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Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35 -37 6/7 Weeks Gestation

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Abstract

Background: The late preterm (35-36 6/7 weeks gestation) and early term (37-37 6/7 weeks gestation) infant exhibits physiologic risk for less than adequate nutritional intake when exclusively breastfeeding. There is little evidence to support the best practice to produce the outcome of sustained breastfeeding in this population.

Purpose: The purpose of this pilot, exploratory, correlational study was to determine the prevalence of sustained breastfeeding in late preterm and early term breastfeeding infants at one and two months of age and to identify the factors that were related to sustained breastfeeding.

Methods: Subjects were identified through purposive sampling, consented to participate, and completed the Breastfeeding Self-Efficacy Scale. Lactation support, supplemental feeding methods used, hospital course and demographic factors were collected. At one and two months of age, telephone structured interviews determined the current feeding status and assessed post discharge lactation support.

Analysis and Results: Descriptive statistical, contingency table methods and bivariate logistic regression analysis were conducted on the sample of 125 mothers. Of those mothers, 82% experienced sustained breastfeeding at 1 month, and 71.2% experienced

sustained breastfeeding at 2 months. A sensitivity analysis was conducted to determine if the noncompleters biased the sample. Significant results still found sustained breastfeeding at 2 months associated with a college complete education (p=0.014), higher Breastfeeding Self-Efficacy scores (p=0.046), and the practice of skin to skin on day 2 or later (p=0.007). High breastfeeding assessment scores on day 1 (Via Christi) were associated with sustained breastfeeding at 2 months (p=0.007) and high day 2 or later breastfeeding assessment scores were associated with sustained breastfeeding at 1 month (p=0.000) and 2 months (p=0.001). Unsustained breastfeeding at 1 and 2 months was associated with the occurrence of supplemental feedings (p=0.001) and pumping at discharge (1 month p=0.002, 2 months p=0.015).

Discussion: Identifying the high sustained breastfeeding rate in this population and the potential factors associated with that outcome, build evidence on what factors should be included in the professional organizations' clinical practice guidelines and protocols, subsequently tested on larger samples in multicenter studies, and therefore lead to impact clinical practice and national public policy regarding the Family Medical Leave Act.

Key Words: Breastfeeding, late preterm infant, early term infant, lactation support, sustained breastfeeding, supplemental feedings, Breastfeeding Self-Efficacy

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Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35 -37 6/7 Weeks Gestation

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Dedication

This dissertation is dedicated to my husband Scott, our children Nicole, Kathleen, Megan, Sam and James, my parents John and Joan Esper, and all of my siblings, in-laws, extended family and friends. Although this research may be my professional legacy, you are my real legacy. I thank you and appreciate all of your love, understanding, support, encouragement, faith, and picking up the pieces by doing more than your share through this daunting process. Without all of you in my life, this truly wouldn't have been possible. I wish you all the belief in yourselves enough to accomplish whatever you choose to do and promise I will be there for you. Thanks for keeping me real and giving me laughs along the way to keep going… I continue to enjoy the ride with you!

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CHAPTER 1: INTRODUCTION

Background

The American Academy of Pediatrics Section on Breastfeeding (AAP), The World Health Organization, LaLeche League International, The International Lactation Consultant Association (ILCA) and The Academy of Breastfeeding Medicine (ABM) all support breastmilk as the optimal source of nutrition for infants for the first year of life and have taken the position that additional nutritional supplementation for the normal healthy infant is unnecessary for the first six months of life (ABM, 2009, Section on Breastfeeding, 2012). The AAP (2012) cites human milk as the normative standard for infant nutrition and considers breastfeeding a public health issue, not only a lifestyle choice. In addition, the AAP recommends "exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant."(Pg. e832) Providing supplemental feedings to the breastfeeding infant in the hospital is contrary to this recommendation unless in situations where there is documented weight loss or other medical conditions that warrant supplementation.

Research has demonstrated that 24% of maternity services, regardless of the gestational age of the infant, provide supplements of commercial infant formula in addition to breastfeeding as general practice in the first 48 hours after birth (Eidelman, 2012.) The disparity between current practice and optimal evidence-based recommendations led the AAP to endorse the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) "Ten Steps to Successful Breastfeeding", which are the basis for achieving a "Baby Friendly Hospital" designation. In addition, the US Surgeon General's Call to Action, the Centers for Disease

Control and Prevention, and The Joint Commission are involved in promoting breastfeeding practices in United States hospitals and communities. Lastly, the AAP advocates that employers should implement workplace policies that support working mothers toward maintaining lactation. The 2012 AAP Policy Statement on "Breastfeeding and Use of Human Milk" also cites the evidence-based health benefits to the infant and mother. These benefits were compiled by the Agency for Healthcare Research and Quality (AHRQ) of the United States Department of Health Human Services.

Ip, et al., (2007) reviewed over 43 primary studies of infant health outcomes and maternal health outcomes, and 29 systematic reviews or meta-analysis, which included 400 individual studies. Their summary on the benefits of breastfeeding promotion and the health of term infants is as follows:

> We found that a history of breastfeeding was associated with a reduction in the risk of acute otitis media, non-specific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma (young children), obesity, type 1 and 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis in infants. There was no relationship between breastfeeding in term infants and cognitive performance. The relationship between breastfeeding and cardiovascular diseases was unclear. Similarly, it was also unclear concerning the relationship between breastfeeding and infant mortality in developed countries. For maternal outcomes, a history of lactation was associated with a reduced risk of type 2 diabetes, breast, and ovarian cancer. Early cessation of breastfeeding or not breastfeeding was associated with an increased risk of maternal postpartum depression. There was no relationship between a history of lactation and the risk of osteoporosis. The effect of breastfeeding in mothers on return-to-pre-pregnancy weight was negligible, and the effect of breastfeeding on postpartum weight loss was unclear (Ip, et al., 2007).

In addition, Dr. Dennis (1999) identified that the level of self confidence in mothers who are breastfeeding their infants impacts whether breastfeeding is sustained or not. This began the researcher's development of the Breastfeeding Self-Efficacy Theory and associated tools. The use of the Breastfeeding Self-Efficacy Scale to anticipate breastfeeding success has been

repeatedly supported in research on multiple cultures with term infants (ABM, 2011, Dennis, 2003).

As an extension of the term infant breastfeeding protocol, the Academy of Breastfeeding Medicine also proposed an evidence-based protocol for breastfeeding the late preterm infant. The late preterm infant, formerly called the near term infant, is defined as infants born between 34- 36 6/7 weeks gestation. This definition evolved in 2005 from a panel of experts assembled by the National Institute of Child Health and Human Development. This term was determined to be a more accurate reflection of the vulnerability of this population and has been endorsed by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the World Health Organization (WHO), and the March of Dimes (MOD), (ABM, 2011). In addition, the Academy of Breastfeeding Medicine (2011) stated that infants born in their 37th week gestation (early term infants) are also likely to be at risk for breastfeeding problems, and therefore, could potentially benefit from similar lactation support interventions as well.

Simultaneously, in Feb 2011, The National Institute of Child Health and Human Development and the Society for Maternal-fetal Medicine met to synthesize the available information on the late preterm and early term births (Spong & Mercer, 2011). The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) have developed clinical practice guidelines that address the need for lactation practices to support breastfeeding in this population specifically (AWHONN, 2010). Similar recommendations for early breastfeeding after birth, skin to skin exposure, promoting rooming in and exclusive breastfeeding are made. Safeguards for health are established through monitoring vital signs, weight change, stool and

urine output and milk transfer. Paramount to the success of breastfeeding is the availability of lactation support for the mother and thorough evaluation of the feeding process. According to the literature, successful interventions identified may include the use of nipple shields, pre and post-feeding infant weights after lactogenesis II has occurred, and provision of supplemental feedings if medically indicated. Lactogenesis I begins during pregnancy when the mammary gland becomes sufficiently capable of secreting small quantities of colostrum. Secretion is then held in check until high circulating levels of progesterone and estrogen fall. Lactogenesis II occurs a few days after birth, when the small volume of colostrum changes over to larger volumes of mature milk (Neville, et al., 2001). If supplemental feedings are needed, the mother is encouraged to protect lactogenesis by pumping in addition to breastfeeding, maintaining the breast stimulation in the absence of exclusive breastfeeding. Ideally, the supplementation should be expressed breastmilk, but hydrolyzed formula is used if breastmilk is unavailable (ABM, 2009). The research on methods by which the supplementation is given is limited. Cup feedings have been demonstrated to be safe in the preterm infant (Dowling, et al., 2002, Marinelli, et al., 2001) but there is little evidence to support the efficacy of using cup and other alternative feeding methods such as finger feedings, syringe feedings, bottle and spoon feedings despite several being in practice with this population (ABM, 2011).

Significance

Breastfeeding the term healthy infant is challenging for women in the first few weeks postpartum. In addition to recovering from the birth process and/or caesarean surgery, she is adjusting to a broken sleep pattern and transition to a new role of parent. The provision of breastmilk as the sole source of nutrition creates a significant feeling of responsibility on the new

mother, as she is responsible for the infant's growth and development. Low Breastfeeding Self-Efficacy scores impact breastfeeding success negatively (Dennis, 1999). The late preterm infant has vulnerabilities related to thermoregulation, glycemic control, stamina, suck and swallow pattern, respiratory stability and low birth weight (ABM, 2011). Therefore, the need to support mothers of late preterm infants is more profound. This additional support is achieved primarily with the nursing staff working on postpartum units in the hospital, the providers and staff in the pediatric practices, and members of the lactation team.

The U.S Department of Health (USDH) has identified through the Healthy People 2020 initiative, several objectives and goals that should be addressed for health promotion and best practice. Specifically, there are several objectives related to breastfeeding and the preterm, and even more specifically, the late preterm and early term infant. In 2007, 8.2% of infants born were low birth weight, infants born weighing less than 2500 grams (5 pounds 8 oz.) (www.HealthyPeople.gov/2020). The goal is to decrease the incidence to 7.8% by 2020. The USDH defines late preterm births as 34-36 and 6/7weeks gestation and identified a rate of 9% with a goal of decreasing it to 8.1%.

The USDH reports the breastfeeding rates for all infants and set goals for improving the proportion of infants who breastfeed, either exclusively or partially, from 74% to 81.9% by 2020. The need to increase sustained breastfeeding is evident as 43.5% of infants breastfeed 6 months and the goal is to increase that rate to 60.6%. Similarly only 22.6 % of infants breastfeed for one year and there is a goal of increasing that population to 34.1% by 2020. The initiative addresses exclusivity of breastfeeding by identifying 33.6% exclusively breastfeed at 3 months and the goal is to increase that to 46.2% at 3 months and at 6 months, exclusive breastfeeding at 14.1%

should be increased to 25.5%. In addition, they cite lactation support availability in the workplace should be increased from 25% to 38% and the aim to decrease formula supplementation in the first two days of life from 24.2% to 14.2%. What is most alarming is that only 2.9% of infants are born in facilities that provide recommended care regarding lactation. The goal is to increase the number of facilities that provide recommended lactation care to 8.1% (www.HealthyPeople.gov/2020). Given that late preterm infants are vulnerable to inability to sustain breastfeeding, and no statistics exist on the breastfeeding rates in this population specifically, it would be beneficial to determine the rate of sustained breastfeeding and identifying factors which can improve these rates for breastfeeding infants born between 35-37 6/7 weeks gestation.

Purpose

The purpose of this pilot study was to determine the prevalence of sustained breastfeeding in the late preterm and early term infant at one and two months of age. In addition, potential key predictors contributing to sustained breastfeeding in the late preterm and early term infant were examined. Specifically, variables of interest for this pilot study were breastfeeding self-efficacy, in-hospital lactation consultations, use of supplemental feeding methods, maternal and infant demographic data and hospital course, characteristics of the birth process, in-hospital feeding practices, and post discharge lactation support. If it is determined that certain supplemental feeding methods and interventions are related to sustained breastfeeding in the late preterm and early term infant, safety and efficacy interventional studies could subsequently be conducted to truly determine the best evidence-based protocol. In addition, if the Breastfeeding

Self-Efficacy of the mother predicts success, then efforts to promote such screening would be further supported.

Theoretical Framework

Breastfeeding Self-Efficacy has been well documented in the literature as predictive of sustained breastfeeding in term healthy infants. Dennis (1999), developed the Breastfeeding Self-Efficacy Scale based on Bandura's Theory of Self-efficacy as a method to measure and explain this phenomena. Research has supported the validity and reliability of the Breastfeeding Self-Efficacy Scale, which has been translated into several languages and tested in varied cultures and populations, including adolescents (Dennis, 2003). No studies using this tool on mothers of infants born between 35-37 6/7 weeks gestation have been published to date. Lactation consultants in clinical practice commonly find that mothers who approach the situation with confidence and obtain competence through lactation education and support have a better outcome than those that struggle obtaining confidence and competence. Therefore, using the Breastfeeding Self-Efficacy Theory as a theoretical framework for studying the factors associated with sustained breastfeeding in the mothers of infants born between 35-37 6/7 weeks gestation is a natural fit. Dennis' (1999) assumption of identifying the phenomena of low breastfeeding confidence and how it relates to breastfeeding failure led her to develop the Breastfeeding Self-Efficacy Theory as a way to explain this; her theoretical research is an extension of Bandura's, (1977) Self-efficacy theory into the practical application to breastfeeding.

Congruent with the Self-efficacy Theory, the Breastfeeding Self-Efficacy Theory identifies four sources of information that individuals use to perform and maintain a behavior:

Performance accomplishments, vicarious experiences, verbal persuasion, and inferences made from one's physiologic and or affective state (Dennis, 1999). These four concepts within the theory are clearly defined. Performance accomplishments include whether they have had success in breastfeeding or portions of breastfeeding in the past. The ways in which a mother perceives her performance impacts this component and therefore affects her Breastfeeding Self-Efficacy perception positively or negatively. For example, if a mother can get her baby latched onto the breast well and positioned well, she feels more confident about the entire breastfeeding process. Vicarious experience includes what observational experiences the mother has had. These included watching others breastfeed, have friends or family that have successfully breastfed or whether breastfeeding is commonplace in the culture. Verbal persuasion is provided to mothers by lactation consultant or health care professional appraisals of the breastfeeding. In addition, friends and family's thoughts impact how the mother views whether breastfeeding is going well or positively regarded. Physiological and affective states impact the mothers' belief about her abilities. Anxiety, stress and pain inhibit oxytocin release, which inhibits the milk ejection reflex, otherwise known as the "let down" and can also negatively impact lactogenesis.

Dennis (1999), identifies that these four sources of information are antecedents in the breastfeeding process that lead to the mother's Breastfeeding Self-Efficacy in her ability to continue breastfeeding her infant. The outcome of the maternal self-efficacy in the breastfeeding experience includes four individual responses: choice of behavior, effort and persistence, thought patterns, and emotional reaction. Choosing to breastfeed is related to the mother wanting to do the task she feels good about. If it is painful or she is not comfortable breastfeeding, she won't want to do it and thus impacts self-efficacy, and ultimately, milk supply and the breastfeeding process. How much effort the mother is willing to put into the breastfeeding process is indeed

predictive of whether she will persevere through the first few weeks and then be successful. Often when having difficulty, it requires persistence to overcome those challenges. The mother who visualizes failure and self-defeat is likely to have low Breastfeeding Self-Efficacy and is associated with breastfeeding failure. The concept of "emotional reactions" encompasses the doubt, anxiety, and emotional lability that often accompany the transition to motherhood. The end result of the theory describes breastfeeding behavior that exhibits whether the mother decides to initiate breastfeeding, how she performs during breastfeeding, whether she continues breastfeeding and ultimately for how long. The theoretical framework is depicted in Figure 1 below. (Dennis, 1999)

Figure 1: Breastfeeding Self-Efficacy Framework

	Social Learning Theory impact here		
Antecedents=>	**Self-efficacy=>**	**Consequences=>**	**Behavior**
Sources of information	**Confidence**	**Individual response:**	**Activity:**
Performance accomplishment Vicarious Experience Verbal Persuasion Physiological and affective states		Choice of behavior Effort and persistence Thought patterns Emotional reactions	Initiation Performance Maintenance

Dennis, 1999 (reprinted with permission, Appendix A-6)

As evidence of the functional adequacy of the theory, the Breastfeeding Self-Efficacy Scale (BSES) was developed to help healthcare professional staff measure maternal breastfeeding self-efficacy. Further, the BSES was then abbreviated to a short form (BSES-SF) and was established as a reliable tool for measuring Breastfeeding Self-Efficacy in a study of 491

women who were breastfeeding. Item redundancy and construct validity was supported by statistically significant results (p=0.001) and led to the deletion of some variables yielding the short form (Dennis, 2003). The self-report instrument assessed Breastfeeding Self-Efficacy expectancies in new mothers, identified mothers that need support and continued assessment, and those who appeared at increased risk for failure, thus showing predictive potential (Dennis, 2006). The theory has been tested with a randomized controlled study with 150 primiparous mothers, using a self-efficacy intervention to promote Breastfeeding Self-Efficacy and sustained breastfeeding at 4 and 8 weeks postpartum. Although the differences weren't statistically significant, the mothers found the intervention to be beneficial and the intervention group had higher rates of Breastfeeding Self-Efficacy, duration, and exclusivity (McQueen, et al. 2011). Further studies are discussed in Chapter 2.

The Breastfeeding Self-Efficacy Theory has shown to be direct theoretically based research that has real life application in multiple populations and cultures. It has been a logical progression from the need to find a theoretical foundation for the evidence that was being discovered. As noted, further research has tested this theory and affirmed its application in the promotion of breastfeeding and in determining factors that can build Breastfeeding Self-Efficacy and contribute to sustained breastfeeding.

In summary, the Breastfeeding Self-Efficacy Theory is pertinent to the nursing field, for work with breastfeeding dyads and childbearing families, both prenatally and postpartum. The prenatal education and care appointments are prime opportunities to optimize their self-efficacy regarding breastfeeding and other parenting abilities. Education to promote the best choice for feeding will help them make the most informed decision. Once mothers decide to breastfeed,

then the task becomes improving their Breastfeeding Self-Efficacy during pregnancy and the short hospitalization to promote sustained breastfeeding for longer periods of time, thus promoting the health of individual children and potentially, for the future of the population. Efforts made to promote the mother's Breastfeeding Self-Efficacy can greatly impact her transition to new parenthood.

Study Questions

Given the above gaps in research regarding breastfeeding and the late preterm and early term infant, alternative methods of feeds, and Breastfeeding Self-Efficacy in mothers of breastfeeding infants born between 35-37 6/7 weeks gestation, the research questions for this pilot study were:

1. What proportions of breastfeeding infants born between 35-37 6/7 weeks gestation experience sustained breastfeeding at 1 and 2 months of age?
2. Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the following variables:
    a. Pre-discharge maternal breastfeeding self-efficacy?
    b. Use of supplemental feeding methods?
    c. In-hospital lactation consultations?
    d. Late preterm vs early term status?
    e. Maternal and infant demographic data and hospital course?
    f. Characteristics of birth process?
    g. In-hospital feeding practices?

differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

3. Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of post-discharge lactation support differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

Definitions of Key Terms

Late Preterm Early Term Infant:

Conceptual definition: Late Preterm: infants born between 34 and 36 6/7 weeks gestation, (Engle, 2006). Early Term: infants are born between 37 and 37 6/7 weeks gestation. (Spong, 2011).

Operational definition: For the purpose of this study, mothers of breastfeeding infants born between 35 and 37 6/7 weeks gestation were recruited as potential subjects and referred to as "late preterm and early term" infants. Infants born prior to 35 weeks are not admitted to the 'well newborn nursery" at the study site and therefore were not available for recruitment.

Sustained Breastfeeding

Conceptual definition: Breastfeeding is defined by the WHO as receiving breastmilk either directly from the breast or expressed breastmilk. Labbok & Starling (2012) identified the need for consistent use of terminology in research for comparison purposes. Representatives from major international breastfeeding organizations suggest that partial breastfeeding be separated into High, Medium, Low and Token categories (Labbok & Starling, 2012).

Operational definition: For the purpose of this study, sustained breastfeeding was determined at 1 and 2 months of age using the structured interview method by asking if the mother was still providing breastmilk to her infant. Further questions yielded whether she was actually feeding the infant at the breast or providing expressed breastmilk. Since one aim of the study was to determine if the use of alternative feeding methods impacts whether the infant continues feeding at the breast or not; sustained breastfeeding, in this study, was identified as actual feeding at the breast. The percentage of feeding (actual feeding at the breast) was separated into high, medium, low and token categories (Labbok, 2012). (See "supplemental feeding" definition for further explanation if expressed breastmilk is being provided to the infant). This data will be analyzed in future secondary analysis.

Supplementary Feeding

Conceptual definition: Feedings provided in place of or in addition to breastfeeding. This may include expressed or banked breastmilk and/or breastmilk substitutes/formula. Any foods given prior to 6 months, the recommended duration of exclusive breastfeeding, are thus defined as supplementary (ABM, 2009).

Operational definition: For the purpose of this pilot study, supplementary feedings was measured by any additional breastmilk, formula or water given during the study period in addition to actual breastfeeding. To identify the level of expressed breastmilk provision to infants, Labbok's definitions were used as high, medium, low and token categories (Labbok, 2012). The method by which the supplementary feeding was provided could be categorized as Supplemental Nursing System (SNS) at breast, syringe, SNS via finger feed, cup, bottle, or other and was recorded as part of routine data collection.

Self-Efficacy:

Conceptual definition: cognitive process of individuals' confidence in their perceived ability to regulate their motivation, thought processes, emotional states, and social environment involved in performing a specific behavior. (Dennis, 1999)

Sources of information leading to Breastfeeding Self-Efficacy Theory

- Performance accomplishments- past personal experience with breastfeeding
- Vicarious experiences- watching others
- Verbal persuasion- encouragement from various sources
- Physiological responses- stress, fatigue, etc. (Dennis, 1999)

Operational definition: for the purpose of this pilot study, the level of self-efficacy a woman feels regarding her breastfeeding ability with her infant was measured by self reported scores on the BSES-SF.

Lactation support:

Conceptual definition: According to the International Lactation Consultant Association, (ILCA.org, 2013), "an International Board Certified Lactation Consultant (IBCLC) is a health care professional who specializes in the clinical management of breastfeeding." The Baby Friendly designation requires the provision of specialized lactation support services be available to patients (Saadeh & Akre, 1996.) In addition, Meerwood, et al. (2006), identified positive

benefits of lactation support that was provided by peer counselors, so that method of support was tabulated if applicable.

Operational definition: for the purpose of this pilot study, lactation support in the hospital was determined by the number of documented lactation consults with the mother and baby, prior to discharge. Specific interventions that are included in lactation management were tabulated on the data collection tool prior to discharge. Lactation support after discharge included attendance at breastfeeding support group, private consultation with lactation consultant or peer counselor, or support provided via the infant's health care provider.

Maternal and Infant Demographic data and hospital course:

Conceptual definition: According to the Academy of Breastfeeding Medicine, certain factors such as the infant's gestational age, weight, and medical course or complication in addition to the mother's educational preparation, age and previous breastfeeding experience can impact the feeding status of breastfeeding late preterm infants (ABM, 2011).

Operational definition: For the purpose of this pilot study, the maternal demographic data that was collected from the medical record included: maternal age, education, race, mother's feeding choice on admission (breastfeeding, formula feeding, or both), and birth of a previous late preterm infant. The infant's demographic that was collected include: sex, singleton status, gestational age, birth weight, classification: appropriate for gestational age (AGA), small for gestational age (SGA), or large for gestational age (LGA), whether the infant required phototherapy in the hospital, if the infant experienced hypoglycemia, and the infant's discharge percentage of weight loss compared to birthweight. Additionally, after consent was obtained,

mothers were asked her height in order to calculate her BMI, what their intended duration of breastfeeding was and whether she had previous breastfeeding experience, items that are marked with an * on Appendix B-2.

Characteristics of the Birth Process:

Conceptual definition: The Ten Steps to Successful Breastfeeding from the World Health Organization cite childbearing healthcare practices that could impact breastfeeding include cesarean delivery and fetal exposure to medications during labor (Saadeh, 1996).

Operational definition: For the purpose of this pilot study, characteristics of the birth process included: method of delivery (vaginal vs caesarean), use of an epidural during labor process, and administration of magnesium sulfate prior to delivery.

In-Hospital Feeding Practices:

Conceptual definition: The AAP section on breastfeeding cites that in-hospital practices should support breastfeeding. Some of the practices cited include skin to skin contact, early breastfeeding experience within one hour after birth, limited separation of mother and infant, and providing education and support to mother-infant dyads during feedings (Section on Breastfeeding, 2012).

Operational definition: For the purpose of this pilot study, in-hospital feeding practices included: occurrence of initial breastfeeding related to time of birth, practice of skin to skin contact, breastfeeding assessment score on the Via Christi scale (appendix C-4), limited separation of mother and infant, and use of a pacifier, breastpump, nipple shield, and/or hand expression. Since documentation on the following practices was variable, after consent obtained,

the mother was asked if she practiced skin to skin contact, if her infant was using a pacifier, if she has family or friends who had breastfed, items that are marked with an * on Appendix B-2.

Summary

New mothers transitioning to the parenthood role while recovering from the childbirth experience are in an incredibly vulnerable state. They have physical, emotional and educational needs. Prenatal education and preparation for bringing a baby home and feeling confident with the ability to meet the infant's needs are imperative to assist in this process. After delivery, mothers learn about and practice providing infant care while recovering from a vaginal or caesarean delivery. This process takes place in the immediate post-delivery period and is complicated by pain, an interrupted sleep pattern, and emotional lability from hormone adjustment. The social support system for a new mother usually involves several visitors, which impacts the amount of time the mother can rest. The hospitalization usually lasts from 2-4 days. In that amount of time, newborns transition to extrauterine life and new mothers are transitioning from lactogenesis I to II, the first step in development of an adequate breastmilk supply (Neville, et al. 2001). The late preterm and early term infant face additional challenges that put them at risk for breastfeeding failure in that time such as weak feeding pattern, hypoglycemia, and increased risk of hyperbilirubinemia (ABM, 2011).

The self-efficacy the mother has regarding breastfeeding has been associated with breastfeeding success or failure. The Breastfeeding Self-Efficacy Theory provides an excellent theoretical framework for this proposal. The promotion of breastfeeding is paramount to assuring the best health outcome for the newborn and mother. Although there is a growing movement on behalf of the March of Dimes to decrease elective births prior to 39 weeks, late

preterm and early term births continue to occur (Ashton, 2010). If supplemental feedings are medically indicated, the body of evidence-based knowledge that determines what method is best to use is limited. Several practices are in place with limited research on safety and efficacy.

Due to the lack of evidence on long term sustained breastfeeding rates in infants born between 35-37 6/7 weeks gestation and the vulnerability that has been identified in this population (ABM, 2011), the results from this pilot study will add valuable information for practical use with breastfeeding promotion in this population. In particular, determining whether an association occurs between methods of supplemental feedings, the use of lactation support in the hospital and post discharge, and the mother's Breastfeeding Self-Efficacy Score to sustained breastfeeding at 1 and 2 months of age will help develop more evidence-based practice guidelines for nursing and lactation staff to use with infants born between 35-37 6/7 weeks gestation. Identifying demographic descriptors that may be predictive of sustained breastfeeding in this population will also guide identification of key lactation practices that can be further evaluated in interventional studies in the future.

CHAPTER 2: REVIEW OF THE LITERATURE

Introduction

The pre-term infant is vulnerable due to immaturity and decreased stamina for feeding well enough without assistance in order to establish their mother's milk supply. Mothers of full term infants need support to continue breastfeeding, and thus, pre-term infants are more at risk without additional support. Exploration of the factors associated with sustained breastfeeding for the late preterm and early term infant will help identify areas for future studies to truly determine best practices.

The research that has been conducted on the Breastfeeding Self-Efficacy Theory is presented as a foundation for this pilot study. Exploring the current state of the science related to breastfeeding the late preterm and early term infant includes understanding their particular vulnerabilities as a population, which often places them at risk for needing supplemental feedings. The research on the late preterm and early term infant's physiology and feeding requirements, and methods by which those supplemental feedings are given is presented. In addition, the literature surrounding lactation support and breastfeeding success at one and 3 months post-discharge for the late preterm and early term infant was presented.

In general, there is a paucity of research that examines long term sustained breastfeeding in the late preterm and early term infant as a population. Practice has typically been extrapolated from evidence on term infants and applied to infants born between 35-37 6/7 weeks gestation. Likewise, practice has also been extrapolated from evidence on breastfeeding and preterm infants and applied to the late preterm and early term infant population. Therefore, presenting the state of the science on these factors in the preterm and term populations in addition to the late

preterm and early term populations, while using Breastfeeding Self-Efficacy as a theoretical framework, gives a foundation for this pilot study and serves as a potential guide for practice.

The search for relevant literature was conducted using the search engines, Pub Med and CINAHL, searching relevant terms: breastfeeding, late preterm and early term infant, and supplemental feedings, feeding methods, alternative methods for supplemental feedings, lactation support, lactation outcomes, successful breastfeeding, sustained breastfeeding, and Breastfeeding Self-Efficacy. In addition, department of public health documents and websites such as the U.S. Department of Health and Human Services (Healthy People 2020), the American Academy of Pediatrics, and the Academy of Breastfeeding Medicine were searched for relevant epidemiology statistics and protocols. From the studies found, primary references were further identified and collected for review. The analysis of the relevant primary research articles collected follows and is presented under content area topics. Limits were utilized for publications in English, and years of publication 1999-2012, focusing on the more recent research, but including landmark publications in the earlier years.

Discussion of the literature surrounding Breastfeeding Self-Efficacy Theory is presented first, followed by an in depth analysis of the current State of the Science of the empirical literature base focusing on susceptibility of infants born between 35-37 6/7 weeks gestation, breastfeeding of infants born between 35-37 6/7 weeks gestation, methods for providing supplemental feedings, and lactation support. A summary is presented at the conclusion of the chapter.

Review of Theoretical Framework

Breastfeeding Self-Efficacy

To support the use of the theoretical foundation for this pilot study, Breastfeeding Self-Efficacy has been well documented in the literature to be predictive of continued breastfeeding. Dr. Cindy Lee Dennis (1999) developed the Breastfeeding Self- Efficacy Theory as a method to explain this phenomenon. Research has supported the validity and reliability of the Breastfeeding Self-Efficacy Scale (BSES), which has been translated into several languages and tested in varied cultures and populations, including adolescents (Dennis, 2003). No use of the BSES with mother's of infants born between 35-37 6/7 weeks gestation has been published to date.

Since the 1970's, the evidence base demonstrating the benefits of feeding human milk has grown. Subsequently, national programs and policy statements to promote breastfeeding and increase national breastfeeding initiation rates has grown. By the late 1990's, Canadian initiation of breastfeeding rates increased from 24% in the 1960's to as high as 80%. This statistic spearheaded Dennis' need to provide a theoretical basis for the research geared toward increasing breastfeeding rates (Dennis, 1999). According to Dennis, a relationship between high maternal Breastfeeding Self-Efficacy had been demonstrated in the literature as contributing toward positive breastfeeding outcomes (Dennis, 1999).

Successful breastfeeding in the term healthy infant as discussed in chapter 1 illustrates the challenge women face in the first few weeks postpartum as they transition to their new role as mother. The mother's ability to breastfeed her infant and provide adequate nutrition to her

infant leads to a significant sense of responsibility and if unsuccessful yields a sense of failure. Although Dennis, (1999), identifies that low Breastfeeding Self-Efficacy levels negatively impact breastfeeding success, research on Breastfeeding Self-Efficacy in mothers of infants born between 35-37 6/7 weeks gestation has not been conducted. Lactation consultants, peer counselors and health care providers and nursing staff provide lactation support during the mother's hospitalization after birth. In addition, prenatal breastfeeding education and post-discharge support by their health care providers are typical sources of support for mothers.

The Breastfeeding Self-Efficacy Theory is focused within the discipline of nursing as the primary source of education and support for breastfeeding as provided by nurses and lactation staff employed in the hospital. The underlying assumption that providing a theoretical foundation for the phenomenon of low maternal confidence as being directly related to breastfeeding outcomes is congruent with Dennis' purpose of developing a theory that could describe this relationship. In addition, the research provides a foundation for Dennis to make this theoretical extension from Bandura's Self-efficacy theory into the practical application with breastfeeding (Bandura, 1977).

Congruent with the Self-efficacy Theory as discussed in chapter 1, the Breastfeeding Self-Efficacy Theory identifies four sources of information that individuals use to perform and maintain a behavior: Performance accomplishments, vicarious experiences, verbal persuasion, and inferences made from one's physiologic and or affective state (Dennis, 1999). As evidence of the functional adequacy applicability of the theory, the Breastfeeding Self-Efficacy Scale (BSES) was developed to help healthcare professionals measure maternal Breastfeeding Self-Efficacy. Further, the BSES was then abbreviated to a short form (BSES-SF) and was established as a reliable tool of Breastfeeding Self-Efficacy in a study of 491 women who were

breastfeeding infants (Dennis, 2003). Item redundancy statistically supported the deletion of some variables yielding the short form that had construct validity and showed significant results at the p=0.001 level (Dennis, 2003).

The self-report instrument assessed Breastfeeding Self-Efficacy expectancies in new mothers, identified mothers who needed support and continued assessment, and those who appeared at increased risk for failure, thus showing predictive potential (Dennis, 2006). The Breastfeeding Self-Efficacy Theory has been tested with a randomized controlled study with 150 primiparous mothers, using a self-efficacy intervention to promote Breastfeeding Self-Efficacy and sustained breastfeeding at 4 and 8 weeks postpartum. Subjects in the intervention group received a self- efficacy intervention and those in the control group did not. Although the differences were not statistically significant, the subjects in the intervention group reported that they found the intervention to be beneficial. Additionally, the intervention group had higher rates of Breastfeeding Self-Efficacy, duration, and exclusivity (McQueen, et al. 2011).

Research supports that when lactation and health care professionals intervene to address the areas that are identified to be lacking efficacy, there is improved sustained breastfeeding with improved Breastfeeding Self-Efficacy Scores (Dennis, 1999) (Blyth, et.al. 2002). For example, if the mother does not has women to serve as role models for successful breastfeeding in her family or friends circle, she could be encouraged to attend prenatal education classes and childcare education classes with other expectant mothers. Kingston, et al. (2007), found preliminary support for women who observed breastfeeding role models through videotapes or received praise from their partners or own mothers showed significantly higher levels of Breastfeeding Self-Efficacy than mothers who did not. In addition, the BFSE-SF has been tested for reliability with the adolescent population of mothers age 15-19 years (Dennis, et al. 2010)

and has been translated with effective reliability in several languages including Turkish (Alus Tokat, et al. 2010), Chinese (Dai & Dennis (2003), Spanish (Torres, et al. 2003), and Polish (Wutke & Dennis, 2007). Translation of the Breastfeeding Self-Efficacy Short Form into all these languages was determined to retain reliability through the translations.

The evidence supporting use of the Breastfeeding Self-Efficacy Theory has been cited by the Academy of Breastfeeding Medicine (2011), as rationale for their best practice protocol for breastfeeding the late preterm and early term infant. However, use of this concept is extrapolated from the term population evidence, not evidence with the late preterm and early term population. Thus, research with this tool in the late preterm and early term population was both valuable and applicable to build the evidence available for breastfeeding the late preterm and early term infant

Review of the Empiric Literature

The evidence on breastfeeding outcomes and lactation support and their relevance to the late preterm and early term population was explored. Identifying the physiologic vulnerabilities of the late preterm and early term infant and discussing the research regarding breastfeeding in this population was presented. There is a growing volume of evidence related to a phenomenon called “nipple confusion” which addresses whether breastfed infants should be exposed to other delivery methods of feeding or if that impacts breastfeeding duration. Therefore, the available research on methods of providing supplemental feeding whether medically indicated or not, is presented in the pages that follow.

Breastfeeding Outcomes

Since Breastfeeding Self-Efficacy is a factor associated with sustained breastfeeding, it is

appropriate to discuss the research relevant to this concept. Mulder, (2006) discussed the concept of effective breastfeeding in a theoretical analysis. In it, the investigator identified the four characteristics needed for effective breastfeeding: Positioning, latch, sucking and milk transfer. As this was a conceptual analysis, part of theoretical research, there was no measurement or testing of this theory.

Riordan & Koehn, (1997) examined the LATCH, IBFAT and MBA breastfeeding assessment tools in relation to sustaining lactation. They were not recommended in clinical practice due to variable inter rater reliability and were unable to predict sustained lactation. In 2001, Riordan, et al., again found no predictive abilities of the LATCH tool. Further development of breastfeeding assessment tools led to Riordan publishing the Via Christi Breastfeeding Assessment Tool in 2005, but it has not been tested clinically for predictive or correlational capacity. There was one unpublished case study identifying the use of this tool in practice (Taha, 2009.) The study agency uses this tool clinically and therefore the breastfeeding assessment score will be reflective of the Via Christi breastfeeding assessment score.

Gilmour, et al. (2009), conducted a pilot descriptive study on 11 mothers to identify factors associated with breastfeeding cessation. Through qualitative analysis, themes identified included midwifery assistance, knowledge, expectations and reality, social influences, and influence of health professionals. Subjects identified lack of visits for lactation support by nurses or midwives and them being very busy at the time of birth or afterward impacted their breastfeeding negatively. In addition, not knowing what to expect was cited, despite having gone to some classes, they wished they knew more ahead of time to help them prepare better. Subjects explained that their expectations didn't match the reality of what the newborn needed

and this impacted how tired they were and limited their stamina to continue breastfeeding. From that, often led the suggestion of health care workers to tell them to use the bottle for feedings if they were going to be too stressed or tired to breastfeed. In hindsight, the subjects wished they knew more and received more support on how to make breastfeeding work for them despite being tired, undereducated, and overwhelmed. This study, although small, suggests that for women and their babies to improve the breastfeeding experience, collaboration between the health and social services, health professionals and community is required.

Radtke, et al., (2012) conducted another qualitative grounded theory analysis by interviewing 10 mothers of late preterm infants. They examined breastfeeding establishment over a 6-8 week period and proposed a theoretical model indicating a need for earlier, more extensive and more qualified breastfeeding support for this population. Their model describes a psychosocial process called "Weighing worth against Uncertain Work" which encompassed the tension among breastfeeding motivation, the intensity of breastfeeding work and the ambiguity surrounding infant behavior and feeding cues. It also included sub-processes that are involved in this experience and include "playing the game", "Letting him be the judge vs accommodating both of us", and "Questioning worth vs holding out hope". The study identified the intense experience mothers endure during the first weeks of breastfeeding their vulnerable infant and although they hope breastfeeding could be sustained, the challenges they faced often is more daunting than expected.

From the literature, it appears that lactation support, whether it be by lactation consultants, counselors, or nurses, is significant in the outcomes of breastfeeding. As stated previously, McQueen, et al., 2011, examined the impact of a Breastfeeding Self-Efficacy intervention on 150 primiparous mothers of term infants as subjects in a randomized controlled

trial. The intervention included a lactation consultation within 24 hours of birth, a second visit within the next 24 hours and a phone contact within the first week home. There was a high rate of compliance with the protocol (85.3%). Long term follow up at 4 ($p=0.08$) and 8 weeks ($p=0.56$) exhibited marginally higher rates of sustained breastfeeding in the intervention group. By eight weeks after discharge, there was a 90% retention rate. Subjects in the experimental group had higher rates of Breastfeeding Self-Efficacy at 4 and 8 weeks compared to the control group, although the results again weren't statistically significant. There were no significant differences in Breastfeeding Self-Efficacy Scores for either group compared at 4 and 8 weeks. Exclusivity of breastfeeding in the intervention group at 4 and 8 weeks was not statistically different between groups ($p=0.35$ and 0.62 respectively). However, the rate of decline in percentage of breastfeeding to total feedings was significantly different between the groups ($p<0.05$). This is an important finding as low Breastfeeding Self-Efficacy led to abrupt cessation of breastfeeding rather than a slow weaning that exposed the infant to breast milk over a longer period of time. Despite the lack of statistically differences, subjects did cite that they appreciated the interventions and found them to be helpful. Information collected from the subjects in the intervention group cited reasons for discontinuation of breastfeeding, which included perceptions of insufficient milk supply, baby in NICU for prolonged period, poor weight gain, too time consuming, too painful, difficulty latching and simply that they'd changed their minds. In the control group, mothers cited reasons for discontinuation of breastfeeding to be a perception of insufficient milk supply, difficulty latching the infant to the breast, mastitis, an infection in the breast, breastfeeding being too stressful, postpartum depression, and following the recommendation by a physician.

Perinatal factors have been examined in relation to breastfeeding outcomes and should be considered when examining sustained breastfeeding. Women who undergo delivery by cesarean section usually have an epidural anesthesia with fentanyl. In addition, women usually get extra intravenous fluids prior to the epidural to prevent hypotension, a complication of the procedure. The additional intravenous fluid load has been implicated in threatening the establishment of lactogenesis. Beilin, et al., (2005) studied the effect of labor epidural analgesia with and without fentanyl on infant breastfeeding. Although the sample size of 59 women was small, the prospective randomized double-blind study design made the results significant. Of those mothers who had stopped breastfeeding by 6 weeks postpartum, it was statistically more likely (P=0.005) that they had been randomly assigned to the epidural group with high or intermediate levels of fentanyl, rather than none (Beilin, et al., 2005). In contrast, women who have had a caesarean section are usually hospitalized longer than those with vaginal deliveries, therefore allowing longer access to lactation support services. Whether or not this is statistically helpful has not been studied, therefore identifying characteristics of the birth process that may be related to sustained breastfeeding.

In order to breastfeed effectively, it has been determined that effective latch, positioning, sucking and milk transfer has to occur. It has also been supported that low Breastfeeding Self-Efficacy can impact breastfeeding duration and therefore longer exposure to breast milk which supports the infant's nutritional status. Subjects have identified that education and support is necessary to promote sustained breastfeeding. What type of lactation support and who gives that support and education is an area ripe for further investigations?

Lactation Support

The research base focusing on lactation support is limited. Merewood, et. al (2006)

conducted the only other research study that has examined an intervention of what type of lactation support would best be given to NICU mothers who are breastfeeding. The purpose of the study was to evaluate the use of peer counselors in the NICU to provide support to 108 breastfeeding dyads whose infants were hospitalized in the NICU. The mean gestational age was 32 weeks and infants and demographic data was consistent between both control and experimental group. At 12 weeks postpartum, women with a peer counselor had a 181% greater chance than women without a peer counselor of providing any amount of breast milk to their infant. The NICU, which served as the study setting was in an inner city teaching hospital and therefore determined that peer counselor support could be helpful in increasing breastfeeding in the vulnerable inner city population. One responsibility of the lactation consultant is to determine if there is a need for interventions beyond education, emotional support and assessment of the breastfeeding dyad. Sometimes, that includes implementation of tools that support breastfeeding such as the nipple shield or shells.

Chertok (2009) conducted a multi-site, international, nonrandomized, prospective study where she examined between group weight gain trends for term infants using or not using a nipple shield. This latter study was an expansion of an earlier pilot study that examined within group differences in maternal prolactin levels and infant test weights when breastfeeding with and without nipple shields. In addition to finding that there was no statistically significant difference in infant weight gain at 2 weeks, one month and two months between those infants who breastfed with and infants who breastfed without a nipple shield, 89.8% of subjects reported a positive experience with nipple shield use and 67.3% of the subjects reported that using the ultra thin nipple shield prevented termination of breastfeeding. It was therefore concluded that

nipple shield use when clinically indicated can be a beneficial intervention for the maternal-infant dyad without risk of decreased weight gain (Chertok, 2009).

The use of manual breast compression in addition to electric pumping as a method of promoting lactogenesis II, the change in production from small quantities of colostrum to larger volumes of mature milk, and improving milk supply for mothers of preterm infants has been studied by Morton. In 67 mothers of infants born less than 31 weeks gestation, combining hand expression in addition to electric pumping, an increase in milk supply was significant at the p=0.004 level of significance at both week 2 and week 8 (Morton, et al., 2009). In this study, mothers began pumping by 6 hours after birth since the mother and infant were separated due to neonatal intensive care hospitalization of the infant. Another study identified that beginning pumping by 1 hour of life yielded a statistically significant volume of milk at 7 days (P=0.05 and at week 3 (P=0.01) and identified a significantly earlier onset of lactogenesis stage II at the .03 level of significance (Parker, et al., 2012). Although these studies were conducted on preterm infants that were separated from their mother, clinical practice may suggest that early stimulation by breastpump and/or manual expression can protect the maternal milk supply if the infant is immature and potentially weak at breastfeeding. Dr. Marianne Neifert described this practice as "triple feeding", which includes breastfeeding, maternal pumping and then feeding the expressed breastmilk to the infant. At times, the infant may require further supplementation of formula if expressed breastmilk is unavailable (Neifert, et al., 2012).

The use of a nipple shield and pumping are common interventions for lactation consultants to implement with their clients, especially with the late preterm and early term infant. As identified above, use of this tool and educational and supportive interventions can support

and sustain breastfeeding for infants. The evidence on late preterm and early term infant and the physiologic vulnerabilities they exhibit, the many underlying etiologies emphasizing the importance of breastmilk to their overall nutritional status, and the many reasons breastfeeding in the late preterm and early term population specifically can be problematic was explored and is now presented.

The Late Preterm and Early Term Infant

Clinical practice with the late preterm and early term population has been drawn from the evidence with preterm infants who become late preterm corrected gestational age while they are learning to orally feed, at the breast or other methods. Likewise, clinical practice and guidelines historically didn't recognize the vulnerability of the late preterm and early term infants and therefore, evidence in the term populations were applied to the late preterm and early term populations. Therefore, it is necessary that the evidence in all these populations were explored and presented in relation to the variables of interest for this study.

physiologic challenges of the late preterm and early term infant.

From a physiologic standpoint, it is well documented that the late preterm and early term infant exhibits several physiologic deficits that put them at risk for health problems unique to this population of infants. Medoff-Cooper, et al. (2012), identified neonatal health risks related to gestational age. In a non-interventional prospective study with data collection at 14 U.S. hospitals, the researchers identified significant risks for hypothermia, hypoglycemia, feeding difficulties, hyperbilirubinemia and respiratory distress in the population of infants born between 34-36 6/7 weeks gestation. This study was a prospective data collection as part of the "AWHONN Late Preterm Infant Research Based Practice Project" which holds promise for

larger scale outcomes measurement after implementation of AWHONN's Clinical Practice Guidelines. De Araujo, et al. (2012), analyzed the neonatal morbidity and mortality statistics of 239 late preterm infants and 698 full term infants. Through a cross sectional design, the researchers determined that the late preterm infant was statistically more likely to develop hypothermia, hypoglycemia, and various respiratory pathologies Additionally, late preterm infants were more likely to require, resuscitation measures in the delivery room, phototherapy, supplementary feeding, mechanical ventilation, venous infusions, antibiotics, and NICU admissions. When infants are admitted to the NICU or remain in the nursery for phototherapy or treatments, these therapies can have negative impact on breastfeeding outcomes. Hospitalizing the infant in the NICU requires that mother and infant be separated during that time, sometimes by miles. While separated, the mother has to establish her milk supply by using an electric breast pump to stimulate milk production since the infant is ill and cannot initiate breastfeeding. This alternative process is more cumbersome and not as enjoyable as simply putting the infant to the breast. If the mother is hospitalized in another location than the infant, she will often seek early discharge so she can be with her infant, which may mean she is discharged when not fully recovered, and also may not have a breastpump made available to her. The NICU, while caring for the infant, usually supports the lactation efforts of the mother as they recommend breastmilk for the infant. However, the mother still has to pump around the clock while recovering herself and managing the stress of having an infant in the hospital.

Given the difficulties late preterm infants exhibit, Ishiguro, et al. (2012) examined the risks associated with prematurity in the late preterm infant, and suggests an evidence-based management strategy or protocol to follow when caring for them. They examined 219 late preterm infants (35-36 weeks gestation) and 2648 "mature" infants, finding a significantly higher

risk of admission to the NICU for diagnoses of apnea and hypoglycemia. Therefore, the authors suggest that all infants born at late preterm should be monitored for at least 2 days for apnea and be screened for hypoglycemia on their first day of life. Apnea, or a pause in breathing for 20 seconds that often is accompanied by a slow heart rate, impacts the oxygenation that the brain receives. Hypoglycemia, or low blood sugar or glucose, affects brain function, as the brain needs a ready source of glucose in order to perform properly. Physiologically, the respiratory center is immature and the glycogen stores are minimal in preterm infants, thus predisposing late preterm infants to these problems. Given that the risk of apnea and hypoglycemia impact brain perfusion and function, and potentially neurodevelopmental and breastfeeding outcomes, management is warranted for this high risk population. Actualizing this management plan would impact rooming in and the ease of breastfeeding ad lib on demand, which is recommended for the breastfeeding dyad. Rooming in is the practice where mothers and infants are kept together as much as possible so mothers can learn to recognize their infants early feeding cues, put the infant to breast whenever the infant shows such cues, and develop an emotional bond with the infant. This is one of the "Ten Steps to Successful Breastfeeding", as identified by the World Health Organization and is supported in the Academy of Pediatrics Statement on Breastfeeding (2012), and the Academy of Breastfeeding Medicine protocol #3 Hospital Guidelines (2009).

In 2007, Meier et al. developed a conceptual framework for poor lactation outcomes in late preterm infants. The immature physiology of the late preterm infant, specifically poor oral motor skills, coupled with the maternal risk factors (i.e. cesarean section delivery, pre-eclampsia) yield delayed or impaired lactogenesis II (the development of a full milk supply), resulting in decreased maternal milk volume and inadequate infant milk intake. Both contribute

to low rates of exclusive breastfeeding and lactation related infant morbidity. (Meier, et al. 2007).

In 2012, Ayton, et al., compared late preterm (34-36 week) and 37 week gestation infants and identified factors associated with the initiation and exclusive breastfeeding at hospital discharge. This retrospective study on 2006 data identified 34-36 week gestation infants as less likely to be discharged exclusively breastfeeding compared to 37 week infants. This confirms the suspicion that early term and late preterm infants have different needs and outcomes. Evidence on the oral feeding challenges this population faces is explored next.

late preterm oral feeding challenges

In an effort to address the challenges preterm infants face as they transition from tube feeding to oral feeding, Lesson (2011), conducted a randomized, controlled, blinded clinical trial on 19 preterm infants, using a Premature Infant Oral Motor Intervention (PIOMI) that was newly developed. Although these infants were preterm, transitioning to oral feeding usually occurs during the late preterm corrected gestational age range. The intervention was introduced daily for 5 minutes every day for seven days at 29 weeks corrected gestational age before introduction of oral feedings in hopes of decreasing the length of time to transition to oral feedings producing a shorter length of stay for the premature infant. The PIOMI consisted of "assisted movement to activate muscle contraction and provide movement against resistance to build strength. The focus of the intervention is to increase functional response to pressure and movement and control of movements for the lips, cheeks, jaw and tongue." (Lesson, 2011). The control group received a sham intervention to keep the parents and staff blinded of the group assignment. Subjects in the intervention group attained total oral feeding status five days sooner than controls ($p=0.043$)

and were discharged 2.6 days sooner than subjects in the control group. Although this study wasn't focused on breastfeeding infants specifically, it did raise the suggestion that infants could receive oral motor stimulation earlier than previously thought and that it had a positive effect on length of stay and feeding. Breastfeeding infants in the NICU often nuzzle at a previously pumped breast in hopes of maintaining familiarity and some potential latch opportunities as a pre-cursor to oral feeding when more physiologically stable.

Late Preterm Infant and Breastfeeding

There are a few research studies that have examined the late preterm infant population and breastfeeding outcomes specifically. Hwang, et al., (2013) did compare breastfeeding and discharge outcomes in the late preterm (34-36 weeks gestation) compared to the early term (37-38 6/7 weeks gestation). They identified that the early term infants were just as likely to be discharged at similar timeframe traditionally expected of term infants. Conversely, late preterm infants were more likely to need extended hospitalization than traditionally expected of term infants. Late preterm infants were less likely to initially breastfeed and less likely to have sustained breastfeeding past 10 weeks. This supports that the two sub-populations have different needs and outcomes to address. The protocol put forth by the Academy of Breastfeeding Medicine on breastfeeding the late preterm infant, integrates existing evidence available for the population, but does extrapolate from the term infant research on breastfeeding as well (ABM, 2011). The American Academy of Pediatrics supports the use of human milk for the premature infant in its 2012 Policy Statement on Breastfeeding and the Use of Human Milk. The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) developed their Clinical Practice Guidelines for supporting lactation in the late preterm infant (AWHONN, 2010). In 2009, Nyqvist, et al. conducted a theoretical exploration to the World Health

Organization's Ten Steps to Successful Breastfeeding, which the American Academy of Pediatrics (AAP) endorses. The theorist proposed the original "Ten Steps" would potentially be revised to include three "Guiding Principles" which would support breastfeeding in Neonatal Intensive Care. These guiding principles include:

1. The staff attitude to the mother must focus on the individual mother and her situation
2. The facility must provide family –centered care, supported by the environment.
3. The health care system must ensure continuity of care, that is, continuity of pre-, peri-, and postnatal care and post discharge care. (Nyqvist, 2009)

Although these principles are proposed theoretically, no research has yet been published on the impact that these guidelines have had on breastfeeding infants hospitalized in the neonatal intensive care unit.

McDonald et al., (2012) compared late preterm infants (34-36 6/7 weeks gestation, n=77) to term infants (n=1150) in relation to sustained breastfeeding, length of stay after birth, re-hospitalization, maternal anxiety, depression, stress, and parenting morale. The bivariate and multivariable analyses resulted in showing late preterm infants having a longer median length of stay after birth ($P<0.001$) and a higher re-hospitalization rate at 4 months ($P<0.001$) and mothers of late preterm infants were more likely to report immediate breastfeeding difficulties ($P<0.001$) and earlier cessation of breastfeeding at 4 months ($P=0.008$). Additionally, multivariable analyses identified the late preterm status as an independent risk factor for excessive symptoms of maternal anxiety, but not for depression, stress, or low parenting morale. This study supports that families of late preterm infants are indeed vulnerable and in need of specific support, education and care (McDonald, et al., 2012). Additional analysis of this same sample identified that the late preterm infant status was an independent risk factor for breastfeeding difficulties attributed to the baby (OR 1.72, 95% CI 1.24-2.38) when compared to term infants. This was

not true for difficulties due to flat or inverted nipples or low maternal milk supply. Additionally, when controlling for household income, mode of delivery and postpartum maternal health, late preterm infants were less likely to sustain exclusive breastfeeding at 4 months compared to term infants (OR 0.67, 95% CI 0.46-0.97) (Nagulesapillai, et al., 2013).

In an effort to promote breastfeeding with infants hospitalized in the NICU, Meier, et al. (2000), reported outcomes for preterm infants whose mothers used nipple shields when they transitioned to oral feedings during the corrected gestational age late preterm timeframe. The 34 infants served as their own controls and the data for two feedings were evaluated, one with the shield and one without. Duration of feeding and milk transfer was assessed in both the intervention group, feedings that used a shield and the control group, feedings during which no shield was used. Paired t-test analysis compared mean milk transfer with and without the nipple shield. Mean milk intake was significantly greater for the feeding with the shield compared to the feeding without the shield (18.4 ml vs 3.9 ml; t=9.25, P=0.0001). The researchers then did further statistical analysis (Student's t-test) comparing means for duration of nipple shield use and total breastfeeding duration between a "milk transfer breastfeeding without a shield" group and a "no milk transfer breastfeeding without a shield" group, identifying no statistical differences between groups regarding weight, or mean gestational age or time of first breastfeeding. Mean volume of milk transferred with the shield was significantly greater in the milk transfer group (t=2.48, P=0.02), but the increase in milk transfer with the shield was similar for the two groups (t= 0.97, P=0.34), suggesting that the shield use may be equally beneficial in increasing milk transfer initially or eventually. Correlation coefficients were used to determine if there was an association between duration of nipple shield use and duration of total breastfeeding. The mean duration of breastfeeding for the 34 infants was 169 days and mean

duration of nipple shield use was 33 days. The correlation revealed that longer nipple shield use was not associated with shortened duration of breastfeeding (r=.1206, P=.5). This was powerful support for use of a nipple shield as a tool to assure adequate breastmilk intake. By supporting use of the nipple shield in this population, the higher milk transfer yields higher rates of breastfeeding at discharge, which positively reinforces the breastfeeding for the mother-infant dyad. In the NICU, late preterm infants are not often exclusively breastfeeding at the time of discharge and are instead employing a combination of breastfeeding with some other form of feeding supplementation. Lactation consultant follow up after discharge from the NICU usually includes telephone support in collaboration with their pediatrician as they continue to transition to full breastfeeding. Although Meier's (2000) study was conducted on preterm infants, it remains applicable to the late preterm infant because often, late preterm infants will also use nipple shields as an intervention to promote higher milk transfer until they are mature enough to transfer enough milk independently for growth.

It is important to note that historically, nipple shields at the time of this study were latex and currently are made of a thinner silicone material, arguably a better product since they are more likely to adhere and not slip off, and anecdotally mothers report a better sensation on the thinner silicone product. In addition, use of nipple shields border on the next discussion of the evidence on alternative methods of providing a feeding. The AAP Section on Breastfeeding (2012), the WHO (Saadeh, 1996), and the ABM (2009), (2011), all cite that avoiding supplementation in addition to exclusive breastfeeding is recommended.

Methods for Providing Supplemental Feedings

Supplemental feedings were conceptually and operationally defined in Chapter 1, page 13-14. Succinctly, supplemental feedings are any substance given to the infant in addition to

breastfeeding. Sometimes, supplemental feeding is done at the mother's request because she does not choose to exclusively breastfeed, or is not aware that supplementation is unnecessary. Historically, water and formula were readily given to infants in addition to breastfeeding. Currently, it is recommended that no supplementation is required for term healthy infants, unless the infants are too sick to breastfeed or the mothers are too sick to allow breastfeeding. The recommendations for late preterm infants also recommend no routine supplementation unless indicated. It is recommended that supplemental feedings be ordered by the health care provider in circumstances such as weight loss of greater than 10% of birth weight, infant illness or poor feeding, infant unable to feed at the breast, has an inborn error of metabolism, or is on contraindicated medications. Infant conditions regarding insufficient intake or alterations in output, excessive weight loss, significant dehydration, and/or hyperbilirubinemia can warrant the need for supplementation. The recommended practice for supplemental feedings is to supplement with mother's expressed breastmilk or donor human milk and if those are not available, then protein hydrolysate formula is preferable to standard formula (ABM, 2009). When a supplemental feeding is ordered, the method by which it is given has to be decided. Often the nurses educate the parents and the decision is left to them to determine the alternative method. (ABM, 2009; Section on Breastfeeding, 2012).

The phenomena of "nipple confusion" that has been identified for the term infant has led to concern that introduction of artificial nipples impacts breastfeeding and therefore, other methods than bottles should be utilized if supplementation is required. In 1995, Neifert conceptualized a hypothesis for explaining the phenomena of "nipple confusion": "Infant's difficulty in exhibiting the correct oral configuration, latching technique and suckling pattern necessary for successful breast-feeding after bottle feeding or other exposure to an artificial

nipple" (Neifert, 1995.) Whether or not this phenomenon is applicable to the late preterm infant is under debate (Dowling & Thanattherakul, 2001). Thorough discussion on the available evidence related to the various methods of supplementation and the how they relate to the late preterm infant follows.

breastfeeding and introduction of supplementation via bottles and pacifiers.

In an effort to support the World Health Organization's stance that pacifiers and bottles should be avoided due to potential negative impacts on breastfeeding, Howard, et al. (2003) proposed a large sample study to support or refute this idea of "nipple confusion". In a randomized controlled study, 700 breastfeeding newborns of 36-42 week gestation were randomly assigned to one of four groups: bottle/early pacifier (2-5 days of life), bottle/late pacifier (after 4 weeks), cup/early pacifier and cup/late pacifier to determine the effect of two types of artificial nipple exposure on breastfeeding duration. The cup or bottle intervention occurred if the infant required and therefore received supplemental feedings (n=251 cup feeders, n=230 bottle feeders). Data were collected at delivery and throughout the first year of life on the newborns. Logistic regression and survival analyses revealed that supplemental feedings, regardless of method had a detrimental effect on breastfeeding duration ($P<0.0001$). There was no difference in cup versus bottle groups for duration of breastfeeding. There was statistical significance for exclusive or full breastfeeding duration when the supplemental feedings given amounted to 3 or fewer ($P=0.0001$-exclusive, $P=0.0002$-full). Although it was determined that there was no advantage to cup feeding supplemental feedings to the general population of healthy breastfed infants, it did demonstrate prolonged breastfeeding duration for mother infant dyads that were born by cesarean and/or required multiple supplemental feedings for medical reasons. It also supported recommendations to avoid pacifier use in the neonatal period, as it

was detrimental to overall breastfeeding rates. Early pacifier introduction resulted in decreased breastfeeding duration (P=0.03). Therefore, the recommendation to avoid exposure to artificial nipples and supplemental feedings in order to support breastfeeding in the healthy term infant is supported.

However, if supplemental feedings are medically indicated, then the method by which they are given could potentially affect the ability to breastfeed. The sample utilized in this study included infants 36-42 weeks gestation (Howard, et al., 2003). At the time of the study, 36-38 week gestation infants were often treated as 'near term gestation" infants. Since then, late preterm infants have been identified infants born between 34-36 6/7 weeks gestation. The phrase "late preterm" was coined to better reflect their vulnerability as being more preterm, than "near term". With the change in terminology, the infants born at 37 weeks gestation were now identified as "early term" infants (Spong, et al., 2011). However, the Academy of Breastfeeding Medicine recommend application of their "Protocol #10: Breastfeeding the late preterm Infant" to be applied to the early term population as well since there are no guidelines identified for this population (ABM, 2011). For this specific population, no studies appear in the literature base.

Cup, paladai, bottle feedings in mixed gestational age infants.

Malhotra, et al (1998), published a study comparing 100 infants using three alternative methods, the cup, paladai, and bottle. The dependent variables of volume ingested, length of feeding, degree of spillage, and satiety were measured. The subjects served as their own control. The subjects were of term and preterm gestation and included low birth weight infants. The paladai is a tool typically used in the Indian culture that looks like a small teapot with a spout. In the cup feeding, the infant laps up the milk out of the edge of the cup. In the paladai, it is tipped into the edge of the infant's mouth a bit at a time. The bottle is self-explanatory. The maximum

volume consumed in the least time was the paladai. Again, spillage was highest with the cup, especially in preterm subjects (Malhotra, et al., 1998).

cup feeding and breastfeeding outcomes in preterm infants.

In 1999, Freer conducted a pilot study to describe the performance and physiological effects of breast and cup feedings in preterm infants. The investigator measured suck/burst length, length of feeding, oxygenation, heart rate, and sucking swallowing, breathe pattern in late preterm infants during breast and cup feedings. The infants served as their own control. The analysis included 64 feeds on 20 premature infants that were born between 28 and 31 weeks gestation. Feedings were tested when the infants were between 31 and 35 weeks gestation, and compared feedings that occurred no more than 24 hours apart. The mean breastfeeding session was slightly longer than the cup feeding sessions and there was a large variability within each group as well as between infants. However, there was more pausing with cup feeding and less time sipping while the breastfeeding exhibited longer sucking bursts inferring that cup feeding is a less efficient method of feeding in preterm infants. In addition, infants exhibited statistically significant higher breathing frequency and marginally higher oxygenation during breastfeeding sucking bursts compared to the lapping bursts in cup feeding sessions (Freer, 1999).

cup feeding in preterm infants.

Findings from the Freer (1999) study were reinforced by Dowling, et al. (2002), when they examined cup feeding in the preterm infant. Their results identified the feeder being unaware of a high amount of drooling (38.5% loss of volume) onto the burp cloth in 8 out of 12 cup feeding sessions. Although there was physiologic stability, there was minimal milk intake (mean=4.6 ml). This finding reinforces the idea that cup feeding in the preterm population may

be inefficient in securing adequate milk intake, which is integral to maintaining physiologic stability to the vulnerable late preterm or early term infant.

nasogastric tube and bottles in preterm infants.

In a prospective randomized controlled, non blinded study, Kliethermes, et al. (1998), examined the use of nasogastric tubes compared to bottles as a method for providing supplementation to 84 preterm infants in the NICU, with birth weights of 1000-2500 grams and a mean gestational age of 32 weeks. Preterm infants in the NICU often require nasogastric tubes until they can orally feed effectively, but whether this is an option for the late preterm infant has been questioned. The dependent variable was the rate of exclusive or partial breastfeeding at discharge, three days, three months and 6 months after discharge. Data on apnea spells, length of hospitalization, and infant weight at discharge in addition to demographic data were collected. Despite randomized assignment, there were significant differences between groups on maternal age, having been previously pregnant, having other children, and previous breastfeeding experience. The tube fed infants were more likely to be breastfeeding at discharge, 3 days, 3 months and 6 months after discharge. Odds ratio with a confidence interval of 95% showed that the group receiving tube fed supplements was 4.5 times more likely to be breastfed at discharge and 9.4 times more likely to be fully breastfed. The tube fed group had fewer apnea episodes, but needed more stimulation to recover from those spells, potentially making them more clinically significant. There was no statistically significant difference in weight at discharge and length of hospitalization between the bottle fed and tube fed groups. Among other limitations, a high degree of bias has been identified with these findings from this study (Collins, et al, 2010). Specifically, the aim to transition preterm infants to the breast exclusively meant parents were motivated to be there more often to breastfeed since they potentially didn't want the nasogastric

tube left in longer and the infants couldn't be discharged with the tube, whereas the infants could go home breastfeeding and bottle feeding. In addition, self report on when the infant stopped breastfeeding could question the validity of results and there was no differentiation between full and partial breastfeeding. The differences between the two groups could account for the higher rate of breastfeeding as more mothers in the tube feeding group were older, delivered the infants vaginally, and began breastfeeding earlier. Statistical secondary analysis attempted to account for these confounding variables (Kliethermes, et al., 1999).

breast and bottle feeding in preterm infants.

To continue to expand on the knowledge related to the impacts of various supplemental feeding among preterm infants, Dowling (1999), compared physiologic responses of eight preterm infants when breast or bottle feeding specifically using the orthodontic nipple. The mean birth weight was 1370 grams and 30.2 weeks gestation at birth and served as their own controls for 14 breastfeeding sessions and 15 bottle sessions which yielded 539 sucking bursts to be evaluated from 13 within infant comparisons of breastfeeding and bottle feedings at comparable gestational ages. The quantitative analysis measured dependent variables of sucking, breathing and oxygen saturations in both methods of feeding. During the breastfeeding sessions, the subjects' respiratory rate increased more during sucking bursts, but was still within the normal range and not significant. There were also more pauses and less sucking bursts later in the feedings compared to earlier in the feedings in both groups ($p=0.016$). There were no statistically significant differences for sucking rates between the two feeding methods, alluding to the hypothesis that faster sucking rates occur when there is milk flow. This study confirmed milk transfer in breastfeeding, which had not been included in methodology in the past. Historically, infants' abilities to maintain oxygen saturation levels during breastfeeding have

been attributed to the physiologic ease of breastfeeding as opposed to bottle feeding. However, in light of the new evidence regarding milk transfer, the investigators were concerned that the ability to maintain oxygen saturations during breastfeeding may be more consistent with lack of milk transfer. In this study, there were episodes of desaturation in both methods. There were some infants who achieved a characteristic sucking waveform associated with organized breathing during bottle feeding with an orthodontic nipple in the qualitative analysis. This finding suggests the potential for using the orthodontic nipple instead of the traditional nipple used for bottle feeding, suggesting that the rate of flow may be more important than the type of nipple or method used (Dowling, 1999).

cup and bottlefeeding in preterm infants.

Mosley, et al. (2001) attempted to build the knowledge base on this topic by conducting a pilot study assessing the viability of a randomized controlled trial of methods of supplementary feeding of breastfed preterm infants. They examined sixteen infants ranging from 32-37 week gestation in a special care nursery. The infants were randomly assigned to bottle or cup fed groups for oral supplemental feedings. The breastfeeding rate at discharge was collected for both groups. There was no difference in breastfeeding rates at discharge between the two groups using the Fisher exact probability test (P=0.592 1 tailed). In addition, no statistically significant differences between the groups were found for the following variables: the impact of using a pacifier (P= 0.406), occurrence of assisted deliveries (P=0.720), previous successful breastfeeding (P=0.545), low gestational age (P=0.594), perceived level of good support (P=0.455), and delayed first breastfeeding (P= 0.126) (Mosley, 2001). A weakness of this study is that it was a small sample size and also occurred at an institution that had an intense support program for breastfeeding infants, which could have impacted breastfeeding rates regardless of

method of feeding and the small sample size, limiting generalizability of the findings.

In 2001, Marinelli et al. conducted a randomized crossover study on 56 infants born at less than 34 weeks gestation. After being randomly assigned to bottle or cup groups, they measured oxygen saturations, milk intake, and heart rate. No untoward effects were seen in cup feeding or bottle feeding, so it was determined to be "safe". The physiologic stability, a lower heart rate (P=0.0001) and increased respiratory rate, (P=0.0001) was better within the cup group, but they took less volume (P=0.001). There was also an increase in desaturations during bottlefeedings, compared to no change from baseline during cup feedings. However, taking this finding into consideration with Dowling's (1999) documentation of the relationship between desaturations and actual milk transfer, the increased frequency of desaturations during bottle feedings in this study may have been attributable to higher milk transfer volumes in the bottle feeding group. Study findings suggest that cup feeds are safe in the preterm population, but not assuring adequate intake is a risk, thus questioning the efficacy of cup feeding (Marinelli, et al., 2001).

Similarly, a stratified randomized experimental study compared cup or bottle feeding for preterm infants and effects on oxygen saturation, weight gain and breastfeeding. Infants were maintained on oral gastric tube feedings until they reached 1600 grams and then were randomized into cup or bottle groups. There were 34 infants in the bottle fed group and 44 infants in the cup fed group with mean gestational age of 37.2 weeks. They found no statistically significant differences in feeding time oxygen saturation, weight gain, or prevalence of breastfeeding at discharge and three months after discharge between the two groups. The researchers did identify a lower incidence of oxygen desaturation during the cup feeding (P=0.024) and a higher prevalence of breastfeeding at three months among those still

breastfeeding at the first follow up visit (P=0.024). This has some potential clinical significance, but statistically with the sample size being small, findings from this study lack the power to acknowledge that potential benefit (Rocha, et al. 2002).

Another randomized controlled large sample study by Collins (2004) consisted of a sample of 319 preterm infants born between 23-33 weeks gestation. In an attempt to determine the effect of artificial teats and cups on breastfeeding in preterm infants, they were randomly assigned to one of four groups: cup/no dummy (pacifier), cup/dummy, bottle/no dummy, and bottle/dummy. Infants were breastfed when the mother was available and when she was not, was given the feeding by the assigned method. The pacifier was given to the infant or not at enrollment. They found no significant differences in breastfeeding rates between the groups. Although cup fed infants were more likely to be fully breastfed on discharge home (P=0.03), they had a longer length of stay (P=.01) and had no difference in breastfeeding rates in the long term. The use of dummies did not affect breastfeeding rates for the preterm infants of any group (Collins, et al. 2004).

Gilks & Watkinson, (2004) conducted a randomized, non blinded, stratified controlled trial to determine if cup or bottle method for providing the supplemental feeding to preterm breastfeeding infant would impact breastfeeding. The sample included 27 cup and 27 bottle fed preterm infants in the two groups. The dependent variable was full or any breastfeeding at discharge, term and 6 weeks post term. They found no long term benefit to cup feeding versus bottle feeding, but initial breastfeeding success at discharge was seen with cup feeding group at the 95% confidence interval. Unfortunately, there was a large attrition rate as mothers decided to stop breastfeeding so the discharge sample size was 15 cup feeding subjects and 24 bottle feeding subjects which could skew the results.

As the data grew on the cup vs. bottle debate, Cloherty, et al. (2005) conducted a qualitative study as they interviewed seventeen midwives, thirty mothers, four neonatal nurses, three assistants, and six physicians to learn about the health care professional's beliefs on the topic. Through qualitative analysis, three themes emerged of difficulties returning to the breast, ease of use, and necessary skills and knowledge. It was suggested that evidence would help create an evidence-based protocol so parents can be educated regarding the best method of providing the supplemental feedings, and teaching skills, so parents can then make informed decisions and optimize the likelihood of promoting and sustaining long term breastfeeding.

In 2010, Al-Sahab, et al. conducted another study with health care professionals in Canada. They conducted a crossover design study with 87 nurses and 16 physicians who worked in well newborn nurseries and special care nurseries and postpartum units on their beliefs regarding nipple confusion. While only15% of special care nurses agreed that bottles could lead to nipple confusion, it was noteworthy that much higher proportions of nurses working on postpartum units and pediatricians, 44.4% and 56.2% respectively, believed that bottles would lead to nipple confusion. The research findings suggested a randomized controlled study to truly determine best practice and educate health care professionals, since at this time; their anecdotal experiences appeared to be determining practice.

A randomized controlled study of 522 infants of 32-35 weeks gestation compared cup feeding to bottle feeding in relation to length of hospital stay and exclusive breastfeeding at discharge, 3 and 6 months after discharge. Infants that were cup fed were 1.58 times more likely to be exclusively breastfed at discharge home, 1.64 times more likely to be exclusively breastfed at 3 months after discharge, and 1.36 times more likely to be breastfed 6 months after discharge. There was no significant difference for length of hospital stay. This study although conducted on

infants more preterm than just late preterm infants, does identify that methods of supplemental feedings can impact outcome without impacting length of stay statistically. This negates the clinical perception that bottle feeding infants are discharged sooner than if non nipple methods are used (Yilmaz, 2014).

finger feedings and preterm infants.

As methods of feeding were evaluated and discussed clinically, Oddy & Glenn (2003), conducted a pre- and post implementation of Baby Friendly Hospital Initiative study, examining breastfeeding rates at discharge from the special care nursery. The Baby Friendly Hospital Initiative suggests using finger feeding to provide supplemental feeds. This is consistent with the Baby Friendly Hospital designation requirement that all artificial teats are to be avoided. Eighteen preterm infants were bottle fed their supplemental feedings in addition to breastfeeding prior to the implementation and 17 preterm infants were finger fed in addition to breastfeeding after the implementation occurred. The finger feeding method was described and introduced to the unit clinically by Newman in a seminar in 1990 and consists of taping a feeding tube attached to the milk reservoir to the pad of the parent's finger. As the infants suck on the finger, they get the supplement from the reservoir through the tubing. Prior to implementation, the breastfeeding rate at discharge from the special care nursery was 44%. After implementation and using finger feeding as a method for supplemental feedings, the breastfeeding rate at discharge rose to 71% showing a statistically significant difference (P=0.025). However use of the finger feeding was just one component of the implementation of the program. Other components in this study included lactation support and education as required by the baby friendly designation, may have influenced breastfeeding rates at discharge, making it difficult to attribute the increase rates to finger feeding alone. Unfortunately, no long term breastfeeding outcome data were collected in

this study. Although this study was underpowered therefore limiting generalizability of the findings, it is noteworthy and worthy of inclusion as this is the only study exploring finger feedings as a method of supplemental feeding (Oddy & Glenn, 2003) published to date.

cup and bottle feeding in late preterm infant.

Only one study located in the literature search was specific to the late preterm population. Abouelfettoh, et al. (2008), compared breastfeeding duration between subjects in cup and bottle feeding groups who were hospitalized late preterm infants in Egypt in a quasi experimental design. Infants were 34-37 weeks gestation with a mean of 35.13 weeks. All subjects stayed in the neonatal intensive care unit until discharge where standard practice was to give all feedings via bottle in addition to breastfeeding. Once the control group was examined, they introduced the concept of cup feedings. The original plan was to follow the mothers' progress for six weeks after the infant's discharge. Due to a large attrition rate over the longevity of the study, and concern for the accurate recall of the subjects, breastfeeding duration could only be measured at the first week and then analyzed. Cup fed infants demonstrated more mature breastfeeding behaviors compared to bottle fed infants ($p=0.01$) and a higher proportion of breastfeeding at one week after discharge ($p=0.03$). Unfortunately, 38% of infants were discharged with no breastfeeding experience prior to discharge, citing inability to visit and/or lack of involvement at visitation to the NICU (Abouelfettoh, et al., 2008).

Summary

Evidence has grown related to cup and bottle feedings as they relate to nipple confusion and the impact on breastfeeding, but is lacking in relation to finger feeding as an alternative method. Additionally, two methods of supplemental feedings (syringe and supplemental nurser system at the breast) were used in practice at the study site but have no evidence published on

their efficacy. There is little long term evidence on breastfeeding outcomes in late preterm infant, the type of lactation support that is most helpful, and the effect of Breastfeeding Self-Efficacy on the late preterm population. For these reasons, this pilot study sought to determine whether an association exists between sustained breastfeeding at discharge, one and three months post discharge and Breastfeeding Self-Efficacy measured at discharge, the method of supplemental feedings provided if indicated, and what type of lactation support was given, if any. Findings from this study may build on the existing body of knowledge so that more evidence-based practice will exist that truly is focused on this population of late preterm infants. Such evidence may guide health care professionals' practice with mothers and late preterm infants.

CHAPTER 3: METHODS

The purpose of this pilot study was to determine the prevalence of sustained breastfeeding in infants born between 35-37 6/7 weeks gestation at one and two months of age, among infants that initiated breastfeeding in the hospital. In addition, exploring potential predictors of sustained breastfeeding in the late preterm and early term infant was a secondary aim. Other variables of interest for this pilot study were breastfeeding self-efficacy, in-hospital lactation consultations, use of supplemental feeding methods, maternal and infant demographic data and hospital course, characteristics of the birth process, in-hospital feeding practices, and post discharge lactation support. Potential research subjects for this pilot study were mothers of infants born between 35-37 6/7 gestation and admitted to the well newborn nursery, who had identified breastfeeding as their chosen method of feeding. The late preterm and early term infant exhibits physiologic risk for less than adequate nutritional intake when exclusively breastfeeding, and therefore may require supplemental feedings. From the current State of the Science presented in Chapter 2, it is clear there is little evidence to support the best practice to produce the outcome of sustained breastfeeding in this population. Additionally, studies that focus on preterm infants cannot be generalized to the late preterm population due the differences in development, severity of medical issues, duration of separation from their mother, the necessity of supplemental feeding methods, and variability in progression to oral feedings.

Mother's perceived self-efficacy related to her breastfeeding ability and experience has been supported by research findings to be integral to success in breastfeeding the term infant. The purpose of this pilot study was to identify potential predictors of sustained breastfeeding in the late preterm and early term infant at one and two months of life. Variables of interest for this

pilot study were breastfeeding self-efficacy, in-hospital lactation consultations, use of supplemental feeding methods, maternal and infant demographic data and hospital course, characteristics of the birth process, in-hospital feeding practices, and post discharge lactation support. Breastfeeding Self-Efficacy was also the theoretical framework for this pilot, exploratory, correlational study.

This chapter presents the methods used in this research study and includes the purpose and design of the study, sampling technique, instrument validity and reliability, and data collection procedures. The chapter then discusses the data analysis process indicated by the study design.

Design of the Study

This study was an exploratory, longitudinal, repeated measures study focused on identifying the prevalence of sustained breastfeeding and exploring what factors were related to sustained breastfeeding in the late preterm and early term infant. In order to determine the potential factors, Breastfeeding Self-Efficacy scores, method of supplemental feeding used, in-hospital and post discharge lactation support, maternal and infant demographic data and hospital course, characteristics of the birth process, and in-hospital feeding practices were evaluated in 125 mothers for possible associations with sustained breastfeeding at one and two months of life for the late preterm and early term infant. If certain supplemental feeding methods or feeding practices were found to be associated with sustained breastfeeding, one can further plan safety and efficacy and intervention studies to truly determine the best evidence-based protocol. In addition, if the Breastfeeding Self-Efficacy of the mother is indicative of success, then efforts to

promote self-efficacy in the new mother who is breastfeeding should be further supported in practice.

Variables

The dependent variable for this pilot study was sustained breastfeeding in infants born between 35-37 6/7 weeks gestation infant at 1 and 2 months of age. Variables of interest were breastfeeding self-efficacy, in-hospital lactation consultations, use of supplemental feeding methods, maternal and infant demographic data and hospital course, characteristics of the birth process, in-hospital feeding practices, and post discharge lactation support. The maternal demographic data that was collected from the medical record included maternal age, education, race, previous breastfeeding experience, and birth of a previous late preterm or early term infant. The infant's demographic collected included: sex, singleton status, gestational age, birth weight, classification (AGA, SGA, LGA). The infant's course of care included whether the infant required phototherapy in the hospital, the occurrence of hypoglycemia, and the infant's discharge percentage of weight loss compared to birth weight. The characteristics of the birth process included method of delivery (vaginal vs caesarean), use of an epidural during labor process, and administration of magnesium sulfate prior to delivery. The data on in-hospital feeding practices included mother's feeding choice on admission (breastfeeding, formula feeding, or both), occurrence of initial breastfeeding related to time of birth, practice of skin to skin contact, maternal newborn separation, breastfeeding assessment score, and use of a pacifier, breastpump, nipple shield, and/or hand expression.

The dependent variable, sustained breastfeeding, was assessed via telephone structured interviews with the mother at 1 and 2 months of age. In addition, data on the variable, post

discharge lactation support was collected via the telephone interview at 1 and 2 months of age. The research design is outlined in Figure 2.

Figure 2. Research Design

Hospital Stay- Predischarge	Discharged Home- first month of life	1 month of age	2 months of age
Eligibility criteria met – potential subject approached with script (Appendix A-1) Informed Consent (Appendix A-2) BFSE-SF collected (Appendix B-1) Demographic data and hospital course collected (Appendix B-2) In-hospital lactation support provided as indicated/per usual	Routine follow up as indicated by programs available/offered to patient	Telephone structured interview conducted with subject (Appendix B-3) Determine sustained breastfeeding status. Determine use of post discharge lactation support	Telephone structured interview conducted with subject (Appendix B-4) Determine sustained breastfeeding status Determine use of post discharge lactation support If complete, incentive sent to subject

Research Questions

1. What proportions of breastfeeding infants born between 35-37 6/7 weeks gestation experience sustained breastfeeding at 1 and 2 months of age?
2. Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the following variables:

a. Pre-discharge maternal breastfeeding self-efficacy?
b. Use of supplemental feeding methods?
c. In-hospital lactation consultations?
d. Late preterm vs early term status?
e. Maternal and infant demographic data and hospital course?
f. Characteristics of birth process?
g. In-hospital feeding practices?

differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

3. Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of post-discharge lactation support differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

Sample

sample access.

The target population, mothers of late preterm and early term breastfeeding infants, was defined as 34-37 6/7 weeks gestation (ABM, 2011). However, in this inner city large teaching hospital that served as the study site, infants born at 35 weeks gestation sometimes were evaluated in the Neonatal Intensive Care Unit (NICU) and were transferred back to the "well" newborn nursery if stable. Infants born at 36 weeks gestation and older were admitted to the "well" newborn nursery. Infants in the "well" newborn nursery did not require special cardiorespiratory monitoring or tube feedings. Therefore, the sample recruited for this pilot study

consisted of breastfeeding infants born between 35-37 6/7 weeks gestation that were cared for and discharged home from the well baby nursery.

sample recruitment.

Subjects for this pilot study were recruited using a non-probability purposive sampling method. English and/or Spanish speaking Mothers, at least 18 years old, of late preterm and early term infants born within the 35-37 6/7 weeks gestation time frame with plans to breastfeed, either exclusively or partially, were identified for possible inclusion in the study. Potential subjects were identified through the lactation office since infants born between 35-37 6/7 weeks gestation have admission order sets that automatically includes a lactation consultation. Once identified, the investigator requested that the nurse use the script from the flyer in Appendix A-5 to ask the potential subject if the researcher could approach her for potential enrollment. The investigator then approached the potential subject and used the script from Appendix A-1 to ask for informed consent. If in agreement to do so, the subject signed the informed consent form (Appendix A-3) and used the master list in appendix A-2, the researcher assigned a case study to the maternal-newborn dyad and identified those that needed an interpreter. The subject received a copy of the signed consent form. If the subject was Spanish speaking, a Spanish translation of the informed consent was available for her to read while the investigator used an interpreter to state her script and answer any questions.

The researcher was able to obtain grant funding for the department store gift cards that were incentives to participate and complete the study. Telephone interviews with English speaking subjects were conducted when the infant was 1 and 2 months old by calling the subjects

contact number given at consent. A language line interpreter service was used if the case was identified as non- English speaking.

inclusion and exclusion criteria.

The researcher approached all English or Spanish speaking mothers of infants born within the study period at the study site that met the inclusion criteria: infants born at 35-37 6/7 weeks gestation with plans to breastfeed either exclusively or partially. The researcher excluded infants who were in the NICU when the mother was discharged. Other exclusion criteria included infants with congenital and/or genetic anomalies. Mothers were required to be 18 years old to sign the informed consent for participation in research; therefore, mothers younger than 18 years old were excluded. Given the current birth rates for the study setting, collecting data at this one institution maintained the most reliability by limiting variation in practice, and this sample size met minimum standards per power analysis for moderate effect size. Mothers of twins were not excluded since multiple births are likely to fall in this population, but no triplets or higher multiples were eligible or included.

protection of human subjects.

Mothers whom met the inclusion criteria were approached by the researcher and invited to participate via the script identified in Appendix A-1. If she agreed to participate, the informed consent (Appendix A-3) was signed and she was provided a copy. Risks were considered minimal unless the mothers experienced discomfort discussing her breastfeeding plans and concerns with the researcher. Although no direct benefits to participants were identified, benefits to the profession of lactation and nursing and potentially to future mothers of

breastfeeding infants born between 35-37 6/7 weeks gestation were possible. To ensure anonymity, once the consent was obtained, a case number was assigned to the mother-infant dyad. All information gathered was de-identified. Appendix A-4 is the agency's Research Authorization for use/disclosure of Protected Health Information form that needed to be signed along with the informed consent. Appendix A-2 tracks the case numbers and de-identified patient information. That form and all consents were kept in a locked filing cabinet within the private lactation office at the hospital. All de-identified information was kept in a locked area of the researcher's office or home office for a period of five years. The Institution Review Board for Hartford Hospital and University of Connecticut request and approval are found in Appendix C-2.

Setting

The institution that served as setting for this pilot study has achieved the "Baby Friendly Hospital" designation by the World Health Organization, as previously described in Chapter 2. In support of the "Ten Steps to Successful Breastfeeding", staff working in the well-baby nursery did not routinely offer artificial teats or nipples to their patients, nor did they offer formula supplementation unless medically indicated or the mother requests to do so. If mothers requested to provide supplemental feedings to their infant, the staff provided education about the risks to breastfeeding of supplementation unless medically indicated and document that conversation. Additionally, the staff within this institution provided lactation support to mothers and infants, as consistent with the Baby Friendly designation. The Breastfeeding initiation rate for infants was 88% at this institution yielding 2300 lactation consults in the preceding year.

The hospital's birth rate for the most recent year was 3700 infants per year. For the three years period prior to this pilot study, there were 189 infants born at 35 weeks gestation, 80% breastfeeding exclusively or partially. Of those, the researcher expected a few to be transferred back to the "well" newborn nursery. The number of infants born at 36 weeks gestation was 401 in that three-year period, 79% of mothers initiating exclusive or partial breastfeeding. There were 1038 infants born at 37 weeks gestation in that three-year period and 83% of them initiated exclusive or partial breastfeeding. The researcher had set a goal of 125 subjects to enroll, and the researcher's timeline for collecting data was over 4-6 months. The population served by the inner city setting served patients of diverse backgrounds culturally and socioeconomically. Given the current birth rates for the study setting, collecting data at this one institution maintained the most reliability by limiting variation in practice, and this sample size met minimum standards per power analysis for moderate effect size.

Instruments

The mother's Breastfeeding Self-Efficacy was measured on the Breastfeeding Self-Efficacy Short Form tool pre-discharge after informed consent was obtained and the mother was enrolled in the study. The tool consisted of a 14 item, 5-point Likert scale questionnaire, totalling a score of 14-70, and asked about the mother's self-efficacy with her breastfeeding status with this infant (Appendix B-1). The Breastfeeding Efficacy Tool was changed to a short form (BSES-SF) and was established as a reliable tool of Breastfeeding Self-Efficacy in a study of 491 women who were breastfeeding (Dennis, 2003). Item redundancy statistically supported the deletion of some variables yielding the short form that had construct validity and showed significant results at the p=0.001 level (Dennis, 2003). The self-report instrument assessed

Breastfeeding Self-Efficacy expectancies in new mothers, identified mothers that need support and continued assessment, and those who appeared at increased risk for failure, thus showing predictive potential (Dennis, 2006). Permission via electronic mail was granted by Dr. Dennis to use the Breastfeeding Self-Efficacy Scale-Short Form (Appendix B-5). In addition, permission was obtained to use the Breastfeeding Self-Efficacy Scale-Short Form in Spanish for those mothers that used a Spanish interpreter for consent (Appendix B-6).

Maternal and infant demographic data and hospital course, characteristics of birth process, in-hospital lactation support and feeding practices for the maternal-newborn dyad, and supplemental feeding methods was collected on an investigator developed form (Appendix B-2) used to collect data from the mother and infant's medical records. This data were nominal or ordinal in nature and was used to identify any potential relation to sustained breastfeeding at 1 and 2 months.

At one and two months post discharge, telephone interviews were conducted to identify whether the mother was still breastfeeding her infant at any point in the day, whether she accessed any post-discharge lactation support, what method of feeding was used if the infant required any supplemental feedings, and if so, how often, and the level of maternal satisfaction with current feeding outcome. Data from this interview was collected on forms found in Appendix B-3 and B-4. The data collected was nominal and ordinal in nature. Higher scores on the ordinal items indicate a more positive breastfeeding outcome. These tools were developed incorporating knowledge the researchers' gained from experience with post-discharge breastfeeding maternal-newborn dyads.

Internal validity would have been threatened by the mother's desire to breastfeed, especially when faced with challenges. Using the BSES-SF, which identified a low score if her

commitment was low, controlled this threat. Using this tool, which has been determined to be both valid and reliable as previously stated, strengthened construct validity. Addressing external validity, lactation support was provided by nursing and lactation staff at the hospital, peer counselors and lactation consultants after discharge. A prospective study was planned to identify factors that were related to sustained breastfeeding rather than predictive factors in order to limit the threat to statistical validity that could occur with practice variability.

The lactation program was unlikely to change during the course of this pilot study, therefore minimizing the threat to internal validity. The hospital planned to maintain its Baby Friendly Hospital designation, and continued the lactation support program as it had existed. Outpatient private consultations and breastfeeding support group were available and offered to all mothers at discharge. The peer counselor program enrolled clients who received health care from the women's health clinic during pregnancy and after birth and provided antenatal and post-discharge breastfeeding education and support through telephone or home visits. The typical schedule included three prenatal education sessions, daily sessions in the hospital, and a home visit at 24 hours, 72 hours, and 2 weeks after discharge. Telephone calls continued at 4 weeks, 8, weeks, 10 weeks, 4 months, and 5 months with visits interspersed at 6 weeks, 3 months, and a final visit at 6 months.

Procedure

Following approval of the dissertation committee, the researcher applied to the Institutional Review Board at Hartford Hospital for permission to conduct this study. Once approved by the hospital IRB (see Appendix C-2), the researcher submitted that determination to the University Institution Review Board as the IRB's currently have an articulation agreement

(see Appendix C-3). Therefore protection of human subjects and ethical conduct of research were assured.

Potential subjects were identified through the lactation office since infants born between 35-37 6/7 weeks gestation had admission order sets that automatically included a lactation consultation. Once identified, the investigator requested the nurse use the script from the flyer in Appendix A-5 to ask the potential subject if the researcher can approach her for potential enrollment. The investigator approached the potential subject and used the script from Appendix A-1 to ask for informed consent. If the subject agreed, the subject signed the informed consent form (Appendix A-3) and using the master list in appendix A-2, the researcher assigned a case study to the maternal-newborn dyad and identified those that need an interpreter. The subject received a copy of the signed consent form. If the subject was Spanish speaking, a Spanish translation of the informed consent was available for her to read while the investigator used an interpreter to state her script and answer any questions. In order to assure confidentiality, the master list was kept in a locked cabinet in the lactation office at the hospital along with all the signed consent forms. All forms from then on were de-identified, using only the case number as a reference.

The subject completed the Breastfeeding Self- Efficacy Short Form (BSES-SF) as identified in Appendix B-1 prior to discharge, she then put it in a sealed envelope and collected by the researcher. The 14 item self report tool used a 5 point likert scale to determine how competent the subject felt about her breastfeeding ability with this infant. A low score indicated lower Breastfeeding Self-Efficacy. Conversely, a higher score reflected more Breastfeeding Self-Efficacy. This tool has demonstrated reliability as a predictor of breastfeeding behavior at 4 ($p < 0.001$) and 8 ($p < 0.001$) weeks postpartum. The short form was developed after item

redundancy correlation analysis was greater than 0.8. The tool was tested for construct validity using factor analysis, known group comparisons (significant at the $p<0.001$ level), and correlations with three other theory related concepts (significant at the $p<0.001$ level). These results all supported the clinical usefulness of this tool as a method to identify mothers at risk for needing support, assess breastfeeding behaviors, verbalize confidence-building strategies, and develop program development and interventions that supported the mothers' self-efficacy.

Maternal and infant demographic data and hospital course, characteristics of birth process, and in-hospital feeding practices in addition to the number of in- hospital lactation consults were collected at discharge from the medical record by the primary investigator or CITI certified research assistant. The maternal demographic data and hospital course that was collected included maternal age, education, race, previous breastfeeding experience, and birth of a previous late preterm or early term infant. The infant's demographic data that was collected included sex, singleton status, gestational age, birth weight, classification (AGA, SGA, LGA), whether the infant required phototherapy in the hospital, and the infant's discharge percentage of weight loss compared to birthweight. The characteristics of the birth process included method of delivery (vaginal vs caesarean), use of an epidural during labor process, and administration of magnesium sulfate prior to delivery. The In-hospital feeding practices included mother's feeding choice on admission (breastfeeding, formula feeding, or both), occurrence of initial breastfeeding related to time of birth, practice of skin to skin contact, the highest breastfeeding assessment score on the Via Christi tool in the first 24 hours and after, and use of a pacifier, breastpump, nipple shield, and/or hand expression. In addition, if the infant received supplemental feedings, and if so, by what method: supplemental nursing system (SNS) at breast, syringe, SNS via finger feeding, cup, bottle or other.

Sustained breastfeeding was assessed via telephone structured interviews with the mother at 1 and 2 months of age and data obtained was collected on forms in Appendix B-3 and B-4. If the subject could not be reached by telephone after 4 attempts, leaving messages if possible, the interview form was sent to the subject with a self-addressed returned envelope for them to return the completed form. If the completed form was not returned by 3 months of age, the case number was closed. Once completion of the second interview occurred, a $10.00 gift card for baby care items was mailed to the subject. If the subject wanted a referral for help with breastfeeding, it was made to available resources that are free of cost. This was noted on the interview record.

There were minimal risks to the mother for participating in this pilot study. At times though, mothers may have felt a sense of failure if they had been unable to continue breastfeeding. If a mother had difficulty breastfeeding and requested help, she was referred to breastfeeding support group or the peer counselor program. If she expressed distress over having had to stop breastfeeding, the investigator praised the mother for providing any and all breast milk she had given to her baby, praised her other parenting skills she was doing to meet her infant's needs and supported her with empathy and helped her put it in perspective. In addition, the investigator inquired if her milk supply had diminished without painful engorgement. If the subject suffered from breast engorgement the investigator educated the mother on appropriate treatment.

Treatment of Data

Once data were collected, it was entered into SPSS version 21 for PC data management tool for analysis. The data were coded as identified in Appendix C-1. If a mother of twins had

one infant in the NICU and the other in the newborn nursery, the data were used on the infant in the newborn nursery. If both infants were being discharged from the newborn nursery, the data for the twin with the highest weight loss % and lowest feeding scores was used. One infant's data was used since the primary subject was the mother and using the worst indication wouldn't skew the results. Any NICU hospitalization was coded as having maternal-newborn separation since the mother would leave the infant in the newborn nursery while she spent time in the NICU. If a mother received a spinal anesthesia instead of an epidural for her caesarean section, the use of an epidural was coded as such since both procedures require a bolus of intravenous fluids prior to receiving them. Subjects who did not complete the interview at 1 and 2 months of life were not included in the primary data analysis. Descriptive statistics were used to compare completers to noncompleters on their characteristics to determine if they differ significantly. In further analysis, descriptive statistics might be helpful in analyzing the Breastfeeding Self-Efficacy scores in these subjects who did not continue in the study past discharge and were lost to attrition.

Data Analysis

Research Question #1: What proportions of breastfeeding infants born between 35-37 6/7 weeks gestation experience sustained breastfeeding at 1 and 2 months of age?

To address the first question, data on all subjects that complete the interview at 1 and 2months of life was collected; it was entered into SPSS version 21 for PC data management tool for analysis. In further analysis, descriptive statistics might be helpful in analyzing the Breastfeeding Self-Efficacy scores in these subjects who did not continue in the study past discharge and were lost to attrition. To address the first question and determine the prevalence of

sustained breastfeeding in the late preterm and early term population, the percentages of subjects that sustained breastfeeding at 1 and 2 months of life were calculated. Each of these percentages, one for sustained breastfeeding at 1 month, and another for sustained breastfeeding at 2 months, constituted an estimate of the proportion "parameter" for the binomial distribution that underlies the random observed count for sustained breastfeeding event within the study sample at the pertinent time point. As parameter estimates, the percentages were reported with the standard errors and 95% confidence intervals that are routinely inferred by the binomial distribution.

The sample size objective of 100 mother/infant dyads with complete data at both the 1 and 2 month time points data were determined by the dual objectives of (1) keeping the standard errors for estimated binomial proportions at or below +/- 5% and (2) limiting the width of the 95% confidence intervals for these proportions to 20% (assuming an asymptotic method of inference). Mathematical properties of the binomial distribution establish that the maximum standard error and maximum confidence interval width for an estimated proportion occur when the estimate is exactly 0.5 = 50%. In that circumstance, the standard error of the estimate is 0.5 divided by the square root of the sample size (N). A straightforward calculation demonstrates that N = 100 implies a maximum standard error of ±0.05 = ±5%. In this circumstance, the width of the 95% confidence interval, estimated using asymptotic methods, is no larger than 4 times the standard error –i.e. is less than 0.2 = 20%. If the estimated proportion is less than 0.5 = 50%, the standard error and confidence interval widths will both be smaller than the ±5% and 20% values, respectively.

It is important to note that Research Question 1 involved only a single sample of participants from a single clinical population –i.e. mother-infant dyads in which the birth occurred between 35 and 37 6/7 weeks gestation. That sample was used to determine the

percentage of dyads in which breastfeeding was sustained at the 1-month time point following birth and the percentage of dyads in whom breastfeeding was sustained at the 2-month time point. Because Research Question 1 concerns description of the evolution of sustained breastfeeding within a single sample, the data analyses that address the question will not involve a contrast of proportions between different samples that represent different clinical populations. Accordingly, the data analyses for Research Question 1 will involve no formal statistical tests and a formal "power" analysis was unnecessary.

1. Research Question #2: Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the following variables:
    a. Pre-discharge maternal breastfeeding self-efficacy?
    b. Use of supplemental feeding methods?
    c. In-hospital lactation consultations?
    d. Late preterm vs early term status?
    e. Maternal and infant demographic data and hospital course?
    f. Characteristics of birth process?
    g. In-hospital feeding practices?

    differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

To address the second research question, which reflects ordinal and nominal level data, descriptive statistics, contingency table methods, and bivariate logistic regression were used. The proportions of sustained breastfeeding at 1 and 2 months were estimated in sub-samples of mother/infant dyads defined by a number of variables. For question 2a, the mother infant dyads were divided into tertiles (lowest, middle and highest thirds) based on Breastfeeding Self-

Efficacy scores that range from 14-70. In exploring the evidence for an association between Breastfeeding Self-Efficacy, a continuous independent variable, and sustained breastfeeding, bivariate logistic regression was applied to assess whether there is a trend in the proportion of dyads that sustain breastfeeding relative to increasing levels of Breastfeeding Self-Efficacy. For question 2b, the dyads were divided into two groups if they received supplemental feedings or not (yes or no). If supplemental feedings were given, the group was further divided into what method was used (SNS at breast, syringe, SNS via finger, cup, bottle, other). For question 2c, the groups were divided into three groups based on the number of in-hospital lactation consultations (0, 1, >1). In exploring the evidence for an association between the number of in-hospital lactation consultations, an ordinal independent variable, and sustained breastfeeding, the Armitage-Mantel Test was applied to assess evidence of a trend. Although SPSS does not directly perform the Armitage-Mantel Test [also referred to as the Cochran-Armitage-Mantel Test], it does provide results from the Linear-by-Linear Association Test for R-by-C contingency tables. When one table variable is dichotomous and the other is ordinal, the chi-square test statistic from the Linear-by-Linear Test differs from the test statistic of the Armitage-Mantel Test only by a factor of (N-1)/N. For "large" sample sizes, the effect of this factor on the resulting p-value is minimal. For smaller sample sizes, the reciprocal of the factor can be applied to the Linear-by-Linear test statistic in order to obtain the Armitage-Mantel test statistic. In turn, that modified test statistic can be used to identify the Armitage-Mantel Test's p-value from a chi-square distribution with 1 degree of freedom. To address question 2d, the mother infant dyads were divided into two groups based on late preterm (35-36 6/7 weeks gestation) versus early term (37-37 6/7 weeks gestation) status and the proportions of dyads that sustain breastfeeding at 1 and 2 months of age was estimated for each group and compared between them. For question

2e, the groups were divided into appropriate nominal or ordinal categories for each of the maternal demographic data subvariables (maternal age, education, race, previous breastfeeding experience, and birth of a previous late preterm or early term infant). The groups were divided into appropriate nominal or ordinal categories for each of the infant's demographic data and hospital course subvariables (sex, singleton status, gestational age, birth weight, classification (AGA, SGA, LGA), phototherapy exposure, hypoglycemia, and the infant's weight loss percentage). For question 2f, the groups were divided into nominal categories for each of the subvariables describing characteristics of the birth process (method of delivery, epidural use, magnesium sulfate exposure). For question 2g, groups were divided into nominal categories for each of the subvariables describing in-hospital feeding practices (maternal feeding choice, time of first feeding, practice of skin to skin contact, breastfeeding assessment score, and use of a pacifier, breastpump, nipple shield, and/or hand expression).

Within the sub samples defined by each grouping, the proportions of dyads who sustain breastfeeding at 1 and 2 months of life was calculated along with the standard errors and 95% confidence intervals. This analysis was appropriate as a method to describe how sustained breastfeeding did and did not vary relative to these different characteristics or events. Calculating both differences in proportions and contingency table testing summarized variation in proportions between groups. Additionally, statistical testing via the Pearson Chi-Square test was conducted to describe the strength of the association that sustained breastfeeding varies relative to these variables. This analysis was appropriate for analyzing potential relationship of the dependent variable to a set of independent variables and met the assumptions of the test.

Research Question #3: Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of post-discharge lactation support differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

To address research question #3, data analysis was similar to the approach in question #2. The proportion of mother/infant dyads that sustain breastfeeding at 1 and 2 months of life was divided into two groups, those that received post discharge support and those that did not. The groups were compared using both differences in proportions and contingency table testing. A Pearson Chi-Square test was applied to evaluate the strength of the available evidence in supporting differences in proportions at the target population level rather than just within the study sample. In addition, the independent variable of post discharge lactation support was coded on an ordinal basis (0,1, >1 sessions) and the Armitage-Mantel Test was applied to assess evidence of a trend in the proportion of dyads that sustain breastfeeding relative to greater exposure to lactation support. Lactation support can include support group, lactation visits or calls by counselors and extra visits to the pediatrician for feeding assistance.

Additional data collected at 1 and 2 months of age regarding the dependent variable of sustained breastfeeding will be analyzed in future secondary analysis using descriptive statistics that will build clinical insight for further work with this population. All statistical tests related to Research Questions 2 and 3 were performed using a 5% level of significance.

Summary

This study is aimed at providing evidence that supported practice and guide education for nursing and lactation personnel working with women who are breastfeeding their late preterm and early term infant. The risks were minimal and the independent researcher limited the

subject's potential for coercion to participate in the study as the primary investigator was the only person allowed to obtain informed consent of the subjects and be the person conducting the telephone structured interview at 1 and 2 months of age. The prospective design of the pilot, cohort correlational study may yield longer term information on the impact lactation interventions and support has in this population. This long term evidence is currently not available and practice has been inferred from research with term infants. In addition, the data on alternative methods for supplementation is lacking in this population and several methods are in use in this institution. Identifying what methods are indicative of sustained breastfeeding was helpful.

This chapter presented the methods planned for use in this research study including purpose, design, target population and sampling selection, instrument validity and reliability, data collection strategies, and the data analysis plan. The results of the data analysis are presented in Chapter 4.

CHAPTER 4: RESULTS

Introduction

Subjects were recruited between September 6, 2013 and March 6, 2014 when the maximum number of subjects, 125 that had been approved by the Institution Review Board, had been reached. There were 10 days during which the researcher was unavailable, during which time subject recruitment did not occur. Follow up structured interview phone calls were conducted during the entire recruitment period and continued for the next two months as planned. During this time frame, there were 179 mothers of infants born at 35-37 6/7 weeks gestation and planning to breastfeed, and therefore eligible for inclusion in the study. One potential subject was excluded due to the identification of neonatal anomalies. There were six subjects excluded due to their infants being in the NICU at the time of the mother's discharge (2), mothers being less than 18 years old (3), and being non English or non Spanish speaking (1). The sample included 11 mothers of twins and 114 mothers of singletons who consented. The remaining 27.7% of the eligible subjects (48) did not consent to participate. At 1 month, the 11.2% attrition rate resulted in a sample size of 111 subjects. At 2 months, the 16.8% attrition rate yielded a sample size of 104 subjects. Although attrition was anticipated, the concern that the sample would change over time and therefore be biased, a sensitivity analysis was conducted in which, all the noncompleters were treated as having unsustained breastfeeding. Data for the original and secondary analysis were entered into SPSS using the codebook identified in Appendix C-1. Results of the data analysis are presented according to each research question.

Sample Description

The demographic characteristics of the mothers in the sample are identified in Table 1. The majority of the sample consisted of mothers in their 20's and 30's, with the majority (54.4%)

being Caucasian and representative percentages in Hispanic (16.8%), African American (13.6%), and Asian (12.8%) races. Regarding the level of education, the subjects were primarily college educated (some college 8% and completed college 48%). About half the subjects had breastfeeding experience (51.2%), had other children (52%), but more than three quarters (75.2%) had never had a late preterm or early term infant before.

Table 1. Maternal Sample Characteristics for Mothers of Breastfeeding Infants 35-37 6/7 weeks Gestation

Characteristic	Full Sample (*n*=125)	Completers 1 month (*n*=111)	Noncompleters 1 month (*n*=14)	Completers 2 months (*n*=104)	Noncompleters 2 months (*n*=21)
Maternal Age					
18-20	1.6% (2)	0.9% (1)	7.1% (1)	1% (1)	4.8% (1)
21-29	37.6%(47)	36% (40)	50% (7)	36.4% (36)	52.4% (11)
30-39	57.6% (72)	60.4% (67)	35.7% (5)	61.5% (64)	38.1% (8)
40 or older	3.2% (4)	2.7% (3)	7.1% (1)	2.9% (3)	4.8% (1)
Maternal Race					
Caucasian	54.4% (68)	56.8% (63)	35.7% (5)	57.7% (60)	38.1% (8)
Hispanic	16.8% (21)	14.4% (16)	35.7% (5)	15.4% (16)	23.8% (5)
African American	13.6% (17)	12/6% (14)	21.4% (3)	10.6% (11)	28.6% (6)
Asian	12.8% (16)	13.5% (15)	7.1% (1)	14.4% (15)	4.8% (1)
Other	2.4% (3)	2.7% (3)	0% (0)	1.9% (2)	4.8% (1)
Maternal Education					
Less than High school	3.2% (4)	2.7% (3)	7.1% (1)	2.9% (3)	4.8% (1)
High school complete	4% (5)	2.7% (3)	14.3% (2)	1.9% (2)	14.3% (3)

Some College	8% (10)	9% (10)	0% (0)	9.6% (10)	0% (0)
College complete	48% (60)	52.3% (58)	14.3% (2)	52.9% (55)	23.8% (5)
Unknown education level	36.8% (46)	33.3% (37)	64.3% (9)	32.7% (34)	57.1% (12)
Primipara	48% (60)	49.5% (55)	35.7% (5)	49% (51)	42.9% (9)
Multipara	52% (65)	50.5% (56)	64.3% (9)	51% (53)	57.1% (12)
No BF experience	48.8% (61)	53.2% (59)	35.7% (5)	51.9% (54)	47.6% (10)
Have breastfed a baby before	51.2% (64)	46.8% (52)	64.3% (9)	48.1% (50)	52.4% (11)
First ET/LPT baby	75.2% (94)	73.8% (83)	78.6% (11)	75% (78)	76.2% (16)
Previous first ET/LPT baby	24.8% (31)	25.5% (28)	21.4% (3)	25% (26)	23.8% (5)

The characteristics of the infants in the sample are identified in Table 2. The sample consisted of mostly singletons (91.2%) but did include 11 sets of twins. Just more than half of the infants were males (55%), and primarily classified as appropriate for gestation age birth weight (90.4%) with one infant being small for gestational age and the remainder (n=11) being large for gestational age. Late preterm infants accounted for 34.4 % of the sample, being born at 35-36 6/7 weeks, while 65.6% of the infants were born at early term status in their 37th week of gestation.

Table 2. Sample Characteristics of Breastfeeding Infants born at 35-37 6/7 weeks Gestation

Characteristic	**Full Sample (*n*=125)**	**Completers 1 month (*n*=111)**	**Noncompleters 1 month (*n*=14)**	**Completers 2 months (*n*=104)**	**Noncompleters 2 months (*n*=21)**
Sex					
Female	44.8% (56)	45.9% (51)	35.7% (5)	46.2% (48)	38.1% (8)
Male	55.2% (69)	54.1% (60)	64.3% (9)	53.8% (56)	61.9% (13)
Singleton Status					
Twin	8.8% (11)	9% (10)	7.1% (1)	9.6% (10)	4.8% (1)
Singleton	91.2% (114)	91% (101)	92.9% (13)	90.4% (94)	95.2% (20)
Gestational Age					
Late Preterm (35-36 6/7 weeks)	34.4% (43)	63.1% (70)	85.7% (12)	34.6% (36)	33.3% (7)
Early Term (37 weeks)	65.6% (82)	36.9% (41)	14.3% (2)	65.4% (68)	66.7% (14)
Birthweight Classification					
Small for Gestational Age (SGA)	0.8% (1)	0.9% (1)	0% (0)	1% (1)	0% (0)
Appropriate for Gestational Age (AGA)	90.4% (113)	91.9% (102)	78.6% (11)	91.3% (95)	85.7% (18)
Large for Gestational	8.8% (11)	7.2% (8)	21.4% (3)	7.7% (8)	14.3%

Age (LGA)				(3)

Table 1 and 2 also present the characteristics of the subjects that completed the 1 month follow up (88.8%) and then the 2 month follow up (83.2%) identifying an attrition rate of 11.2% and 16.2% at 1 and 2 months respectively. The goal of having at least 100 subjects at the 2 months follow up for outcome analysis was achieved.

Analysis of Research Questions

research question #1.

What proportions of breastfeeding infants born between 35-37 6/7 weeks gestation experience sustained breastfeeding at 1 and 2 months of age?

The proportion of breastfeeding infants born between 35-37 6/7 weeks gestation that sustained any breastfeeding at 1 month out of the subjects who completed the study at 1 month was 82%, 95% CI, [0.736, 0.886]. At 2 months the proportion of sustained breastfeeding of infants who completed the study at 2 months was 71.2%, 95% CI, [0.614 0.796]. Due to the attrition of the sample over time, the percentages of sustained and unsustained breastfeeding out of the entire sample including those that had unknown outcomes at 1 and 2 months are presented in Table 3.

Table 3. Sustained Breastfeeding rates at 1 and 2 months

Breastfeeding Outcome (n = 125)	**Sustained BF**	**Unsustained BF**	**Noncompleters Unknown status**
1 Month	72.8% (91)	16% (20)	11.2% (14)
2 Months	59.2%(74)	24% (30)	16.8% (21)

research question #2a.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the pre-discharge maternal breastfeeding self-efficacy differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

For question 2a, the mother infant dyads were divided into tertiles (lowest, middle and highest thirds) based on Breastfeeding Self-Efficacy scores that range from 14-70. These data are presented in Table 4. In exploring the evidence for an association between Breastfeeding Self-Efficacy, an ordinal independent variable, and sustained breastfeeding, bivariate logistic regression was applied to assess whether there was a trend in the proportion of dyads that sustain breastfeeding relative to increasing levels of Breastfeeding Self-Efficacy (BSES). There was no statistical significance for the association of BSES to sustained breastfeeding X^2=3.985 (2, 111) p=0.136 at 1 months and X^2=3.052 (2,104) p=0.217 at 2 months. However, the linear by linear association does suggest a clinical trend approaching a significant value of 2.884 (1, 111) p=0.089 at 1 month and 2.943 (1,104) p=0.086 at 2 months. This finding suggests that the highest BSES scores may be associated with sustained breastfeeding, but at what threshold on the scale makes the difference to sustained breastfeeding will require further statistical analysis.

Table 4. Breastfeeding Self-Efficacy Scores (BSES) in Relation to Sustained Breastfeeding

Predischarge BSES	**Full Sample (*n*=125)**	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=74)**	**Unsustained BF 2 months (*n*=30)**
Lowest tertile (score 14-32)	11.2% (14)	11% (10)	15% (3)	9.5% (7)	16.7% (5)
Middle Tertile (score 33-51)	45.6% (57)	39.5% (36)	60% (12)	39.2% (29)	50% (15)

Highest Tertile (score 52-70)	43.2% (54)	49.5% (45)	25% (5)	51.3% (38)	33.3% (10)

research question 2b.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of supplemental feeding and methods differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

To address the second research question, which reflects nominal level data, descriptive statistics and contingency table methods were used. The proportions of sustained breastfeeding at 1 and 2 months were estimated in sub-samples of mother/infant dyads defined by a number of variables. For question 2b, the dyads will were divided into two groups, if they received supplemental feedings or not. If supplemental feedings were given, the group was further divided into what method was used (SNS at breast, syringe, SNS via finger, cup, bottle, other, and multiple methods). Each method of supplemental feeding was then compared to the group that received no supplemental feedings and therefore no method was used. These data are presented in Table 5. There was statistical significance for supplemental feedings being associated with unsustained breastfeeding at one month X^2=8.230 (1,111) p=0.004 and at two months X^2=8.166 (1,104) p=0.004. In other words, those subjects whose infants were not given supplemental feedings are more likely to sustain breastfeeding at 1 and 2 months (p=0.004).

Examining which methods for supplemental feedings were more associated with sustained breastfeeding was originally analyzed via contingency tables and resulted in a Pearson X^2=10.838 (5, 111) p=0.055. Since these methods were nominal in nature, it was appropriate then to analyze each method in relation to having received no supplemental feeding. The sample size in this pilot study did not support a multiple regression analysis unfortunately.

Since only two cases use of the supplemental nursing system (SNS) at the breast as their only method of supplemental feeding, a chi square was unable to be calculated at 1 month, but at 2 months, the results were X^2=3.642 (1, 29) p=0.056, not significant. Having received no supplemental feedings was found to be statistically significant for association with sustained breastfeeding when compared to use of an oral syringe for supplemental feeding (X^2=6.183 (1, 53) p=0.013) at one month and (X^2=4.139 (1, 51) p=0.042) at two months. Again, comparing SNS/finger feeding method only with no supplemental feedings given, results showed no significance. Having just 2 cases didn't result in any value at one month and found no significance at 2 months X^2=0.159 (1, 29), p=0.69. Using a bottle as the only method for supplemental feeding compared to no supplemental feeding given resulted in X^2=6.972 (1, 41), p=0.008 at 1 month and X^2=6.621 (1, 39), p=.01 at 2 months. This would mean that infants who didn't receive supplemental feedings compared to those that did receive them via bottle are more likely to sustain breastfeeding. Likewise, it appears the same is true with use of multiple methods for supplemental feedings versus receiving no supplemental feedings. The results of X^2=9.920 (1, 69) p=0.002 at 1 month and X^2=8.785 (1, 64) p=0.004 at 2 months suggest that infants who don't receive supplemental feedings are more likely than those that use multiple methods to provide supplemental feedings to sustain breastfeeding at 1 and 2 months.

Table 5. Supplemental Feedings and Methods

	Full Sample (*n*=125)	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=74)**	**Unsustained BF 2 months (*n*=30)**
Supplemental Feedings given	76.8% (96)	69.2% (63)	100% (20)	66.2% (49)	93.3% (28)
No supplemental feedings	23.2%(29)	30.8% (28)	0% (0)	33.8% (25)	6.7% (2)

given/No methods used					
Method	(*n*=96)	(*n*=63)	(*n*=13)	(*n*=49)	(*n*=28)
SNS at breast only method	1.6% (2)	2.2% (2)	0% (0)	2% (1)	3.6% (1)
Syringe only method	23.2% (29)	22% (20)	25% (5)	34.7% (17)	25% (7)
SNS via finger only method	1.6% (2)	2.2% (2)	0% (0)	24.1% (2)	0% (0)
Cup only method	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Bottle only method	16% (20)	11% (10)	15% (3)	14.3% (7)	17.9% (5)
Multiple Methods	34.4% (43)	31.9% (29)	60% (12)	44.9% (22)	53.6% (15)

research question #2c.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, does in-hospital lactation consultations differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

For question 2c, the groups were divided into three groups based on the number of in-hospital lactation consultations (0, 1, >1). In exploring the evidence for an association between the number of in-hospital lactation consultations, an ordinal independent variable, and sustained breastfeeding, the Armitage-Mantel Test was applied to assess evidence of a trend. The data is presented in Table 6. Although 72% of the subjects received more than 1 consult during their hospitalization, there was no statistically significant association between in hospital lactation consults and sustained breastfeeding at 1 month (X^2=0.480 (2,111) p=0.786) and at 2 months (X^2=1.509 (2, 104), p=0.470). There also was no correlation for sustained breastfeeding with the

trend of increased lactation support as evidenced by higher numbers of consults. The linear by linear result was 0.221 (1, 111), p=0.638 at 1 month and 1.509 (2, 104), p=0.247 at 2 months. Of note, regarding the four subjects who received no in-hospital lactation consultation, two sustained breastfeeding at 1 and 2 months, and two did not complete the study at 1 month and therefore has an unknown outcome. Further case analysis focusing on feeding scores, Breastfeeding Self-Efficacy, and post discharge support of those two subjects who sustained breastfeeding despite receiving no official lactation consultation in the hospital could yield better understanding of this phenomena, although in a very small sample.

Table 6. In Hospital Lactation Support In Relation to Sustained Breastfeeding

	Full Sample (*n*=125)	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=74)**	**Unsustained BF 2 months (*n*=30)**
0 consults	3.2% (4)	2.2% (2)	0% (0)	2.7% (2)	0% (0)
1 consults	24.8% (31)	26.4% (24)	25% (5)	27% (20)	20% (6)
>1 consults	72% (90)	71.4% (65)	75% (15)	70.3% (52)	80% (24)

research question #2d.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the late preterm vs early term status differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

To address question 2d, the mother infant dyads was divided into two groups based on late preterm (35-36 6/7 weeks gestation) versus early term (37-37 6/7 weeks gestation) status and

the proportions of dyads that sustain breastfeeding at 1 and 2 months of age was estimated for each group and compared between them. The data for these two variables is presented in Table 7. There was no statistical significance to suggest a difference in sustained breastfeeding between late preterm or early term status at 1 month (X^2= 0.098 (1,111), p=0.754) and at 2 months (X^2= 1.416 (1, 104), p-0.234).

Table 7. Late Preterm versus Early Term Status In Relation to Sustained Breastfeeding

	Full Sample (*n*=125)	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=74)**	**Unsustained BF 2 months (*n*=30)**
Late Preterm (35-36 6/7 weeks)	34.4% (43)	36.3% (33)	40% (8)	31.1% (23)	43.3% (13)
Early Term (37 -37 6/7 weeks)	65.6% (82)	63.7% (58)	60% (12)	68.9% (51)	56.7% (17)

research question #2e.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the maternal and infant demographic data and hospital course differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

For question 2e, the groups were divided into appropriate nominal or ordinal categories for each of the maternal demographic data subvariables (maternal age, education, race, previous breastfeeding experience, and birth of a previous late preterm or early term infant. These data are presented in Table 8. There was no statistically significant association between maternal age and

sustained breastfeeding (X^2=0.986 (3, 111) p=0.805) at 1 month and (X^2=2.710 (3, 104) p=0.439) at 2 months. When analyzing the level of maternal education as an ordinal variable, not including the subjects with an unknown level of education, the results showed no significant association with sustained breastfeeding at one month (X^2=2.668 (3, 74) p=0.440 with a linear association of p=0.139. By two months however, the evidence showed a trend toward sustained breastfeeding and higher levels of education (X^2= 5.260 (3, 74) p=0.154) with a linear by linear association of p=0.024. However, when including the unknown level of education data, the results showed a Pearson X^2=2.646 (4,111) p=0.619 at 1 month and X^2=5.919 (4,104) p=0.205, both not statistically significant for an association. There was no significant association between maternal race and sustained breastfeeding (X^2=4.525 (4,111) p=0.340) at 1 month and (X^2= 5.143 (4, 104) p=0.273) at 2 months. However, looking at the raw data, there is the inclination to think that Asian (86.7%) and African American (81.9%) subjects were more likely to sustain breastfeeding at 2 months than Caucasian (68.3%) and Hispanic (56.3%), but due to small cell sizes from the sample breakdown, it was not significant. The sustained breastfeeding potential in African American mothers is different than the current literature suggests. Subjects who had breastfeeding experience were no more likely than those without breastfeeding experience to sustain breastfeeding (X^2=1.375, (1,111) p=0.241) at 1 month and (X^2=2.199 (1,104) p=0.138) at 2 months. Notably, there was no data collected on the previous breastfeeding experience, just that the mother had breastfed previously. Lastly, having a previous late preterm or early term infant showed no association with sustained breastfeeding either (X^2=0.353 (1,111) p=0.552) at 1 month and (X^2=0.062 (1,104) p=0.803) at 2 months.

Table 8. Maternal Characteristics In Relation to Sustained Breastfeeding

Characteristic	Full Sample (*n*=125)	Sustained BF 1 month (*n*=91)	Unsustained BF 1 month (*n*=20)	Sustained BF 2 months (*n*=74)	Unsustained BF 2 months (*n*=30)
Maternal Age					
18-20	1.6% (2)	1.1% (1)	0% (0)	1.4% (1)	0% (0)
21-29	37.6%(47)	35.2% (32)	40% (8)	31.1% (23)	43.3% (13)
30-39	57.6% (72)	60.4% (55)	60% (12)	63.5% (47)	56.7% (17)
40 or older	3.2% (4)	3.3% (3)	0% (0)	4.1% (3)	% (0)
Maternal Race					
Caucasian	54.4% (68)	52.7% (48)	75% (15)	55.4% (41)	63.3 % (19)
Hispanic	16.8% (21)	14.3% (13)	15% (3)	12.2% (9)	23.3% (7)
African American	13.6% (17)	14.3% (13)	5% (1)	12.2% (9)	6.7% (2)
Asian	12.8% (16)	15.4% (14)	5% (1)	17.6% (13)	6.7% (2)
Other	2.4% (3)	3.3% (3)	0% (0)	2.7% (2)	0% (0)
Maternal Education					
Less than High school	3.2% (4)	2.2% (2)	5% (1)	1.4% (1)	6.7% (2)
High school complete	4% (5)	2.2% (2)	5% (1)	1.4% (1)	3.3% (1)
Some College	8% (10)	7.7% (7)	15% (3)	8.1% (6)	13.3% (4)
College complete	48% (60)	54.9% (50)	40% (8)	59.5% (44)	36.7% (11)
Unknown education level	36.8% (46)	33% (30)	35% (7)	29.7% (22)	40% (12)
No BF experience	48.8% (61)	50.5% (46)	65% (13)	47.3% (35)	63.3% (19)
Have breastfed	51.2% (64)	49.5% (45)	35% (7)	52.7% (39)	36.7% (11)

a baby before					
First ET/LPT baby	75.2% (94)	73.6% (67)	80% (16)	74.3% (55)	76.7% (23)
Previous ET/LPT baby experience	24.8% (31)	26.4% (24)	20% (4)	25.7% (19)	23.3% (7)

The groups were divided into appropriate nominal or ordinal categories for each of the infant's demographic data and hospital course subvariables (sex, singleton status, gestational age, birth weight, classification (AGA, SGA, and LGA), phototherapy exposure, hypoglycemia, and the infant's weight loss percentage. These data are presented in Table 9. There was no statistically significant association between sustained breastfeeding and infant gender (X^2=0.161 (1,111), p=0.688) at 1 month and (X^2=0.874 (1, 104), p=0.350) at 2 months. There was evidence approaching statistical significance for association between sustained breastfeeding and singleton status (X^2= 3.595 (1, 111) p=0.058) at 1 month and showing significance at 2 months (X^2=5.232 (1,104) p=0.022) which would mean that by 2 months of life, mothers of singletons were more likely to sustain breastfeed than mothers of twins. The late preterm or early term status showed no significant evidence as addressed in the results for question 2d. There was no statistically significant association between birth weight classification and sustained breastfeeding (X^2=0.410 (2, 111) p=0.815) at 1 month and (X^2=0.481 (2, 104) p=0.786) at 2 months. There was no statistically significant association between infants needing phototherapy and sustained breastfeeding (X^2=1.151 (1, 111) p=0.283) at 1 month and (X^2=2.129 (1, 104) p=0.144) at 2 months. There was also no statistically significant association between infants who experienced hypoglycemia and sustained breastfeeding (X^2=0.854 (1, 111) p=0.355) at 1 month and (X^2=0.098 (1, 104) p=0.755) at 2 months. Lastly, there was no statistically

significant association between infants' weight loss classification and sustained breastfeeding (X^2=1.952 (2, 111) p=0.377) at 1 month and (X^2=1.420 (2, 104) p=0.492) at 2 months.

Table 9. Infant Characteristics and Hospital Course in Relation to Sustained Breastfeeding

Characteristic	**Full Sample (*n*=125)**	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=74)**	**Unsustained BF 2 months (*n*=30)**
Sex					
Female	44.8% (56)	45.1% (41)	50% (10)	43.2% (32)	53.3% (16)
Male	55.2% (69)	54.9% (50)	50% (10)	56.8% (42)	46.7% (14)
Singleton Status					
Twin	8.8% (11)	6.6% (6)	20% (4)	5.4% (4)	20% (6)
Singleton	91.2% (114)	93.4% (85)	80% (16)	94.6% (70)	80% (24)
Gestational Age					
Late Preterm (35-36 6/7 weeks)	34.4% (43)	36.3% (33)	40% (8)	31.1% (23)	43.3% (13)
Early Term (37 weeks)	65.6% (82)	63.7% (58)	60% (112)	68.9% (51)	56.7% (17)
Birthweight Classification					
Small for Gestational Age (SGA)	0.8% (1)	0.1% (1)	0% (0)	1.4% (1)	0% (0)
Appropriate for Gestational	90.4% (113)	91.2% (83)	95% (19)	90.5% (67)	93.3% (28)

Age (AGA)					
Large for Gestational Age (LGA)	8.8% (11)	7.7% (7)	5% (1)	8.1% (6)	6.7% (2)
Phototherapy exposure (PT)	6.4% (8)	5.5% (5)	0% (0)	6.8% (5)	0% (0)
No PT exposure	93.6% (117)	94.5% (86)	100% (20)	93.2% (69)	100% (30)
Hypoglycemia occurred	10.4% (13)	12.1% (11)	5% (1)	12.2% (9)	10% (3)
No Hypoglycemia occurred	89.6% (112)	87.9% (80)	95% (19)	87.8% (65)	90% (27)
Percent weight loss classification (less than 7%)	57.6% (72)	54.9% (50)	70% (14)	54.1% (40)	60% (18)
Percent weight loss classification (7-9.9%)	28% (35)	29.7% (27)	15% (3)	31.1% (23)	20% (6)
Percent weight loss classification (>10%)	14.4% (18)	15.4% (14)	15% (3)	14.9% (11)	20% (6)

research question #2f.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the characteristics of birth process differ between those who experienced sustained breastfeeding at 1 month or 2 months of age and those who do not?

For question 2f, the groups were divided into nominal categories for each of the subvariables describing characteristics of the birth process (method of delivery, epidural use,

magnesium sulfate exposure). These data are presented in Table 10. There was no statistically significant association between method of delivery and sustained breastfeeding (X^2= 0.242 (1, 111) p=0.623) at 1 month and (X^2= 1.128 (1, 104) p= 0.288) at 2 months. There also was no statistically significant association between subjects who received epidural or spinal anesthesia and sustained breastfeeding (X^2 =2.957 (1, 111) p= 0.086) at 1 month and (X^2 =2.339 (1, 104) p= 0.126) at 2 months. Lastly, there was no statistical association between exposure to magnesium Sulfate and sustained breastfeeding (X^2 =0.017 (1, 111) p= 0.897) at 1 month and (X^2 =0.015 (1, 104) p= 0.903) at 2 months. Of note, the epidural rate of 90.4% and the caesarean section rate of 47.2% suggest these interventions to be very common in this group.

Table 10. Characteristics of Birth Process In Relation to Sustained Breastfeeding

Characteristic	**Full Sample (*n*=125)**	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=104)**	**Unsustained BF 2 months (*n*=30)**
Vaginal Delivery	52.8% (66)	56% (51)	50% (10)	54.8% (57)	46.7% (14)
Caesarean Section	47.2% (59)	44% (40)	50% (10)	45.2% (47)	53.3% (16)
Epidural/Spinal Anesthesia	90.4% (113)	86.8% (79)	100% (20)	89.4% (93)	96.7% (29)
No Epidural/Spinal	9.6% (12)	13.2% (12)	0% (0)	10.6% (11)	3.3% (1)
MgSO4 post delivery	9.6% (12)	11% (10)	10% (2)	10.6% (11)	10% (3)
No MgSO4 given	90.4% (113)	89% (81)	90% (18)	89.4% (93)	90% (27)

research question #2g.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, do in-hospital feeding practices differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

For question 2g, groups were divided into nominal categories for each of the subvariables describing in-hospital feeding practices including: maternal feeding choice (exclusive or partial breastfeeding), time of first feeding (first hour or first four hours), practice of skin to skin contact day 2 on, breastfeeding assessment score on day 1 and day 2 on, and use of a pacifier, use of breastpump (early and at discharge), use of nipple shield, use of hand expression and maternal-newborn separation. The data is reported in Table 11.

There was no statistical significance for the association of the initial plan of feeding with sustained breastfeeding (X^2=1.011 (1,111) p= 0.315) at 1 month and (X^2=1.097 (1,104) p=0.295) at 2 months. There also was no statistical significance for an association between sustained breastfeeding and breastfeeding within the first hour of birth (X^2=0.104 (1,111) p= 0.747) at 1 month and (X^2=1.011 (1,104) p=0.917) at 2 months. Likewise, there was no statistical significance for an association between sustained breastfeeding and breastfeeding within the first four hours of birth (X^2=0.029 (1,111) p= 0.864) at 1 month and (X^2=0.062 (1,104) p=0.803) at 2 months. There was no statistical significance for an association with sustained breastfeeding and skin to skin contact at 1 month (X^2=2.754 (1,111) p= 0.097), but did however show statistical significance at 2 months (X^2=5.747 (1,104) p= 0.017). This supports that sustained breastfeeding is more likely to occur with mothers that practice skin to skin past the first 24 hours in the hospital. High day 1 Via Christi breastfeeding assessment scores approach

statistically significant association with sustained breastfeeding at 1 month (X^2=3.462 (1,111) p=0.063. At 2 months, high day 1Via Christi breastfeeding assessment scores show significance for an association with sustained breastfeeding (X^2=6.738 (1, 104) p= 0.009). Additionally, high day 2 on Via Christi breastfeeding assessment scores show significance for very likely association with sustained breastfeeding at both 1 month (X^2=14.876 (1, 111) p= 0.000) and 2 months (X^2=8.288 (1, 104) p= 0.004). There was no statistically significant association between pacifier use and sustained breastfeeding (X^2=0.008 (1, 111) p= 0.930) at 1 month and (X^2=0.258 (1, 104) p= 0.611) at 2 months. At 1 month, there is no statistically significant association between early breast pumping (within the first 24 hours) and sustained breastfeeding (X^2=2.116 (1, 111) p= 0.146) or at 2 months (X^2= 2.498 (1,104) p=0.114.

Clinicians could cite that since early pumping wasn't associated with sustained or unsustained breastfeeding, then perhaps having the mother start pumping early to preserve lactogenesis may be beneficial. In comparison to pumping within the first 24 hours, subjects that were breast pumping at discharge were more likely to stop breastfeeding as evidenced by statistically significant values at 1 month (X^2=7.954 (1, 111) p= 0.005) and at 2 months (X^2=7.906 (1, 104) p= 0.005), compared to those that weren't pumping at discharge. Regarding use of a nipple shield in the hospital, results showed no association between use of the nipple shield and sustained breastfeeding at 1 month (X^2=1.236 (1,111) p=0.266). However, at 2 months, there was a significant association with sustained breastfeeding and not using a nipple shield during their hospital stay (X^2=6.619 (1,104) p=0.010). This might suggest that women who had to use a nipple shield in the hospital were less likely to sustain breastfeeding their infant for the longer term. There was no statistically significant association between practicing hand expression and sustained breastfeeding (X^2=2.001 (1,111) p= 0.157) at 1 month and (X^2=0.668

(1,104) p=0.414) at 2 months. Likewise, maternal newborn separation as identified as being longer than one hour at a time wasn't associated with sustained breastfeeding with results of X^2=0.453 (1,111) p= 0.501 at 1 month and X^2=0.414 (1,104) p=0.520 at 2 months.

Table 11. In Hospital Feeding Practices In Relation to Sustained Breastfeeding

Feeding Practice	**Full Sample (*n*=125)**	**Sustained BF 1 month (*n*=91)**	**Unsustained BF 1 month (*n*=20)**	**Sustained BF 2 months (*n*=104)**	**Unsustained BF 2 months (*n*=30)**
Initial plan: Exclusive Breastfeeding	74.4% (93)	80.2% (73)	70% (14)	82.4% (61)	73.3% (22)
Initial Plan: Partial Breastfeeding	25.6% (32)	19.8% (18)	30% (6)	17.6% (13)	26.7% (8)
First attempt to BF Within 1 hr of birth	70.4% (88)	71.4% (65)	75% (15)	74.3% (55)	73.3% (22)
No attempt to BF within 1 hr of birth	29.6% (37)	28.6% (26)	25% (5)	25.7% (19)	26.7% (8)
First attempt to BF Within 4 hrs of birth	89.6% (112)	91.2% (83)	90% (18)	91.9% (68)	93.3% (28)
No attempt to BF within 4 hrs of birth	10.4% (13)	8.8% (8)	10% (2)	8.1% (6)	6.7% (2)
Skin to Skin day 2 on	86.4% (108)	89% (81)	75% (15)	93.2% (69)	76.7% (23)
No Skin to Skin day 2 on	13.6% (17)	11% (10)	25% (5)	6.8% (5)	23.3% (7)
Via Christi Score first 24 hours 7 or less	42.4% (53)	37.4% (34)	60% (12)	32.4% (24)	60% (18)
Via Christi Score first 24 hours 8-10	57.6% (72)	62.6% (57)	40% (8)	67.6% (50)	40% (12)

Highest Via Christi Score 7 or less in 25 hours to discharge	17.6% (22)	9.9% (9)	45% (9)	8.1% (6)	30% (9)
Highest Via Christi Score 8-10 in 25 hours to discharge	82.4% (103)	90.1% (82)	55% (11)	91.9% (68)	70% (21)
Pacifier used in hosp	24.8% (31)	20.9% (19)	20% (4)	18.9% (14)	23.3% (7)
No pacifier used in hosp	75.2% (94)	79.1% (72)	80% (16)	81.1% (60)	76.7% (23)
Began pumping first 24 hrs.	40% (50)	37.4% (34)	55% (11)	37.4% (27)	53.3% (16)
Did not pump during first 24 hours	60% (75)	62.6% (57)	45% (9)	63.5% (47)	46.7% (14)
Pumping at discharge	70.4% (88)	62.6% (57)	95% (19)	62.2% (46)	90% (27)
Not pumping at discharge	29.6% (37)	37.4% (34)	5% (1)	37.8% (28)	10% (3)
Nipple shield used	24% (30)	23.1% (21)	35% (7)	18.9% (14)	43.3% (13)
No Nipple shield used	76% (95)	76.9% (70)	65% (13)	81.1% (60)	56.7% (17)
Hand expression practiced	85.6% (107)	82.4% (75)	95% (19)	83.8% (62)	90% (27)
No hand expression practiced	14.4% (18)	17.6% (16)	5% (1)	16.2% (12)	10% (3)
Maternal Newborn Separation occurred	28% (35)	27.5% (25)	35% (7)	27% (20)	33.3% (10)
No Maternal newborn separation occurred	72% (90)	72.5% (66)	65% (13)	73% (54)	66.7% (20)

research question #3.

Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of post-discharge lactation support differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

To address research question #3, data analysis was similar to the approach in question #2. The proportion of mother/infant dyads that sustained breastfeeding at 1 and 2 months of life was divided into two groups, those that received post discharge support and those that did not. The groups were compared using both differences in proportions and contingency table testing. A Pearson Chi-Square test was applied to evaluate the strength of the available evidence in supporting differences in proportions at the target population level rather than just within the study sample. In addition, the independent variable of post discharge lactation support was coded on an ordinal basis (0,1, >1 sessions) and the Armitage-Mantel Test was applied to assess evidence of a trend in the proportion of dyads that sustain breastfeeding relative to greater exposure to lactation support. Lactation support can include support group, lactation visits or calls by counselors and extra visits to the pediatrician for feeding assistance. The frequency data is presented in Table 12. There was no significant association with post discharge lactation support and sustained breastfeeding with results of X^2=0.452 (2,111) p=0.798 at 1 month. The linear by linear association of 0.057 and p=0.811 at 1 month indicates no trend with sustained breastfeeding and more post discharge lactation support. At 2 months, the results showed no association or trend again (X^2=0.016 (2,104) p=0.992 with linear by linear association of p=0.900).

Table 12. Post Discharge Lactation Support in relation to Sustained Breastfeeding

	Full Sample (*n*=125)	Sustained BF 1 month (*n*=91)	Unsustained BF 1 month (*n*=20)	Sustained BF 2 month (*n*=74)	Unsustained BF 2 months (*n*=30)
0 home support	44% (55)	50.5% (46)	45% (9)	48.6% (36)	50% (15)
1 session	13.6% (17)	14.3% (13)	20% (4)	13.5% (10)	13.3% (4)
>1 session	31.2% (39)	35.2% (32)	35% (7)	37.8% (28)	36.7% (11)
Unknown	11.2% (14)				

Sensitivity Analysis

In order to address whether the statistically significant findings for factors associated with sustained breastfeeding was true or a product of the attrition in the sample over the two months prospective data collection, a sensitivity analysis was done for each of those factors. Assuming the noncompleters did not sustain breastfeeding, the sensitivity analysis would use the worse case scenario and determine if the variables were still statistically significant at 1 and 2 months. The results for the significant associated factors before the attrition rate is included and the results for the sensitivity analysis are presented in Table 13.

The higher the subject's level of education in the original analysis didn't show statistically significant results. However, after the sensitivity analysis, the results showed a statistically significant (p=0.014) association with sustained breastfeeding at 2 months and a college complete level of education. This would seem reasonable in that those that have higher education may be more knowledgeable of the health benefits for the mother and infant and be

inclined to breastfeed longer. Higher Breastfeeding Self-Efficacy scores were found to be statistically significant (p=0.046) with sustained breastfeeding at 2 months after the sensitivity analysis was conducted. This would mean that some of the noncompleters had low Breastfeeding Self-Efficacy scores. The significant findings having received supplemental feedings and unsustained breastfeeding were reinforced by the sensitivity analysis (p=0.001).

Originally, singletons were more likely to sustain breastfeeding at 2 months, but the sensitivity analysis did not support this finding (p=0.107). The practice of skin to skin on day 2 or later was significant (p=0.007) at 2 months in the sensitivity analysis, but was significant at both 1 and 2 months originally. High breastfeeding assessment scores for day 1 and day 2 or later remained statistically significant at 1 month (p=0.007) and 1 (p=0.000) and 2 months (p=0.001) respectfully. Breastpumping at discharge was associated with unsustained breastfeeding in the original analysis and remained significant associated at 1 (p=0.002) and 2 months (p=0.015) in the sensitivity analysis. However, the use of the nipple shield being originally suggested an association with unsustained breastfeeding at 2 months, was found not to be significant with the sensitivity analysis (0.109).

Table 13. Factors Associated with Sustained Breastfeeding after Sensitivity Analysis

Factors Associated with Sustained Breastfeeding (SBF) or Unsustained BF (UBF) *=Significant p-value	1 month Pearson X^2 Results before Sensitivity Analysis *n*=111	1 month Linear by Linear Association before Sensitivity Analysis (if applicable) *n*=111	1 month Pearson X^2 Results Sensitivity Analysis *n*=125	1 month Linear by Linear Association Sensitivity Analysis (if applicable) *n*=125	2 months Pearson X^2 Results before Sensitivity Analysis *n*=104	2 months Linear by Linear Association before Sensitivity Analysis (if applicable)	2 months Pearson X^2 Results Sensitivity Analysis *n*=125	2 months Linear by Linear Association Sensitivity Analysis (if applicable) *n*=125

						n=104		
Education and Sustained Breastfeeding (SBF)	2.646 (4) p=0.619	---	8.504 (4) p=0.075	---	5.919 (4) p=0.205	---	12.546 (4) p=0.014 *	---
BSES (Breastfeeding Self-Efficacy Score) and SBF	3.985 (2) p=0.136	2.884 (1) p=0.089	5.715 (2) p=0.057	3.138 (1) p=0.076	3.052 (2) p=0.217	2.943 (1) p=0.086	4.915 (2) p= 0.086	3.987 (1) p=0.046 *
Supplemental Feeding (SF) and Unsustained BF (UBF)	8.230 (1) p=0.004 *	---	10.758 (1) p=0.001 *	---	8.166 (1) p= 0.004 *	---	11.402 (1) p=0.001 *	---
Singleton status and SBF	3.595 (1) p=0.058	---	2.030 (1) p=0.154	---	5.232 (1) p=0.022 *	---	2.604 (1) p=0.107	---
Skin to Skin practice Day 2 or later and SBF	2.754 (1) p=0.017 *	---	1.941 (1) p=0.164	---	5.747 (1) p=0.017 *	---	7.228 (1) p=0.007 *	---
High BF Assessment Score Day 1 and SBF	3.462 (1) p=0.017 *	---	3.476 (1) p-0.062	---	6.738 (1) p=0.009 *	---	7.378 (1) p=0.007 *	---
High BF Assessment Score Day 2 on and SBF	14.876 (1) p=0.000 *	---	13.713 (1) p=0.000 *	---	8.288 (1) p=0.004 *	---	11.268 (1) p=0.001 *	---
Pumping at discharge and UBF	7.954 (1) p=0.005 *	---	9.674 (1) p=0.002 *	---	7.906 (1) p=0.005 *	----	5.907 (1) p= 0.015 *	---
Nipple Shield Use and UBF	1.236 (1) p=0.266	---	0.156 (1) p=0.693	---	6.619 (1) p=0.010	---	2.567 (1) p=0.109	---

					*			

Summary

In summary, the following results were found for each research question. The answer to research question 1 found that of breastfeeding infants born between 35- 37 6/7 weeks gestation, 82% experienced sustained breastfeeding at 1 month, and 71.2% experienced sustained breastfeeding at 2 months. Assuming the worse case scenario by counting those that didn't complete the study as having stopped breastfeeding, those sustained breastfeeding rates changed to 72.8% at 1 month and 59.2% at 2 months.

Analysis addressing question 2a suggest that those breastfeeding infants who sustain breastfeeding at 1 and 2 months approached statistical significance for higher Breastfeeding Self-Efficacy scores, indicating a clinical trend that higher scores result in sustained breastfeeding. The sensitivity analysis supported this theory with significant findings at 2 months for sustained breastfeeding and higher Breastfeeding Self-Efficacy Scores. Analysis for questions 2b addressed the use of supplemental feeding and various methods to provide such feedings and found significance for supplemental feedings being associated with unsustained breastfeeding at 1 and 2 months. Compared to no supplemental feeding methods being used, methods such as bottle only, syringe only, and multiple methods all were significantly associated with unsustained breastfeeding at 1 and 2 months. However, to truly understand the phenomena of what method was best, a multiple regression analysis would be necessary and the sample size doesn't support this. Analysis for question 2c found there was no significance for association between the amount of in hospital lactation consultations and sustained breastfeeding. Likewise, analysis for question 2d found no significance for association of the infant's late preterm versus early term status and sustained breastfeeding. Question 2e analysis found that maternal demographics

found significant association of higher education with sustained breastfeeding at 2 months when it was analyzed as an ordinal variable without including the nearly 37% of the sample with unknown level of education. The linear by linear association value was 5.104 (1,70) p=0.024 suggested an association with a higher level of education and sustained breastfeeding at 2 months. However, when including the subjects with unknown level of education, the nominal variable analysis was X^2=2.646 (4,111) p=0.619 at 1 month and X^2=5.919 (4, 104) p=0.205 at 2 months, indicating no association with higher education and sustained breastfeeding. Further, when accounting the noncompleters as subjects that did not sustain breastfeeding in the sensitivity analysis, subjects with a college education was found to be statistically significant with sustained breastfeeding at 2 months (p=0.014).

There were no statistically significant results for race, but the raw data is suggestive of increased rates in the Asian and African American population. No significant results were found for maternal age, previous breastfeeding experience and birth of a previous late preterm or early term infant subvariables. Infant demographic analysis resulted in a p-value that is near, but did not fall below the threshold for statistical significance for singletons more than twins to sustain breastfeeding at 1 month and significance with sustained breastfeeding at 2 months. However, when including the noncompleters in the sensitivity analysis, there was no significant association. No significance was found for infant gender, birth weight classification, phototherapy exposure, hypoglycemia, and infant's weight loss percentage.

Question 2f found no significant association with any characteristics of the birth process (method of delivery, epidural use, magnesium sulfate exposure) and sustained breastfeeding at 1 and 2 months in this population. Analysis for questions 2g found significant results for skin to skin being practiced on day 2 on and sustained breastfeeding at 2 months, but not at 1 month.

There were significant results for higher breastfeeding assessment scores on day 1 being associated with sustained breastfeeding at 2 months and this was reinforced with significant findings in the sensitivity analysis at 2 months. Higher breastfeeding assessment scores on day 2 or later were found to be associated with sustained breastfeeding at 1 and 2 months both in the original analysis and the sensitivity analysis. Subjects who were not using a breastpump at discharge were more likely to have sustained breastfeeding at 1 and 2 months again in the original analysis and in the sensitivity analysis. Early breastpumping within the first 24 hours was not found significant in the original or sensitivity analysis.

The finding that the non-use of a nipple shield in the hospital was significantly associated with sustained breastfeeding at 2 months, indicated the clinical concern that long term breastfeeding could be decreased by implementing this nipple shield intervention. However, sensitivity analysis found no association between nipple shield use and sustained breastfeeding. There was no statistical significance found for association of sustained breastfeeding with maternal feeding plan, time of first feeding (first 1 or 4 hours), use of a pacifier, hand expression and maternal newborn separation subvariables.

Results addressing question 3 found no significant association between sustained breastfeeding in infants 35 – 37 6/7 weeks gestation and post discharge lactation support. It would be suggested then, that infants have a higher risk of stopping breastfeeding or a worse prognosis for sustained breastfeeding if they had lower breastfeeding self-efficacy, low breastfeeding assessment scores on day 1 and day 2 on, were breastpumping at discharge, had received supplemental feedings in the hospital, and had not been practicing skin to skin on day 2 or later in the hospital. Additional concerns could be if the mother had a high school or lower education. Further analysis is required to make a recommendation regarding the methods of

supplemental feedings to be used. Further discussion on these findings will be presented in Chapter 5.

CHAPTER 5: DISCUSSION

Introduction

The results of this investigation will be discussed in relation to the variables as they were presented in the Review of the Literature . After explaining how the completers and noncompleters compared and some study site practice changes that occurred during the study period, discussion on the theoretical framework of Breastfeeding Self-Efficacy and its tool of measurement will be presented as it has implications for use in practice. Results related to the other variables of breastfeeding outcomes specific to the late preterm and early term infant, lactation support, and supplemental feeding methods will be discussed thoroughly. Finally, limitations of the study and implications for future practice, research and staff education will be presented.

Completer and Noncompleters Comparison

The samples of completers and noncompleters at both 1 and 2 months were compared for maternal age, late preterm or early term status, education, race, breastfeeding experience, previous late preterm infant experience, infant gender, singleton status and birth weight classification. Finding no difference in demographics between these two samples supports the reliability of the results before the sensitivity analysis. The only statistically significant finding comparing completers and noncompleters was related to maternal education at 1 month with a X^2=13.498 (3,111) p=0.004 and at 2 months with a X^2=14.279 (3, 104) p=0.003. Unfortunately 36.8% of the sample didn't have the maternal level of education documented in the medical record so this data was unknown and could have skewed this result. There were more college educated than high school and less than high school educated subjects in the completer category that potentially explain this significant finding. Possibly, it could be assumed that college

educated subjects would be more likely to complete a research study than those with less education. This finding was consistent with other literature linking higher education with sustained breastfeeding.

Study Site Practice Changes

During the study period, the study hospital also implemented some practice changes. Just prior to the start of the study, the study site began to admit infants born at 35 weeks gestation to the newborn nursery. The investigator was aware of this plan and the protocol that had been developed to address these infants' needs which included glucose screening, potentially early breastpumping and provision of supplemental feedings, whether they were expressed breastmilk or formula depending on the infant's needs. There was also an educational initiative, called "the sacred hour", to promote the first attempt at breastfeeding with skin to skin practiced within one hour of birth in the delivery or recovery room. Nursing staff education was provided in October, 2013 and the practice piloted in November, with protocol implementation for all infants starting in the end of December, midway through the subject recruitment process.

Theoretical Framework: Breastfeeding Self-Efficacy

The use of the Breastfeeding Self-Efficacy Theory as the theoretical framework for this study was appropriate and beneficial. Clinicians will often cite the maternal attitude toward breastfeeding as being associated with a mother's success sustaining breastfeeding. How the mother builds her Breastfeeding Self-Efficacy is related to prenatal education, self-study, and desire to want to breastfeed. Additionally, Breastfeeding Self-Efficacy scores take into account how the mother handles other challenging tasks in her life such as continuing or quitting. This contributes to her ability to persevere through the first few weeks of breastfeeding her infant, which often are challenging to a new mother. The theory was also applicable to the study

because of its development of the Breastfeeding Self-Efficacy Scale Short Form (BSES-SF). The subjects found this tool easy to complete rather quickly. This generation of mothers may find an electronic version of the scale more feasible in documented their confidence related to their feeding plan for their baby. It could also be used as a screening tool by prenatal educators, staff nurses and lactation consultants for determining the support they would need if they are facing challenges feeding their baby. In this study, the higher BSES scores showed a clinical trend with sustained breastfeeding. Re-coding the BSES data, as a continuous variable instead of an interval variable would identify at what point on the scale, the subject was more likely to continue breastfeeding. This could have practice implications for using the tool with high-risk cases or to identify high-risk cases. The sensitivity analysis did find a significant relationship between sustained breastfeeding at 2 months and higher Breastfeeding Self-Efficacy scores. This would mean that most of the noncompleters at 2 months that were assumed to have stopped breastfeeding also had lower Breastfeeding Self-Efficacy scores. Therefore, this tool shows promise for clinical application to screening patients that may be more likely to sustain breastfeeding and those at higher risk for stopping. This study reinforces the reliability of the Breastfeeding Self-Efficacy Scale as a valid tool in practice and research, both theoretically and clinically in this population of late preterm and early term breastfeeding infants.

Breastfeeding Outcomes and The Late Preterm and Early Term Infant

The sustained breastfeeding rates at 1 and 2 months for this population were high, (82% at 1 month and 71.2% at 2 months), in comparison to national statistics, but still identify room for improvement and confirm that the challenges this population faces are unique. These rates also may be high because they are from among infants who initiated breastfeeding in the hospital, not all late preterm and early term infants. Additionally, the hospital's designation as

"Baby Friendly" may indeed promote a higher sustained rate. Assuming the worst case scenario in that the noncompleters all stopped breastfeeding, these rates could have been as low as 72.8% and 59.2% at 1 and 2 months respectfully. Since the results showed no difference between the late preterm infant and the early term infant with sustained breastfeeding at 1 month (p=0.754) and 2 months (p=0.234), it is clear that even early term infants face challenges to sustain breastfeeding. Since the study site had separate protocols for each population, perhaps this is evidence that the late preterm protocol is appropriate to address the physiologic vulnerabilities such as hypoglycemia, hypothermia, and hyperbilirubinemia that often require maternal newborn separation. The results of no significance for infant phototherapy exposure, higher weight loss percentages and hypoglycemia also support this statement. Likewise, women experiencing preeclampsia are likely to need magnesium sulfate treatment and that wasn't an associated factor either. If a mother is treated with magnesium sulfate, usually there is maternal separation as the mother stays in the labor and delivery unit for a day after delivery. In this small sample size, this separation wasn't a factor associated with impacting sustained breastfeeding.

Since 47.2% of the sample had caesarean deliveries, and 90.4% of the sample had either an epidural or spinal anesthesia that require intravenous fluid boluses prior, it was encouraging to note that neither of these birth characteristic subvariables was associated with impacting sustained breastfeeding. Clinicians may find these results surprising in that the increased pain and recovery after caesarean sections could potentially impact the mother's stamina and comfort in breastfeeding their infant. However, the length of hospitalization after a caesarean section compared to a vaginal delivery is longer and staff may support the breastfeeding dyad with breastfeeding through the lactogenesis process during the hospitalization.

The significant findings for higher maternal education and sustained breastfeeding at 2 months (p=0.024) seems reasonable in that one with more education may value the benefits of longer breastfeeding. Given the fact that there was missing data in 36.8% of the sample, this result must be reviewed with caution. Therefore, repeating the Pearson chi square analysis including the subjects with an unknown level of education found no significant results. However, when assuming the worst case scenario that noncompleters stopped breastfeeding, there was a statistically significant finding associating college complete education with sustained breastfeeding at 2 months. In addition to the fact that those with higher educations may be more likely to sustain breastfeeding longer due to their knowledge of the health benefits for themselves and their babies, this also reflects that the noncompleters had lower education levels, perhaps not appreciating the conduct of research.

Although there were no statistically significant results for race being associated with sustained breastfeeding, the raw data did imply a clinical trend for higher breastfeeding rates among Asian and African American races at 1 month (p=0.039) and 2 months for Asian race. However, this conclusion may also be suspect since the analysis had small cell sizes when comparing 5 sub-variables. Of note, all Asian and Hispanic mothers who sustained to 1 month, continued to sustain to 2 months. Street and Lewallen (2013), have identified that although breastfeeding outcomes are reported by race, the cultural impact of the people that surround them, regardless of race are more important in feeding decisions. This study results suggests that the cultural influence of how infants are usually fed in their culture is supportive to mothers, having role models and common experience to help them through the challenges.

Singletons, rather than twins were found to be more likely to sustained breastfeeding with a p-value that is near, but did not fall below the threshold for statistical significance at 1 month

(p=0.058) and significance at 2 months (p=0.022). However, when including the noncompleters in the analysis as subjects with unsustained breastfeeding, this finding did not continue to be significant. Damato, et al., (2005), found that mothers of twins that sustained breastfeeding at one point in time were more likely to sustain breastfeeding at the next point in time. The results of this study support that evidence when the sensitivity analysis was completed. Those mothers of twins that sustained to one month, sustained to two months. However, this study does not support an association of singletons with sustained breastfeeding, statistically speaking. It was interesting that there were no significant findings for maternal age, previous breastfeeding experience or having a previous preterm infant being linked with sustained breastfeeding.

The in-hospital feeding practices subvariables that were found to be associated with sustained breastfeeding were remarkable. Practicing skin to skin on day 2 or later in the hospital was associated with sustained breastfeeding at 2 months (p=0.017). This could mean that the bond created from that continued holding helped the mother persevere through the challenges to keep breastfeeding or it could mean that the skin to skin contact kept the infant in touch with where he was supposed to eat and eventually became proficient. Either way, promoting the mother to hold the infant skin to skin even after the first few hours seems to have a positive impact on breastfeeding. Given that this study site was a “Baby Friendly” Hospital, skin to skin is encouraged and 89% of the sample practiced it. However, the sensitivity analysis only found significant findings at 2 months (p=0.007) which still promotes that skin to skin is a good practice to continue after the initial first day attempts at breastfeeding. There are certainly no negative outcomes from this practice, and other research supports its efficacy to reduce post partum hemorrhage, hypothermia, and improve breastfeeding outcomes (Saxton, et al., 2013).

Confirming the need for objective breastfeeding assessments was identified through the results that linked higher breastfeeding assessment scores on day 1 with sustained breastfeeding at 2 months (p=0.009). At 1 month it approached significance at p=0.063. Even assuming the worst case scenario, the sensitivity analysis supported that sustained breastfeeding at 2 months was associated higher Via Christi breastfeeding assessment scores on Day 1 and a likely association at 1 month. High breastfeeding assessment scores on day 2 on in the hospital were found to be associated with sustained breastfeeding at 1 month (p=0.000) and at 2 months (p=0.004). In the sensitivity analysis this finding was reinforced with significant results at 1 and 2 months even accounting for those noncompleters having stopped breastfeeding. Clinicians would agree that if the infant "knows how to feed", mothers feel more confident, continue to want to do it because it is enjoyable, not painful and not a "fight". Identifying infants with low breastfeeding assessment scores can be used clinically to provide more support, education, and assistance during feedings so that the scores will hopefully improve. This research study supports the validity and reliability of the Via Christi Breastfeeding assessment tool, which has limited evidence published to date, and supports it's use in practice (as it is used in the study agency) as being predictive of sustained breastfeeding.

Although the use of the nipple shield was found to be negatively associated with sustained breastfeeding at 2 months (p=0.010), it does bring forth the idea that a mother requiring a nipple shield is a case that suggests the mother is already at risk and would benefit from additional support and follow up after discharge. It wasn't significant at 1 month (p=0.266), which could mean that mothers who were using the nipple shield after discharge sustained for 1 month, but by 2 months found it too difficult to continue. The data on nipple shield use at 1 and 2 months was collected and would be worthwhile to analyze. Additionally, in

the sensitivity analysis, the nipple shield was not found to be negatively associated with sustained breastfeeding. This would mean that many of the noncompleters were also those that used a nipple shield in the hospital. Most clinicians would agree that implementing a nipple shield is an intervention that requires follow up since weaning off it requires guidance and support. Upon first glance, it seems that the use of the nipple shield in the hospital could put the mother at a higher risk for stopping breastfeeding. Another perspective could be that the mother who has worse breastfeeding problems requiring a nipple shield was likely to stop breastfeeding. Either way, the use of a nipple shield should identify a high risk case for follow up.

The other factor that was collected on the follow up calls was if the mother was back to work and this often factors into why the sustained breastfeeding rates decrease between 1 and 2 months for all populations. This data would be helpful to use for support of extending the length of time for paid leaves postpartum in the Family Medical Leave Act legislation. Extending paid leaves in many of the European countries has resulted in increased breastfeeding rates at and other health improvements for children (Staehelin, et al., 2007).

In examining the issue of milk expression or breast pumping that can be started within the first day of birth or during the hospitalization, by nursing or lactation staff, the goal is intended to establish and preserve lactogenesis and the maternal milk supply. The results were not significant to associate pumping within the first day of life with unsustained breastfeeding at 1 month ($p=0.146$) and at 2 months ($p=0.114$). Clinically, this practice is debated as being too burdensome to add pumping to the regime of the new mother right after birth (Morton, et al, 2009). This study suggests that pumping in the first 24 hours may be helpful but isn't predictive of sustained or unsustained breastfeeding. However, the clinical practice of discharging the mother with breastpumping being part of the plan did yield statistically significant results.

Subjects who were pumping at discharge were more likely to stop breastfeeding at 1 month (p=0.005) and 2 months (p=0.005). This result was reinforced in the sensitivity analysis as well with a p=0.002 at 1 month and 0=0.015 at 2 months. Clinically, this practice is a necessary component to care, but does reinforce that when staff recommended the mothers pump as part of the discharge feeding plan, their infants aren't feeding well enough on their own, and therefore identify the high-risk cases for unsustained breastfeeding.

Most clinicians may be surprised that there was no significant association with the maternal feeding plan to exclusively or partially breastfeed, with the timing of the first feeding, with practice of hand expression or pacifier use. The "Baby Friendly" practice of avoiding artificial teats in term infants has been carried over to the late preterm and early term population. The premature infants hospitalized in the NICU are readily exposed to pacifiers as it is a source of non-nutritive sucking in absence of the ability to orally feed. This practice is intended to promote developmental, feeding and gastrointestinal maturation while also relieving pain. Although this sample size is small, from the data one could surmise then that the late preterm and early term infant may have more in common with their premature counterparts than their term counterparts when it comes to pacifier use. This could impact clinical protocol and staff education that is usually directed by the lactation support staff.

Lactation Support

The lactation support staff at the study site was available 7 days per week for patient consultations. Four subjects received no lactation consults. This could have been due to a process issue or due to the fact that the mother declined services feeling she didn't need them. If the mother is there for a cesarean delivery, it is common to have at least 3 consults. For the mother who is there for a vaginal delivery, it is common to have 1-2 consults. It was surprising

to the researcher that there was no significant association with sustained breastfeeding and in-hospital lactation support regardless of whether it was 0, 1 or more than 1 consults. From clinical experience, the researcher would be hesitant to make any judgment on the value of the lactation consultation service. For the 72% of the sample that received more than 1 consult, it would be quite reasonable that they provided valuable information and support in addition to the nursing and medical staff. The one explanation possible for this would be that the nursing staff has received so much lactation focused education that the mothers were well supported and lactation consults with the lactation consultant specifically were just additional support. The implementation of lactation interventions such as breastpumping, use of a nipple shield, conducting breastfeeding assessment scores are done by nursing staff as well as lactation staff.

The lactation consultants are an integral component of the nursing staff's education on breastfeeding and implementation of those interventions in their clinical practice and therefore are a necessary member of the healthcare team. It also would be worth analyzing the data to identify whether the mother received 2, 3, or 4 consults instead of just more than 1, if the sample size could support such analysis with more subvariables. Additionally, it is important to note that besides lactation consultation directly to patients, the lactation consultants provide immeasurable support and education to the nursing staff and outpatients.

Examining the impact of post-discharge lactation support on sustained breastfeeding again had surprising results, finding no association at 1 month ($p=0.798$) and 2 months ($p=0.90$). Again, coding this differently may yield more meaningful results and using maternal satisfaction data may be more appropriate. Clinically, practitioners that conduct post discharge lactation consults find that mothers who are challenged with actual feeding at the breast are more at peace with their outcome if they make an informed decision to stop breastfeeding or simply pump and

provide expressed breastmilk after accessing assistance from a professional. This situation often includes the need for supplemental feedings and use of alternative feeding methods, which seem to be one of the challenges these infants faced when attempting to sustain breastfeeding.

The study was conducted prospectively and analyzed to determine association rather than predictive ability in order to limit the threats to statistical validity due to practice variability. As often as the lactation staff at the institution aim for consistency in assessment and content delivered and are required to document on the same form, the style of each lactation consultant and nurse working with the dyad in addition to the specific nature of each breastfeeding situation, created a situation subject to external variation. Likewise, post discharge lactation support included phone support, individual consultations or group support settings. So, the subject may not have found them helpful, or may have found them very helpful. Therefore, further analysis of lactation interventions, the type of support given, and maternal satisfaction will yield more clinical insight regarding breastfeeding outcomes.

Methods of Supplemental Feedings

Over 76% of the sample received supplemental feedings. For the purpose of this study this included expressed breastmilk or formula that was given in addition to the breastfeeding. This definition was chosen to keep the data clean because if any additional substance was given to the infant, even expressed breastmilk, a method to deliver it would have to be used. Clinically, this is often the source of much debate, what method to use, what impact it has on the outcome, and if the mother has the stamina to handle yet another intervention (Neifert & Bunik, 2013). The results of this study showed significance before and after the sensitivity analysis for association with unsustained breastfeeding outcomes at 1 and 2 months and the occurrence of supplemental feeding. This reinforces the evidence in the term infant population in regard to the

dangers of supplemental feedings. However, in the late preterm and early term infant, supplementation to support the infant's physiologic vulnerability is often needed. This doesn't mean that the clinician should supplement routinely, but the high incidence of supplementation in the sample is evidence that it is often necessary. If supplemental feedings are needed, whether it is expressed breastmilk, donor milk or formula, then how to give it is still up for debate.

In this study, the bivariate analysis compared using each method that was used singly to no method used. Additionally, there was 34.4% of the sample that received supplemental feeds via multiple methods. Breastfeeding infants that received no supplemental feeding method used were more likely to sustain breastfeeding than oral syringe only, bottle only, and multiple methods. Only two subjects used the SNS on the finger only and two subjects used the SNS at the breast only so drawing any conclusions from that data was impossible. Of note, finger feedings and syringe feedings have no data to support it safety, let alone efficacy in practice, but is often a practice in "Baby Friendly" designated institutions, since the avoidance of artificial teats is paramount. This is the case with the study site… syringe and finger feedings using a supplemental nurser system are commonly used in practice and therefore, this study can build evidence on these practices in further analysis.

If the sample size could support a multiple regression analysis and the multiple methods category was re-coded to include each method used, interpreting this data might be more meaningful. Out of the reported results though, it is reasonable to say that when breastfeeding infants receive supplemental feedings, it is an indication of a high-risk case. When multiple methods of providing supplementation were used, there was a clinical trend toward being more prognostic for a poor outcome. Clinically, this is seen when the mother has a sleepy baby who doesn't feed well at the breast, often then is unable to be supplemented via the SNS at the breast

and therefore tries using the SNS on the finger. In an effort to maintain her milk supply, she may get a few drops of breastmilk by pumping and that has been given to the baby by syringe because of the volume. Sometimes, she is so exhausted and frustrated at this point, she opts to use the bottle. The image presented in this scenario is certainly at high risk for unsustained breastfeeding down the road unless there is some effective support from professionals or family to encourage her and help with all the other infant care besides feeding so she can rest and recover amidst these feeding challenges. These results would concur with mounting qualitative evidence that the maternal experience of facing these challenges is a daunting process to endure (Demirci, et al., 2012).

Limitations

One limitation of this study was that the maternal level of education was only documented in 63.2% of the sample. Therefore, the strength of the significant finding for those mothers with at least some college education being more likely to sustain breastfeeding at 2 months may be suspect. The sample size of 111 subjects at 1 month and 104 subjects at 2 months is another limitation. When comparing multiple subvariables such as race and supplemental feeding methods, the cell sizes became small and therefore limit it's generalizability to the late preterm and early term population. The risk of the sample changing over time and therefore being biased was addressed by conducting the sensitivity analysis. Ideally, the promotion of March of Dime's "39 week plus" elective birth initiative would expect this population to continue to decline, but late or early term infants will continue to be born for other reasons and need care and support to sustain lactation which will benefit their overall health in the future.

Technically speaking, the late preterm infant is considered to be infants born at 34-36 6/7 weeks gestation. Since infants born less than 35 weeks gestation are not admitted to the newborn nursery at the study site, those born at 34 weeks gestation were not included in the sample. Therefore the generalizability of these results to this population need to consider that 34 week infants were excluded and that all these infants were discharged from a newborn nursery, not a NICU. Additionally, this study was conducted at a single center which limits it's generalizability more than if it was a multi-site research study. Lastly, there may have been some degree of Hawthorne effect in that the subjects may have wanted to sustain breastfeeding until the researcher called them at 1 and 2 months because they knew they would be contacted. By calling them and checking on their feeding status, referral to resources were at times made and that may have also impacted use of post discharge support and sustaining breastfeeding.

Implications for Practice

This research study identified several factors that put the mother at high risk for not sustaining breastfeeding in the late preterm and early term infant. Incorporating these factors into the clinical practice guidelines and clinical protocols that directs patient care can improve breastfeeding rates. Both the Academy of Breastfeeding Medicine's protocols and the Association of Women's Health, Obstetric and Neonatal Nurses' clinical practice guidelines are strong national resources and this evidence can support some of their content. Simple interventions like encouraging skin to skin, educating the mother to improve her breastfeeding self-efficacy, perhaps using the BSES tool to identify high risk cases, assisting with feedings to improve the feeding assessment scores can improve outcomes. Using the Breastfeeding Self-Efficacy screening tool for those mothers that have several high-risk interventions in place (nipple shield, pumping, multiple methods for supplemental feeds, and having twins) may give

insight on how to help her before she reaches her breaking point and stops. The tool could also be used prenatally to identify mothers at risk. Implementing these practices in one agency is integral to quality patient care. However, extending those practice changes into national guidelines and protocols can have a larger impact and provide more opportunities to measure outcomes in larger samples to improve practice through research. Until those changes can be made on the larger scale, the study agency's protocols for late preterm and early term breastfeeding infants can reflect the suggested practice changes.

Implications for Future Studies

As with any research investigation, this study identified further questions that can be addressed with additional analysis of the data collected. Data collected on Apgar scores, socioeconomic status, maternal BMI, re-hospitalization, and maternal sources of support are all demographic data that would be interesting to analyze in relation to sustained breastfeeding. Re-coding the Breastfeeding Self-Efficacy scores to be a continuous variable instead of an interval one would help identify at what point, the score was inclined to promote sustained breastfeeding more clearly. Likewise, a multiple regression analysis of the different methods of supplemental feedings would be more helpful than comparing them to no supplementation individually. Additionally, differentiating between supplemental feedings given of expressed breastmilk versus expressed breastmilk and formula would be beneficial in a further analysis regarding supplementation. This would add to understanding the significance of pumping at discharge being associated with unsustained breastfeeding. Analyzing the data on supplemental feeding methods will add to the bare evidence on the use of syringe and finger feedings in practice. Another perspective would be to examine the impact of post discharge lactation support when there are multiple lactation interventions in place and low breastfeeding assessment scores

indicating a high risk case for unsustained breastfeeding. The data on social support could also be analyzed on this sample to identify the impact of having family or friends that have experience breastfeeding.

The investigator was surprised by the lack of statistical association with sustained breastfeeding and in hospital lactation consults and post discharge lactation support. Although the in hospital lactation support could be explained from system issues with a heavy case load for the lactation consultants on staff and timing of the consult in relation to the nursing staff's implementation of the plan, the examination of the in-hospital feeding practices such as pumping and supplementation should shed some light on the nurses' implementation of the lactation plan and protocols. Another option to address the post-discharge lactation support and lack of an association with sustained breastfeeding, would be to analyze maternal satisfaction compared to the mother's initial feeding plan and code in hospital lactation consults and post discharge lactation support differently to yield potentially more meaningful results. During the follow up structured telephone interviews and mailed responses, it became clear that mothers wanted to explain why they had to stop, expressed guilt over their decision, and that this seemed to impact their satisfaction with their feeding outcome. Although this study defined sustained breastfeeding as feeding directly at the breast, the data is available for mothers who were pumping and providing breastmilk to what extent, which is consistent with Labbok's definitions. A mixed method study that includes some qualitative analysis of the anecdotal notes taken during the interview in addition to quantitative analysis of maternal satisfaction in relation to Labbok's definitions for sustained breastfeeding would be very powerful.

Similarly, the investigator identified a case study that would be interesting to report. There was a memorable mother of 35 week gestation twins in the study who received intense

lactation support in the hospital, accessed intense post discharge lactation support and faced many challenges along the way, but her intent to breastfeed was strong and she persevered to sustain at 2 months.

Implications for Staff Education

It is important to note that this study was conducted in an agency with the "Baby Friendly" designation which means it has an active lactation program with additional education for nursing staff related to lactation. Implementing clinical practice protocols that incorporate this evidence will require much staff education. The content and depth of what can be covered will depend on the level of knowledge of the current staff. At the very least, identifying specific protocols for the late preterm and early term population of breastfeeding infants in the "normal newborn nursery" is indicated by the mounting evidence that this population has physiologic vulnerabilities that threaten sustained breastfeeding and require unique care different than their term counterparts.

Implications for Policy

The sustained breastfeeding rates in this sample of 82% of the completers at 1 month or 72.8% of the entire sample and 71.2% of the completers at 2 months and 59.2% of the entire sample are important findings to apply to the goals set forth by the US Department of Health and Human Services (DHHS). Having more data on sustainment rates in this study population is helpful because the national statistics available are out of all infants born, regardless of the feeding choice initiated. This study results were based on infants who began breastfeeding in the hospital. The current initiation rates of 74% with a sustained 6 month breastfeeding rate of 43.5% suggest that the findings in this study are higher, but are in line with the decline of sustained breastfeeding that happens over time. Analyzing the data collected on the exclusivity

of breastfeeding at 1 and 2 month would be helpful to compare to the DHHS's three month exclusive breastfeeding rate of 33.6% with a goal of increasing that by 2020 to 46.2%. However, keep in mind that this breastfeeding rate includes all infants, regardless of how they were fed from birth. Additionally, factors impacting a mothers' decision to stop breastfeeding was also collected and will need to be analyzed. That information may identify the impact of challenges such as employment has on sustained breastfeeding. The DHHS cites that only 25% of workplaces currently provide lactation support and have a goal to increase that by 38%. This study can support the need for public policy that supports the Family Medical Leave Act (FMLA) legislation that promotes breastfeeding by supporting the working mother who is breastfeeding their infant. (www.HealthyPeople.gov/2020).

Summary

Chapter 5 presented discussion of the results as they relate to clinical practice regarding the theoretical framework and variables of Breastfeeding Self-Efficacy, breastfeeding outcomes specific to the late preterm and early term infant, lactation support (in-hospital and post discharge), and methods for supplemental feedings. Limitations of the study including sample size, missing data, scope of population and generalizability were discussed. There also may have been a Hawthorne effect involved for subjects. Implications for Practice, future studies and staff education were also presented. As with any research study, often more questions arise that need answers.

CONCLUSION

This investigation, "Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35 -37 6/7 Weeks Gestation" was conducted at an inner

city large hospital that was designated as “Baby Friendly” from September, 2013 to May, 2014. The investigation literature search and study planning began in August, 2012 and approval from the Institution Review Board at the study site was received in August, 2013. A sample of 125 subjects was recruited with 111 subjects retained at the 1 month follow up and 104 subjects retained at the 2 month follow up call. Data analysis address three research questions related to the prevalence of sustained breastfeeding at 1 and 2 months of age for these late preterm and early term infants. The research questions were:

1. What proportions of breastfeeding infants born between 35-37 6/7 weeks gestation experience sustained breastfeeding at 1 and 2 months of age?
2. Among breastfeeding infants born between 35-37 6/7 weeks gestation, do the following variables:
    a. Pre-discharge maternal breastfeeding self-efficacy?
    b. Use of supplemental feeding methods?
    c. In-hospital lactation consultations?
    d. Late preterm vs early term status?
    e. Maternal and infant demographic data and hospital course?
    f. Characteristics of birth process?
    g. In-hospital feeding practices?

    differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

3. Among breastfeeding infants born between 35-37 6/7 weeks gestation, does the occurrence of post-discharge lactation support differ between those who experience sustained breastfeeding at 1 month or 2 months of age and those who do not?

The theoretical framework used to guide this study was Breastfeeding Self-Efficacy that also had a measurable tool that could be used as one of the variables. Other variables addressed included use of supplemental feeding methods, in hospital and post discharge lactation support, maternal and infant demographics, characteristics of the birthing process, and in-hospital feeding practices.

Significant results were found for several factors to be associated with sustained breastfeeding, reinforcing the multifactorial nature of understanding the best clinical practice model for these breastfeeding mother-newborn dyads. Of note, the most strongly associated factors aligned with sustained breastfeeding in the late preterm early tem population were higher education levels, higher Breastfeeding Self-Efficacy scores, practicing skin to skin on day 2 or later, and higher breastfeeding assessment scores. As with any research study, more questions were also identified that merit investigation. Further analysis of the data collected will yield more understanding and direct practice guidelines that can be implemented clinically.

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Appendix A-1: Recruiting Script

Introduction: Hi, my name is Joan Kuhnly. I am a doctoral student at University of Connecticut and I'm conducting a study breastfeeding for my dissertation in partial fulfillment of my degree from University of Connecticut.

Invitation to Participate: You were selected as a potential participant for a research study entitled "Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 Weeks Gestation" because your infant was born between 35 and 37 6/7 weeks of pregnancy. I am asking for you to participate in this study to help understand how the feeding progresses for infants born at this age.

Agreement to Participate: If you agree to participate, I will need you to read and sign the consent form, fill out a one page survey describing how you feel the breastfeeding is going at discharge, and allow me to speak with you on the phone for about 5-10 minutes when your baby is one and two months old. It will also allow me to gather some information from your chart.

Anticipated Risks: The risks associated with this study are minimal but could include a breach of confidentiality, social discomforts talking about breastfeeding, or feelings of being pressured to participate in this study. Should you need to discuss your feelings about participating in this research, please feel free to speak with me or the staff here at the hospital. My contact information is on the informed consent. You will receive a copy.

Confidentiality of Data: All information identifying you will remain in a locked cabinet in the lactation center here at the hospital. You were assigned a case number so your records will remain confidential.

How the Study Will Help: Your participation will greatly benefit future mothers who are breastfeeding their late preterm infant. We will guide our practice to provide the right support with future moms and babies based on what we learn from this study. In addition, if you want assistance with breastfeeding when I call for the interview, I can refer you to resources that may be of help. When you complete the study after the phone call when your baby is 2 months of age, you will receive a gift card to buy diapers or baby supplies.

Decision to Participate or Not and withdrawal of Consent: Your decision whether or not to participate will not affect your care while hospitalized or affect any care or support you receive after discharge. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. If you decide to withdraw from the study prior to the one and two month interviews, simply don't answer the phone or return my call. If you have questions concerning the study, now or in the future, I was happy to answer them. You can contact me by email at joan.kuhnly@uconn.edu or by phone at (860)486-6130.

Appendix A-2: Master List CONFIDENTIAL (Mark with * if Spanish Speaking)

Case #	Last Name	first name	Contact phone #	MR #	file/visit#	DOB	Incent sent
1mom							
1baby							
2 mom							
2 baby							
3 mom							
3 baby							
4 mom							
4 baby							

Appendix A-3: Informed Consent Form

Hartford HealthCare

Informed Consent for Research

6816

Principal Investigator: Joan Kuhnly, MS, NNP-BC, APRN, IBCLC,CNE
Women's Health
860-486-6130

You have been asked to participate in the research study, Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 weeks Gestation. This research study is supposed to last 6 months.

You are being asked to be involved in a research study at Hartford Hospital that is part of a doctoral student's school project from University of Connecticut School of Nursing.

You realize that your involvement in this study is entirely voluntary and you may withdraw from the study at any time you wish. If you decide to stop your involvement in this study, your care will not be affected.

You understand that all study data will be kept confidential. However, this information may be used in nursing publications or presentations.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

We are asking you to be part of this study because your infant was born more than 2 weeks before their due date and you are planning to breastfeed your baby. We are interested in finding out what helps mothers continue breastfeeding their baby who was born before his/her due date. We hope to learn what kind of breastfeeding help is best to give mothers in the hospital, what method of supplemental feeding is best if needed, and what kind of support after discharge is most helpful.

A.2. What procedures are involved with participation in this research study?

If you agree to take part in the study, you will be asked a couple of questions on previous breastfeeding experiences and you will be asked to fill out a breastfeeding self-efficacy form about how confident you are with breastfeeding your baby before you go home. You will be interviewed for about 5-10 minutes on the telephone by the researcher when your baby is 1 and 2 months old. The questions will ask about how your baby is feeding, what help you have gotten since discharge and how that has affected feeding your baby No identifying information will be included on the notes taken during the interview.

A.3. Which of these procedures is experimental?

The experimental part of this study includes collecting information from your baby and your hospital chart. This information includes: your age, education, race, type of delivery, what your previous experience with breastfeeding and previous babies (late preterm infants if applicable) has been and how the feeding is going with your current infant. Other experimental parts of the study include collecting the following information on

Hartford HealthCare

Informed Consent for Research

6816

your baby: his/her birthweight, born at what week of pregnancy, where he or she will get their care after leaving the hospital, and if he or she needed any treatment for low blood sugar or jaundice, as well as collecting phone calls about your baby's feeding habits at one and two months. .

A.4. Where will participation take place?

The study will take place on the maternity unit before you are discharged from the hospital and you will receive a call on your cell phone or home telephone when your baby is 1 and 2 months old.

A.5. How long will participation last?

Your participation will last two months, in which you will receive your second and last phone call.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

The only risk involved in this study is if you are uncomfortable talking about how breastfeeding your baby is going. If such discomfort occurs, you will be referred to appropriate resources for help.

If you cannot speak English, the researcher will use an interpreter from the hospital to ask for your permission to participate and answer the initial questions, and then use an interpreter on the telephone language line to speak with you for the telephone interviews when your baby is 1 and 2 months old.

C. There are possible benefits to you or others to be expected from your participation in this research.

What we learn from this study may help either you or other mothers to breastfeed their infants that were born early. In addition, you may be referred for help with breastfeeding if you request that.

D. There are alternatives to participation in this study that you should consider.

This is not a treatment study. You may choose not to participate in this study without any penalty to you.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about	Contact	Phone #
the research, research-related treatments, or a research related injury	Joan Kuhnly	(860) 486-6130
your rights as a research participant	An IRB Representative	(860) 545-2893

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the research in general	Vice President, Research	(860) 545-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Relations	(860) 545-1400

F. Your participation in the research is voluntary.

You may refuse to participate, withdraw your consent, and discontinue participation in the research at any time. You may do so without penalty, or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital.

G. You will receive financial compensation for your participation in this research.

A $10 gift card to Target for purchasing baby care items will be sent to your home after completing your 2nd month interview. You will be sent the gift card after the 1 month call if you have stopped breastfeeding, or have chosen to withdrawal from the study altogether.

A note about the Internal Revenue Service (IRS): Hartford Hospital is required to report payments of $600 or more to the IRS. This means that if you receive $600 or more from Hartford Hospital during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form. The data will be stored on a password protected, encrypted computer, in a locked office, and any hard copy data will be stored in a locked cabinet in a locked office, both only accessible by the research staff.

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

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If you have medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from your insurance company. If you are not fully covered by insurance or uninsured, the research sponsor of the study or Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

Hartford HealthCare

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J. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 weeks Gestation, and that you consent to the performance of the procedures listed above.

Participant's Signature Date

Person Obtaining Participant's Signature Date

Witness signature Date
(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

Page:	5 of 5	IRB Approval Dates	
PI:	Kuhnly	Approval:	August 28, 2013
Account #:	KUHN004112HU	Valid Through:	August 27, 2014
Version:	August 28, 2013	IRB Signature:	Robert D. Siegel (FC)

Appendix A-4: Research Authorization for Use/Disclosure of Protected Health Information

Hartford Hospital
A Hartford HealthCare Partner

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Research Authorization for Use/Disclosure of Protected Health Information

Participant Name: _____
D.O.B.: _____
Address: _____
_____

In connection with my participation in the research study described below at Hartford Hospital, I, the undersigned participant, understand that private identifiable health information about me will be obtained, used and disclosed for purposes of the research project. Accordingly, I hereby authorize the use or disclosure of my health information, including, if applicable, protected drug and/or alcohol abuse, confidential HIV-related and psychiatric information ("Protected Health Information") in the manner described herein, for purposes related to my participation in the following research study (the "Research Study"):

[describe study, such as by title and purpose or by reference to an attached description and consent document]

Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 Weeks Gestation

Such purposes shall include all activities related to the conduct of the research study, as well as activities that ensure that my rights as a participant in a research study are being protected and that the research is being conducted properly.

I. **Information Covered by Authorization.** The Protected Health Information that may be used or disclosed in connection with this authorization includes the following: *[check all applicable items]*

- ☒ Existing medical records or information accessed by researchers as part of Research Study;
- ☒ Information from interviews and questionnaires conducted as part of Research Study, including medical history;
- ☐ All data obtained during any study procedure;
- ☐ All medical records or reports created in connection with Research Study, such as any radiology reports, lab results, psychological test results, consultation reports, results of physical examinations, summary notes and treatment records;
- ☐ Other *[describe]*:

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II. Authorized Uses/Disclosures. This form authorizes the following persons or entities to obtain, use or disclose my Protected Health Information in connection with the Research Study:

- Hartford Hospital
- The principal investigator, Joan Kuhnly
- The co-investigators, Nikaela Larossa
- Any researchers or Hartford Hospital staff working under the principal investigator's or any co-investigator's direct supervision

The Protected Health Information may be disclosed to the following *[check applicable items]:*

☒ Hartford HealthCare Research Institute Administrative staff or Institutional Review Board members
☒ Any government agency overseeing this research at HH for which authorization would be required by law;
☐ The research sponsor, ;
☐ My physician, Dr. , for purposes of providing information about my health to my regular physician;
☐ Other researchers for data comparison purposes, provided data used for this purpose is stripped of personally identifying information;
☐ Other *[identify by name or category]*:

III. Authorization to Access Existing Health Information. *[Check and complete this section if participation in Research Study will require researchers to access participant's health information from other providers (i.e. not generated as part of Research Study)]*

☐ I hereby authorize Hartford Hospital, the principal investigator and any co-investigators identified in the Research Study to obtain my Protected Health Information from the following providers (list by name):

Name/Facility: _____
Address: _____
Phone (if known): _____

Name/Facility: _____
Address: _____
Phone (if known): _____

Other Facility:

The nature and extent of the Protected Health Information to be obtained from the above-named providers shall be: *[describe or indicate "All health information"]*

"All health information"

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II. Authorized Uses/Disclosures. This form authorizes the following persons or entities to obtain, use or disclose my Protected Health Information in connection with the Research Study:

- Hartford Hospital
- The principal investigator, Joan Kuhnly
- The co-investigators, Nikaela Larossa
- Any researchers or Hartford Hospital staff working under the principal investigator's or any co-investigator's direct supervision

The Protected Health Information may be disclosed to the following *[check applicable items]:*

☒ Hartford HealthCare Research Institute Administrative staff or Institutional Review Board members
☒ Any government agency overseeing this research at HH for which authorization would be required by law;
☐ The research sponsor, ;
☐ My physician, Dr. , for purposes of providing information about my health to my regular physician;
☐ Other researchers for data comparison purposes, provided data used for this purpose is stripped of personally identifying information;
☐ Other *[identify by name or category]*:

III. Authorization to Access Existing Health Information. *[Check and complete this section if participation in Research Study will require researchers to access participant's health information from other providers (i.e. not generated as part of Research Study)]*

☐ I hereby authorize Hartford Hospital, the principal investigator and any co-investigators identified in the Research Study to obtain my Protected Health Information from the following providers (list by name):

Name/Facility: _____
Address: _____
Phone (if known): _____

Name/Facility: _____
Address: _____
Phone (if known): _____

Other Facility:

The nature and extent of the Protected Health Information to be obtained from the above-named providers shall be: *[describe or indicate "All health information"]*

"All health information"

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IV. Authorization to Continue Research at New Institution. *[Participants must give permission for research data to be taken to and used at another institution by personally initialing the appropriate line following this statement. The Investigators/Research Staff may not make that decision for the participant.]*

In the event the principal investigator of the Research Study identified above moves his/her research work to an institution other than Hartford Hospital (the "Successor Institution"), by initialing the line below, I authorize the principal investigator to retain records relating to my participation in the Research Study and further authorize the disclosure of my Protected Health Information to the Successor Institution and the continued use and disclosure of such information by the Successor Institution, the principal investigator and other researchers working under the principal investigator at the Successor Institution in connection with the Research Study as otherwise contemplated above. I understand in such event records relating to the Research Study will no longer be maintained at Hartford Hospital.

_____ Participant Initials

OR

I do not authorize the disclosure of my Protected Health Information to the Successor Institution, in the event the principal investigator leaves Hartford Hospital.

_____ Participant Initials

V. General Provisions. I understand that by signing this authorization I agree to the use and disclosure of my Protected Health Information as described above. I understand that I am not required to sign this authorization, but if I do not sign this authorization I may not participate in the Research Study. My decision not to sign this authorization will not affect my ability to obtain future treatment from Hartford Hospital or any other health care provider named in this authorization, except for any research-related treatment.

I understand that I am entitled to a copy of this authorization form. I agree that a copy of this authorization will be as valid as the original. I understand that I may revoke this authorization at any time by notifying Joan Kuhnly in writing, but if I do it won't have any effect on actions taken prior to receipt of the revocation. If I revoke this authorization I understand that I will not be eligible to continue to participate in the Research Study. I also understand that once revoked, Hartford Hospital and the investigators named above may continue to use or disclose my Protected Health Information as necessary to maintain the integrity and reliability of the Research Study. I will send any notice of my desire to revoke this authorization to:

Joan.Kuhnly@uconn.edu or Joan Kuhnly U-4026 School of Nursing, University of CT, Storrs, CT 06269

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This Authorization *[check one]*:

☐ does not have an expiration date. ***[**do not check if PHI involves HIV or drug and alcohol treatment information]***

☒ shall expire at the completion of the research project.

I understand that under applicable law recipients of my Protected Health Information may not be subject to the federal privacy laws. Consequently, information disclosed under this authorization may be subject to further disclosure by the recipient and may no longer be protected by the federal privacy regulations. Such information, however, may continue to be protected for recipients that are subject to the federal privacy regulations or other state or federal confidentiality laws or contractual confidentiality obligations.

I understand that I may obtain a copy of the Hartford Hospital Privacy Notice for a complete description of the Hospital's privacy practices for protected health information, and that I have a right to review such Notice before signing this authorization.

_____ _____

Participant Signature (or authorized representative) Date

Print Name: _____

****Note**, if you are signing as the legally authorized representative of the participant, please indicate your relationship to the participant here (this should demonstrate your authority to consent to health care for the participant):

_____

PI: Kuhnly

Reference # /Account #: KUHN004112HU

Version: August 15, 2013

Appendix A-5: Recruitment Flyer

Congratulations Mom!

If your baby was born more than 2 weeks before your due date and you are planning to breastfeed, we would like to ask you to volunteer for a study.

You will need to sign permission, fill out a one page form before you go home, and talk on the phone for about 5 to 10 minutes with the researcher when your baby is 1 and 2 months old. After that, you will receive a $20 gift card in the mail to buy diapers or baby items.

If interested, please contact Joan Kuhnly at (860)486-6130 or Joan.kuhnly@hhchealth.org

Appendix A-6: Permission to use Breastfeeding Self-Efficacy Theoretical Framework

Dear Joan,
Thank you for your email. Yes, you can use my theoretical framework in your dissertation but I would prefer it not be published in any publications. I would like my 1999 publication to be the sole reference for my model. I hope you understand. Good luck with your studies.
Warm regards,
C-L

Cindy-Lee Dennis, PhD
Professor in Nursing and Medicine, Dept. of Psychiatry; Canada Research Chair in Perinatal Community Health; Shirley Brown Chair in Women's Mental Health Research, Women's College Research Institute; University of Toronto
155 College St
Toronto, Ontario
Canada M5T 1P8
Tel: (416) 946-8608
www.cindyleedennis.ca

-----Original Message-----
From: Kuhnly, Joan [mailto:joan.kuhnly@uconn.edu]
Sent: January 19, 2013 7:56 AM
To: Cindy-Lee Dennis
Subject: RE: BSES-SF request

Hello again Dr. Dennis-

I appreciate your permission to use your short form tool in my proposed study for my doctoral dissertation. Attached please find your very familiar 1999 theoretical underpinnings article as a PDF. I'm inquiring if I can reprint figure 1 with your permission in the theoretical framework portion of my dissertation and related publications after. Of course proper citation would be included. If so, do you have an electronic version of the table that you would like me to use?

Thank you again for considering another request from me. I'm hopefully going through the IRB this spring and would start conducting the study this summer into fall.

Sincerely, Joan

Joan Kuhnly, RN, IBCLC, NNP-BC, MS
Assistant Clinical Professor
Chairperson, Prelicensure Programs Task Force University of Connecticut School of Nursing
Office phone 860-486-6130 Cell Phone 860-306-0342 Beeper 860-762-0264 email
Joan.Kuhnly@uconn.edu

Appendix B-1: Breastfeeding Self-Efficacy Scale –Short Form

The Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF) is under the copy right of Dr. Cindy-Lee Dennis (2003). Permission to use the BSES-SF must be obtained in writing or via email prior to use. There is no charge for this use. However, the requester must agree to forward a copy of all research to the developer following any investigation.

Email or mail all correspondence to:

Dr. Cindy-Lee Dennis
University of Toronto
Lawrence S. Bloomberg Faculty of Nursing
155 College Street
Toronto, Ontario, Canada
M5T 1P8

Cindylee.dennis@utoronto.ca

Breastfeeding Self-Efficacy Scale – Short Form

For each of the following statements, please choose the answer that best describes how confident you are with breastfeeding your new baby. Please mark your answer by circling the number that is closest to how you feel. There is no right or wrong answer.

1 = not at all confident
2 = not very confident
3 = sometimes confident
4 = confident
5 = very confident

		Not at all confident				**very confident**
1	I can always determine that my baby is getting enough milk	1	2	3	4	5
2	I can always successfully cope with breastfeeding like I have with other challenging tasks	1	2	3	4	5
3	I can always breastfeed my baby without using formula as a supplement	1	2	3	4	5
4	I can always ensure that my baby is properly latched on for the whole feeding	1	2	3	4	5
5	I can always manage the breastfeeding situation to my satisfaction	1	2	3	4	5
6	I can always manage to breastfeed even if my baby is crying	1	2	3	4	5
7	I can always keep wanting to breastfeed	1	2	3	4	5
8	I can always comfortably breastfeed with my family members present	1	2	3	4	5
9	I can always be satisfied with my breastfeeding experience	1	2	3	4	5
10	I can always deal with the fact that breastfeeding can be time consuming	1	2	3	4	5
11	I can always finish feeding my baby on one breast before switching to the other breast	1	2	3	4	5
12	I can always continue to breastfeed my baby for every feeding	1	2	3	4	5
13	I can always manage to keep up with my baby's breastfeeding demands	1	2	3	4	5
14	I can always tell when my baby is finished breastfeeding	1	2	3	4	5

Appendix B-2: Demographic Data Collection Tool (Collected from medical record except items marked with *-collected via interview with mother after consent obtained)

Case # _____ Case contact phone (_____) _____-_____ Interpreter used: _____

Gestational age: _____ DOB: ____/____/____ Singleton ☐ Twin ☐

Infant sex: Male ☐ Female ☐ Apgars: 1 min ☐ 5 min ☐

Infant birth weight: SGA ____ AGA____ LGA ____

% weight loss at discharge: <7% ☐ 7-9.9% ☐ > 10% ☐

Phototherapy required in hospital: Y ☐ N ☐ Insurance: state assist ☐ private ☐

Mother's age: ____yrs old *Mother's Height ____ft ___in Mother's pregnancy wt _____

Delivery: Vaginal ☐ C/S ☐ Epidural given: Y ☐ N ☐ MgSo4: Y ☐ N ☐

Maternal educ:<High school ☐ High school ☐ Some college ☐ College complete ☐ unknown ☐

Mother's race: Caucasian ☐Hispanic ☐ African American ☐ Asian ☐ Other ☐

First baby: Y ☐ N ☐ *First baby breastfed: Y ☐ N ☐

Bf within 1 hour of birth: Y ☐ N ☐ Bf within 4 hours of birth: Y ☐ N ☐

*Skin to skin done first day: Y ☐ N ☐ *Skin to skin done day 2 or later: Y ☐ N ☐

Mother-Baby separated due to medical complications: Y ☐ N ☐ Rooming in Y ☐ N ☐

First late preterm and early term baby: Y ☐ N ☐ *First late preterm and early term baby breastfed: Y ☐ N ☐

Plan to breastfeed: Exclusive ☐ Partial ☐ *Intended duration of BF ____ mo *Hand expression done in hosp: Y ☐ N ☐

Began pumping in first 24 hrs: Y ☐ N ☐ Pumping at discharge: Y ☐ N ☐

*Baby using pacifier in hosp: Y ☐ N ☐ Baby receiving supplemental feeding in hosp: Y ☐ N ☐

Reason for supp: N/A ☐ Hypoglycemia ☐ Weight ☐ Mother's request ☐ Other ☐

Supplementation method if given: N/A ☐

SNS at breast ☐ Syringe ☐ SNS via finger ☐ Cup ☐ Bottle ☐ Other ☐

Highest Via Christi score first 24 hrs: <7 ☐ 8-10 ☐

highest Via Christi score in hosp: <7 ☐ 8-10 ☐

Number of lactation consults in hospital: 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ >4 ☐

Using nipple shield: Y ☐ N ☐ *Father of baby support of BF Y ☐ N ☐

*Have family member who has BF Y ☐ N ☐ *Close friends who have BF Y ☐ N ☐

Appendix B-3: Structured Interview at 1 Month of age

Case # _____ Call Date: ____/____/___ interpreter used Y ☐ N ☐ contact number#:_____

1. Are you still breastfeeding? Y ☐ N ☐ Are you using nipple shield? Y ☐ N ☐ Are you pumping? Y ☐ N ☐ Are you back to work Y ☐ N ☐

If yes feeding-How many times per day are you breastfeeding the baby? 1-2 times/day ☐ 3-4 times/day ☐ 5-6 times /day ☐ 7 or >times/day ☐

Are you supplementing with breast milk in addition to breastfeeding: Y ☐ N ☐ what % of the feedings are breast milk? 76-100% ☐ 50-75% ☐ 25-49% ☐ <25% ☐

Are you supplementing with formula in addition to breastfeeding: Y ☐ N ☐ What % of the feedings are formula? 76-100% ☐ 50-75% ☐ 25-49% ☐ <25% ☐

Is your baby only receiving breast milk? Y☐ N ☐

Supplementation method if given:

SNS at breast ☐ Syringe ☐ SNS via finger ☐ Cup ☐ Bottle ☐ Other ☐

To help us understand why you have been able to continue breastfeeding, what would you say has been the most helpful to you?
Lactation education and support in hospital ☐ Lactation support after discharge ☐
Family/ social support ☐ Knowledge of breastfeeding before delivery ☐ provider advice/support ☐
Baby's breastfeeding ability ☐ Other ☐ _____

How long do you plan to continue to breastfeed; 3 mo ☐ 6 months ☐ 9 months ☐ ≥1 year ☐

If no: when did you stop bf:By 1 week/age ☐ 2 weeks/age ☐ 3 weeks/age ☐ Within the past week ☐

To help us understand why you had to stop breastfeeding, can you tell us what the biggest reason you stopped breastfeeding was?

Mother didn't want to do it any longer ☐ Too many challenges to do it ☐ Insufficient milk supply ☐
Lack of family/social support ☐ lack of professional support ☐
Mother went back to work ☐ Dr. told mother it was OK ☐ other ☐ _____

2. Did you get any help for breastfeeding since you were discharged such as support group, lactation visits or phone support, extra visits to the pediatrician? Y ☐ N ☐
If yes, what kind of help was it? Support group ☐ Lactation visit or calls ☐
Extra feeding visits to the doctor ☐ other ☐ _____
How many sessions 0 ☐ 1 ☐ >1 ☐

3. Did you feel you knew the feeding plan when you went home? Y ☐ N ☐

4. How satisfied are you with how the feeding is going now? Very dissatisfied ☐ Dissatisfied☐ Neutral ☐ Satisfied ☐ Very satisfied ☐

Referral made: Y ☐ N ☐

Appendix B-4: Structured Interview at 2 Month of age

Case # _____ Call Date: ____/____/___ interpreter used Y ☐ N ☐ contact number#:_____

1. Are you still breastfeeding? Y ☐ N ☐ Are you using nipple shield? Y ☐ N ☐

Are you pumping?Y ☐ N ☐ Are you back to work Y ☐ N ☐

If yes feeding-How many times per day are you breastfeeding the baby? 1-2 times/day ☐ 3-4 times/day ☐ 5-6 times /day ☐ 7 or >times/day ☐

Are you supplementing with breast milk in addition to breastfeeding: Y ☐ N ☐ what % of the feedings are breast milk? 76-100% ☐ 50-75% ☐ 25-49% ☐ <25% ☐

Are you supplementing with formula in addition to breastfeeding: Y ☐ N ☐ What % of the feedings are formula? 76-100% ☐ 50-75% ☐ 25-49% ☐ <25% ☐

Is your baby only receiving breast milk? Y☐ N ☐

Supplementation method if given:
SNS at breast ☐ Syringe ☐ SNS via finger ☐ Cup ☐ Bottle ☐ Other ☐

To help us understand why you have been able to continue breastfeeding, what would you say has been the most helpful to you?
Lactation education and support in hospital ☐ Lactation support after discharge ☐
Family/social support ☐ Knowledge of breastfeeding before delivery ☐ provider advice/support ☐
Baby's breastfeeding ability ☐ Other ☐ _____

How long do you plan to continue to breastfeed; 3 mo ☐ 6 months ☐ 9 months ☐ ≥1 year ☐

If no: when did you stop bf:By 5 week/age ☐ 6 weeks/age ☐ 7 weeks/age ☐ Within the past week ☐

To help us understand why you had to stop breastfeeding, can you tell us what the biggest reason you stopped breastfeeding was?

Mother didn't want to do it any longer ☐ Too many challenges to do it ☐ Insufficient milk supply ☐
Lack of family/social support ☐ lack of professional support ☐
Mother went back to work ☐ Dr. told mother it was OK ☐ other ☐ _____

2. Did you get any help for breastfeeding since you were discharged such as support group, lactation visits or phone support, extra visits to the pediatrician? Y ☐ N ☐
If yes, what kind of help was it? Support group ☐ Lactation visit or calls ☐
Extra feeding visits to the doctor ☐ other ☐ _____
How many sessions 0 ☐ 1 ☐ >1 ☐

3. Did you feel you knew the feeding plan when you went home? Y ☐ N ☐

4. How satisfied are you with how the feeding is going now?

Very dissatisfied ☐ Dissatisfied ☐ Neutral ☐ Satisfied ☐ Very satisfied ☐

Referral made: Y ☐ N ☐

Appendix B-5: Permission to use Breastfeeding Self-Efficacy Scale- Short Form

Dear Joan,
Thank you for your email and interest in my Breastfeeding Self-Efficacy Scale. I have attached the short-form to be used in your dissertation. Good luck with your dissertation.
Very warm regards,
Cindy-Lee

Cindy-Lee Dennis, PhD
Professor in Nursing and Medicine, Dept. of Psychiatry;
Canada Research Chair in Perinatal Community Health;
Shirley Brown Chair in Women's Mental Health Research, Women's College Research Institute;

University of Toronto
Lawrence S. Bloomberg Faculty of Nursing
155 College St
Toronto, Ontario
Canada M5T 1P8
Tel: (416) 946-8608
Fax: (416) 978-8222
www.cindyleedennis.ca

Mothering Transitions RESEARCH

From: Kuhnly, Joan [mailto:joan.kuhnly@uconn.edu]
Sent: October 29, 2012 11:17 PM
To: Cindy-Lee Dennis
Subject: BSES-SF request

Hello Dr. Dennis-
I have read with great interest your work in developing the Breastfeeding Self-Efficacy Scale and then, the short form. I am currently in a Doctorate of Nursing Practice program at University of CT School of Nursing in addition to working there on faculty. My proposed dissertation addresses the Successful breastfeeding of the late preterm infant. In particular, I would like to identify if there is a relationship between successful breastfeeding and Breastfeeding Self-Efficacy, method of supplemental feedings used and the type and amount of lactation support provided and accessed. I became truly excited when I found your theory of Breastfeeding Self-Efficacy and saw how nicely it would fit as a theoretical foundation for my Clinical practice dissertation.

Would it be possible to have your permission to use your BSES-SF in my study? Please let me know how I should proceed if this is agreeable to you or if you have any questions.

Thank you very much. Joan

Joan Kuhnly, RN, IBCLC, NNP-BC, MS, CNE
Assistant Clinical Professor
Chairperson, Prelicensure Programs Task Force
University of Connecticut School of Nursing
Office phone 860-486-6130
Cell Phone 860-306-0342
Beeper 860-762-0264
email Joan.Kuhnly@uconn.edu

"Life is not about waiting for the storm to end; it's about learning to dance in the rain" Nutmeg's Wall

Appendix B-6-7: Permission to use Breastfeeding Self-Efficacy Scale- Short Form Spanish Version and Spanish Version of Short Form

No problem at all – attached is the US Spanish version.

Cheers

C-L

Cindy-Lee Dennis, PhD
Professor in Nursing and Medicine, Dept. of Psychiatry;
Canada Research Chair in Perinatal Community Health;

Shirley Brown Chair in Women's Mental Health Research, Women's College Research Institute;

University of Toronto
155 College St
Toronto, Ontario
Canada M5T 1P8
Tel: (416) 946-8608
www.cindyleedennis.ca

From: Kuhnly, Joan [mailto:joan.kuhnly@uconn.edu]
Sent: April 2, 2013 12:21 AM
To: Cindy-Lee Dennis
Subject: Spanish version of BSES-SF

Hello again Dr. Dennis-

I apologize for the repeated emails. You have given me permission to use the BSES –SF for my dissertation research project with mothers of late preterm and early term infants. The population I want to study has a high percentage of mothers who speak Spanish. I know you have confirmed reliability in several language translations. Could I please use the tool that has been translated into Spanish? Thank you again.. Joan

Joan Kuhnly, RN, IBCLC, NNP-BC, MS
Assistant Clinical Professor

Chairperson, Prelicensure Programs Task Force
University of Connecticut School of Nursing

Escala de Auto-Eficacia para Lactancia

Para cada una de las siguientes frases, favor escoger la respuesta que mejor describe cuán segura te sientes amamantando a tu bebé. Favor marcar tu contestación haciéndole un círculo al número que mejor describe cómo te sientes. No hay contestaciones correctas o incorrectas.

1 = Nada segura
2 = No muy segura
3 = Mitad del tiempo segura
4 = Bastante segura
5 = Siempre segura

---

1. Cuán segura te sientes de siempre poder saber si tu bebé está tomando suficiente leche del pecho. 1 2 3 4 5

---

2. Cuán segura te sientes de siempre poder enfrentar con la tarea de amamantar con éxito como has enfrentado otros retos en tu vida. 1 2 3 4 5

---

3. Cuán segura te sientes de siempre poder amamantar a tu bebé, sin tener que utilizar fórmula como suplemento. 1 2 3 4 5 .

---

4. Cuán segura te sientes de siempre poder sentir si tu bebé está agarrando el pecho apropiadamente. 1 2 3 4 5

---

5. Cuán segura te sientes de siempre poder 1 2 3 4 5

manejar la situación del amamantamiento
a tu satisfacción.

---

6. Cuán segura te sientes de poder amamantar incluso si tu bebé está llorando. 1 2 3 4 5

---

7. Cuán segura te sientes de siempre poder mantener el deseo de lactar. 1 2 3 4 5

---

8. Cuán segura te sientes de siempre poder amamantar cómodamente con los miembros de tu familia presentes. 1 2 3 4 5

---

9. Cuán segura te sientes de siempre poder sentirte satisfecha con tu experiencia de amamantar. 1 2 3 4 5

---

10. Cuán segura te sientes de siempre poder entender el hecho de que lactar consume tiempo. 1 2 3 4 5

---

11. Cuán segura te sientes de siempre poder terminar de amamantar a tu bebé en un pecho, antes de cambiar al otro pecho. 1 2 3 4 5

12. Cuán segura te sientes de siempre poder lograr el amamantamiento de tu bebé en cada una de sus alimentaciones.	1 2 3 4 5
13. Cuán segura te sientes de siempre poder satisfacer las demandas de amamantamiento de tu bebé.	1 2 3 4 5
14. Cuán segura te sientes de siempre poder reconocer cuando tu bebé ha terminado de lactar.	1 2 3 4 5

Appendix C-1: Codebook for Data Entry

CODEBOOK
Any Missing data=unknown

Data Codebook- Question 1 outcome of sustained BF

Variable	Variable Label	Value	Category of measurement
Sustained BF 1mo	SBF1	0=no 1=yes	Nominal
Sustained BF 2 mo	SBF2	0=no 1=yes	Nominal

Data Codebook- Completer vs. Non Completer Comparison

Variable	Variable Label	Value	Category of measurement
Completer Status 1 month	Completer1	0=no 1=yes	Nominal
Completer status 2 month	Compelter2	0=no 1=yes	Nominal

Data Codebook- Outcomes Questions 2a-

Variable	Variable Label	Value	Category of measurement
2a. Predischarge maternal BF Self-Efficacy	BSES	0=low (score 14-32) 1=mod (score 33-51) 2=high (score 52-70)	Ordinal
2b. Supplemental Feeding received	SF	0=no 1=yes	Nominal
2b. Supp feeding method	SFM	0=SNS breast 1=syringe 2=SNS finger 3=cup 4=bottle 5=other 6= multiple methods 7=no method used	Nominal
SNS at breast SFM	Snsb	0-no method used 1-sns breast only used	Nominal
Syringe SFM	Syringe	0=no method used 1-syringe feeding only used	Nominal
SNS finger SFM	Snsfinger	0= no method used 1=sns on finger only used	Nominal
Bottle SFM	Bottle	0=no method used	Nominal

		1=bottle only used	
Multiple methods of SFM	Multmeth	0=no method used 1=multiple methods used	Nominal
2c. Lactation consults in hosp	LC	0=none 1=1 2=more than 1	Ordinal
2d. Preterm status	LPT_ET	0= late preterm (35-36 6/7 wks) 1= early term (37 wks)	Nominal
2e Maternal demographics			
Maternal Age	Mom age	0=18-20 years old 1=21-29 years old 2=30-39 years old 3= 40 or greater yrs	Ordinal
Maternal level of education	Mom educ	0-less than high school 1- high school completion 2- some college 3-college degree 4=unknown level of education	Ordinal 0-3 Nominal 0-4
Maternal race	Mom race	0=Caucasian 1=Hispanic 2=African American 3=Asian 4=Other	Nominal
Primipara status	First baby	0=no 1=yes	Nominal
BF experience	BF exp	0=no 1=yes	Nominal
Previous LPT/ET infant	Prev PT baby	0=no 1=yes	Nominal
2e-infant demographics			
Infant Gender	Gender	0-male 1-female 999 missing	Nominal
Singleton status	Singleton	0=no 1=yes (twin)	Nominal
Birth weight classification	BWclass	0-SGA 1-AGA 2-LGA	Ordinal
R2 Birth weight	BW		Continuous

S2lowest weight in hosp	lowweight		Continuous
T DC weight	DC wt		Continuous
U percent wt loss calculated	pctwtloss		Calculated
V D/C wt loss percentage	wtlossclass	0-less than 7% 1- 7-9.9% 2 –10% or greater	Ordinal
Hypoglycemia experienced	Hypoglyc	0=no 1=yes	Nominal
Phototherapy required in hosp	PT	0=no 1=yes	Nominal
Maternal Infant separation	Separation	0=no (rooming in) 1=yes	Nominal
2f- characteristics of birth process			
Method of delivery	Vag	0=no (C/S) 1-yes	Nominal
Epidural use	Epidural	0=no 1=yes	Nominal
Magnesium Sulfate used	Mgso4	0=no 1=yes	Nominal
2g. In hospital feeding practices			
Maternal feeding Plan	BFplan exclusive	0=no (partial) 1=yes	Nominal
BF within 1 hour	BF Sacred hour	0=no 1=yes	Nominal
BF within 4 hours	Early BF	0=no 1=yes	Nominal
Skin to Skin practiced day 2 or later	StoS	0=no 1=yes	Nominal
BF assessment day 1- VC score less than or equal to 7	VC day 1	0= no (8-10) 1=yes	Nominal
BF assessment after day 1-BC score less than or equal to 7	VC day 2on	0=no (8-10) 1=yes	Nominal
Use of pacifier	Pacifier	0=no 1=yes	Nominal
Use of breastpump first 24 hours	Early pump	0=no 1=yes	Nominal
Use of breastpump before discharge	Hosp pump	0=no 1=yes	Nominal
Nipple shield use	NS	0=no 1=yes	Nominal
Hand expression use	HE	0=no 1=yes	Nominal

Data Codebook- Question 3- Post D/C Lactation support

Variable	Variable Label	Value	Level of Measurement
# post discharge lactation support	Home LC	0=none 1=1 visit 2=>1 visit	Ordinal

Appendix C-2: IRB Approval Hartford Hospital

Hartford HealthCare

Research Institute
(860)545-2865

80 Seymour Street
(860)545-5112 (FAX)

Hartford, CT. 06102
research@harthosp.org

9/4/2013

Joan Kuhnly

Research Approval/Award Letter

This letter is your confirmation that the above project has been approved by the Research Committee and has been assigned a research account number. This is the final step in the approval process.

Important: Please read the information below regarding the details of this approval. This section outlines the responsibilities and obligations assumed by the principal investigator upon initiation of this project.

Principal Investigator: **Joan Kuhnly,**
Study Title: **Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 Weeks Gestation**

Research Account Information:
Research Account: 333819
Funding Type: Unfunded

In-Kind
This project has an estimated total In-Kind amount of $24,414.00 for the following projected period:
Start Date: 8/14/2013 End Date: 5/14/2014 .

Principal Investigator Responsibilities
The Principal Investigator (PI) is responsible for conducting this research activity in accordance with all applicable hospital policies and procedures, including but not limited to the following:

1. Budget Management Policy, if funded: The PI is responsible for the proper management of the project's finances in accordance with the Budget Management Policy. If project expenses exceed the amount awarded and your project goes into deficit, you will be expected to deposit or transfer sufficient funds to cover the deficit.
2. Patent Policy: The PI is responsible for ensuring that all inventions and potential inventions resulting from research conducted at Hartford Hospital are disclosed to and processed by Research Administration in accordance with the Hartford Hospital Research Program Patent Policy.
3. Timely Renewal: The PI is responsible for ensuring that all required progress reports and supporting materials are submitted to Research Administration for the project's continuing review and renewal. The PI is also responsible for the timely notification of study completion.
4. Abstracts / Publications: It is expected that all abstracts and publications resulting from this project acknowledge support by HH Research Endowment Funds, if applicable. **PI's funded by NIH are required to comply with NIH Public Access Policy, effective April 07, 2008.** Link for more information: http://publicaccess.nih.gov/policy.htm

You may contact our research staff at (860)545-4592 for a copy of the policies.

Sincerely,

Lenworth M. Jacobs, MD, MPH, DSc(Hon), FACS, FWACS (Hon)
Vice President of Academic Affairs and Chief Academic Officer
Hartford Hospital
Professor of Surgery
Professor and Chairman
Department of Traumatology and Emergency Medicine
Assistant Dean, Academic Affairs
University of Connecticut Health Center
Chairman, Trauma Institute/LIFE STAR
Hartford Hospital

cc: Joel Sorosky, MD

Project #: KUHN004112HU

Printed: 9/4/2013: 03:03 PM

Appendix C-3: IRB Approval University of Connecticut

University of Connecticut
Office of Research Compliance

To: Robert D. Siegel, M.D., Chairman
Institutional Review Board
Hartford Hospital
Office of Research Administration
80 Seymour Street
P.O. Box 5037
Hartford, CT 06102-5112

From: Douglas Bradway, MA, CIP
Office of Research Compliance

Date: September 5, 2013

Re: Acceptance of IRB Review – Designation as IRB of Record
Protocol Title: Exploration of Factors Related to the Prevalence of Sustained Breastfeeding in Infants Born Between 35-37 6/7 Weeks Gestation
HH IRB Number: KUHN004112HU
HH Principal Investigator: Joan Kuhnly
Storrs Principal Investigator: Joan Kuhnly
Storrs Student Investigator: Nikaela Larossa (Data Collection Only)
Storrs IRB Number: HHKUHN004112HU
Storrs OSP Proposal Number: N/A

On September 5, 2013, the Institutional Review Board of the University of Connecticut (UConn) accepted the review conducted by your institution for the study noted above. Per the cooperative agreement in place, the IRB of Hartford Hospital will serve as the IRB of record for this study, and, therefore, be responsible for all continuing review and review of amendments. Additionally, the UConn IRB is to be informed of all instances of non-compliance or unanticipated problems, related to this study, should they occur.

Please forward copies of IRB approval letters and study related activities to the UConn Office of Research Compliance.

cc: Storrs PI

An Equal Opportunity Employer

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Storrs, Connecticut 06269-1246

Telephone: (860) 486-8802
Facsimile: (860) 486-1044
web: compliance.uconn.edu

Appendix C-4: Via Christi Breastfeeding Assessment Tool

	0	1	2	score
Latch-on	**No Latch on achieved**	**Latch-on after repeated attempts**	**Eagerly grasped breast to latch on**	
Length of time before latch-on and suckle	**Over 10 min.**	**4-6 min.**	**0-3 min.**	
Suckling	**Did not suckle**	**Suckled but needed encouragement**	**Suckle rhythmically with lips flanged**	
Audible Swallowing	**None**	**Only if stimulated**	**Over 48 hours: Frequent**	
Mom's evaluation	**Not pleased**	**Somewhat pleased**	**Pleased**	

Total Score _____