceptions of patient safety to the parenting roles they adopted in the NICU will be illustrated.

Parent Perceptions of Patient Safety

Parent perceptions of safe care for their infants in the NICU surrounded three types of interactions that parents had with the NICU 1) the security and infection control

practices of the environment, 2) the way clinicians interacted with their baby and 3) the communications they had with clinicians about their baby. During each of these interactions, parents felt safe when clinicians and staff were present, intentional and respectful.

Environment. When asked about patient safety in the NICU, the first response for a majority of parents related to the secure environment of the unit. Parents appreciated the security procedures to monitor visitors gaining access into NICU. All persons entering needed to show identification with every visit to a hospital coordinator stationed at the front desk and be on the list approved by the parent. Having someone at the front desk at all times strictly adhering to visitation policies gave them assurance that their baby was safe when they left the NICU. Being able to identify the designated persons who were allowed to see their baby in the NICU and when, was also important to parents in feeling their baby was in a secure environment.

...like you want to know who's coming in the room, who's going to touch him, or if somebody's looking at him, like who are you? Who you with? (#11)

Because you hear so much on the news nowadays where people come in and trying to take babies...this hospital has like just the security, you know, of everything. When I leave here, I feel safe and secure that (baby) is secure. So there's not going to be any issues, or I don't have any worries that something might happen to him. (#20)

The NICU is comprised of two distinct units, a 68-bed unit for higher acuity (level IV/III) care and a 30-bed unit on a separate floor for lower acuity (level II) care. The level IV/III NICU contains 8 pods with 8 beds each. Two of the pods contain 2 private rooms and one pod is all private rooms, used primarily for babies needing isolation. The level II NICU is on a separate floor and is comprised of private rooms to accommodate rooming in by parents. The parents interviewed had babies who were all admitted to Level IV/III in an open pod. Most parents described feeling safer in a pod since they felt the security of

having more staff available if their baby needed immediate attention. Parents were given the option for a private room when their baby reached Level II status but were often fearful that their baby would have less attention, especially if they were unable to stay overnight with their baby. A few of the parents, whose babies moved to private rooms in the Level III or Level II NICU, preferred the privacy and decreased noise of the private room over the pod. Parents did not like moving their baby to a different location in the unit because it meant changing nurses but when it was in the best interest of their baby they often agreed. Nurses were sensitive to the apprehension of parents in the NICU about moving and rarely moved babies, even within the pod, unless absolutely necessary for patient safety.

Parents were comforted by seeing clinicians following safety procedures and routines that stressed infection control like handwashing, use of bedside hand sanitizers, wearing gloves during procedures, keeping the environment and equipment clean around the babies, and making sure visitors, including the parents themselves, were free from illness.

All of the hand washing, don't come in if you are sick. They eliminated multiple visitors for a little bit here whenever the RSV and all that stuff was going around real bad. It was all of the unnecessary people, don't come. Yes, that did make me feel safe and feel better. (#1)

What makes me feel the safest, if I do see them sanitize between everything. Every touch I do, and I'm very—I'm a germaphobe, so that makes me feel safe. (#2)

Conversely, parents saw a threat to safety when they felt unit practices were incongruent with infection control procedures. One parent described her concern over a new baby admitted to the middle of the NICU pod. Red tape had been placed on the floor in a three to four foot perimeter around the baby's isolette. While she respected the other family's right to privacy about the baby's condition, she was unsure if the procedures taken were adequate protection for her baby.

I know the baby was brought here in a helicopter, because I was here when the baby got here... You know, they have like the biohazard things you put stuff in, this and that, you know, it's got all kinds of little stuff so I'm just thinking like if they have all of that, then that baby shouldn't be in the middle...of the kids, you know what I'm saying?— it's almost like if you have the pinkeye. If you had pinkeye and I'm sitting across from it, no, it's not going to jump out of your eye and come to me and I'm going to catch it. So like this baby, whatever this baby had was not going to jump out of her area and come over there and give it to another kid, but if I see you with pinkeye I'm going to ... want to talk to you. It's restricted... that baby can't have any outside contact really, unless you are well dressed equipped. And if that's the case, then for the safety of that kid, you shouldn't have the kid in the middle of all of us. Or for the safety of others' kids, you shouldn't have the baby in the middle of all of us. (#10)

Interactions with their baby. A majority of parents also described safe care as the presence of a nurse watching over their baby, quickly responding to emergent needs, and interacting with their baby as if their own.

The way they treat him. The way they come and they see him in the monitor, he's desatting, or doing something, and they go there and check on him. They do whatever they need to do. Or when I'm there with him, with the baby, they come and they check, "Is everything okay?" They still keep a close eye on him even though when I'm there with him...And because they know the baby very well... They're—like they're there every day, so they know, basically, it's like me being there. And so they told the doctors, "Well, I don't think he likes this, and stuff like that." And it's the same thing I think. (#11)

Parents felt safe knowing nurses were physically present in the unit, near their baby, to respond to their physical and comfort needs especially when they could not be in the unit. Most parents could give examples of when nurses responded quickly to emergencies with their baby or other babies in the NICU. They felt confident when clinicians calmly responded to emergencies and worked as a team, often surprised at the number of clinicians responding to assist. Parents were sensitive to the intention of the nurse when interacting with their baby. It was important to see nurses respond to alarms having looked at their baby first and not solely silencing alarms.

And when certain nurses are in the pod, I've seen them ...if the heart rate is going up or down they'll stand or they'll look. Or they'll stand there for a while and see if it will change. And if not, then they'll go in and stimulate the baby. Because ...

when they're in their isolettes, you can't see that quickly because they're so little when they're in there... I mean just like that example of my son. He was already extubated. But if the nurse had not paid attention to his desatting and just turned him up and didn't hear him—he was crying—he had a voice—she would not be able to intervene in time. (#20)

They described feeling safer with nurses who interacted with their baby in a personal way by talking to them, patting them and treating them like their own babies.

I appreciate when they talk to him, when they just don't go in there and do their job. I mean, because, that's what I like, when they go in there, it's like, "Hey, little man, I'm about to take your blood pressure." I love that they talk to him and not just go in there and startle him and then just do what they have to do. He's a little person, okay? (#4)

Even though I know he was in the hospital and those nurses (were) paid to take good care of those babies, but I felt like, "Okay. There is another mom for him there that was not me." That was so nice... I love that. (#17)

When asked about issues of unsafe care, many parents found it difficult to describe negative issues and instead responded with compliments for the care their infants received in the NICU. A few parents stated they "never felt unsafe" or "saw anything that made (them) question the safety of (their) child". Parents described feeling safer with the nurses they had chosen to be primary nurses for their baby. Parents were told of their option to choose primary nurses by the staff. After being in the NICU for several weeks and getting to know the nurse/s assigned to their infant, parents chose nurses they were most comfortable with to be the primary nurse. Sometimes after a nurse established a rapport with the parents and baby, the nurse asked the parents' permission to be the primary nurse for their infant. A couple of parents stated they did not have primary nurses and seemed unaware of the practice. Parents described a connection with the nurse based on the way the nurse interacted with their baby especially during the most critical times of their care.

Despite the overall contentment with care, most parents could describe at least one issue which gave them concern about the care their baby received. Parents were

concerned when they observed nurses who seemed inattentive to the needs of the babies, even if the inattention was not directed to their baby.

Because it was one time where there was a baby that was crying and she was just crying, crying, and crying, and I know she is—she was spoiled. Like, she wanted someone to hold her, but this particular time when they picked her up, she burped. So she was uncomfortable. But she had cried for... (an) extended amount of time. And when the nurse finally got her, she burped. (#2)

Other situations in which parent felt unsafe were observations of nurses who seemed more concerned with completing computer work or preoccupied with admitting an infant to the NICU rather than to responding to the immediate needs of their baby.

When they admit—and it's not just me—because a lot of other parents who've been—that I've spoken to—had also mentioned—because they said, "Didn't you notice that when they're admitting someone, they don't handle—like, this alarm had been going off for two minutes already, and nobody's—nobody would pay attention? —when the pod is full, it's good because there won't be any admissions. But if it's not, and there's an admission, I'm concerned for my baby. " (#21)

Over time, parents became more aware and were sensitive to the interactions received by all of the babies in the pod which shaped their views of safety. They observed how clinicians interacted with other babies wanting to see the same care provided for all the babies. They were also aware of babies whose parents did not visit as often and were concerned with their safe care.

I feel sad for the babies. They want some interaction. They want to feel the love. I think that parents should be involved, or like at least call, "Are you going to see the baby? Are you coming any time soon, or—"or when the baby's like sick, or critical, they only come for that time, and then they leave. (#11)

Because when I pray for my baby, I pray for all the babies. I don't just pray for mine. (#10)

Clinician–parent communication. An important aspect of safety for parents was in the communication they received from clinicians. Parents liked clinicians inviting them to rounds, asking them questions about their preferences in care and getting their feedback about their baby's responses to care. They appreciated receiving daily phone

calls from the physician or nurse practitioner if they were not present in rounds. Receiving regular and honest information from clinicians from the very beginning about what would take place, why and what to expect, made parents feel more like parents. Even when adverse events occurred, such as a time when a baby, whose parents were Jehovah's Witness, received a blood transfusion without the parents' permission, parents felt respected that the clinicians provided an environment for them speak up about their concerns and were responsive in planning how to prevent future occurrences. Another parent echoed the importance of the staff encouraging her to speak up when her child experienced a delay in treatment due to a management decision.

So we felt comfortable because we were surrounded by people, other nurses that made us feel, "Look, you can talk. You can communicate." And they gave us that background and made us feel comfortable the first few weeks in the NICU. So even though it was uncomfortable talking about a negative incident, it was easier to do so with that kind of network in place. (#15)

Parents weren't always confident of the importance of the issues they raised but when they did speak up they wanted to know their concerns were addressed by the staff.

So I asked the nurse, "Is it normal for him, for his head to be like this and his body to be kind of slightly turned?" And she's like, "No, let me turn him completely so he can breathe a little bit better." And she went over there. She adjusted his little breathing thing and he was good to go. (#12/13)

Having a sick infant in the NICU created a variety of emotions in parents. At times, parents struggled to be present with their baby when they felt uncertainty or an inability to cope. These feelings can be intensified by negative communications from the staff. One mother described more intensive feelings of depression when she felt clinicians interpreted her actions as a lack of commitment to her baby.

She had, like, three or four different infections and ... we had been staying here, so, I got into this routine where I would wake up to pump and every time I would wake up to pump, I would call to check on her and then after her major surgery, I woke up one night, maybe seven, eight in the morning, and I called to check on her and said, "can I talk to the nurse in charge of Baby xxx," so, I guess she thought she had put me on hold and she was talking to somebody in the, in the room and

she was like, do you have Baby xxx? And then the nurse said..."she's right here at (one of the parent rooms). I don't understand why she doesn't just come over here and check on her and ...this poor girl, they only come in and see her for, like, five minutes and they leave". And, I mean, like, that hurt me because...I mean, it was hard to come in and see her the way that she was ... And then I told my husband that whole week I was so depressed. Because, I mean, I was already depressed because of everything that had happened.

Parents were concerned about safety when they experienced or heard about clinicians not respecting the warnings raised by other parents.

I did speak to a mom in here, and she was scheduled to go home on a Sunday, and Saturday her baby was crying, and crying, and crying, and she asked the nurse—, "You know, what's wrong with him?" And she was like, "Oh, you know, babies cry." And she went to her baby, and she was like, "No, because he never just cries like this." —that was the day shift nurse, and then she said the night shift nurse came, and she was like, "Something's wrong with him. He's crying." And I think they called someone and did an x-ray. They came to find out he had NEC (Necrotizing Enterocolitis). (#2)

Nonverbal communications from clinicians that could be seen as disapproval can also create situations for parents to feel unsafe. During a field observation, an interaction was witnessed between a parent and nurse just after the infant had been reintubated.

A young mom was at the bedside with her infant who was in an open bed, with warming lights on and three nurses and a respiratory therapist at the bedside. The mom looked nervous, concerned and was asking the nurse questions. The nurse was focused on the baby, situating the equipment to hold the breathing tube in place. The nurse's face was solemn with tight lips. Her attention was entirely on the baby and didn't seem to be exhibiting any comfort to the mother or looking at her when answering her questions. The mother mentioned she will return later and says "thank you for bringing her back" as she walks out of the unit. I learn from a third nurse that the infant became extubated while the mother was holding her. The third nurse explained that they tape the ET tube to the mother's shirt to prevent pulling of the tube but the mother kept nodding her head like she was sleeping. She stated they mentioned to the mom several times to watch the baby's tube and to not move her head while holding the baby but it happened anyway. I asked if the mom was sleepy but the third nurse didn't know. The third nurse said the mom mentioned that she would be afraid to hold the baby again after this happened. It didn't appear that anyone was with the mom when she left.

Multiple attempts to interview the mom described in the scenario were unsuccessful despite repeated visits to the NICU during her customary visiting time. The primary nurse

of the infant relayed that the mom was 19 or 20 years old and worked nights at a fast food restaurant.

Parents formed perceptions of safe care through their observations and interactions in three areas within the NICU, 1) the unit structures and environment of the NICU, 2) the interactions with their baby and 3) the communications by the NICU clinicians and staff. Within each of these areas, parents were cognizant of the presence, intention and respect displayed by clinicians and staff in promoting the safety of their baby. The presence of security and infection control procedures, having staff present to watch over their baby and having clinicians especially doctors and nurse practitioners present to communicate with them about their baby's status made parents feel safe. In addition to a sense of presence, parents wanted clinicians and staff to be intentional in following safe procedures, coming to their baby's bedside, and inviting them to rounds or asking for their feedback about their baby. Lastly parents related feelings of safe care to the respectful behaviors of clinicians and staff to honor rules of visitation, follow parent preferences for providing care to their baby, for knowing their baby and listening to their concerns. Disrespectful behaviors of clinicians, for instance not listening when parents voiced their concerns about their baby's discomfort, made parents feel unsafe and posed threats to safe care by delaying the diagnosis of serious conditions such as necrotizing enterocolitis.

Role of Parents in NICU Safety

For most parents, the journey through the NICU was an experience like no other. Filled with episodic waves of emotions, they experienced many ups and downs in the care of their fragile infants. Most parents described their first days in the NICU as "surreal" and feeling "helpless". They were uncertain of what was ahead and felt dependent on the NICU clinicians to provide care for their newborns and teach them how to interact with their new baby.

Well, she was so tiny, she was so small that whenever, they gave her to me, I was, scared to even, like move or to do anything that would, like, hurt her or, you know, any little movement would, I don't know. I would, just, like hold her and just not move. And at first I would try to hold her for, like, three or four hours because I could only hold her one time a day. But... it was scary because of the way that, like she was so tiny and she still had her breathing tube and, you know, she still had her, her stitches from her surgery so ... I didn't want to do anything to cause her any pain (#14)

Parents recognized clinicians, especially the nurses, as partners in parenting their babies in the journey through the NICU. As seen in figure 1, parents gradually assumed five roles as learner, caregiver, advocate, decision-maker and guardian to support the safe care of their infants within their partnership with clinicians in the NICU.

Learner. One of the first roles parents assumed was that of a learner. Parents were acutely aware of what they didn't know. With encouragement from the clinicians, they took advantage of opportunities to learn anything they could about their baby. They attended rounds, asked questions of clinicians, read the pamphlet of information provided by the NICU and watched as clinicians taught them about the special needs of their baby. Parents appreciated the tremendous responsibility to learn as much as possible to be able to ask the right questions, make good decisions and safely manage the care of their baby when they went home.

My responsibilities while I'm in here. Basically just to try my best to know her needs. So when I go home, her needs—her concern—what to look for—what not to look for. I tell nurses all the time, I say, look, what you say is gold. What you tell me is gold. So they're very knowledgeable here. Every nurse ... And if they don't know, they'll find out for you. Or if they don't know they're going to find somebody right then and there...the most important thing, I just want her to get all that she can while she's here. You know, every nurse has something to tell me different. (#10)

Some parents supplemented what they were told by clinicians by searching the internet or reading medical journals. One parent (father) felt that it was difficult for clinicians to discuss his daughter's diagnosis with him in depth. He wanted to know all of the details of his daughter's condition to be able to ask the right questions and speak to

clinicians frankly about the reality of her critical condition. He read medical journals about her condition so that he could effectively converse with physicians. For him, it took three weeks to “earn the trust” of the physicians to be able to dialogue with him at the level he needed. While not all parents needed this level of dialogue, all parents wanted to partner with clinicians to learn about their babies. Once parents learned something was a critical measure of their baby’s health status, they learned to ask for updates about the measure and questioned when results were delayed. Because they knew what to ask, one parent identified echocardiogram results that had not been read and another parent alerted nurses to a baby who had been without a bowel movement for a week. Parents also sought to learn about their baby’s likes and dislikes for comfort and care and expected clinicians to reciprocate in learning about their baby’s preferences.

Caregiver. Interacting with their baby as a caregiver was another important role for parents. Being able to hold their baby, feed them, change diapers, or even touch them for the first time was often long awaited. Parents wanted to interact with their babies as much as possible yet their fears of “hurting” their baby were difficult to overcome.

He was my first baby and him being born so early, it was scary, but they (nurses) helped me feel comfortable. And he was sick and there was not much I could do for him, but they helped me to take care of him, save his bath for me. And his bed change and stuff like that. That made me very comfortable and happy as a mom because I couldn’t do nothing to help him heal. But I was doing all the things for him and that felt great. Yes. I liked that. And, you know, if he had anything going on they will call me and ask me, “Oh, do you want me to save this for you? Are you coming soon?” It felt great. They did their best to make me feel like a mom. (#17)

As parents became more aware of the ways they could provide care, they were often dependent on the encouragement and support of the clinicians at the bedside in carrying them out.

And I think that was another great thing about this NICU is that they really push that intimacy with your babies. As you know, you(re) doing all the safety aspects of things as well. But they did it in a safe manner, but yet really push you. I don’t think we would have changed the diaper or did Kangaroo Care or anything of that nature

*as soon as we did if we didn't have the support of the doctors and the nurses.
(#15)*

Eventually parents established routines with the primary nurse and/or bedside nurse caring for their baby to take on the responsibility of doing specific activities at specific times which further supported their role as caregiver for their baby. In providing care for their baby, parents noticed how their baby responded to suctioning, feeding, positioning and comfort measures. For most parents, primary nurses were influential in helping them recognize their babies' preferences which empowered parents to notice even more. As parents interacted more directly with their babies, they were able to identify the levels of normal for their baby and alert new staff who might be caring for their baby for the first time. One mom, who was also a nurse, knew her baby did not often have bradycardia with his apneic episodes. When calling in to get a status report one night the nurse discounted the mom's urgings to watch his breathing stating she (the nurse) hadn't seen any related bradycardia.

You want your nurse to be understanding and realize that you know your child. Even though you're not there 24 hours a day, you know this child, and you've been there around the clock. You see these different things. You're talking to the nurse. And if this is your first time interacting with my baby, I want you to take me at my word. Yes, technically, we're supposed to go by the book in nursing and stuff, but the parent is a good key source in learning about your new patient... it definitely is frustrating when a nurse is trying to tell you something different. And I'm trying to educate you about my baby so I can leave and be comfortable. (#4/5)

Advocate. As parents gained more confidence understanding NICU care strategies and interacting with their baby and the clinicians, they often assumed the role of advocate for their baby especially as clinicians caring for their baby changed. When questions arose about the plan of care or something that didn't seem right, parents felt the need to speak up on behalf of their baby.

Her left eye was red...And it was like, for two weeks. And I kept calling the doctor over, and I was like, "Her eye is red." And it was draining. And then she said, "Well, it's not infectious. I know what you're thinking, 'it's an infection.' It's not an infection. It's irritated." And I kept saying..., "Something's not right, because why would her

eye be red and runny?” Like, something is wrong. It’s not—it won’t just do that. And I kept, like, mentioning it, mentioning, mentioning. And they just kept, it’s like, “Oh, no. It’s this.” And then turned out—come to find out she had Glaucoma. (#2)

Many parents were encouraged to speak up when their primary nurses and physicians listened to their concerns and took action. Most parents were acutely aware of their baby’s physical appearance noticing small changes immediately upon arriving to the bedside.

We come every day, we talk to the nurses. We’re not shy, but we’re also not overbearing. We try not to be, you know? But we communicate, we ask questions. And then when we see something like when we saw xxx’s foot was swollen, I asked the nurse. And she said, “Oh, I hadn’t noticed that. Well, let’s ask the doctor when he comes in for the rounds.” (#6/7)

Other parents mentioned their hesitation to bring up issues of concern to the clinicians because they didn’t want to upset those caring for their babies. One mom became empowered to advocate for her daughter through consultations with a licensed counselor whom she sought to assist her in coping with the struggles of her NICU experience.

I go to counseling every two weeks. And so I told her about it a while ago... I was like, “I don’t want to feel like I’m stepping on anyone’s toes when I’m there,” and she was like, “Basically, you have to be an advocate for her. You know, you have to—“And it’s just like, even if you think it’s minimal, or you think it’s simple, still say it, because you never know what the outcome. So every little thing I do... I don’t even have to, like, do an assessment over her. I just walk up to her and I’ll see something. I’m like, “Oh, she has a rash,” or, you know, and I’ll bring it to their attention...Because at the end of the day, this is your child and so you have to just treat it that way... Just like if they were at home, you would, you know, stand up and, like, try to make it right. If they fall, you’re going to fix it, so it’s the same thing here. (#2)

Decision-maker. Parents are the ultimate decision-maker for their children. Yet when faced with the intense clinical decisions in the NICU, parents depended on the expert guidance of the clinicians in managing the care for their babies. Over time, parents sometimes felt the need to challenge patterns of decision-making when attempts to resolve an issue were repeatedly unsuccessful or waiting seemed to delay the goal of care for their baby.

She's been having reflux for the longest. And so they didn't want to give her medicine at first because she was so small... So I was like well let's give her medication, I mean, I just don't want to see her in discomfort. And they were saying that, "Okay, we're gonna go through the weekend and if it's still bad by Monday, we'll give her the medicine." And my thing was why? Why are we waiting until Monday? It's not like it's going to change. This is something you already know, so let's just be proactive. So I don't want to wait until Monday. (#10)

She's been on TPN fluids three times. The first two times, they did it their way... The first time I just listened. The second time I had something to say. The third time I was like, you know what? We did it y'all guys way twice so this let's just hear for my way. I don't want you to do the same thing you did the first two times, because that's something we know it doesn't work... Don't do that no more...— she couldn't tolerate her feeds too often... they move her up each day... based on her weight and all that. And my thing was don't move up so fast. So if each day if she does good on two, then six, then 10, then 12...if ... she did go to 15, but she spits up at 20, instead of stopping her feeds trying to figure out what's going on and start all the way back over and stop her feeds, just go back to 10. Don't go all the way basically to the beginning. Just go back a little bit. And then work from there... so that's what we did this time...it worked for her. (#10)

Parents saw the primary nurses as partners and often engaged them in discussing decisions. Opportunities for parents to engage in decision-making made them feel more like parents.

I let the doctors know, "You know what? I don't think he likes this. We need to go back to this." And then his primaries are with me, she'll agree, "Yeah. He didn't like this." "How about we do this?" (#11)

Guardians. Ensuring their infants were in a secure and protected environment was a primary focus for parents in promoting patient safety in their role as guardian. Parents found comfort in following the rules for security checks and visitation to protect their infants. The potential threat of their baby being taken from the NICU was real for many parents especially at times when they could not be present with their baby in the unit. Having a shared responsibility with the front desk personnel and the nurses gave parents a sense of comfort in knowing who was present with their baby at all times. Conversely when the rules were not followed and visitors were allowed in the NICU, one mom felt concerned and frustrated that her wishes were not respected.

Parents trusted their primary or bedside NICU nurses to be the guardian of their baby in their absence and found comfort in being able to call to the NICU at any time to get a status report when they could not be there. Several parents recommended the use of “face time” with their primary nurse as a means to see their baby via webcam when they could not be in the unit. Parents also took responsibility in following rules for infection control to protect their babies.

You know, he's (dad) sick right now...but we don't want—to risk the other babies...the other babies getting sick and, in turn—If he's, you know, walking down the hall and coughs, and then—...somebody else gets sick. (#08)

Parents liked the constancy staff maintained for enforcing hand washing, wearing protective gear and the use of hand sanitizer to other staff and visitors, even members of their own family. They expected the front desk and nursing staff to jointly support efforts to keep persons who might be ill out of the unit. Parents felt it was within their role to point out persons to the nursing staff who were coughing and not wearing a mask or family members who were roaming about the pod looking at other babies, both seen as safety issues by parents.

A Conceptual Model for Engaging Parents in Patient Safety in the NICU

Parents recognized they had a shared role with the clinicians in protecting their infants and described their role in promoting safety within the context of their relationships with the clinicians caring for their baby. As seen in figure 1, parents experienced positive partnerships with the NICU clinicians who were present, intentional and respectful in their interactions to assure patient safety. A strong partnership between clinician and parent promoted confidence in parents to develop their roles to promote safe care in the NICU.

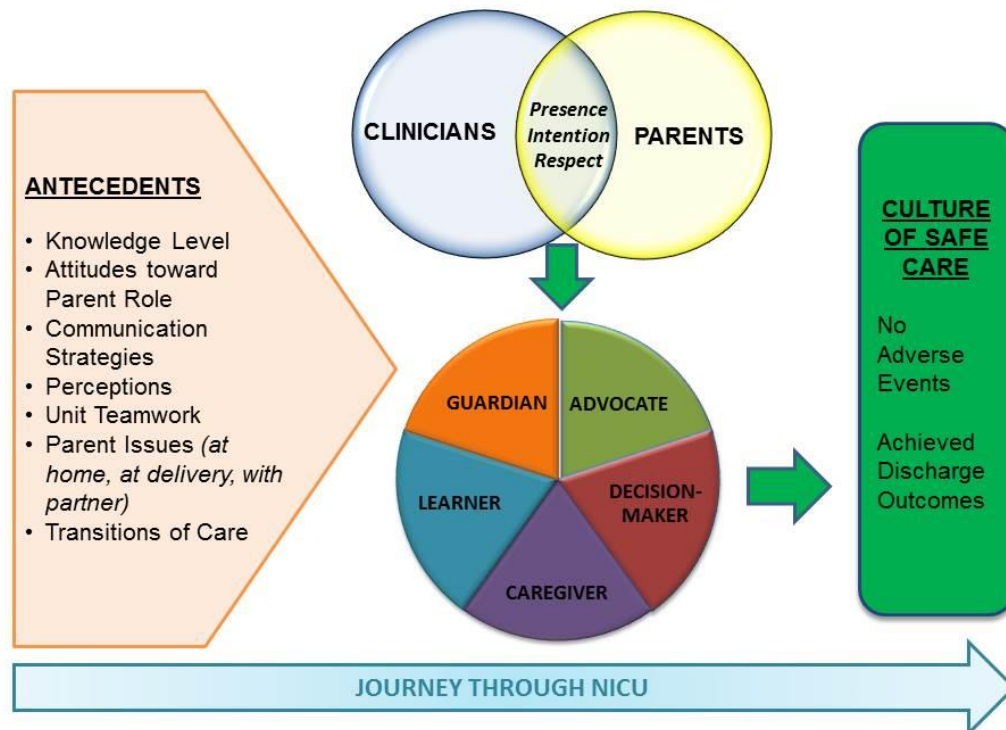


Figure 1. Achieving Parent-Clinician Partnership of Patient Safety in the NICU

Parents needed varying degrees of time and support to gain confidence in their parental roles. Several antecedents were recognized as impacting the way parents developed their roles of promoting safety in the NICU. While not the focus of this paper, a preliminary listing of antecedents included the knowledge of clinicians and parents, attitudes of the parent role in the NICU, communication strategies, unit teamwork, parent issues (i.e. returning to work, managing the care of other children, distance between home and NICU) and the multitude of transitions in their infant's care. These antecedents impact the formation of the clinician–parent partnership and the development of parent roles of safety throughout the neonatal journey. This model posits that a patient safety culture based upon a clinician–parent partnership of patient safety leads to safe care, without preventable harmful adverse events while achieving discharge outcomes.

Discussion

This study was important in understanding that neonatal parents want to be involved as partners in promoting safe care for their babies in the NICU. Engaging patients and families as partners in supporting patient safety initiatives is growing across healthcare (Berger, Flickinger, Pfoh, Martinez, & Dy, 2014). This study examined the relationship of parent and clinician as a shared partnership in promoting safety. Often parents in the neonatal ICU feel ill-equipped for the role of parenting in this highly technical and intensive environment. They depend on the encouragement and support of knowledgeable and capable nurses and physicians to support their involvement in the NICU. Other studies have shown that infant–parent interaction in NICU can improve a child’s later development (Jiang, Warre, Qiu, O’Brien, & Lee, 2014), care–by–parent programs have improved infant weight gain, decreased nosocomial infections, decreased NICU length of stay and decreased bronchopulmonary dysplasia (Jiang et al., 2014) and that parent involvement decreases child’s pain and reduces parental stress (Gallegos–Martinez et al., 2013).

The results of this study indicate that parents perceive safe care through the actions of clinicians. In another recent qualitative study of neonatal parents by (Lyndon, Jacobson, Fagan, Wisner, & Franck, 2014) parents described clinicians “watching over my baby” as key dimension in patient safety. In both this study and that of Lyndon et. al., parents described the importance of having good communication with clinicians, receiving timely and detailed information about their infant, and having opportunities to parent in order to feel safe. Parents were astute in witnessing breaches of safety and were able to identify mistakes or problems in care. Parents in both studies described the majority of clinicians to be knowledgeable and competent in caring for their baby. Yet some parents felt concerned about skill level of new nurses, when nurses seemed too busy to hold or feed their baby and when nurses didn’t know their baby. While both studies cite the

importance of decision-making, parents in this study highlighted the importance of partnering with clinicians to promote safe care. The partnership between clinician and parent was essential for parents to develop their parenting roles and for clinicians to engage with parents in patient safety.

Involving parents in the care of their infants in the NICU is an important element in helping them develop their roles as parents. Mothers who visit more often in the NICU have less problems with role conflict (Carmona, Vale, Ohara, & Abrão, 2013). However as found in this study, parents often struggle with having to return to work, responsibilities of caring for other children or suffer financial constraints due to the daily costs of travel and parking to the NICU. It has been shown that mothers may feel threatened by clinicians when they feel they cannot provide care adequately (Carmona et al., 2013) and may not visit during the most critical times. Other studies have shown that parents become angry and hostile when they are unable to provide care for their baby (Gallegos-Martinez et al., 2013) giving further support for clinicians to actively engage parents in all aspects of care. Studies have found parents can positively impact their infants care through involving them in comfort rounds (Graci, 2013) and comfort management (Skene, Franck, Curtis, & Gerrish, 2012). Bedside nurses play a key role to engage, teach and encourage parents to interact with their newborns (Feeley, Waitzer, Sherrard, Boisvert, & Zerkowitz, 2013). The more involved parents are in the care of their infants in the NICU the more aware they are of subtle changes in their infant's status and to partner with clinicians in promoting safe care.

Promoting patient safety in the NICU is a team effort requiring the contributions of clinicians, staff and parents. Previous studies have shown that lack of teamwork and poor communication are often causes of reported adverse events in the NICU (Profit et al., 2012). Given the large number of clinicians involved in caring for an infant in the NICU, the

parents are the one constant. Tremendous efforts in patient safety have been instituted to engage and empower patients and families in efforts to promote safer healthcare (Maurer et al., 2012). Listening to parent concerns, engaging them in decision-making for their infant's care, and asking for their feedback about what they see and hear are all ways parents can engage with clinicians in promoting safer care in the NICU. To help parents engage with the health care system, clinicians need to seek an understanding of the circumstances neonatal parents may be experiencing when they are not comfortable or able to visit or interact with their baby. Building strong relationships of safe care between clinicians and parents is an important step towards developing a culture of safety in the NICU.

Limitations

There were several limitations in conducting this study. Non-English speaking parents were not included due to the limitations in language by the investigator and the lack of translators. It was noted during field observations that several parents who indicated they were non-English speaking parents did not interact as much as other parents with their infants. It is not known if language barriers between the staff and parents contributed to their level of interaction. Parents were enrolled from a single NICU located in a large academic institution. Previous studies have shown a wide variation in safety culture across NICUs (Profit et al., 2012) therefore it is possible that parents in smaller community-based NICUs may have different perceptions.

Future Research

Several tools exist to measure the safety culture of NICUs. Given the important role parents play in the neonatal safety culture, creating a tool to obtain parental views of patient safety would be helpful in examining parent-centered issues of patient safety. It is

not known if the differences in safety culture across NICUs could lie in the differences of the relationships between parents and clinicians. Unanswered questions remain about the barriers parents have in being present and involved with their babies in the NICU. It is unclear which clinician behaviors support and which prevent parent engagement in the NICU. While we identified several antecedents impacting the patient safety partnership between parent and clinician, examining each of those factors with more depth could provide better understanding of the types of interventions to improve the partnership. Given the large numbers of non-English speaking parents, studies are needed to understand their perceptions of safe care in the NICU and the role language plays in parents assuming roles of advocate, learner, guardian, caregiver and decision-maker. Lastly more research is needed to examine best approaches for supporting parents, especially in engaging fathers, in developing their roles in promoting safety and which parent roles are most effective in achieving a safe culture.

Relevance to Practice

This research is important because it adds insight about the perceptions of safety by parents in NICU and the roles they engage in to promote safety. In addition to defining the roles of parents in promoting safe care, we were able to further contribute to the literature by examining the perceptions of an ethnically diverse group of neonatal parents. Neonatal clinicians can benefit by understanding how parents perceive safe care and encouraging an open system of communication to alleviate and address parents' fears and concerns. As clinicians, we need to ensure we are respecting and fostering the roles of neonatal parents to parent and protect their infants in the NICU environment. Parents want to know someone is present and responsive to their infant's needs and have a role in decision-making in the care for their infant. Neonatal clinicians are challenged with the essential goal of partnering with all parents and families to achieve safe care while meeting the goals of discharge.

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Appendix A

University of Texas Health Science Center at Houston

Appendix A
 University of Texas Health Science Center at Houston
 Committee for the Protection of Human Subjects Approval



Committee for the Protection of Human Subjects

*6410 Fannin Street, Suite 1100
 Houston, Texas 77030*

Dr. Jason Etchegaray
UT-H - MS - Internal Medicine, General Div

NOTICE OF APPROVAL TO BEGIN RESEARCH

July 31, 2013

HSC-MS-13-0499 - Understanding parents' perceptions of NICU safety culture: Development of the Parent-Centered Safety Culture Tool

Number of Subjects Approved: Target: 325 /Screen: 350

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: 07/30/2013

APPROVAL DATE: 07/31/2013

EXPIRATION DATE: 06/30/2014

CHAIRPERSON: John C. Ribble, MD

Subject to any provisions noted above, you may now begin this research.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT DETERMINATION: Signed Informed Consent Required

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA): Exempt from HIPAA

Waiver for Screening and Recruitment granted:

Information to be accessed/retained: Name, telephone number

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent and HIPAA documents if required, in a manner that ensures subject confidentiality.

Appendix B

Memorial Hermann Health System Approval

Appendix B
Memorial Hermann Health System Approval

September 19, 2013



**MEMORIAL HERMANN HEALTH SYSTEM
APPROVAL FOR
CHILDREN'S MEMORIAL HERMANN**

Thank you for choosing Memorial Hermann as your service provider for this research study.

IRB ID: HSC-MS-13-0499 **PRINCIPAL INVESTIGATOR:** Jason Etchegaray, PhD
STUDY TITLE: Understanding parents' perceptions of NICU safety culture: Development of the Parent-Centered Safety Culture Tool
NUMBER OF SUBJECTS: 325

Approval is hereby granted by Memorial Hermann Health System to initiate this research study at the Children's Memorial Hermann – Texas Medical Center location. This approval is subject to the Principal Investigator's acceptance of the following stipulations:

STUDY-SPECIFIC STIPULATIONS

1. The Principal Investigator will ensure that Research Associate, Aitebureme Aigbe completes Research Credentialing for Memorial Hermann – Texas Medical Center. To begin the credentialing process, please contact Adnan Imam, CIRI Research Associate, at adnan.imam@memorialhermann.org, or by phone at 713-704-5115.
2. All data security computer devices used in this study must be password protected and/or data encrypted.
3. Please remember to acknowledge the Children's Memorial Hermann in any publications resulting from this study, and provide a copy of the publication to the Executive Director of the Memorial Hermann Clinical Innovation & Research Institute (Cheryl.Chanaud@memorialhermann.org). The methods of acknowledgement may include:
 - a. Children's Memorial Hermann as an author's affiliation;
 - b. mention in an "acknowledgement" section; or
 - c. as a footnote.

Please sign and return a copy of this letter to the Memorial Hermann Clinical Innovation & Research Institute, c/o Memorial Hermann Hospital, Mailbox 90, via FAX (713) 704-5124, or scanned .pdf file to Cassandra.Varscilli@memorialhermann.org to indicate your acceptance of our terms and policies (guidelines attached).

This study may not be initiated until the letter is signed and returned to the Memorial Hermann Clinical Innovation & Research Institute.

If you have questions or need additional information, please contact the Memorial Hermann Clinical Innovation & Research Institute at (713) 704-4226.

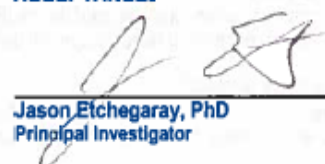
APPROVED:

 9/16/13

Cheryl M. Chanaud, PhD, CCRP
System Executive Director, Research
Memorial Hermann Health System

Date

ACCEPTANCE:

 9/19/13

Jason Etchegaray, PhD
Principal Investigator

Date

cc:

Madelene Ottosen, RN, MSN, CCRS - Study Coordinator
Eric Thomas, MD - Co-Investigator
Karen Brumley, MSN, RN – Administrative Director, Neonatal Services
Amir Khan, MD, Medical Director NICU

Attachments:

Memorial Hermann Clinical Innovation and Research Institute Guidelines

Appendix C

Individual Parent Informed Consent Form

Appendix C
Individual Parent Informed Consent Form



INFORMED CONSENT FORM TO TAKE PART IN RESEARCH
PARENT PERCEPTIONS OF PATIENT SAFETY IN THE NICU
HSC-MS-13-0499

INVITATION TO TAKE PART

You are invited to take part in a research project called, Understanding Parent Perceptions of Patient Safety in the NICU, conducted by Jason Etchegaray, PhD and Madelene Ottosen, MSN, RN, of The University of Texas Health Science Center at Houston (UT Health). For this research project, they will be called the Principal Investigators or PIs.

Your decision to take part is voluntary. You may refuse to take part or choose to stop from taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from Memorial Hermann Hospital-Texas Medical Center or UT Health Physicians.

You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of The University of Texas Health Science Center at Houston as HSC-MS-13-0499.

PURPOSE

The purpose of this research study is to determine what parents can tell us about the safety of care in the neonatal intensive care unit (NICU). We will use the information we learn to better understand what parents experience and observe while in the NICU which could help us improve care. This information will also help us design a survey specifically for parents to share their views about how we can improve care in the NICU.

The study will enroll up to 30 parents who have infants admitted to the NICU at Memorial Hermann Texas Medical Center. The study is supported by funds from The University of Texas Health Science Center at Houston.

PROCEDURES

What to expect as a parent in this study:

- If you decide to take part in the study you will be asked to attend 1 interview appointment. The interview will be done in person in a conference room located near the NICU. The time of the interview will be scheduled at your convenience.
- The interview will discuss your experience of being the parent of a child in the NICU, your thoughts about the things that affect patient safety and how you think parents can help us learn how to improve

Version 1.0/3July2013

1
IRB NUMBER: HSC-MS-13-0499
IRB APPROVAL DATE: 08/08/2013

the care in the NICU. We will have some questions prepared to help guide us through the interview. As parents tell us their thoughts, we might come across an important question which wasn't asked when you were interviewed or need to clarify something you told us. If this happens, we would like your permission to contact you over the phone at a later time.

☐ Yes you may contact me again if needed about this study.

☐ No I prefer that you not contact me again about this study.

- An audio recording of the interview will be made from the information you tell us. Your name or identity will not be associated with the recording. A written copy of the audio recording will be made to help us review and analyze the responses. We will not be used the recoding for any other reason. It will be destroyed at the end of the study.
- We will generate a report of the combined information shared by you and the other parents for the doctors and nurses of the NICU. We will not use any names. If you tell us something which we agree is of a serious nature, we will ask you to share with your doctor or a NICU nurse. If you are not able or are uncomfortable doing so, we will agree to share it with your doctor or the appropriate NICU nurse.

TIME COMMITMENT

The total amount of time you will take part in this research study is about an hour and half.

BENEFITS

You may find sharing your experiences helpful. Your help in the study may benefit future patients.

RISKS AND/OR DISCOMFORTS

Some people may find talking about their experience of being a parent of child in the NICU emotionally stressful. You are free to skip any question or stop the interview at any time.

ALTERNATIVES

As we stated, this study is completely voluntary so you can choose to not to take part in this study.

STUDY WITHDRAWAL

Your decision to take part is voluntary. You may decide to stop taking part in the study at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you or your baby. If you choose to withdraw from the study at any time during the interview, we will stop the recording and will ask you if you want us to erase the recording. We will comply with your wishes.

COSTS, REIMBURSEMENT AND COMPENSATION

If you decide to take part in this research study, you should not incur any additional costs. To ensure this, we will provide you with a \$50 gift card in appreciation for your time in the interview and parking validation to cover your parking costs.

CONFIDENTIALITY

You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special number (code) will be used to identify you in the study and only the investigator will know your name.

To help protect your confidentiality, the audio recording and all study related documents will be de-identified. All study related material will be stored in locked offices. Electronic information will be stored on firewall protected UT servers utilizing passwords and data encryption. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

NEW INFORMATION

Once this study is complete, we will publish the results and will provide you a copy of the article via the mail. If you do not want us to mail you anything, please inform us below,

☐ I prefer that you do not send me anything about this study.

QUESTIONS

If you have questions at any time about this research study, please feel free to contact Madelene Ottosen, MSN, RN at 281-414-8552. She will be glad to answer your questions, discuss any problems, listen to your concerns, and provide you with information about the research. You may also contact Dr. Jason Etchegaray at 713-500-6782.

SIGNATURES

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. You may also call the Committee if you wish to discuss problems, concerns, and

Version 1.0/3July2013



IRB NUMBER: HSC-MS-13-0499
IRB APPROVAL DATE: 08/08/2013

questions; obtain information about the research; and offer input about current or past participation in a research study. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject

Signature of Subject

Date

Time (If applicable)

Printed Name of Person Obtaining Informed Consent

Signature of Person Obtaining Informed Consent

Date

Time (If applicable)

CPHS STATEMENT: This study (HSC-MS-13-0499) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.

Appendix D

Group Informed Consent Form



INFORMED CONSENT FORM TO TAKE PART IN RESEARCH
PARENT PERCEPTIONS OF PATIENT SAFETY IN THE NICU
(GROUP INTERVIEWS)
HSC-MS-13-0499

INVITATION TO TAKE PART

You are invited to take part in a research project called, Understanding Parent Perceptions of Patient Safety in the NICU, conducted by Jason Etchegaray, PhD and Madelene Ottosen, MSN, RN, of The University of Texas Health Science Center at Houston (UT Health). For this research project, they will be called the Principal Investigators or PIs.

Your decision to take part is voluntary. You may refuse to take part or choose to stop from taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from (Memorial Hermann Hospital-Texas Medical Center or UT Health Physicians).

You may refuse to answer any questions asked or written on any forms. This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of The University of Texas Health Science Center at Houston as HSC-MS-13-0499.

PURPOSE

The purpose of this research study is to determine what parents can tell us about the care of their infant in the neonatal intensive care unit (NICU). We will use the information we learn to better understand what parents experience and observe while in the NICU which could help us improve care. This information will also help us design a survey specifically for parents to share their views about how we can improve care in the NICU.

The study will enroll about 30 parents who have infants admitted to the NICU at Memorial Hermann Texas Medical Center. The study is supported by funds from The University of Texas Health Science Center at Houston.

GROUP INTERVIEW PROCEDURES

What to expect as a parent in this study:

- If you decide to take part in the study you will be asked to attend a group interview with a small group of other parents from the NICU. The interview will be done in person in a conference room located near the NICU. The time of the interview will be scheduled at your convenience.
- The interview will discuss experiences of being the parent of a child in the NICU, thoughts parents

Version 1.0/3July2013



IRB NUMBER: HSC-MS-13-0499
IRB APPROVAL DATE: 05/22/2014

have about the things that affect quality and patient safety and how parents want to help us learn how to improve the care in the NICU. We will have some questions prepared to help guide us through the interview. As parents share their thoughts, we might come across an important question which wasn't asked during the interview or we may want to clarify something we heard in the group. If this happens, we would like your permission to contact you over the phone at a later time.

____ Yes you may contact me again if needed about this study.

____ No I prefer that you not contact me again about this study.

- An audio recording of the interview will be made from the information you tell us. Your name or identity will not be associated with the recording. A written copy of the audio recording will be made to help us review and analyze the responses. We will not be used the recording for any other reason. It will be destroyed at the end of the study.
- We will generate a report of the combined information shared by you and the other parents for the doctors and nurses of the NICU. We will not use any names. If you tell us something which we agree is of a serious nature, we will ask you to share with your doctor or a NICU nurse. If you are not able or are uncomfortable doing so, we will agree to share it with your doctor or the appropriate NICU nurse.

TIME COMMITMENT

The total amount of time you will take part in this research study is about an hour and half.

BENEFITS

You may find sharing your experiences helpful. Your help in the study may benefit future patients.

RISKS AND/OR DISCOMFORTS

Some people may find talking about their experience of being a parent of child in the NICU emotionally stressful. You are free to skip any question or stop participating in the interview at any time.

ALTERNATIVES

As we stated, this study is completely voluntary so you can choose to not to take part in this study.

STUDY WITHDRAWAL

Your decision to take part is voluntary. You may decide to stop taking part in the study at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you or your baby. If you choose to withdraw from the study at any time during the interview, we will stop the recording and will ask you if you want us to erase the recording. We will comply with your wishes.

COSTS, REIMBURSEMENT AND COMPENSATION

If you decide to take part in this research study, you should not incur any additional costs. To ensure this, we will provide you with a \$50 gift card in appreciation for your time in the interview and parking validation to cover your parking costs.

CONFIDENTIALITY

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies, and the Committee for the Protection of Human Subjects (CPHS) of The University of Texas Health Science Center (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. To help protect your confidentiality, the audio recording and all study related documents will be de-identified. All study related material will be stored in locked offices. Electronic information will be stored on firewall protected UT servers utilizing passwords and data encryption. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Clinical Trials.Gov Language:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

NEW INFORMATION

Once this study is complete, we will publish the results and will provide you a copy of the article via the mail. If you do not want us to mail you anything, please inform us below,

☐ I prefer that you do not send me anything about this study.

QUESTIONS

If you have questions at any time about this research study, please feel free to contact Madelene Ottosen, MSN, RN at 281-414-8552. She will be glad to answer your questions, discuss any problems, listen to your concerns, and provide you with information about the research. You may also contact Dr. Jason Etchegaray at 713-500-6782.

SIGNATURES

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study. If you have any questions or concerns about your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-7943. You may also call the Committee if you wish to discuss problems, concerns, and questions; obtain information about the research; and offer input about current or past participation in a research study. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject or Legally Authorized Representative

Signature of Subject or Legally Authorized Representative

Date

Printed Name of Person Obtaining Informed Consent

Signature of Person Obtaining Informed Consent

Date

CPHS STATEMENT: This study (HSC-MS-13-0499) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.

Appendix E

INTERVIEW GUIDE (Group or Individual)

Appendix E
INTERVIEW GUIDE (Group or Individual)

Thank you for agreeing to talk with me today. As I mentioned I will be recording this interview.

I will also take notes while we talk so that if I can jot down questions or important points I want to remember.

- Tell me about your experience in the neonatal ICU, how has it been for you?
 - Tell me about what brought your baby to the NICU.
(Include if this information is not addressed after the first question.)
 - *How long has your baby been in the NICU?*
 - *Was your baby delivered here at Memorial Hermann?*
- How would you describe the NICU to your friends and family?
- How have your views of the NICU changed over time? How are they different from when your baby was first admitted?
- What do you know or what have you heard about hospitals making the quality of care better and safer for patients?
- Are there any particular issues with patient safety that you have heard about?
 - Where have you heard it? Or where did find that information?
 - If they haven't heard of anything, mention our purpose is to identify what parents observe and experience which can impact the quality of care in the NICU. Things like the good communication, teamwork among hospital staff and doctors and consistent handwashing are ways we can improve patient care.
- We are interested in understanding what parents know about the quality and safety of the care that babies receive in the NICU. Since you have been here can you tell me what comes to mind when you think about what is done to provide good quality care and promote patient safety for the babies in the NICU.
 - Tell me about a time in the NICU when you felt the care was safe.
 - What did you observe or hear that made it seem safe?
 - Tell me about a time when you felt or heard about something that was unsafe

- What types of things did you observe or hear that made it seem unsafe?
- If you noticed a questionable behavior or incident what do you think you would do or what do you think other parent's might do?
- Tell me what you think would encourage parents to speak up about a questionable incident?
- What would prevent a parent from speaking up about this type of incident?
- Do you know who the persons are that provide care for your baby?
 - Can you name the differing roles of the caregivers/providers that help take care of your baby?
 - Do you have a primary caregiver ie primary nurse or primary doctor responsible for your baby?
- Tell me how the hospital staff talk with you about your baby.
 - How do you think the hospital staff talk with each other in general?
 - How do you think the physicians, nurses and other healthcare providers in the NICU function as team in providing care to your baby?
- Tell me what it is like when you ask questions about your baby.
 - Are your questions answered so that you understand?
 - How do people respond?
 - What are the positive responses like?
 - What are the negative responses like?
 - Who provides you the best information to your questions?
 - Does everyone?
- How involved do feel in the care of your baby?
 - Tell me what your role as a parent is while your baby is in the NICU.
 - What should the role of parents be?

- What makes that difficult?
- What thoughts or ideas to suggest how the quality of care might be better in the NICU: environment, communication among providers, communication between providers and parents?
- What would you want to tell the doctors and nurses about your child's care that would help them take better care of their patients and families in the NICU?
- How should we involve parents in learning how to improve the care of babies in the NICU?
- How would you want to share your concerns about the care your baby has received in the NICU? When would be the best time?

Thank you so much for your time. Do you have any you would like to tell me that I didn't ask you about?

Appendix F

Group Interview Flyer

Appendix F Group Interview Flyer



We want to learn from you!

Consider joining an individual or group interview with other NICU parents, to share what you think we can do better!

We are conducting a research study to learn what you think about being a parent of a baby in the NICU and how the doctors and nurses talk to and involve you in the care of your baby. We all want to work together in caring for your baby and want to learn from parents about how we can do this better. We would like you to consider having a one-on-one interview or joining a group of 2 to 3 other parents in sharing your thoughts about being a parent in the NICU. A couple of group interviews will be conducted by Madelene Ottosen, a nurse doing this study in the Memorial Hermann Children's NICU. The interview is completely voluntary and will be scheduled at a convenient time for the parents who are interested. If you would be willing to participate, please contact her at 713-500-7910 or email her at madelene.j.ottosen@uth.tmc.edu. If you have questions, ask your nurse or feel free to call Madelene.

To thank you for your time, you will be given a Target gift card and validation



Jason Etcheagaray, PhD
Madelene Ottosen, MSN, RN
Study Investigators

Phone: 713-500-7910

Email: Madelene.J.Ottosen@uth.tmc.edu

Jason.Etcheagaray@uth.tmc.edu

Study Title: Understanding parents' perceptions of NICU safety culture: Development of the Parent-Centered Safety Culture Tool
CPHS#: HSC-MS-13-0499

This study is funded through a grant by the Agency for Healthcare Quality and Safety (AHRQ), R03 HS22944-01 and is approved by the UT-Committee for the Protection of Human Subjects (CPHS) and Memorial Hermann Hospital Office of Research.

Appendix G

Demographic Data Collection Form

Appendix G
Demographic Data Collection Form

**Understanding Parents Perceptions of NICU
Safety Culture
Data Collection Form**



HSC-MS-13-0499

Participant Initials: _____ Study ID: _____

Please mark the correct answer to the questions in the white boxes. (Shaded areas for study staff only.)

Visit Number		Initials	Comments
Interview Date ____/____/____	<input type="checkbox"/> Consent Signed and Received		
	1. Interviewee Relationship to Baby <input type="checkbox"/> Mother Interviewee (1) <input type="checkbox"/> Father Interviewee (2) <input type="checkbox"/> Both Mother and Father Interviewee (3) <input type="checkbox"/> Other (4) _____		
	2. Gender <input type="checkbox"/> Female (1) <input type="checkbox"/> Male (2)		
	3. Current Age: _____ years <input type="checkbox"/> < 18 years (unable to interview) <input type="checkbox"/> 18- 30 years <input type="checkbox"/> 31- 45 years <input type="checkbox"/> 46- 64 years <input type="checkbox"/> 65- 75 years		
	4. Race: <input type="checkbox"/> White Non-Hispanic <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Other _____		
	5. Marital Status <input type="checkbox"/> Married (1) <input type="checkbox"/> Single (2)		
	6. Number of viable pregnancies (20 wks +) by mom including this baby Parity of mom: <input type="checkbox"/> _____		
	7. Baby's gestational age upon admission to NICU <input type="checkbox"/> _____ weeks.		
	8. Site of infant's birth <input type="checkbox"/> MH-TMC <input type="checkbox"/> MH-SW <input type="checkbox"/> Other MH facility _____ <input type="checkbox"/> Other facility _____		

**Understanding Parents Perceptions of NICU
Safety Culture
Data Collection Form**



HSC-MS-13-0499

	9. Length of time in the NICU <input type="checkbox"/> _____ days.		
	<input type="checkbox"/> a. NICU POD _____ Length of time _____		
	<input type="checkbox"/> b. NICU POD _____ Length of time _____		
	<input type="checkbox"/> c. NICU POD _____ Length of time _____		
	10. Did you have a primary nurse caring for your baby? <input type="checkbox"/> Yes <input type="checkbox"/> No		
	11. City where parents reside _____		
	12. Approximate times per week you were able to visit your baby in the NICU. <input type="checkbox"/> 1 or less <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 to every day		
	13. Who were other family members that regularly visited your baby at least once a week in the NICU? _____		
	14. Gift card given <input type="checkbox"/> Yes <input type="checkbox"/> No		

Appendix H

Qualitative Codes

Appendix H
Qualitative Codes

AdmissionReason AdmittingNewBaby Advocacy AfraidtoHarm anxiety AttentionToDetail AwareofBaby'sSpecificLikes Baby'sResiliency BarriersinCommunication BeGentle BestNICUImage BirthPlan Calm Challenges ChangeinPerception CheckAudio CheckBaby Cleanliness Comfort Communication ConfidenceinCare Consistency Coping Decision-Making DischargeIssues DoesItTheWayIWouldDolt EndofLife Environment ExtraEffort FamilyResponse FatherExperience FeedbackPreference Feeding FeelingsofMom Focused Frustration Handoffs HardtoLeave highRiskClinic Honesty Improvement IntegratedinProcessofCare Intimate JuicyQuote KeepingBabyAlive KnowledgeBeforeDelivery LaborExperience Learning Loss MakeAConnection MedicalTerms MHissue MomToMom	Monitors Morale NICUExperience NICUPamphlet NightShift NotGettingHopesUp Nurse OtherParents Overwhelming ParentAdvocate ParentAware ParentEducation ParentPreferencesofCaregivers ParentPreferencesofCommunication ParentRole ParentSupport Parking Passion PatientSafety Personal Physician Presence PrimaryNurse Privacy ProvideCare Pumping QuestioningCare Recommendations ResponseRate RonaldMcDonald Rounds SafeCare SafetyEventMentioned Sanitation/InfectionControl Security Siblings Sleep Smiling SourceofInformation SpanishSpeaking SpeakUp StaffBehavior StaffCommunication survey TalktoInfant Teamwork Technology ThisIsMyChild UnsafeIssues UpsAndDowns Visiting WhenImNotHere
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CURRICULUM VITAE
Madelene Jewell Ottosen, MSN, RN

EDUCATION:

University of Texas Health Science Center Houston, TX.	2015	PhD	Nursing
Catholic University of America Washington, DC	1992	MSN	Nursing
University of St. Thomas Houston, TX.	1982	BSN	Nursing

PROFESSIONAL POSITIONS:

Program Manager University of Texas–Memorial Hermann Center for Healthcare Quality and Safety (CHQS) The University of Texas Medical School at Houston Houston, TX.	2012 – present
Associate Director Clinical Trials Resource Center University of Texas Health Science Center at Houston Houston, TX.	2008 – 2012
Nursing Manager, Clinical Research Unit at Memorial Hermann Hospital Center for Clinical and Translational Sciences University of Texas Health Science Center, Houston, TX.	1993 – 2008
Staff Nurse Cardiothoracic Recovery and Intensive Care Georgetown University Hospital, Washington, DC	1990 – 1993
Cardiac Rehabilitation Nurse Veteran's Administration Hospital, Washington, DC.	1992 – 1992
Nursing Manager Postoperative/Cardiovascular Acute Care Unit St. Luke's Episcopal Hospital, Houston, TX.	1988 – 1990
Cardiovascular Liaison Nurse St. Luke's Episcopal Hospital, Houston, TX.	1985 – 1988

Staff Nurse	1982 – 1985
Cardiovascular Recovery/Intensive Care Unit	
St. Luke's Episcopal Hospital,	
Houston, TX.	

PROFESSIONAL MEMBERSHIPS & COMMITTEES:

American Society of Professionals in Patient Safety Member	2015- present
Texas Nurses Association Member	2014 – present
Southern Nursing Research Society Member	2013-present
International Association of Clinical Research Nurses (IACRN) Founding Member	2008 – present
Board member	2008–2012
Chair of Education committee	2008–2010
Research Committee	2012-2014
Society of Clinical Research Professionals (SOCRA) Member	2006 – 2012
Association of Clinical Research Professionals (ACRP) Member	2006 – 2015
Association of Clinical Research Nurses (ACRN) Founding Member	2003 – present
President	2008 – 2009
Education Coordinator	2010 - 2014
National Association of GCRC Nurse Managers Member	1993 – 2006
President	2003 – 2004
Sigma Theta Tau International Member	1992 – Present

UT COMMITTEE APPOINTMENTS:

Committee for the Protection of Human Subjects Member	1995 – 2007, 2012 – present
Co–Chair Committee #3	2005 – 2007
Study Coordinator Advisory Board Member	2006 – 2012
IRB Accreditation Planning Committee Member	2005 – 2006

PUBLICATIONS:

Etchegaray, J, **Ottosen, M**, Burrell, L, Sage, WM, Bell, SK, Gallagher, TH, & Thomas, EJ, (2014) Structuring patient and family involvement in medical error event disclosure and analysis. *Health Affairs*, 33, doi: 10.1377/hlthaff.2013.0831.

Hastings, C, Fisher, C, McCabe, M....**Ottosen, M**, et al, (2012) Clinical research nursing: a critical resource in the national research enterprise, *Nursing Outlook*, 60, 10.1016/j.outlook.2011.10.003

McCoy, A., Wright, A., Laxmisan, A., **Ottosen, M.**, McCoy, J., Batten, D., & Sittig, D. (2012) Development and evaluation of a crowdsourcing methodology for knowledge base construction: identifying relationships between clinical problems and medications, *Journal of American Medical Informatics Association*, 19, doi:10.1136/amiajnl-2012-000852

Houston, S., Luquire, R., & **Jewell, M** (1992) Crafting postop care for sternal wound omentoplexy, *American Journal of Nursing*, 92: doi:10.2307/3426652

LECTURE PRESENTATIONS:

July 2014	Safety Culture: Implications for Practice and Patient–Centered Care, Comparative Effectiveness Course, DNP program, UT School of Nursing, Houston, TX.
June 2014	Partnering with Patients in Event Analysis, Engaging Patients as Partners to Improve Patient Safety Research Dissemination Conference, Marriott Medical Center, Houston, TX.
Jan. 2013	Developing a Professional Poster or Presentation, Monthly meeting Association of Clinical Research Nurses, Houston, TX.
Oct. 2012	Financial Management of Clinical Trials, Pre–Conference Workshop International Association of Clinical Research Nurses Annual Conference, Houston, TX.
Mar. 2011	Assessing Feasibility in Clinical Trials, Financial Management in Research Workshop, UTHSC–Houston Office of Research, Houston, TX.
Jan. 2011	Developing Research Best Practices in Your Department, Center for Clinical and Translational Sciences (CCTS), Houston, TX.
Oct. 2010	Good Clinical Practices Workshop, Neurology Department, UT Medical School, Houston, TX.
May 2009	Quality Management in Clinical Trials, Clinical Research Education: An Introduction to Safe and Ethical Research Practice, UTHSC–Houston Office of Research, Houston, TX. (Oct. 2009, May 2010)

May 2009	Budget Development and Financial Management of Clinical Trials, Clinical Research Education: An Introduction to Safe and Ethical Research Practice, UTHSC–Houston, Houston, TX. (Quarterly sessions 2009 – 2011)
Jan. 2009	Clinical Research Billing Practices, Clinical Research Education: An Introduction to Safe and Ethical Research Practice, UTHSC–Houston, Houston, TX. (Quarterly sessions 2009 – 2011)
Nov. 2008	Practical Applications of Good Clinical Practice Course, CCTS, Houston, TX.
June 13, 2008	Collaborations in Clinical Research. UT School of Nursing DNP program, Houston, TX.
April 25, 2008	Changes in the GCRC through the CTSA award. 2008 ACRP Annual Conference, Boston, MA.
Nov. 28, 2007	Dealing with Difficult People: Anger Management (Yours and Theirs). 2007 Public Responsibility in Medicine and Research (PRIMR) Meeting, Boston, MA.
Nov. 16, 2007	Clinical Research Nursing: An evolving specialty. Clinical Practice Lecture, UTHSC–Houston School of Nursing, Houston, TX.
Sept. 13, 2006	Nursing Care of Research Patients. Nursing Education Program in Clinical Research: A Model for Safe and Ethical Research Practice for Clinicians, UTHSC–Houston, Houston, TX. (May 2007, Oct. 2007, Mar. 2008, Oct. 2008)
Sept. 13, 2006	Roles and Responsibilities of the Research Team. Nursing Education Program in Clinical Research: A Model for Safe and Ethical Research Practice for Clinicians, UTHSC–Houston, Houston, TX. (May 2007, Oct. 2007, Mar. 2008, Oct. 2008)
May 8, 2006	The Evolving Role of Clinical Research Nursing, 2006 Nurses' Week Keynote Address, Rockefeller University, New York, NY
July 21, 2006	Clinical Research: History, Ethics and Case Studies, HEADS UP Teacher Summer Science Institute, UTHSC–H Center for Health Promotion and Prevention Research, Houston, TX.
July 20, 2006	Clinical Research Nursing: An Evolving Specialty, Association of Clinical Research Nurses, VA Medical Center, Houston, TX.
Mar. 16, 2006	Future of Clinical Research Nursing, 2006 National Meeting Association of GCRC Nurse Managers, Washington, DC
Aug. 19, 2005	The General Clinical Research Center, an Aid for Clinical Research. Clinical Research Lecture Series, UT–Houston Medical School.

- July 22, 2005 Nursing Careers in Clinical Research, HEADS UP Teacher Summer Science Institute, UTHSC–H Center for Health Promotion and Prevention Research, Houston, TX.
- Feb. 22, 2005 Conflicts of Interest in Clinical Research, Protocol Development and Research Study Management course, UTHSC– H School of Nursing Graduate Program, Houston, TX.
- Sept. 14, 2004 The General Clinical Research Center, an Aid for Clinical Research; Association of Clinical Research Nurses, Houston, TX.
- Feb. 18, 2004 Roles of the Investigative Team, Protocol Development and Research Study Management course, UTHSC– H School of Nursing Graduate Program, Houston, TX.
- Aug. 13 & 20, 2004 Good Clinical Practice and Clinical Trials, Introduction to Clinical Research Lecture Series, UTHSC–H Medical School, Houston, TX.

POSTER PRESENTATIONS:

Ottosen, MJ, Etchegaray, JM, Aigbe, A, Sedlock, EW, Bell, S, Gallagher, T, & Thomas EJ. *Creating IMPACT: A Patient–Centered Engagement Tool for Hospitals to Improve Post–Event Analysis Communication with Patients and Families*. Poster accepted 2015 Annual Research Meeting Academy Health, Minneapolis, MN, June 2015.

Ottosen, MJ, Etchegaray, JM, & Engebretson, J. *How Parents In Neonatal Intensive Care View Patient Safety*. Poster accepted to Council for the Advancement of Nursing Science, 2015 Special Topics Conference: Emerging Areas of Family Health Research Across the Lifespan, Washington, DC, October 2015.

Etchegaray, J.M., **Ottosen, M.J.**, Aigbe, A., Webster, E., & Thomas, E.J. *Patients' Knowledge about the Factors that Contributed to Their Own Unexpected Events*. Poster presented at 2014 Annual Research Meeting of Academy Health, June 8, 2014, San Diego, CA.

Etchegaray, J.M., **Ottosen, M.J.**, Aigbe, A., Alawadi, Z., Webster, E., & Thomas, E.J. *Understanding Reasons that Clinicians Do Not Speak Up*. Poster presented at 2014 Annual Research Meeting of Academy Health, June 8, 2014, San Diego, CA.

Alawadi, Z, Etchegaray, J, **Ottosen, M**, Aigbe, A, Sedlock, E, Landgren, R & Thomas E. *Why Do Surgeons Fail to Disclose Medical Errors?* Poster presentation at the American College of Surgeons Annual Meeting, San Francisco, CA on October 30, 2014.

Ottosen, M, Etchegaray, J, Danscak, T & Thomas, E. *Barriers to Speaking Up for Patient Safety*, Poster Presentation for International Conference on Communication in Healthcare, Montreal, Canada, October 2013

Hodges, P., Yu, E., **Ottosen, M.**, & Frazier, L. *Behavioral & Immunological Effects of Mindfulness-Based Cognitive Therapy on Heart Failure Patients with Depression: A Feasibility Study*, poster presentation, Southern Research Nursing Society Annual Conference, New Orleans, LA, March 2013.

Thomas, E, Etchegaray, J., Gallagher, T, Sage, W, Bell, S. Burress, L & **Ottosen, M.** *The TX. Disclosure and Compensation Study: Best Practices for Improving Safety*, poster presentation, Building the Bridge Maintaining Quality in the Face of Change, San Antonio, TX September 2012.

Ottosen, M., Etchegaray, J, Burress, L. Ottenbacher, A. and Thomas, E., *Learning from Errors through Patients and Families*, poster presentation, Summer Institute on Evidenced-Based Quality Improvement Conference, San Antonio, TX, July 2012.

GRANT SUPPORT:

Ongoing

1R03HS022944-01, Etchegaray (PI), \$100,000 4/1/14 – present
 AHRQ, R03, Role: Co-Investigator
 Title: Understanding Parent Perceptions of Safety Culture in the NICU
 The goals of this two-phase project are to determine parent perceptions of safety culture in the NICU and to develop a Parent-Centered Safety Culture tool specific to the NICU population.

GRANT SUPPORT

Completed

70763, Grimes (PI), \$194,471 5/1/2013 – 10/31/14
 Robert Wood Johnson, Role: Research Coordinator
 Project Title: State Regulations for Advanced Practice Registered Nurses (APRNs), physician/APRN collaboration, the culture of patient safety and patient outcomes in primary care
 The purpose of this study is to determine the impact of state regulations on APRN/physician teamwork/collaboration and patient outcomes in Federally Qualified Health Centers of the most and least restrictive states in the US.

1 R25 DA033009-01, Bowling (PI), \$2000 10/1/11– 6/1/2013
 Rice University, Role: Clinical Trials Consultant
 National Institute on Drug Abuse Special Emphasis Panel,
 Title: Blueprint for Neuroscience Research Science Education Award (R25)
 Goal: develop a game for use by teachers to educate students, and potentially their families, about the scientific process of discovery, testing, and adoption of new drugs or treatments that emerge from neuroscience research, aligned with high school science curriculum standards.

HS019561, Thomas (PI), \$1.8 million 5/1/11– 6/30/2014
 AHRQ, Texas Disclosure and Compensation Study, Role: Research Nurse
 Goal: Determine how to make disclosure and compensation a process that will not only serve the needs of individual patients, but take more advantage of the patient's experience to help hospitals change their systems and improve safety for subsequent patients.

1 R18 HS019561, Gallagher (PI), \$17,000 5/1/11– 5/12/2012
 Doctors Company, subcontract from University of Washington,
 Role: Research coordinator
 Title: Talking with parents about birth injuries.
 Goal: Determine the general experiences of parents, obstetricians and pediatricians with conversations about adverse birth outcomes and their suggestions for improving communication around adverse birth outcomes.

5UL1RR024148 Davies (PI), \$25 million 9/1/06 – 8/31/2008
 NIH/NCRR, Role: Nurse Manager
 Center for Clinical and Translational Science
 Goal: Transform clinical and translational research by combining epidemiologic, genetic, and functional genomic, proteomic, immunologic, and imaging methodologies with innovative programs for early clinical trials and community based research.

5UL1RR024148, Ottosen (PI), \$1000 5/29/08 – 11/1/2009
 CCTS: Clinical Research Unit, Role: PI
 Title: A pilot study: using standardized patients to improve communication skills used in the informed consent process.
 Goal: Examine the use of standardized patients in training research coordinators/nurses to conduct the research consent process.

Anne R.Wilford Endowment, \$10,000 7/1/07–6/30/2008
 Nursing Education Program in Clinical Research: A Model for Safe and Ethical Research Practice for Clinicians
 Goal: Develop and implement a clinical research practice curriculum for research nurses and bedside clinical nurses to support the safe and ethical care of patients enrolled in clinical trials
 Role: Curriculum Planner/Presenter

MO1 RR02558 Buja (PI), \$1.5 million 3/1/01–8/31/2006
 NIH/NCRR
 General Clinical Research Center
 Overall goal: Provide an environment for the study of normal and abnormal body function, 2) investigate the cause, progression, prevention, control and care of human disease; 3) to furnish an optimal setting for controlled clinical investigations by UTHHSC scientists; 4) to serve as an environment for training health professionals in clinical research
 Role: Nurse Manager

AWARDS AND RECOGNITION

Sigma Theta Tau Induction Catholic University of America	1992
Certified Clinical Research Coordinator Association of Clinical Research Professionals	2008
PhD Award Sigma Theta Tau International Zeta Pi Chapter	2014