BREASTFEEDING THE LATE PRETERM INFANT: A GROUNDED THEORY STUDY

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Bachelor of Science in Nursing, University of Pittsburgh, 2005

Master of Science in Nursing, University of Pittsburgh, 2010

Submitted to the Graduate Faculty of

School of Nursing in partial fulfillment

of the requirements for the degree of

Doctor of Philosophy

University of Pittsburgh

2012

UNIVERSITY OF PITTSBURGH

SCHOOL OF NURSING

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May 23, 2012

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Late preterm infants (LPIs), born between 34 0/7 and 36 6/7 weeks gestation, are reported to experience suboptimal breastfeeding rates and significant morbidity related to inadequate breast milk intake. Although unrecognized physiological immaturities are often implicated in these issues, breastfeeding is a complex phenomenon impacted by multiple and interrelated social, medical, and system-level factors. This dissertation addresses the available evidence on breastfeeding outcomes and patterns within the LPI population and also includes a population-level analysis of LPI breastfeeding initiation. The main study, however, utilized grounded theory techniques to examine the maternal experience of breastfeeding a late preterm infant. Ten late preterm mother-infant dyads participated in the study, which incorporated serial interviews and several other data collection methods, over a 6-8 week period after delivery. Breastfeeding in the LPI population was found to be a fluctuating, cascade-like progression of trial and error, influenced by a multitude of contextual factors and events and culminating in breastfeeding continuation (with or without future caveats regarding breastfeeding duration or exclusivity) or cessation. The trajectory was explained by the basic psychosocial process *Weighing Worth against Uncertain Work*, which encompassed the tension between breastfeeding motivation, the intensity of breastfeeding work, and ambiguity surrounding infant behavior and feeding cues. Several sub-processes were also identified: *Playing the Game*; *Letting Him be the Judge vs. Accommodating Both of Us*; and *Questioning Worth vs. Holding out Hope*. Our theoretical model

indicates that mothers of LPIs require early, extended, and intensive breastfeeding support that emphasizes management strategies and the connection between infant prematurity and observed behaviors.

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Really great people make you feel that you, too, can become great.—Mark Twain

As much as the past five and a half years have been an academic journey, they have also been a time of personal growth. I have learned not only how to conduct a systematic review and write a compelling study proposal, but also how to accept criticism, build upon my strengths, work around my shortcomings, and display confidence even while learning. I have found a research area that I am passionate about and envision becoming part of my life's work. These are gifts that have enriched my life beyond the satisfaction of receiving a degree or a title, and they were realized, in large part, because of my mentors.

I find it difficult to convey in words the respect and gratitude I have for each member of my dissertation committee. I am so appreciative of the time, insights, and knowledge they shared so freely and generously. I am indebted to Dr. Bogen, who has cultivated my passion for improving the breastfeeding experience for vulnerable mothers and their infants. Her support and mentoring have meant everything, and I am thrilled to have an opportunity to continue to work with and learn from her. I am grateful to Dr. Albrecht, who has been an invaluable teacher, role model, and mentor. I am humbled by her support and confidence in me. Because of her, I became involved in AWHONN (Association of Women's Health, Obstetric, and Neonatal Nurses), which has been one of the most enriching and rewarding experiences during my education.

Both Dr. Happ and Dr. Cohen have influenced my life in a remarkable way. A decade ago, Dr. Happ gave me an opportunity as an undergraduate student, encouraged me to apply to the PhD program, and continued to mentor me throughout my time in the program. I see that same collaborative, generous spirit continued with new students, and it is gratifying to realize that people like her exist. I have learned so much from her, and I am thankful to count her among the best mentors I have ever had the pleasure of working with.

I met Dr. Cohen when I began the PhD program, but since then, she has become so much more than an academic advisor. She is a mentor in every sense of the word, an inspirational teacher, and a trusted confidante. In the most unobtrusive way, she inspired confidence, conviction and curiosity of thought, and the desire to know more and do greater. She provided reassurance when I needed it and gave me the self-permission and freedom I needed to explore, learn for myself, and find my passion. I am thankful to know her.

I would like to acknowledge others within the University who have helped me along the way. I thank Jake Dechant, Judy Tate, Dana DiVirgilio, Sandy Founds, Betty Braxter, Annette DeVito Dabbs, Judy Erlen, Elizabeth Schlenk, Susan Sereika, Lauren Terhorst, Jan Dorman, and Dean Dunbar-Jacob for their support. I also thank Sarah Martin for her assistance with transcription during the study. I am grateful to Kathi Perozzi and Donna Abriola, my undergraduate obstetric nursing instructors, who helped me discover my niche in maternal-child nursing. I would like to thank my fellow PhD students who have made my time in the PhD program so enjoyable. In particular, I would like to thank Aom (Phensiri) Dumrongpakapakorn, Jing Wang, Grace Campbell, Monica DiNardo, Mandy Bell, Karen Wickersham, Marci Nilsen, Jessica Devido, and Kelley Baumgartel.

I am grateful to the participants in my study, who so generously gave their time and shared their stories with me. They have opened my eyes, and, in turn, I hope to open the world's eyes to their struggles and successes. I also thank Magee Womens Hospital staff for facilitating participant recruitment. In particular, I would like to thank Leslie Gostic, Lynn Cimino, and the nursing staff in the postpartum units and NICU.

I thank the National Institutes of Nursing Research (NINR) and Sigma Theta Tau International, Eta Chapter for their support of this project. I was also fortunate enough to benefit from many scholarships over the years, and I wish to acknowledge the donors, including Margaret E. Wilkes, Beryl B. Haughton Jackson, and Doris and Davina Gosnell.

Lastly, I would not be in the position I am today without the unconditional love and support of my family. In particular, I want to thank my parents, Klaus Radtke and Kathy Waddell; my sister, Renee Loll; and my husband, Mehmet Demirci. My mother, Kathy, was my first and most important teacher. She taught me accountability, independence, kindness, empathy, and perseverance. She has given me everything, and I am forever grateful for her in my life.

My husband, Mehmet, has made all of the time, struggles, setbacks, and successes worth it. He is my best friend, sounding board, biggest advocate, and the inspiration behind everything I do. I thank him for believing in me, loving me, and reminding me that no matter what is achieved in life, the greatest joy is the time spent with those you love.

1.0 INTRODUCTION/STUDY PROPOSAL

Late preterm infants—those born between $34^{0/7}$ and $36^{6/7}$ weeks of gestation—account for nearly three-quarters of preterm births in the United States and are the fastest growing cohort of premature infants (Davidoff et al., 2006; B. E. Hamilton, Martin, & Ventura, 2007; Martin et al., 2007). Although they often resemble term infants in both outward appearance and birth hospitalization course, late preterm infants lack comparable developmental maturity in almost all body systems (Engle, Tomashek, & Wallman, 2007). The literature suggests that these "hidden" medical vulnerabilities contribute to decreased medical vigilance and inadequate caretaker anticipatory guidance, leading to high rates of late preterm morbidity and re-hospitalization (Committee on Obstetric Practice, 2008; Engle et al., 2007; Escobar, Clark, & Greene, 2006; Escobar et al., 2005; Wang, Dorer, Fleming, & Catlin, 2004). Of particular concern, late preterm infants who are breastfed tend to be re-hospitalized with diagnoses of failure to thrive, jaundice, and dehydration more frequently than those who are not breastfed, a finding largely attributed to insufficient breast milk intake (Escobar et al., 2002; Gartner, 2001; Shapiro-Mendoza et al., 2006; Tomashek et al., 2006; Wight, 2003). This trend is disconcerting, considering the many, significant, and empirically-validated advantages that breastfeeding provides, particularly for infants born prematurely (Callen & Pinelli, 2005).

Late preterm breastfeeding complications are often traced to infant-related issues, including immature suck/swallow/breath coordination and underdeveloped state regulation

(Medoff-Cooper, McGrath, & Bilker, 2000; Medoff-Cooper & Ray, 1995; Wight, 2003). Yet, breastfeeding is a reciprocal activity involving both the infant and mother. The maternal component of the process, as described in the general preterm literature, may be fraught with multiple and interdependent barriers, both physiological and psychological in nature. These include anxiety and stress related to a traumatic birth or medically fragile infant, delayed onset of lactogenesis II, and poor milk supply resulting from medical complications, inadequate milk removal, and/or pump dependency (Chen, Nommsen-Rivers, Dewey, & Lonnerdal, 1998; Dewey, 2001; Hartmann & Cregan, 2001; Neville & Morton, 2001; Sweet, 2008). Research indicates that mothers of term infants experience somewhat different breastfeeding obstacles, including competing work/school obligations, lack of support, and breastfeeding discomfort (Arora, McJunkin, Wehrer, & Kuhn, 2000; Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003; O'Campo, Faden, Gielen, & Wang, 1992). It is unclear how, or even if, similar influences operate to affect the establishment and course of breastfeeding among late preterm mother-infant dyads, as circumstances that affect breastfeeding, including infant behavior and medical stability, maternal preparedness for birth and breastfeeding, and discharge and social support are likely to differ considerably between this group and earlier preterm and full-term populations. By delineating the nature of the late preterm maternal breastfeeding process, however, these infants' health and breastfeeding outcomes may be improved and the respective maternal-infant relationship enhanced.

1.1 PURPOSE AND SPECIFIC AIMS

The purpose of this qualitative, grounded theory study was to describe and explain the process of breastfeeding initiation and continuation among late preterm mother-infant dyads. Secondary aims were to:

1. Place breastfeeding within the broader context of mothering a late preterm infant; and

2. Identify factors influencing the late preterm mother's decision to initiate and continue breastfeeding.

1.2 BACKGROUND AND SIGNIFICANCE

1.2.1 Scope of the late prematurity problem

In 2005, there were nearly 375,000 late preterm births. This figure corresponds to a dramatic increase in the incidence of late prematurity within the past two decades in the U.S.—by 25% from 1990 to 2005, and by 9.6% between only 2000 and 2005 (Martin et al., 2007). In contrast, the percentage of infants ≥ 40 weeks of gestation has decreased by 15% since 1990, and infants born before 34 weeks of gestation have increased only moderately—by 8.5% from 1990 to 2005 (Davidoff et al., 2006; Martin et al., 2007). Despite growing recognition of this late preterm "epidemic," late preterm births decreased by only a tenth of a percentage point between 2006 and 2007 (Martin et al., 2010). A number of inter-related factors have been implicated in regard to the recent pervasiveness of late prematurity, including increases in the number of multiple births,

the national obesity epidemic and related fetal macrosomia, the trend toward later-life childbearing, consumer demand and preferences for elective inductions and cesarean sections, proliferation of obstetric malpractice litigation, practice guidelines opposing post-term deliveries, and advancements in fetal monitoring (Engle & Kominiarek, 2008; Fuchs & Gyamfi, 2008; Raju, 2006).

In concordance with the growing late preterm population, a study from the federal Healthcare Cost and Utilization Project revealed that non-extreme preterm infants ($28^{0/7}$-$36^{6/7}$ weeks of gestation) consume two-thirds of all hospital expenditures related to prematurity (Russell et al., 2007). The authors postulate that these expenses are attributable mainly to late preterm infants, in direct proportion to their prevalence, rather than acuity of illness. A cost analysis performed through a review of 185 near-term (defined by authors as $35^{0/7}$-$36^{6/7}$ weeks gestation) and full-term infants' electronic medical records showed that near-term infants consume a mean of $2,630 more in medical costs than infants ≥ 37 weeks gestation (Wang et al., 2004).

Despite appearances and weights often comparable to their term counterparts, late preterm infants tend to lag behind in terms of their cardiorespiratory, metabolic, immunologic, neurologic, and motor development (Engle & Kominiarek, 2008; Engle et al., 2007). In recognition of this contradiction, a multidisciplinary expert panel assembled by the National Institute of Child Health and Human Development in 2005 made the recommendation to classify infants born between $34^{0/7}$ and $36^{6/7}$ weeks gestation as "late preterm," rather than "near term," in order to convey the medical vulnerability extant within this cohort (Raju, Higgins, Stark, & Leveno, 2006). Consistent with this assertion, but not with terminology, a medical record review reported that near-term infants ($35^{0/7}$-$36^{6/7}$ weeks gestation) were four times more likely than

term infants to be diagnosed with jaundice, respiratory distress, poor feeding, temperature instability, or hypoglycemia during the birth hospitalization (Wang et al., 2004). The most common of these complications were jaundice (54%), suspected sepsis (37%), and feeding difficulties (32%).

Another medical record analysis, which included more than 33,000 infants born at seven different Kaiser Permanente facilities, found that late preterm infants not admitted to the NICU were more likely than infants of all other gestational ages to be readmitted to the hospital within two weeks (adjusted odds ratio [AOR] = 3.10, 95% confidence interval [CI]: 2.38-4.02) (Escobar et al., 2005). The most frequent reasons for re-hospitalization were jaundice (34%) and feeding difficulties (26%). Another study by the same authors found that a gestational age of 36 weeks was one of only three predictors of re-hospitalization at 15 to 182 days following discharge (Cox hazard ratio = 1.67, 95% CI: 1.23-2.25) (Escobar et al., 2006). Most recently, a chart review of more than 200,000 deliveries between 2002-2008 in the U.S. revealed that late preterm infants were significantly more likely than term infants to develop respiratory morbidity, including respiratory distress syndrome (AOR of RDS at 34 weeks compared to 39-40 weeks gestation = 40.1, 95% CI: 32.0-53.3) (Consortium on Safe Labor, 2010).

Several studies report significant mortality risks for late preterm infants. In one study (Kramer et al., 2000), the etiological fraction of mortality for moderately preterm infants ($32^{0/7}$-$36^{6/7}$ weeks gestation) exceeded that of very preterm infants (28-$31^{6/7}$ weeks gestation). Another analysis (Khashu, Narayanan, Bhargava, & Osiovich, 2009) noted significantly higher perinatal (RR = 8.0, 95% CI: 6.2-10.4), neonatal (RR = 5.5, 95% CI: 3.4-8.9), and infant mortality (RR = 3.5, 95% CI: 2.5-5.1) for late preterm (unconventionally defined as $33^{0/7}$-$36^{6/7}$ weeks gestation) as compared to term infants. Analogously, a 2008 committee publication by The American

College of Obstetricians and Gynecologists reported that late preterm infants have a mortality rate 4.6 times that of term infants, a figure that has increased gradually since 1995 (Committee on Obstetric Practice, 2008).

1.2.2 Late preterm breastfeeding-associated morbidity

Emergent from these statistics is the paradoxical finding that late preterm neonates who are breastfed at hospital discharge tend to fare worse than infants of similar gestation who are not breastfed. In a population-based cohort study involving 9,522 late preterm infants in the U.S., breastfeeding at the birth hospitalization discharge emerged as the single greatest risk factor for the infant's re-hospitalization (adjusted risk ratio [aRR] = 1.65, 95% CI: 1.33-2.04) (Shapiro-Mendoza et al., 2006). In another cohort study utilizing the same vital statistics database, the authors reported that among infants who breastfed at hospital discharge, late preterm infants were significantly more likely than term infants to be re-hospitalized (aRR = 2.2, 95% CI: 1.5-3.2) and to receive hospital-related care after discharge (aRR = 1.8, 95% CI: 1.3-2.5). This difference was not observed between term and late preterm infants who were not breastfeeding at discharge (Tomashek et al., 2006). Wang and colleagues (2004) reported in their medical record review—a sample wherein roughly 80% of mothers initiated breastfeeding, that infants $35^{0/7}$-$36^{6/7}$ weeks gestation were significantly more likely than term infants (≥ 37 weeks gestation) to experience a hospital discharge delay due to "poor feeding" ($p = 0.029$). In addition, a retrospective review of registry data found that infants $35^{0/7}$-$36^{6/7}$ weeks gestation ("nearly all breastfeeding") were significantly more likely than infants ≥ 37 weeks to have severe posticteric sequelae ($p < 0.01$) (Bhutani & Johnson, 2006).

Other studies have noted higher rates of morbidity, including re-hospitalizations, due to "feeding problems" and jaundice among late preterm infants but have not delineated breastfeeding from formula feeding (Jain & Cheng, 2006; Lubow, How, Habli, Maxwell, & Sibai, 2009). Alternatively, some studies have found both late prematurity (or younger term gestations) and breastfeeding to be independently and significantly related to higher rates of hospital readmissions, but do not account for the interaction between breastfeeding and gestational age (Escobar et al., 2002; Maisels & Kring, 1998; Oddie, Hammal, Richmond, & Parker, 2005). Notably, Escobar and colleagues (2002) reported that within their large, retrospective case-control nested cohort study, the most prominent factors contributing to a re-hospitalization for dehydration among infants ≥ 36 weeks gestation included exclusive breastfeeding (AOR = 11.2, 95% CI: 3.9-32.6) and gestational age < 39 weeks (AOR = 2.0, 95% CI: 1.5-6.0).

1.2.3 Breastfeeding rates in the late preterm population

Individual study data indicate that breastfeeding initiation rates among late preterm mother-infant dyads at around 59-70% are less than that of term infants and, possibly, younger preterm infants (Colaizy & Morriss, 2008; Donath & Amir, 2008; Merewood, Brooks, Bauchner, MacAuley, & Mehta, 2006; Shapiro-Mendoza et al., 2006; Tomashek et al., 2006). Although national breastfeeding rates for preterm infants as an exclusive group are not compiled, this estimate is less than the overall U.S. average for early postpartum breastfeeding as last reported by the CDC in 2007 at 75.0% ± 1.2 % (Centers for Disease Control and Prevention, 2010).

Breastfeeding duration and exclusivity statistics among late preterm infants are difficult to compile due to wide variations in measurement periods, inconsistent breastfeeding and

gestational age classifications, and regional differences. However, study data suggest that breastfeeding tends to decrease over the postpartum period within the late preterm population, and rates may even be less than that for either term or earlier preterm infants at several weeks postpartum (Colaizy & Morriss, 2008; Donath & Amir, 2008). Colaizy and Morriss (2008) suggest that their finding of higher breastfeeding rates among early preterm infants (< 32 weeks) may be a result of extra vigilance, breastfeeding support, and importance placed on breast milk feedings in the NICU, where younger preterm infants tend to outnumber late preterm infant admissions.

1.2.4 Benefits of breastfeeding among infants born prematurely

Given the morbidity statistics, it may appear counterintuitive to recommend exclusive breastfeeding and engage in efforts to increase rates among late preterm mother-infant dyads. Yet research suggests that the problem lies in the process (inadequate milk transfer), rather than product (breast milk). Indeed, preterm infants who lack the stamina to breastfeed but are supplemented with expressed breast milk tend to have better psychomotor, neurological, circulatory, and cognitive outcomes than those who are formula-fed (Lucas, Morley, Cole, & Gore, 1994; Rao, Hediger, Levine, Naficy, & Vik, 2002; Simeoni & Zetterstrom, 2005). An extensive body of research has elucidated the many specific benefits of breast milk for preterm infants, which, with its complex and temporally-variant composition dependent upon post-conceptional age (Charpak, Ruiz, & K. M. C. Team, 2007), includes: enhanced gastrointestinal maturation; bolstered immunity demonstrated to decrease the incidence of necrotizing enterocolitis, other infections and allergies; and acceleration of myelinization (which may be only 70% of that of term infants at birth), possibly leading to improved childhood cognitive

function (Adams-Chapman, 2006; Callen & Pinelli, 2005; Engle & Kominiarek, 2008). Breastfeeding itself may offer other advantages for preterm infants including improved neuromotor development (Barradas, Fonseca, Guimaraes, & Lima, 2006; Dodd, 2005) and the fostering of mother-infant bonding and secure infant attachment, the latter two of which achieved at least partly through the reciprocity inherent in the act (Britton, Britton, & Gronwaldt, 2006; Callen & Pinelli, 2005; Dodd, 2005; Klaus & Kennel, 1976).

Breastfeeding has been found to decrease the risk of later life obesity (Owen, Martin, Whincup, Smith, & Cook, 2005), and exclusive breastfeeding has been noted to save an estimated $200-475 on pediatrician office visits, hospitalizations and prescriptions per infant during the first year, which is attributed to breast milk's immunologic protection against minor infant ills, including otitis media and respiratory tract infections (Ball & Wright, 1999; Hoey & Ware, 1997). Similarly, a recent cost analysis projected a savings of $13 billion per year and prevention of over 911 deaths if the rate of breastfeeding exclusivity reached 90% in the U.S. (Bartick & Reinhold, 2010).

1.2.5 Causes of poor late preterm breastfeeding outcomes

1.2.5.1 Infant-related

Neither the trajectory nor the causes of poor breast milk intake among late preterm infants have been adequately addressed. The literature suggests several physiologic issues, mainly developmental immaturities in the infant, which seem to contribute to suboptimal breastfeeding in this group. These include: cardiorespiratory instability contributing to rapid fatigue during feeding and subsequent inefficient breastfeeding; metabolic disturbances that necessitate supplementation; NICU admission and other medical conditions that separate mother and infant

and limit the successful establishment of breastfeeding; immaturity of state regulation leading to overstimulation and fatigue during feeding; longer sleep intervals contributing to less overall time breastfeeding; uncoordinated suck, swallow, breathe organization; and, relative to term infants, decreased oro-motor tone which minimizes the negative pressure required for adequate milk flow (Committee on Obstetric Practice, 2008; Medoff-Cooper et al., 2000; Medoff-Cooper & Ray, 1995; Wight, 2003).

These issues may concomitantly contribute to incomplete emptying of the breast, interfering with the supply-demand mechanism of breast milk production. Left unchecked, the phenomenon of insufficient milk supply ultimately ensues and infants who are exclusively, or mostly breastfed may experience significant morbidities related to inadequate caloric intake (Meier, Furman, & Degenhardt, 2007; Wight, 2003). Unfortunately, this cascade of events typically transpires with the onset of lactogenesis II—copious milk production occurring two to three days post-birth (Meier et al., 2007), after the late preterm infant with no immediate health concerns has been discharged home (Wight, 2003).

1.2.5.2 Mother-related—preterm and term populations

While developmental immaturities of the infant likely play a significant role in breastfeeding difficulties within the late preterm population, breastfeeding itself is a complex, reciprocal activity between the infant and mother. The maternal component of the issue has not been examined, except to note that there may be difficulties due to maternal conditions causing or associated with the preterm birth. For example, type I diabetes, obesity, cesarean sections, and pregnancy-induced hypertension may delay lactogenesis II (Hartmann & Cregan, 2001; Rasmussen, Hilson, & Kjolhede, 2001; Sozmen, 1992). Infections, multiple births, and medications used to treat some of these conditions (e.g., antibiotics, labor analgesia/anesthesia)

may lead to postpartum separation of mother and infant, preventing early breastfeeding establishment (Wight, Morton, & Kim, 2008).

Numerous studies generalized to premature and low-birthweight infants describe maternal perceptions of breastfeeding. These qualitative analyses describe feelings of disparity between breastfeeding expectations and reality (Sweet, 2008), objectification of breast milk (Sweet, 2006), concerns regarding inadequate milk volume and composition (Callen, Pinelli, Atkinson, & Saigal, 2005; Kavanaugh, Mead, Meier, & Mangurten, 1995), a duty versus reciprocal breastfeeding viewpoint (Flacking, Ewald, Nyqvist, & Starrin, 2006; Flacking, Ewald, & Starrin, 2007), and the act of breastfeeding as providing a claim on the infant and validating maternal identity (Kavanaugh, Meier, Zimmermann, & Mead, 1997).

Maternal anxiety, stemming from an early or traumatic birth and/or the fragility of a preterm infant, has also been cited in the preterm literature as a contributor to breastfeeding failure. Specifically, anxiety has been implicated in the delay of lactogenesis II, though the pathophysiology of this process remains somewhat obscure (Chen et al., 1998; Hartmann & Cregan, 2001; Neville & Morton, 2001). Some have postulated a negative effect of psychological stress on pulsatile oxytocin release, which inhibits the milk ejection reflex and may contribute to poor establishment of milk supply (Dewey, 2001; Lau, 2001; Ueda, Yokoyama, Irahara, & Aono, 1994). This process is supported by at least one randomized controlled trial involving 65 breastfeeding mothers of premature infants, which found that an audiotape of relaxation and visual imagery techniques listened to every other day for a week resulted in 63% more milk yield in the treatment group compared to the control group, as measured during a single pumping one week later (Feher, Berger, Johnson, & Wilde, 1989).

Numerous studies of term infants have also demonstrated a negative association between anxiety and breastfeeding—revealing that the existence of postpartum anxiety independently accounts for breastfeeding non-initiation and early breastfeeding cessation (Britton, 2007; Papinczak & Turner, 2000; Ystrom, Niegel, Klepp, & Vollrath, 2008). In one study (Taveras et al., 2003), insufficient milk was the most frequently cited reason for early breastfeeding cessation, and lack of confidence in ability to breastfeed doubled the odds of breastfeeding discontinuation at two weeks postpartum (OR = 2.8, 95% CI = 1.02-7.6).

Other barriers to breastfeeding within the general population have been elucidated within the literature. These include competing work/school obligations (O'Campo et al., 1992), inadequate or conflicting breastfeeding information from health care providers, lack of breastfeeding support from significant others (Arora et al., 2000), breastfeeding problems or discomfort (e.g., cracked, sore nipples) (Taveras et al., 2003), and early use of pacifiers and breast milk supplementation (Dewey et al., 2003).

1.2.6 Gaps in knowledge

Infants born in the late premature period remain a largely understudied group. These infants appear to have poorer rates of breastfeeding initiation and duration compared to term (and possibly earlier preterm) infants, and those who are breastfed appear more vulnerable to significant morbidity. The scope and causes of substandard breastfeeding rates and outcomes among late preterm infants remain uncertain, however.

For example, it is unknown whether the same perceptions, anxieties, and resultant effects on breastfeeding observed among mothers of term and early preterm infants exist for mothers of late preterm infants. It may be hypothesized that maternal anxiety, thought to interfere with

breast milk production, increases exponentially with the precariousness of the infant's medical condition and degree of prematurity. However, a recent prospective cohort study of 116 premature infants found that higher maternal perception of child vulnerability was predicted by maternal anxiety but not associated with neonatal illness severity factors, including gestational age, birthweight, or length of mechanical ventilation (Allen et al., 2004). Likewise, Holditch-Davis et al. notes that the mother-premature relationship is complex, in that mothers of medically-fragile infants may be *more* responsive to their infants than mothers of non-chronically ill premature infants (Holditch-Davis, Cox, Miles, & Belyea, 2003) and that increased stress related to caring for a premature infant is associated with more positive maternal involvement (Holditch-Davis, Schwartz, Black, & Scher, 2007).

Evidence suggesting that the current late preterm breastfeeding support is ineffective is provided by Escobar and colleagues (2005, 2006), who report an ostensibly protective effect of NICU admission on morbidity among breastfed late preterm infants—suggested to be due to the provision of additional guidance and breastfeeding support inherent in the NICU milieu. The finding is strengthened by Colaizy and Morriss (2008), who report higher breastfeeding rates among late preterm infants admitted to the NICU as compared to the well-baby nursery. Similarly, in the only randomized controlled trial found on breastfeeding interventions within the late preterm population, breastfeeding infants 35-$37^{6/7}$ weeks gestation who were discharged early and received home support from a lactation consultant had higher rates of exclusive breastfeeding at 5-12 days postpartum as compared to a standard care control group (73.3% vs. 67.7%); however, the sample was very small and results not statistically significant (McKeever et al., 2002).

Breastfeeding (and breast milk provision) evidence-based guidelines for late preterm mother-infant dyads are currently lacking. Despite the paucity of research, several publications exist that provide suggestions, guidelines, and frameworks for breastfeeding support in this population. These include the AWHONN Near-Term Infant Initiative (Medoff-Cooper, Bakewell-Sachs, Buus-Frank, Santa-Donato, & Near-Term Infant Advisory Panel, 2005), guidelines from the Academy of Breastfeeding Medicine (The Academy of Breastfeeding Medicine, 2008), and suggestions by individual authors and lactation consultants. Common recommendations include: immediate skin-to-skin contact, pediatrician follow-up 24-48 hours post-birth, hyperbilirubinemia risk assessment and monitoring, clinician and parental education regarding common late preterm breastfeeding patterns, early interventions to protect milk supply and ensure adequate caloric intake if breastfeeding is ineffective (e.g., pumping, SNS, supplementation), a written, individualized feeding discharge plan, and professional, experienced lactation support pre/post-discharge (Engle & Kominiarek, 2008; McKeever et al., 2002; Meier et al., 2007; Smith, Donze, & Schuller, 2007; The Academy of Breastfeeding Medicine, 2008; Walker, 2008; Wight, 2003). Though these protocols reflect best practice based on the state of the science, most are based upon expert opinion and breastfeeding patterns in the general preterm population.

1.2.7 Importance of proposed research

Although growing, there exists a paucity of research and clinical awareness pertaining to the complications of late prematurity. In particular, study of the breastfeeding process, inclusive of maternal and maternal-infant interactional components, within the late preterm populace is lacking. It is unknown whether similar conceptual frameworks and clinical pathways utilized to

describe preterm and term breastfeeding processes and relationships can be applied to late preterm mother-infant dyads as a medically-, and possibly socially-unique, group. Through identification of the process and specific factors affecting late preterm breastfeeding establishment, researchers can eventually design and implement tailored interventions to decrease breastfeeding-associated morbidity and maximize the short and long-term breastfeeding health benefits for this vulnerable group.

1.3 PRELIMINARY STUDIES

I have worked clinically for five years on a mother-baby unit, gaining significant breastfeeding experience in that role, as well as IBCLC certification (International Board Certified Lactation Consultant). I have also worked with the dissertation chair and co-chair on numerous research posters, manuscripts, and oral presentations. Pertinent to the substantive area of this dissertation, I conducted a systematic review on breastfeeding rates and associated morbidity within the late preterm population, which was published in the journal JOGNN (see Chapter 3). Additionally, as a means to define the scope of the problem in this research proposal, I obtained IRB approval and conducted an analysis, utilizing Pennsylvania birth certificate data, of prevalence and predictors of early breastfeeding in the late preterm population (see Chapter 4).

1.4 RESEARCH DESIGN AND METHODS

This qualitative study will employ grounded theory methodology to develop a substantive theory regarding the process of breastfeeding a late-preterm infant. Grounded theory, originally conceived by Glaser and Strauss in their seminal work, *The Discovery of Grounded Theory*, seeks to "discover theory from data systematically obtained from social research" (Glaser & Strauss, 1967). This qualitative research approach is based on a philosophy of symbolic interactionism, in which all behavior and human interaction has meaning (Blumer, 1969). Thus, grounded theory is a method, or set of inductive guidelines, for providing both explanation and description of social processes in human interactions, within the framework of a conceptualized theory, from data that has been systematically collected and analyzed (Charmaz, 2000; Cutcliffe, 2000).

The grounded theory approach was selected for this study based upon its utility in explaining process, the recognition of breastfeeding as a socially-based and progressively-negotiated *process*, and past use of the methodology within similar populations (Flacking et al., 2007; Hauck & Irurita, 2003; Locklin & Naber, 1993; Willis, Hannon, & Scrimshaw, 2002). A strong case is also made for grounded theory considering the publication of late preterm clinical care practice guidelines from the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) (Medoff-Cooper et al., 2005). Though these recommendations function as an invaluable resource based upon the current state of knowledge and are based in a sound conceptual model incorporating family role, care environment, nursing care, and infant physiologic-function status, the literature cited to specifically support the breastfeeding practice component reflects the scarcity and atheoretical state of the science in this area (Medoff-Cooper et al., 2005; "Patient page. What parents of near-term infants need to know," 2007). Furthermore,

theoretical frameworks utilized in breastfeeding research in term and preterm populations, such as the attunement/working model of feeding (Pridham, Schroeder, Brown, & Clark, 2001) and the Family Management Style (Bernaix, Schmidt, Jamerson, Seiter, & Smith, 2006; Krouse, 2002), may be inappropriate for use within the late preterm population, as circumstances impacting breastfeeding are likely to differ considerably amongst these variant groups.

Variations in the conduct of grounded theory reflect the evolution of the method since Glaser and Strauss. Depending upon one's epistemological and ontological subscriptions, one may choose a Glaserian approach reflecting positivism and realism, the Strauss and Corbin version vacillating between objectivist and constructivist distinctions (Charmaz, 2000; Mills, Bonner, & Francis, 2006), or any one of the "branches" of grounded theory that have emanated from these interpretations, including Schatzman's dimensional analysis, Clarke's situational analysis, or Charmaz's constructivist approach (Morse et al., 2009).

Here, we subscribe to an "evolved" grounded theory most aptly reflected in Charmaz's conceptualization of constructivist grounded theory. This is congruent with our: 1) a relativist ontological position which acknowledges reality as socially constructed and comprised of multiple individual realties influenced by context, and 2) a subjectivist epistemological view, which espouses knowledge as a subjective co-creation between researcher and participant, based upon experiences, values, and social worlds (Mills et al., 2006; Morse et al., 2009). Constructivist grounded theory thus goes beyond superficial renderings of data by situating analyses within particular social and historical circumstances, seeking to interpret "liminal meanings" and "tacit actions," as well as explicit statements (Charmaz, 2004), and viewing the product as a construction that lends understanding to reality rather than an objective, discovered truth (Charmaz, 2000; Mills et al., 2006; Morse et al., 2009). By virtue of making action,

language, meaning and context transparent (Charmaz, 2004; Sandelowski, 2006) and recognizing the resulting theory as contingent, conditional, and partial (Morse et al., 2009), the constructivist researcher fulfills the original pragmatist underpinnings of grounded theory. That is, she facilitates an informed decision regarding theory transferability and symbolic and conceptual utilization (Sandelowski, 2004, 2006).

Within the constructivist framework, a quadri-hermeneutic stance will be adopted. This philosophical position compels the researcher to reflexively consider language, underlying meanings, social ideologies, power, and interpretative acts, but places the text at the forefront of analysis, considering participants words to reflect a "real world" (Alvesson & Skoldberg, 2000; Sandelowski, 2006). This stance prevents a slide into radical relativism, wherein no truth may be discerned and pragmatism is essentially lost. As suggested by Sandelowski (2006), reflexivity may take the form of multiple critical/discursive readings of the empirical research/transcripts.

Despite the many permutations on grounded theory, all methods subscribe to some common key features, which will be utilized in this project. They include: 1) the iterative and concurrent nature of data collection and analysis; 2) theoretical sampling; 2) the construction of codes and theory from data rather than pre-existing philosophies and concepts; 3) memo writing to develop categories and identify gaps in knowledge; and 4) the constant comparative method of data coding and analysis, in which comparisons occur between participants, individuals over time, new "incidents" and existing categories, and categories themselves (Charmaz, 2000, 2006; Glaser & Strauss, 1967; Speziale & Carpenter, 2007).

1.4.1 Procedures

1.4.1.1 Setting

Participants will be recruited from the maternity wards and NICUs of Magee-Womens Hospital of UPMC (primary site) and possibly The Western Pennsylvania (West Penn) Hospital (secondary site if needed). Magee-Womens Hospital has been recognized as a National Center for Excellence in Women's Health and delivers 10,000 infants per year, which accounts for 45% of the births in Allegheny County (inclusive of the city of Pittsburgh). Additionally, Magee has the largest Level III NICU in Pennsylvania, treating more than 1,500 infants per year. In 2008, there were approximately 787 late preterm births at Magee.

1.4.1.2 Participants and sampling

Based upon the numbers of participants in qualitative studies within similar fields of inquiry (Bernaix et al., 2006; Borucki, 2005; Flacking et al., 2007; Kavanaugh et al., 1995; Schmied & Barclay, 1999; Segeel & du Plessis, 2006; Shakespeare, Blake, & Garcia, 2004; Sweet, 2006), 10-18 postpartum mothers of late-preterm infants may provide theoretical saturation (i.e., redundancy of themes). However, consistent with grounded theory methodology, this number will be modified as data collection and analysis proceed. This number may in fact be less than 10, given the density of data that would be expected through multiple interviews and methods of data collection, which were not part of the cited studies. Enrollment will cease when redundancy of themes occurs (Glaser & Strauss, 1967) and the full range of variation in identified categories is accounted for (i.e., saturation) (Charmaz, 2006).

Also following grounded theory procedures, initial sampling will be purposeful in nature, striving for maximal variation in participant characteristics. As noted by Glaser, "Initial

[sampling] decisions…are based only on a general sociological perspective about a substantive area within a population…" (Glaser, 1978). For example, participants representing a variety of socioeconomic statuses, races, and ages and differing in parity, weeks of completed gestation, and type of infant hospital admission (i.e., NICU, Level I nursery), etc. will be preferentially recruited at the study's outset. Although this purposive sampling will ultimately be superseded by theoretical sampling, it presents as the best option for preliminary identification of range of categories (Cutcliffe, 2000). Recruitment of the expected sample could feasibly be accomplished in the proposed timeframe (Table 2) utilizing only the primary site (Magee); however, both sites are included as a possible means to achieve maximal participant variation, if needed. For example, with a smaller volume of postpartum patients and the designation of Magnet status at West Penn, clinical care approaches and breastfeeding support may differ between the two hospitals.

After the first few interviews, as data analysis proceeds concurrently with data collection, it is expected that several salient categories will emerge. At this point, theoretical sampling will commence. That is, participants will be recruited based upon the likelihood of their insights contributing significantly to the developing theory and providing saturation of existing categories (Glaser, 1978).

1.4.1.3 Enrollment procedures

At Magee, where I have clinical privileges, maternal delivery records, postpartum infant charts, and NICU infant charts will be screened on an ongoing basis for mothers of infants meeting eligibility criteria, as well those fulfilling the evolving sampling decisions. If West Penn is used as a recruitment site, the screening process will be facilitated by Dr. Cicco (study consultant) in conjunction with the hospital's lactation consultants, who see all hospitalized breastfeeding

mothers. I will call or meet with the lactation consultants at the West Penn study site as needed to identify eligible participants satisfying theoretical sampling decisions. Potential participants at both sites will be approached for enrollment after an uninvolved third party (e.g., staff nurse, lactation consultant) obtains their agreement to be contacted. Enrollment will occur within the hospital setting, either during the postpartum admission or when visiting the infant in the NICU. The study will be explained to the participant, the interviewee will confirm eligibility criteria, and written informed consent will be obtained for both mother and infant (mother provides consent for infant). See Appendix G for informed consent forms.

1.4.1.4 Inclusion and exclusion criteria

Inclusion criteria include the following:

1. Postpartum mothers of infants delivered between $34^{0/7}$ and $36^{6/7}$ weeks of completed gestation
2. 18 years of age or older
3. Intention to breastfeed for any length of time, fully or partially, or provide any breast milk to the infant (e.g., pumping breast milk and feeding by bottle)
4. English-speaking (interviews will be conducted in English)

Exclusion criteria include the following:

1. Conditions which necessitate an ethical obligation to discourage breastfeeding **(**e.g., positive maternal HIV test)

2. Conditions which would preclude or significantly complicate breastfeeding beyond what would be expected for the late preterm period
    a. Critically-ill infant or mother, in which case medical staff do not anticipate the possibility of provision of maternal breast milk
    b. Congenital abnormalities or major fetal anomalies expected to directly interfere with breastfeeding (e.g., cleft palate)

1.4.1.5 Data collection

Serial, semi-structured interviews and observational field notes will be the main source of data in the proposed study. The latter will be recorded during all interviews (inclusive of setting, mood, distractions, participant appearance, interaction with infant, etc.) to lend context to the dialogue. The participant will also be presented with options of self audio-recording thoughts on breastfeeding as they occur (timing/frequency of tapings at her discretion), emailing me regarding her breastfeeding experience, or, alternatively, having a number of her breastfeeding sessions video-recorded.

If audio-recording is selected, the participant will be encouraged to turn on a provided digital recorder as she begins breastfeeding to "talk through" the process—a variation on the "Think Aloud" technique permitting an unfiltered, real-time account of thought processes (Van Someren, Barnard, & Sandberg, 1994). If she is uncomfortable with this, audio "diary entries" (e.g., after a breastfeeding session) may be promoted. Audio files will be copied to an external password protected computer file from the digital recorder for transcription at each follow-up.

If chosen, video-recording of breastfeeding sessions will occur before, during, or after a scheduled interview. These videos will be reviewed with participants at the next follow-up utilizing "stimulated recall interviewing." This technique is designed to elicit self-review and

reflection of underlying thought processes or feelings associated with particular events in an interaction (Busse & Ferri, 2003). For example, the researcher may ask the participant to "describe what is happening here," or note an observation and probe, "how were you feeling at this point?" These video debriefings will be audio-recorded and analyzed similar to the other study data. Though no studies have directly addressed the acceptability of video-recording of breastfeeding sessions for research purposes to our knowledge, several researchers investigating aspects of breastfeeding have used video data collection with success in terms of achieving participant retention and analyzable results (Colson, Meek, & Hawdon, 2008; Ransjo-Arvidson et al., 2001). This includes one study which, similar to the proposed methodology, utilized a participant reflective review of videotaped breastfeeding sessions (Pridham et al., 2001). If desired, participants will be provided a copy of their video(s) and audio diary(ies) at study completion.

Multiple options have been chosen for participants to record their descriptions of and thoughts about their breastfeeding encounters in recognition that new mothers must cope with competing time and caregiving demands, as well as their own fatigue. In particular, young women may be more apt to email about their experience than handwrite in a journal, which was considered, but based on my clinical experience of the time constraints inherent in caring for a newborn, is likely not feasible (Beck & Watson, 2008; Mezzacappa, Guethlein, & Katkin, 2002; Thomas & Shaikh, 2007). There is compelling evidence that electronic media widely accepted in the childbearing age cohort, are excellent sources of participant narratives for qualitative research and may, in fact, facilitate an opportunity for deeper participant and/or researcher reflection (Beck & Watson, 2008; Egan, Chenoweth, & McAuliffe, 2006; R. J. Hamilton & Bowers, 2006; Pierce, Steiner, Havens, & Tormoehlen, 2008). If a participant chooses to email

regarding her breastfeeding experience, utmost prudence will be exercised in ensuring confidentiality (e.g., copying and pasting the body of the text without participant identifiers, deleting participant entries and emptying trash, etc.). These measures are described in greater detail in Section 1.5.

After enrollment, instructions will be provided as necessary for emailing or operation of the digital recorder, and a mutually-agreed upon interview time will be established. During this time, background demographic, obstetrical, and breastfeeding information will be abstracted from the medical chart, or, where appropriate, obtained verbally from the participant. LATCH breastfeeding scores and supplemental feeding volumes will also be abstracted for each birth hospitalization day from the hospital infant feeding record (see Appendices A, B, and C).

Optimally, the first interview will occur in a private room in the hospital setting, either in the NICU or postpartum unit. The participant will be encouraged to bring her infant to all interviews and also to breastfeed during or after it, if she is comfortable in doing so. This will provide an opportunity to observe the interaction between mother and infant, enriching the data. Videotaping, if elected, will not commence until after hospital discharge due to privacy concerns inherent in the clinical setting.

An interview guide, partially adapted from the interview schedules of several existing breastfeeding studies (Kavanaugh et al., 1995; Krouse, 2002; Schmied & Barclay, 1999) and consisting of open-ended questions and probes pertaining to the process of breastfeeding and mothering a late preterm infant, will be utilized (Appendix D). Modifications will be made to the interview guide over time as new categories or themes emerge (Appendix E). It is expected that interviews will last approximately 15 minutes to one hour, and all will be audio-recorded. After the initial interview, I anticipate at least two to three more interviews, occurring at one week, two

weeks, and six to eight weeks postpartum. These will be scheduled, via telephone, at a mutually-agreed upon time and place, but every effort will be made to choose a private location in which the interviewee feels comfortable (e.g., participant's home).

The initial short spacing of interview intervals reflects the intention to capture processes related to breastfeeding discontinuation, which often occurs shortly after birth; six to eight weeks marks a breastfeeding milestone, indicative of good establishment of breastfeeding and milk supply and also a common point at which mothers may begin formula supplementation (DiGirolamo, Grummer-Strawn, & Fein, 2008; Hill & Aldag, 2007). The methodological decision to conduct multiple, prospective interviews is based upon the desire to achieve a data-rich analysis and accurate depiction of how mothers of late preterm infants establish and continue breastfeeding. The interview schedule may be modified, however, according to the needs of the evolving theory, characteristics of participants (e.g., additional interviews for a particularly articulate or informative participant), and whether breastfeeding continues. A participant who indicates that she has ceased breastfeeding efforts will be excluded from continuation in the study, but a final interview may be conducted to ascertain the factors leading to discontinuation.

I will strive to maintain an observational/non-interventionist stance during interviews, referring participant breastfeeding concerns to lactation services and presenting the study as an inquiry into breastfeeding management, without the explicit expectation that breastfeeding be continued. Adherence to this position will be assessed as part of mentored analysis of interviews with the co-chair. In addition, all data collection methods will be pilot-tested on study participants, and appropriate adjustments to the study protocol will be instituted based on participant feedback, perceived feasibility of the process, and pending IRB re-approval.

Table 1. Data collection schedule

	Enrollment/ hospitalization	Follow-up #1 ~1 week pp	Follow-up #2 ~2 weeks pp	Follow-up #3 6-8 weeks pp	*Additional/ fewer follow-ups if needed*
Demographics & obstetric history	x				
Interviews	x	x	x	x	x
Optional: Collect audio files; videotape review		x (no video review)	x	x	x

**If participant choses the email option, collection of entries will be ongoing; "pp"=postpartum*

1.4.1.6 Participant retention

In recognition of the time investment and richness added to the data by individual participants longitudinally, incentives for study participation will be provided on a tiered scale. IRB-approved University of Pittsburgh Cash Cards in amounts of $10 will provided after the completion of each of the respective interviews, except the last, at which time participants will receive a $50 cash card. Participants will be given a $10 Cash Card for each additional interview if their schedule is modified based upon theoretical saturation. A package of infant diapers will be provided at the last interview if the participant has sent any emails or completed any video/audio recordings.

1.4.1.7 Data analysis

Descriptive statistics will be calculated for demographic and obstetrical data where applicable. Audio-recordings (i.e., interviews, breastfeeding self “talk throughs,” audio-taped video reviews)

will be professionally transcribed. I will transcribe field notes and also compare all transcription to the original recordings to ensure accuracy and add contextual clarification. This review will occur as soon as possible after fieldwork in order to preserve memory. All transcriptions and text of participant emails will be analyzed as described below. It is important to note that video data will be used to stimulate the participant's own analysis of the observation, but will not be analyzed in a behavioral or ethological manner. The incorporation of these variant data forms will serve to strengthen the emergent theory through data triangulation.

Consistent with grounded theory, data analysis will proceed concurrently with data collection. After reading through a transcript or email several times to get a sense of the whole, coding will occur. This will progress from open or initial coding, in which I will go segment by segment in the transcript, identifying all salient processes and assigning an action code as close to the participant's actual words as possible, to focused coding, which is more selective and conceptual. Focused codes consist of significant, frequently used initial codes that synthesize the data most precisely. Through constant comparison, memoing, and possibly use of one or several of the techniques described below (e.g., diagramming), categories are developed from and subsumed by the focused codes. Certain categories may hold particular explanatory power and connectedness to other categories and are thus elevated to the level of theoretical concepts. These concepts are then interwoven and integrated into a cogent analytic framework or theory that is sufficiently grounded in the data and interpretive. Though presented linearly, this process is actually an iterative or abductive endeavor, most heavily relying on the technique of constant comparison (Charmaz, 2000, 2006; Morse et al., 2009). The following data analysis techniques may be utilized to enhance the analytic process: 1) dimensional analysis—identification of attributes, antecedents and consequences (Kools, McCarthy, Durham, & Robrecht, 1996); b)

matrix construction; c) diagramming; d) questioning and/or flip-flop technique (Miles & Huberman, 1994; Strauss & Corbin, 1998).

Theoretical memoing will occur throughout data collection and analysis. Theoretical memos "are the theorizing write-up of ideas about codes and their relationships as they strike the analyst while coding…the frontier of the analyst's thinking," (Glaser, 1978). Glaser cites theoretical memos as the core component of theory development (Glaser, 1978), and Charmaz (2006) reiterates this view by noting that memos are crucial in developing insights, crystallizing direction, and prompting early, focused, and systematic analysis. Consistent with these assertions, any other work will be vigilantly interrupted to record all ideas, as they occur, pertaining to theoretical insights, meanings, and relationships among categories or concepts identified within the data. During coding, a list of all theoretical memos will be kept handy in order to compare, expand, and modify these concurrently with the development of categories and theoretical concepts. During the final stages of theory development, a literature review will be conducted, and theoretical memos will then also encompass linkages between the data and pertinent theoretical relationships and constructs identified in the literature. This will serve to refine, compare, and differentiate the developed theory from existing conceptual models.

1.4.1.8 Data management

All participants (mothers and infants) will be assigned a pseudonym, and this will be used on all documentation, rather than the participants' actual names. Contact information, linked with participants' pseudonyms, will be stored in a password-protected, encrypted, user-restricted computer file. All other study materials, including consent forms, will be kept in a locked desk drawer (accessible only to me) within a locked room in the PhD student study area.

To ensure successful audio capture, all interviews will be "doubly recorded" using two different digital recorders. Additionally, replacement batteries will be carried to each interview session. Digital audio data will be stored on a flash drive in the locked desk drawer for a minimum of 5 years.

ATLAS.ti will be utilized for data management, providing a storage and analysis site for all transcribed memos, audio recordings, and emails. Microsoft Excel will be used for storage of background and demographic data without subject identifiers. This data will also be password-protected.

1.4.1.9 Rigor

Rigor will be addressed in the following ways within this study (Chiovitti & Piran, 2003): Credibility: While an interview guide will be utilized to begin or refocus the interview, the participants will ultimately guide the direction of the interview (i.e., new leads/concepts relevant to the subject matter brought up by the participants will be pursued). Sensitizing concepts (i.e., extant theories/ideas relevant to the research question) will be recognized as relevant and plausible starting points or supplementation to the theory, but utmost prudence will be exercised in adhering as closely to the data as possible during theory development (see #6 below, a "data-near" analysis (Charmaz, 2000; Sandelowski, 2010)). To enhance credibility, I will: 1) return to participants to confirm the *direction* of the emerging theory (a variation on the contested validity of "member checks"); 2) record ongoing reflexive memos and engage in post-interview debriefings with the co-chair in order to develop self-awareness of biases and preconceived notions; 3) maintain regular consultation with a qualitative expert (co-chair) and study consultants to discuss the emergent theory in relation to actual data; 4) present my ongoing work for feedback in a qualitative analysis workgroup; and 6) to the degree possible, use participants'

actual words in the codes and theory. Care will be taken to avoid the pitfalls of a "flimsy," superficial analysis by collecting a sufficient amount of data necessary to "saturate" the range of properties observed within categories and to complete the theoretical rendering. This will be accomplished through the conduct of serial interviews over six to eight weeks postpartum, projected inclusion of 10-18 participants, multiple and varied data mediums (e.g., observations, interviews, audio/written journaling), and engagement in prolonged immersion with the data, spending 16-18 months in data collection and analysis.

Auditability: I will maintain an audit trail by means of methodological memos detailing all analysis decisions and emerging ideas pertaining to code development/definition and assignment, theory development, and sampling decisions.

Transferability: The scope of the theory will be defined during presentation and dissemination by recognizing it as a substantive, rather than formal theory, providing a thorough description of participant characteristics, and situating findings within their social and historical contexts, as well as the broader literature on breastfeeding and prematurity.

1.4.1.10 Study limitations

There are several limitations to consider in the proposed study. Because I have passed the IBLCE exam and am a postpartum staff nurse on one of the units to be included in the study, issues of self-disclosure of qualifications and role separation may occur. This situation will be managed through honest self-representation to participants, clarification of role, referral of participants back to hospital staff/lactation consultants with questions, and regular debriefing with my dissertation committee—particularly the chair and co-chair. Also, some participants may be concerned with privacy during breastfeeding, particularly in relation to videotaping and audio-recording. For this reason, participants will be given the option of participating in these

alternative data collection methods. It should be noted, too, that as a postpartum nurse, I have interpersonal and experiential skill in putting mothers at ease during breastfeeding.

Table 2. Originally proposed project timetable

	Jan 2011-Jul 2012	Aug 2012-Oct 2012	Nov 2012
Participant enrollment	x		
Data collection (interviews, video/audio data, email)	x		
Data analysis	x		
Manuscript preparation		x	
Dissertation defense			x

1.5 RESEARCH PARTICIPANT RISKS AND PROTECTIONS

1.5.1 Risks to human subjects

This qualitative study will enroll approximately 10-18 postpartum women who have delivered infants between $34^{0/7}$ and $36^{6/7}$ weeks of gestation and intend to breastfeed. As per inclusion and exclusion criteria, study participants will be non-critically ill individuals of childbearing age over 18 years (anticipated range: 18-45 years) and their non-critically ill infants without major congenital or fetal anomalies. Rationale for exclusion of maternal participants under 18 is provided in the "Inclusion of Children" section below.

Potential participants will be identified through screening of maternal delivery records, maternal postpartum medical records, or NICU infant charts by either the candidate at Magee Womens Hospital study site or the lactation consultant staff at the Western Pennsylvania Hospital study site. See IRB approvals (Appendix F). An unbiased third party will approach the potential participant to gain entrée for the candidate to discuss the study, and mothers who

express interest will be provided more detailed information. Written informed consent will then be obtained. No data collection will commence before informed consent is acquired. Participants will be made aware upon enrollment that they may withdraw from the study at any time without it affecting their medical care.

After informed consent is obtained, the following data will be collected from participants: personal demographic and obstetrical data obtained verbally from participants and abstracted from the medical record (Appendix A), infant feeding data abstracted from the medical record and supplemented via verbal report from participants (Appendices B and C), and audio-recorded and transcribed interview data pertaining to breastfeeding and mothering. Optional video, audio, and/or email breastfeeding data will be collected from participants comfortable in providing this data. Only I will have access to personal identifiers linking the participant to study data after enrollment. Protection of this information is described below. Risks of participation in this study are minimal, and include the possibility that some participants may perceive the background questions and/or the discussion of breastfeeding or becoming a mother as uncomfortable or intrusive. Additionally, the use of video or audio recording during breastfeeding may be construed as an invasion of privacy. If email is utilized, there exists the possibility that entries may inadvertently be visible to others on the Internet. These issues are addressed below.

1.5.2 Adequacy of protections against risks

Measures to protect participant privacy and confidentiality are described in the data management section (Section 1.4.1.8), and include assigning all participants (mother and baby) a pseudonym to be used on all documentation in lieu of the actual names, storing contact information and linkage information between the maternal and infant participant in a password-protected,

encrypted, user-restricted computer file, and storing all other study materials, including consent forms, video recordings, and audio recordings, in a locked desk drawer (accessible only to me) within a locked room (the PhD student office area). Audio- and video- recordings will be stored for a minimum of 5 years. Additionally, non-vital identifying information will be modified or omitted from the final research report in order to protect participant anonymity.

Special considerations apply for the use of video-recording in research. This is particularly true pertaining to video-recording of breastfeeding, due to the intimacy of the act, accompanying privacy issues, and risk of exposure of the breast, which, because of sexual connotations, could be considered inappropriate by some individuals. It should be noted that the utmost prudence will be exercised in ensuring that video-recording is participant-directed. Specifically, participants may decline this portion of the research study or request via writing withdrawal from the study and destruction of video data during the data collection period. A separate option in the written informed consent specifies whether participants will allow the videos to be stored for future research or presentations. Drawing on the suggestions of one research group experienced in video data collection and analysis (Broyles, Tate, & Happ, 2008), oral confirmation of informed consent for video-recording will be on a continuous basis (e.g., before any video session rather than just at entry into study), only *positive* exemplars of breastfeeding will be used in any presentations with participant consent, and care will be taken to minimize unnecessary exposure of the breast (e.g., "blurring" of areola/nipple if not critical to evaluate some aspect of breastfeeding, such as poor latch due to nipple trauma/soreness). Additionally, I will be particularly vigilant of participant verbal and non-verbal cues indicating discomfort with the video process. For example, participants may be uneasy if certain family

members are present during the taping, so I will be flexible in arranging alternate times for this data collection to occur.

Similar privacy concerns may exist in relation to audio-recording "talk-throughs" of breastfeeding. For this reason, this method of data collection will also be optional and participant-directed. Although the password-protected and encrypted audio files will be stored in a locked desk drawer in a locked room for a minimum of 5 years, the actual audio will not be utilized for any additional research or presentations without participant permission in the informed consent.

All videos obtained for the study will be stored only as digital files on a USB flash drive and back-up, both encrypted and password-protected. No hard copies of the videos (e.g., CD's, VHS tapes) will be created. Any potentially identifying information on the audio files will be deleted.

If email is used in data collection, additional safeguards will be employed to protect participant confidentiality. As per the suggestions of Hamilton and Bowers (2006), this will include reminding participants to secure their e-mail account with a password and advising participants to delete their responses and empty their trash as soon as they send an entry.

Additionally, upon receipt of an electronic response, I will cut and paste the text into a word document, removing all personal identifiers and substituting in the participant's assigned pseudonym. No participant contact information will be stored in my email address book, and all participant emails will be deleted and moved to the trash after copying to the word file.

If, during the course of the study, a participant becomes uncomfortable or exhibits emotional distress, data collection will cease and contact information for support services will be provided, if warranted. Likewise, if a participant expresses concern for the safety of herself or

others, emergency medical services will be contacted. If a potentially harmful situation for mother or baby is observed during a home or hospital visit (e.g., suspicion or witness to intimate partner violence/child abuse, unsafe home environment for a child), this will be dealt with on a case-by-case basis in consultation with dissertation chair, institution, and IRB according to state regulations. In appreciation of the potential risks inherent in home visits, I will take appropriate precautions, including carrying a mobile phone and notifying others of location and anticipated time for interviews.

Regarding possible mother distress when viewing their videotapes, a specific plan will be enacted. First, as an experienced clinician, I have skill in detecting verbal and non-verbal signs of maternal distress and anxiety, particularly in regard to breastfeeding. I will be vigilant for these signs (e.g., crying, restlessness) and will immediately cease the review should these signs of distress be evident. I will then attempt to calm the participant, validate her concerns (e.g., noting that seeing oneself on video in such a situation can be upsetting), and refer her to her obstetrical care provider or primary care physician for further assistance.

1.5.3 Potential benefits of the proposed research

There are no known direct participant benefits of study participation, though participants may find that talking about their breastfeeding experience is cathartic and/or enjoyable. The minimal acknowledged risks to participants are outweighed by the potential benefit of advancing the state of the science in breastfeeding among late premature mother-infant dyads.

1.5.4 Importance of the knowledge to be gained

As a paucity of research exists pertaining to the medical concerns of late preterm infants, particularly related to breastfeeding, it is expected that the scientific contributions of this qualitative study will offset the possible risks of a breach of confidentiality or participant psychological discomfort related to data collection.

1.5.5 Data and safety monitoring plan

Because this study is not a clinical trial, a Data Safety Monitoring Board will not be utilized. I will meet weekly during active data collection, and more frequently as needed, with the chair, co-chair, and/or consultants in order to review aspects of data collection and analysis and any other pertinent issues arising. Appropriate changes will be discussed and instituted based upon these meetings. I will ultimately be responsible for participant safety and ongoing evaluation of the study's progress.

1.5.6 Inclusion of women and minorities

Because this study is investigating breastfeeding, only postpartum *women* will be enrolled as maternal participants. However, both male and female infants between $34^{0/7}$ and $36^{6/7}$ weeks of gestation, whose mothers have also been enrolled in the proposed study, will be included in the videotaped portion of the study and medical record review. Given current birth rates, we expect to enroll a relatively equal number of female and male infants. However, no participants (mothers or infants) will be excluded from study based on infant gender.

1.5.7 Inclusion of children

Children ages 18-21 years may be enrolled as maternal participants in this study. Maternal participants younger than 18 will be excluded, as the developmental maturity of this cohort may limit the insight into the phenomenon of interest. Additionally, the circumstances surrounding birth and breastfeeding are likely to differ considerably between adolescents and those older than 18.

Late preterm singleton or twin infants between $34^{0/7}$ and $36^{6/7}$ weeks of gestation whose mothers have also been enrolled in the proposed study will be included in the videotaped and medical record review portion of the study. Written informed consent will be obtained from all mothers for their infants' participation. It is estimated that total enrollment in this study will be 20-38 participants, accounting for approximately two possible twin infant enrollments. This number will include 10-18 mothers, and 10-20 infants.

1.5.8 Ethnicity and racial composition

In 2006, the racial composition of Allegheny County (the area served by the two study site hospitals) was 83.1% White, 13.3% Black or African American, 2.3% Asian, 0.2% American Indian or Alaskan Native, and less than 0.1% Native Hawaiian or Other Pacific Islander. The ethnic composition of Allegheny County in 2006 was 1.2% Hispanic or Latino. Based upon these statistics, it is expected that roughly 16% of the study sample will be of a minority status, and of this percentage, predominantly African American. However, because African American women tend to initiate and continue breastfeeding at lower rates than Caucasian women (60% initiation

rate versus 78%, respectively) (Centers for Disease Control and Prevention, 2010), the anticipated percentage of minority inclusion may be more difficult to achieve.

Therefore, in order to obtain a racially-diverse sample, while remaining cognizant of theoretical sampling decisions, the University of Pittsburgh Center for Minority Health Community Research Advisory Board (CRAB) may be consulted to assist in identifying potential minority participants or to offer suggestions pertaining to recruitment methods. However, it should be noted that Magee Womens Hospital and The Western Pennsylvania Hospital are likely to capture the largest percentage of racially- and ethnically-diverse participants in the area, as these hospitals serve the largest volumes of obstetric patients in Allegheny County and, additionally, the majority of the population of Pittsburgh, which has a higher percentage of African Americans than Allegheny County (29% in 2001). No potential participants will be excluded from the study based upon race or ethnicity. See targeted enrollment table below based on the maximum number of participants (n=38).

Table 3. Targeted/planned enrollment

ETHNIC CATEGORY	FEMALES	MALES	TOTAL
Hispanic or Latino	0	0	0
Not Hispanic or Latino	28	10	38
Ethnic category: Total of all subjects	28	10	38
RACIAL CATEGORY			
American Indian/Alaskan Native	0	0	0
Asian	1	1	2
Native Hawaiian or other Pacific Islander	0	0	0
Black or African American	4	1	5
White	23	8	31
Racial categories: Total of all subjects	28	10	38

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2.0 SUMMARY OF STUDY

The purpose of this study was to describe the process of breastfeeding initiation and continuation among late preterm mother-infant dyads, while secondary aims were to: 1) place breastfeeding within the broader context of mothering a late preterm infant (LPI), and 2) identify factors influencing the late preterm mother's decision to initiate and continue breastfeeding. Three manuscripts, directly or indirectly related to these aims, are included in the succeeding chapters. The first manuscript, published in the Journal of Obstetric, Gynecologic, & Neonatal Nursing (JOGNN) in January 2011, provided background on the late preterm breastfeeding problem through a systematic review of LPI breastfeeding prevalence, breastfeeding-associated morbidity and mortality, benefits and barriers to breastfeeding within this population, and current LPI breastfeeding guidelines. The second manuscript, submitted to the Journal of Public Health and Epidemiology (JPHE), is an examination of the prevalence and social, medical and system-level factors impacting late preterm breastfeeding initiation using Pennsylvania birth certificate data. These data partly address secondary aim #2, but were analyzed separate from and prior to data collection in the main study. Manuscript #3, formatted for submission to Social Science & Medicine, is the main results paper reporting study findings. While this paper focuses on the primary study purpose, it also briefly addresses the secondary aims as themes within the theoretical framework.

Within this chapter, findings related to each study aim will be summarized. In addition, issues encountered, methodological revisions, strengths, limitations, implications, and recommendations will be addressed.

2.1 FINDINGS RELATED TO THE PRIMARY AIM

Primary aim: To describe the process of breastfeeding initiation and continuation among late preterm mother-infant dyads.

Findings related to this aim are discussed in detail in manuscript #3. Briefly, breastfeeding establishment (initiation and continuation to 6-8 weeks postpartum) in the LPI population was a fluctuating, cascade-like progression of trial and error involving infant physiological issues and maternal reactions, positive and negative management strategies which persisted or were corrected, secondary issues dependent upon management, and, finally, breastfeeding cessation or continuation. The process was explained by the basic psychosocial process *Weighing Worth against Uncertain Work*, which encompassed the tension between breastfeeding motivation, the intensity of breastfeeding work, and ambiguity surrounding infant behavior and feeding cues. Several sub-processes were also identified: *Playing the Game*—the guesswork that characterized early breastfeeding; *Letting Him be the Judge vs. Accommodating Both of Us*—for mothers with positive continued breastfeeding management, the struggle between meeting maternal needs and the breastfeeding demands of the infant as wakefulness issues resolved and other life responsibilities became more prominent; and *Questioning Worth vs. Holding out Hope*—for mothers with uncorrected negative breastfeeding management strategies, the increasing difficulty justifying the work of breastfeeding (but remaining hopeful

that the process would improve) while milk supply dropped and infants continued to have difficulty with at-breast feeds.

The LPI breastfeeding trajectory shared characteristics typical of breastfeeding establishment in both term and preterm populations, although mothers rarely made a conscious connection between the infant's prematurity, behavior, and breastfeeding difficulties. Uncertainty stemmed from seemingly inexplicable infant behavior related to physiologic immaturity that occurred in a term-oriented environment. Compared to the more transient nature of breastfeeding issues among term dyads (Brandon et al., 2011) and more intensive breastfeeding support noted within preterm NICU populations (Aagaard & Hall, 2008; Lupton & Fenwick, 2001), LPI breastfeeding was found to follow a less tightly regulated, often unsupported, and more convoluted trajectory.

2.2 FINDINGS RELATED TO SECONDARY AIM #1

Aim: To place breastfeeding within the broader context of mothering a late preterm infant.

This aim was addressed briefly in the context of worth attached to breastfeeding in manuscript #3. Findings indicated that participants did perceive a connection between mothering and breastfeeding, and this was invariably tied to motivation to breastfeed. The majority of study participants identified breastfeeding as central to their role as a mother and cited bonding and infant immunologic, cognitive, and developmental benefits as primary reasons they chose to and continued to breastfeed. For these women, breastfeeding "wasn't even a question." It was seen as a "responsibility" to one's children and "what being a mom is all about." Breastfeeding was viewed as "natural," "rewarding," "nurturing," and "something only I can give [him]." A smaller

number of participants (n=2), primarily motivated to breastfeed by convenience, guilt, and/or maternal benefits (e.g., postpartum weight loss), found questions regarding how breastfeeding fit into mothering difficult to answer. However, they eventually acknowledged some of the benefits noted by other participants, including "bonding," the naturalness of breastfeeding, and the fact that breastfeeding was "best for [the] baby" in terms of enhanced immunity, brain or cognitive development, or "nutrition-wise." These accounts are consistent with the literature addressing maternal feelings and motivation to breastfeed within the general population (Arora, McJunkin, Wehrer, & Kuhn, 2000; Burns, Schmied, Sheehan, & Fenwick, 2010; Sheehan, Schmied, & Barclay, 2010).

For at least two participants, breastfeeding became more of a bonding experience when their infants began to exhibit more prolonged wakefulness and success with at-breast feeds, as opposed to pumping milk and feeding via bottle. For one participant whose infant was in NICU, breastfeeding provided an early opportunity for bonding—a "chance" to hold her baby outside the incubator and "see him as normal, not under watch 24/7." These sentiments correspond with accounts in the preterm literature, noting a risk of impaired early bonding or altered expectations when breastfeeding is a non-reciprocal event, focused solely on breast milk provision rather than the relational interplay between mother and infant (Bernaix, Schmidt, Jamerson, Seiter, & Smith, 2006; Flacking, Ewald, Nyqvist, & Starrin, 2006; Flacking, Ewald, & Starrin, 2007). Unlike these accounts, however, the motivation or pressure to breastfeed among study participants was self-imposed, rather than stemming from a NICU staff conditioned to promote breastfeeding as critical to the health of vulnerable infants.

2.3 FINDINGS RELATED TO SECONDARY AIM #2

Aim: To identify factors influencing the late preterm mother's decision to initiate and continue breastfeeding.

Manuscript #2 indicated that sociodemographic factors, including marital status, education, parity, race, age, smoking status, and WIC status (Special Supplemental Nutrition Program for Women, Infants, and Children) were among the most influential variables associated with early LPI breastfeeding, which is consistent with research in general and preterm populations (Mitra, Khoury, Hinton, & Carothers, 2004; Ryan & Zhou, 2006; Scott & Binns, 1999; Zachariassen et al., 2010). While most of these variables were associated with breastfeeding initiation in the expected direction (e.g., positive association with markers of higher social status, including married, educated, non-smoker; negative association with factors typically associated with lower breastfeeding rates in the general population, including Black race and WIC) (Centers for Disease Control and Prevention, 2010), the multivariate analysis revealed that these variables were also involved in several significant, counterintuitive interactions with each other. These findings suggest that early LPI breastfeeding behavior is a complex phenomenon, heavily influenced by non-modifiable sociodemographic factors in a non-additive manner. It could also indicate that variables such marital status, parity, and WIC may be proxy factors for employment, income, and additional home or childcare responsibilities.

Findings from the main study indicated that LPI mothers were motivated to initiate breastfeeding for a variety of reasons, which were addressed in Section 2.2. Additional breastfeeding "benefits" noted by participants included the "calming effect" on mother and infant, transference of a "nurturing" personality or demeanor to the infant, and financial savings. Only two mothers noted an added developmental advantage of breastfeeding for a premature

infant. This corresponded with the general lack of prematurity recognition among study participants.

Main study findings also revealed that a multitude of external events, personal circumstances, and thought processes shaped by individual experiences were major influences on the continuation of breastfeeding within the late preterm population. These included hospital policy and practices, breastfeeding support from healthcare providers and others, and "trigger" events perceived to mark the beginning of breastfeeding difficulties (e.g., formula supplementation, circumcision, re-hospitalization). Other influential factors included prior breastfeeding experience and awareness of breastfeeding mechanics, the cumulative time and energy-drain of responsibilities external to breastfeeding (e.g., career, other children), attitude/personality, familial support, relationship stressors, special circumstances inherent in breastfeeding twins (e.g., exhaustion, coordination of feedings), and prematurity issues (e.g., breastfeeding preparedness, lack of awareness of possible breastfeeding difficulties).

Breastfeeding support, or lack thereof, from healthcare personnel warrants additional attention. This was a recurrent theme through most interviews and, due to space limitations, was not fully detailed in the results manuscript. Our findings indicate that breastfeeding support from healthcare professionals varied widely. Despite several accounts of positive breastfeeding management advice (e.g., proactive introduction of breast pumps, techniques to minimize "nipple confusion," such as paced feedings), the majority of participants received care inconsistent with The Academy of Breastfeeding Medicine late preterm breastfeeding protocol (The Academy of Breastfeeding Medicine, 2011). For example, at least two participants had a delayed first pediatrician follow-up appointment after hospital discharge. One participant had an initial appointment but did see the pediatrician again until a one-month follow-up appointment,

despite breastfeeding concerns. Some practitioners, including pediatricians and nurses, provided incorrect, outdated, or otherwise poor management advice. This included refuting the existence of galactogogues (medication or supplement to increase milk supply), instructing participants to consume more water to increase milk supply, and counseling mothers to supplement with formula to ensure the infant was "getting enough" or gaining enough weight, despite an adequate milk supply.

Participants were additionally troubled by inconsistencies between nurses, lactation consultants, and pediatricians regarding "timing" of at-breast feeds and concurrent management of pumping, breastfeeding, and formula supplementation. Some participants felt that advice offered was too general, and there was a lack of "troubleshooting" when breastfeeding difficulties were encountered. The quality of in-hospital breastfeeding assistance from staff nurses received mixed reviews. Nurses who had themselves breastfed and shared their experiences were perceived as more knowledgeable and helpful. With few exceptions, pediatricians were generally viewed as available, but not necessarily knowledgeable or approachable with regard to breastfeeding. Lactation consultants were uniformly viewed as knowledgeable about breastfeeding, however many women were not aware of their services after hospital discharge.

2.4 METHODOLOGICAL ISSUES

There were two changes from the original study proposal in terms of study sampling. First, a decision was made to not utilize the Western Pennsylvania Hospital as a data collection site. Because there were no problems recruiting an adequate and varied sample at the primary site

(Magee Womens Hospital of UPMC), it became unnecessary to include a secondary site. The other change involved the ethnic background of those enrolled. While initial plans included enrollment of at least one mother-infant dyad of Asian descent, the available study pool at times of recruitment did not permit this. Enrollment of male and female infants, as well as Black participants, was closely aligned with initial projections, however.

Table 4. Actual study enrollment

ETHNIC CATEGORY	FEMALES	MALES	TOTAL
Hispanic or Latino	0	0	0
Not Hispanic or Latino	14	8	22
Ethnic Category: Total of All Subjects	14	8	22
RACIAL CATEGORY			
American Indian/Alaskan Native	0	0	0
Asian	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Black or African American	3	1	4
White	11	7	18
Racial Categories: Total of All Subjects	14	8	22

The additional data collection methods instituted in an attempt to achieve methodological triangulation had mixed success. While no participants attempted audio diaries, five completed one or more email diary "entries" and two took part in the video-recorded breastfeeding and stimulated recall interviews. Reasons for non-participation in video data collection included lack of preparatory grooming, breastfeeding sessions not coinciding with scheduled interviews, and privacy concerns. Reasons for non-participation in email or audio diaries included a lack of time, unfamiliarity and complexity associated with the audio-recording device, and no computer

access. The limited uptake of these exploratory data collection methods indicates that future implementation may require more explicit participant direction (e.g., setting expectations for frequency and content of diaries, demonstrating operation of audio-recorder), pilot-testing, improved coordination of timing of data collection, integration of more user-friendly audio recording devices, and added incentives for participation. Despite these issues, the email and video review data contributed to more focused interviews, clarification of participant statements, and confirmation of emergent themes. Because the email diaries were participant-driven, they also permitted insight into thoughts and events as they occurred and reduced the possibility of investigator bias.

Additional implementation issues involved the impact of volume during video reviews on transcription accuracy and the difficulty in managing the video-recorder while interviewing and taking fieldnotes simultaneously. The latter issue underscores the value of a second data collector to operate devices or take field notes. The volume problem was resolved by muting sound during the video reviews, thereby placing emphasis on participants' responses to what was happening in the videos, rather than what was being said. Occasionally, this (and email diaries) led to discrepancies between maternal memory and real-time interview data. Though a natural reflection of how information is processed over time and represented to others (Sandelowski, 1993), the inconsistencies required some form of action or resolution. When they occurred, clarification was sought, which sometimes led to even deeper reflection and understanding. When the discrepancy persisted, real time event data was considered "correct."

The interview schedule instituted (1-2 days, 1 week, 2 weeks, and 6-8 weeks postpartum) seemed to adequately capture early breastfeeding establishment among late preterm dyads and did not appear overly burdensome. Indeed, with few exceptions related to participant time

conflicts, this schedule was adhered to. However, at the final interview at 6-8 weeks postpartum, several participants anticipated modifying breastfeeding based on return to work, family issues, or new information received from healthcare providers. For this reason, around the time that the sixth participant was being interviewed, the decision was made (after IRB approval, see Appendix F) to re-contact all participants at 4-6 months postpartum to ascertain breastfeeding outcome. At the time of this writing, eight of ten mothers have been re-contacted via mail, and five have sent back written responses. As suspected, the two mothers who were considering breastfeeding cessation at the time of the last interview did stop at around 2.5 months. Two other mothers, both successful in establishing at-breast feeds and a milk supply during the early postpartum period, continued to breastfeed exclusively to 3 and 6 months, respectively. The former participant introduced formula at 3 months and ceased breastfeeding altogether at 5 months, because "bottles and formula were easier [at that point], since she [was] in daycare." A fifth participant, who had early difficulty with at-breast feeds but diligently worked to maintain milk supply, was still breastfeeding at the time of re-contact (approximately 6 months postpartum) and had continued at-breast feeds exclusively until 4 months, at which time other foods had been introduced.

The length and nature of in-home interviews were well received by participants, as indicated by their positive verbal feedback and 100% participant retention rate. Although mothers had the option of interviewing elsewhere (e.g., coffee shop), they felt that their homes were most convenient and comfortable. The fact that they did not have to prepare their infants to leave the house or find a babysitter for other children was perceived as advantageous. For the most part, the home environment also provided privacy, perhaps allowing participants to share more and breastfeed more openly than they may have in a public setting or unfamiliar location.

For some participants, however, the home interview setting may not have been ideal, as they split their attention in caring for other children during the interview. Some mothers also had limited space and privacy from other family members during home interviews, leading to palpable discomfort at times. For one participant, a 21 year-old, there was a distinct change in her demeanor from the first two hospital interviews (without family present) to the last two home interviews, in which close quarters did not afford any privacy. For these latter interviews, the participant became more defensive and defiant as family members offered their opinions during the interview process. Another participant confided in the last interview that her spouse had actually been unsupportive in her breastfeeding efforts. It was noted that this was the only interview in which her spouse had not been present. These experiences highlight the need to discuss the dynamics of the home setting prior to scheduling in-home interviews if possible. When appropriate, alternate settings, still convenient for the participant, should be suggested.

2.5 STRENGTHS AND LIMITATIONS

The study design was strengthened by its longitudinal nature and multiple data collection methods, which provided analytical depth. In addition, the high approach-to-consent ratio (~80%) and completion of the study by all enrolled participants increases confidence that the late preterm breastfeeding experience was adequately captured. In addition, the focus on the maternal experience of breastfeeding a late preterm infant enabled an intensive, detailed exploration of the problem from the point of view of, arguably, the primary stakeholder.

As with all qualitative work, the study findings are limited in their transferability to other settings. Circumstances are likely to differ considerably at different places in different times, and

the findings may not reflect the experiences of less educated, more culturally-diverse women and infants younger than 35 gestational weeks. Caution should be exercised in applying the study's principles and recommendations without prior assessment and comparison of context.

The length of study follow-up also presented as a limitation. Although some valuable information was garnered from the 4-6 month follow-up, an additional scheduled interview or interviews may have provided more insight into the full trajectory of the late preterm breastfeeding experience. It remains unclear how breastfeeding ultimately evolves for this group.

2.6 IMPLICATIONS AND RECOMMENDATIONS

The theoretical model indicates that interventions to improve late preterm breastfeeding success should commence early (prior to onset of the negative management cascade) and focus on modifiable factors influencing breastfeeding management, including detrimental hospital policies and practices, lack of provider and maternal breastfeeding knowledge (particularly among primiparas), and misguided expectations among healthcare providers and mothers alike regarding LPI breastfeeding behavior. Mothers of LPIs and health care providers should be educated on basic breastfeeding interventions and qualified breastfeeding support resources. Additionally, the connection between infant behavior, physiological immaturity, and the high likelihood for problems compromising milk supply should be repeatedly emphasized to mothers of LPIs. Early breastfeeding interventions to assist with latching and milk transfer (e.g., supplemental nursing systems, nipple shields, supplementation via bottle) should be strongly considered, given the likelihood for decreased energy reserves and insufficient suction pressures common among LPIs (Medoff-Cooper, McGrath, & Bilker, 2000; Meier, Furman, &

Degenhardt, 2007). However, caution should also be exercised with regard to the risk-benefit ratio of formula supplementation, the increased probability for "nipple confusion" when alternating between at-breast and bottle feeds within the LPI population, and the balance between work and worth. For example, mothers who are extremely committed to breastfeeding may be amenable to more intensive interventions.

Future research building on study findings might include an examination of LPI breastfeeding beyond 6-8 weeks postpartum, inclusion of "early term" (37-38 weeks gestation) infants, who are also likely to experience breastfeeding issues related to neurologic immaturity (Kinney, 2006), and participant recruitment in areas known to be more ethnically diverse. Considering the complexity of events, external factors, individual variations, management decisions, and consequences found to impact the LPI breastfeeding trajectory, a systems-based analysis would add significantly to the science. This might take the form of a mixed-methods examination of hospital policies and practices, follow-up support, and perceptions or experiences of other "players" (e.g., pediatricians, home-visiting nurses, family members). Alternatively, intervention studies at this juncture might include an examination of the effectiveness of the following: 1) LPI peer breastfeeding support groups, as prior breastfeeding experience was perceived to significantly impact breastfeeding success; 2) provision of early, in-person breastfeeding management education, as participants repeatedly emphasized their desire to be "shown," rather than told, how to manage breastfeeding; and 3) early introduction of breastfeeding interventions, such as breast pumps and nipple shields. Outcomes might be measured in terms of breastfeeding continuation and exclusivity, breastfeeding-associated morbidities and re-hospitalizations, volume of milk output, and/or maternal satisfaction, confidence, or anxiety related to breastfeeding. Methodologically, delivering part of the

intervention electronically (e.g., an iPhone “app”) may be a cost-effective alternative to exclusive in-person meetings and a preferable communication medium for some participants.

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3.0 MANUSCRIPT #1: THE PARADOX OF BREASTFEEDING-ASSOCIATED MORBIDITY AMONG LATE PRETERM INFANTS

3.1 ABSTRACT

Objective: To synthesize the published research pertaining to breastfeeding establishment and outcomes among late preterm infants and to describe the state of the science on breastfeeding within this population.

Data Sources: Online databases Ovid MEDLINE, CINAHL, PubMed, and reference lists of reviewed articles.

Study Selection: Nine data-based research articles examining breastfeeding patterns and outcomes among infants born between 34 0/7 and 36 6/7 weeks gestation or overlapping with this time period by at least 2 weeks.

Data Extraction: Effect sizes and descriptive statistics pertaining to breastfeeding initiation, duration, exclusivity, and health outcomes among late preterm breastfed infants.

Data Synthesis: Among late preterm mother/infant dyads, breastfeeding initiation appears to be approximately 59% to 70% (U.S.), whereas the odds of breastfeeding beyond 4 weeks or to the recommended 6 months (exclusive breastfeeding) appears to be significantly less than for term infants, and possibly less than infants ≤34 to 35 weeks gestation. Breastfeeding exclusivity is not routinely reported. Rehospitalization, often related to "jaundice" and "poor

feeding," is nearly twice as common among late preterm breastfed infants as breastfed term or nonbreastfed late preterm infants. Barriers to optimal breastfeeding in this population are often inferred from research on younger preterm infants, and evidence-based breastfeeding guidelines are lacking.

Conclusions: Late preterm infants are at greater risk for breastfeeding-associated rehospitalization and poor breastfeeding establishment compared to their term (and possibly early preterm) counterparts. Contributing factors have yet to be investigated systematically.

3.2 INTRODUCTION

Late preterm infants—those born between 34 0/7 and 36 6/7 weeks gestation—account for nearly three fourths of preterm births in the United States and are the fastest growing cohort of premature infants (Davidoff et al., 2006; Hamilton, Martin, & Ventura, 2007; Martin et al., 2007). In 2005, there were nearly 375,000 late preterm births. This figure corresponds to a dramatic increase in the incidence of late prematurity within the past two decades in the United States—by 25% from 1990 to 2005, and by 9.6% between only 2000 and 2005 (Martin et al.). In contrast, the percentage of infants ≥40 weeks of gestation has decreased by 15% since 1990, and infants born before 34 weeks of gestation have increased only moderately—by 8.5% from 1990 to 2005 (Davidoff et al.; Martin et al.). A number of interrelated factors, including increases in the number of multiple births, the national obesity epidemic and related fetal macrosomia, the trend toward later-life childbearing, consumer demand and preferences for elective inductions and Cesarean births, proliferation of obstetric malpractice litigation, practice guidelines opposing postterm deliveries, and advancements in fetal monitoring have been implicated in regard to the

recent pervasiveness of late prematurity (Engle & Kominiarek, 2008; Fuchs & Gyamfi, 2008; Raju, 2006).

In concordance with the growing late preterm population, a study utilizing Nationwide Inpatient Sample (NIS) data from the federal Healthcare Cost and Utilization Project revealed that nonextreme preterm infants (28 0/7–36 6/7 weeks of gestation) consume two thirds of all hospital expenditures related to prematurity (Russell et al., 2007). The authors postulate that these expenses are attributable mainly to late preterm infants, in direct proportion to their prevalence, rather than acuity of illness. A cost analysis performed through a review of 185 near-term and full-term infants' electronic medical records showed that near-term infants (35 0/7–36 6/7 weeks gestation) consume a mean of $2,630 more in medical costs than infants ≥37 weeks gestation (Wang, Dorer, Fleming, & Catlin, 2004).

Despite appearances and weights often comparable to their term counterparts, late preterm infants tend to lag behind in terms of their cardiorespiratory, metabolic, immunologic, neurologic, and motor development (Engle, Tomashek, & Wallman, 2007). In recognition of this contradiction, a multidisciplinary expert panel assembled by the National Institute of Child Health and Human Development in 2005 made the recommendation to classify infants born between 34 0/7 and 36 6/7 weeks gestation as “late preterm,” rather than “near term,” to convey the medical vulnerability extant within this cohort (Raju, Higgins, Stark, & Leveno, 2006). Consistent with this assertion (but not with terminology), a medical record review reported that near-term infants were 4 times more likely than term infants to be diagnosed with jaundice, respiratory distress, poor feeding, temperature instability, or hypoglycemia during the birth hospitalization (Wang et al., 2004). The most common of these complications were jaundice (54%), suspected sepsis (37%), and feeding difficulties (32%).

Another medical record analysis, which included more than 33,000 infants born at seven different Kaiser Permanente Medical Care Program facilities, found that late preterm infants not admitted to the Neonatal Intensive Care Unit (NICU) were more likely than infants of all other gestational ages to be readmitted to the hospital within 2 weeks (adjusted odds ratio [aOR]=3.10, 95% confidence interval [CI] [2.38, 4.02]) (Escobar et al., 2005). The most frequent reasons for rehospitalization were jaundice (34%) and feeding difficulties (26%). Another study by the same authors found that a gestational age of 36 weeks was one of only three predictors of rehospitalization at 15 to 182 days following discharge (Cox hazard ratio=1.67, 95% CI [1.23, 2.25]) (Escobar, Clark, & Greene, 2006). Most recently, a chart review of more than 200,000 deliveries between 2002 and 2008 in the United States revealed that late preterm infants were significantly more likely than term infants to develop respiratory morbidity, including respiratory distress syndrome (RDS) (aOR of RDS at 34 weeks compared to 39 to 40 weeks gestation=40.1, 95% CI [32.0, 53.3]) (The Consortium on Safe Labor, 2010).

Kramer et al. (2000) and Khashu, Narayanan, Bhargava, and Osiovich (2009) report significant mortality risks for infants considered mild or moderately preterm (32 0/7–36 6/7 weeks gestation) and “late preterm” (unconventionally defined as 33 0/7–36 6/7 weeks gestation), respectively. In the Kramer et al. study, the corresponding etiological fraction of mortality for moderately preterm infants exceeded those of very preterm infants (28–31 6/7 weeks gestation), whereas the Khashu et al. study noted significantly higher perinatal (risk ratio [RR]=8.0, 95% CI [6.2, 10.4]), neonatal (RR=5.5, 95% CI [3.4, 8.9]), and infant mortality (RR=3.5, 95% CI [2.5, 5.1]) in late preterm as compared to term infants. Analogously, a 2008 committee publication by the American College of Obstetricians and Gynecologists reported that

late preterm infants have a mortality rate 4.6 times that of term infants, a figure that has increased gradually since 1995 (Committee on Obstetric Practice, 2008).

Of particular concern, late preterm infants who are breastfed tend to be readmitted to the hospital with diagnoses of failure to thrive, jaundice, and dehydration more frequently than those who are not breastfed, a finding largely attributed to insufficient breast milk intake (Escobar et al., 2002; Gartner, 2001; Shapiro-Mendoza et al., 2006; Tomashek et al., 2006). This trend is disconcerting, considering the many, significant, and empirically validated advantages that breastfeeding provides, particularly for infants born prematurely (Callen & Pinelli, 2005). The purpose of this article is to address this paradox through synthesis of the available evidence on breastfeeding-associated infant rehospitalization, morbidity, and mortality and rates of breastfeeding initiation, duration, and exclusivity/supplementation within the late preterm population. A secondary objective is to describe the state of the science on breastfeeding among late preterm mother/infant dyads, including benefits and barriers to breastfeeding and current breastfeeding recommendations. The latter objective will be achieved through review of expert opinion and clinical review papers, as data-based research is currently lacking in this area.

3.3 METHODS

Electronic databases including CINAHL, Ovid MEDLINE, and PubMed, as well as the reference lists of reviewed articles were searched for English language, data-based research studies published between 1990 and 2010 examining breastfeeding patterns and outcomes among human infants of gestations spanning or falling within the late preterm classification (34 0/7 – 36 6/7 weeks gestation) by at least 2 weeks. Studies conducted in developing countries were excluded

due to differences in breastfeeding rates, health care delivery, infant morbidity and mortality, and other cultural variations.

Within the electronic databases, the following indexed subject headings were searched: lactation, breastfeeding, premature birth, infant/premature, gestational age, morbidity, mortality, perinatal mortality, infant mortality, incidence, and prevalence. Late preterm, late prematurity, and near term were searched as key words. Combined electronic searches using OvidMEDLINE without outcome subject headings (e.g., morbidity, mortality, etc.) yielded 793 citations. The search was narrowed by combining the initial search with each outcome subject heading, which yielded 90 results. These citations' abstracts were scanned for sample and outcomes meeting inclusion criteria, and when present, the full-text article was retrieved for more detailed review. No unique, additional studies meeting inclusion criteria were identified through identical searching within other databases. Nine original research articles were included in the final review; two addressed breastfeeding patterns and outcomes, two described only breastfeeding outcomes (i.e., morbidity), and five addressed only breastfeeding patterns (see Figure 1).

Level of evidence was assessed according to the Scottish Intercollegiate Guidelines Network (2004). In this system, Level 1 represents the highest level of evidence (randomized controlled trials [RCTs] or systematic reviews of RCTs), whereas Level 2 denotes cohort or case-control studies. Level 3 includes nonanalytic studies (e.g., case reports), whereas Level 4 is expert opinion.

3.4 RESULTS

3.4.1 Breastfeeding-associated rehospitalization, morbidity, and mortality within the late preterm population

Of the four studies identified discussing breastfeeding outcomes, all were retrospective chart reviews, considered Level 2 evidence. Notably, no studies provided data on mortality. All were biased to some degree by the secondary nature of data sources and lack of quantification of breastfeeding. Tomashek et al. (2006) and Shapiro-Mendoza et al. (2006) adjusted for factors known to affect breastfeeding outcomes (e.g., parity, prenatal care), whereas Bhutani and Johnson (2006) noted no significant between-group differences in baseline variables. Wang et al. (2004) did not control for potential group differences. Generalizations between studies are complicated by differing gestational age classifications, comparison groups, and outcomes of interest. As a group, however, these studies do seem to suggest that neonates born in the late preterm period who are breastfed at hospital discharge tend to fare worse than full-term breastfed infants or infants of similar gestation who are not breastfed.

In the first study, a population-based cohort study in Massachusetts involving 9,522 late preterm infants, breastfeeding at the birth hospitalization discharge emerged as the single greatest risk factor for the infant's rehospitalization (adjusted risk ratio [aRR]=1.65, 95% CI [1.33, 2.04]) (Shapiro-Mendoza et al., 2006). In another cohort study utilizing the same Massachusetts vital statistics database, the authors reported that among infants who breastfed at hospital discharge, late preterm infants were significantly more likely than term infants to be rehospitalized (aRR=2.2, 95% CI [1.5, 3.2]) and to receive hospital-related care after discharge (aRR=1.8, 95% CI [1.3, 2.5]). This difference was not observed between term and late preterm

infants who were not breastfeeding at discharge (Tomashek et al., 2006). Wang et al. (2004) reported in their medical record review—a sample wherein roughly 80% of mothers initiated breastfeeding, that near-term infants (35 0/7–36 6/7 weeks gestation) were significantly more likely than term infants (≥37 weeks gestation) to experience a hospital discharge delay due to "poor feeding" (p=.029). Bhutani and Johnson (2006) found in their retrospective review of registry data that infants 35 0/7 to 36 6/7 weeks gestation ("nearly all breastfeeding") were significantly more likely than infants ≥37 weeks to suffer from severe posticteric sequelae (p<0.01). Table 5 summarizes the main outcomes of these studies.

Other studies not meeting inclusion criteria for this review have noted higher rates of morbidity, including rehospitalizations, due to "feeding problems" and jaundice among late preterm infants but have not delineated breastfeeding from formula feeding (Jain & Cheng, 2006; Lubow, How, Habli, Maxwell, & Sibai, 2009). Alternatively, some studies have found late prematurity (or younger term gestations) and breastfeeding to be independently and significantly related to higher rates of hospital readmissions but do not account for the interaction between breastfeeding and gestational age (Escobar et al., 2002; Maisels & Kring, 1998; Oddie, Hammal, Richmond, & Parker, 2005). Notably, Escobar et al. reported that within their large, retrospective case-control nested cohort study, the most prominent factors contributing to a rehospitalization for dehydration among infants ≥36 weeks gestation included exclusive breastfeeding (aOR=11.2, 95% CI [3.9, 32.6]) and gestational age younger than 39 weeks (aOR=2.0, 95% CI [1.5, 6.0]).

Hall, Simon, and Smith (2000) did not include a separate category for late preterm infants in their retrospective medical record review of 125 breastfeeding infants but similarly concluded that younger gestational age at or near term was a "significant risk factor [for hyperbilirubinemia

and/or excessive weight loss/hypernatremia] leading to [hospital] readmission." However, statistics to support this assertion were not included.

In contrast, a large population-based cohort study in Sweden found NICU-admitted moderately preterm infants (30 0/7–34 6/7 gestational weeks) who were breastfeeding at hospital discharge to have a hospitalization 2.7 days shorter than nonbreastfed infants (p=.001) (Altman, Vanpée, Cnattingius, & Norman, 2009). However, because the infant population included in this analysis is younger and likely more acute than that observed in the other late preterm studies, comparisons may be imprudent.

3.4.2 Breastfeeding initiation, duration, and exclusivity within the late preterm population

Seven studies were identified discussing breastfeeding patterns within the late preterm population. Three reported rates of breastfeeding initiation only, two discussed breastfeeding initiation and duration, one accounted for breastfeeding duration and exclusivity, and one reported breastfeeding exclusivity only. Major sources of bias present across these studies included secondary data sources, exclusion of multiple births, differing gestational age groupings, non-U.S. study settings, and small sample size and/or no reported effect size, all of which precluded broad generalizations among analyses. Study designs included retrospective chart reviews, cohort, and descriptive studies, and were thus considered Level 2 evidence of late preterm breastfeeding rates. The exception to this was the McKeever et al. (2002) study, which was a RCT. The level of evidence rating is nonapplicable to this particular analysis, as the design of the study was intended to compare breastfeeding rates based on an intervention, not to examine breastfeeding rates within the general late preterm population.

As the individual study data indicate in Table 6, breastfeeding initiation rates among late preterm mother/infant dyads at around 59% to 70% are less than that of term infants and, possibly, younger preterm infants (Colaizy & Morriss, 2008; Donath & Amir, 2008; Merewood, Brooks, Bauchner, MacAuley, & Mehta, 2006; Shapiro-Mendoza et al., 2006; Tomashek et al., 2006). Although national breastfeeding rates for preterm infants as an exclusive group are not compiled, the late preterm breastfeeding initiation rate found here is less than the overall U.S. average as last reported by the Centers for Disease Control & Prevention (CDC) in 2010 at 75% (Centers for Disease Control and Prevention, 2010).

Breastfeeding duration statistics for late preterm infants are difficult to compile among studies due to wide variations in measurement periods (e.g., days, weeks, months), type of breastfeeding examined (e.g., exclusive vs. any), regional differences (e.g., rates higher in some countries, such as Australia), and inconsistencies in gestational week classification categories (e.g., infants of 30 0/7–35 6/7 weeks often grouped as “moderately preterm”; “late preterm” or “near-term” may include gestational weeks 34-<40). However, as study data demonstrate in Table 6, with the exception of one study (Wooldridge & Hall, 2003), breastfeeding tends to decrease over the postpartum period within the late preterm population, and rates may even be less than that for either term or earlier preterm infants at several weeks postpartum (Colaizy & Morriss, 2008; Donath & Amir, 2008). Colaizy and Morriss suggested that their finding of higher breastfeeding rates among early preterm infants (<32 weeks) may be a result of extra vigilance, breastfeeding support, and importance placed on breast milk feeds in the NICU, where younger preterm infants tend to outnumber late preterm infant admissions. As the incidence of late prematurity rises, breastfeeding rates within the late preterm population will likely become pivotal factors in achieving and maintaining Healthy People 2010 breastfeeding goals of 50%

continuation at 6 months and 75% initiation, respectively (U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion, 2000).

Only two reviewed studies (both conducted outside the United States) reported on breastfeeding exclusivity. Wooldridge and Hall (2003) found breastfeeding exclusivity among moderately preterm infants (30-35 6/7 weeks) to be approximately 60% during weeks 1 to 4, while percentages of partial breastfeeding at these times were less than 15%. McKeever et al. (2002) reported breastfeeding exclusivity at 67.7% 5 to 12 days postpartum in a control group of 12 infants 35 to 37 6/7 weeks gestation breastfeeding at hospital discharge (see Table 6). Discrepancies and omissions in the reporting of breastfeeding exclusivity are problematic, as both the American Academy of Pediatrics and World Health Organization recommend exclusive breastfeeding to 6 months postpartum.

3.4.3 Benefits of breastfeeding among infants born prematurely

Given the morbidity statistics, it may appear counterintuitive to recommend breastfeeding as the optimal infant feeding method and engage in efforts to increase breastfeeding rates among late preterm mother-infant dyads. Yet research suggests that the problem lies in the process (inadequate milk transfer), rather than product (breast milk). Indeed, preterm infants who lack the stamina to breastfeed but are supplemented with expressed breast milk tend to have better psychomotor, neurological, circulatory, and cognitive outcomes than those who are formula fed (Lucas, Morley, Cole, & Gore, 1994; Rao, Hediger, Levine, Naficy, & Vik, 2002; Simeoni & Zetterstrom, 2005). Additionally, an extensive body of research has elucidated the many specific benefits of breast milk for preterm infants, which, with its complex and temporally-variant composition dependent upon postconceptional age (Charpak, Ruiz, & Team, 2007) includes

enhanced gastrointestinal maturation; bolstered immunity demonstrated to decrease the incidence of necrotizing enterocolitis, other infections, and allergies; and acceleration of myelinization, possibly leading to improved childhood cognitive function (Adams-Chapman, 2006; Callen & Pinelli, 2005; Engle & Kominiarek, 2008).

More generally, breastfeeding has been found to decrease the risk of later-life obesity (Owen, Martin, Whincup, Smith, & Cook, 2005), and exclusive breastfeeding has been noted to save an estimated $200 to 475 on pediatrician office visits, hospitalizations, and prescriptions per infant during the first year of life, which is attributed to breast milk's immunologic protection against minor infant ills, including otitis media and respiratory tract infections (Ball & Wright, 1999; Hoey & Ware, 1997). Similarly, a very recent cost analysis projected a savings of $13 billion per year and prevention of more than 911 deaths if the rate of breastfeeding exclusivity reached 90% in the United States (Bartick & Reinhold, 2010). One study suggests that the enhanced immunity noted in premature breastfed infants may be due, in part, to a greater total antioxidant capacity in premature breast milk, as compared to more mature breast milk or formula (Ezaki, Ito, Suzuki, & Tamura, 2008).

Breastfeeding itself may offer other advantages for preterm infants including positioning favorable for neuromotor development (Barradas, Fonseca, Guimaraes, & Lima, 2006; Dodd, 2005) and the fostering of mother/infant bonding and secure infant attachment, the latter two of which achieved at least partly through the reciprocity inherent in the act (Britton, Britton, & Gronwaldt, 2006; Callen & Pinelli, 2005; Dodd; Klaus & Kennel, 1976). Despite all of the documented advantages of breastfeeding among preterm infants, however, the extent of these benefits has not been systematically established for late preterm infants as a unique group.

3.4.4 Barriers to breastfeeding in the late preterm population

3.4.4.1 Infant-related barriers

Neither the trajectory nor the causes of poor breast milk intake among late preterm infants have been adequately addressed. Indeed, late prematurity in general has only recently been defined and studied in any depth. The literature suggests several physiologic issues, mainly developmental immaturities in the infant, which seem to contribute to suboptimal breastfeeding among late preterm infants. These include cardiorespiratory instability contributing to rapid fatigue during feeding and subsequent inefficient breastfeeding; metabolic disturbances that necessitate supplementation; NICU admission and other medical conditions that separate mother and infant and limit the successful establishment of breastfeeding; immaturity of state regulation leading to overstimulation and fatigue during feeding; longer sleep intervals contributing to less overall time breastfeeding; uncoordinated suck, swallow, breathe organization; and, relative to term infants, decreased oro-motor tone that minimizes the negative pressure required for adequate milk flow (Committee on Obstetric Practice, 2008; Medoff-Cooper, McGrath, & Bilker, 2000; Medoff-Cooper & Ray, 1995; Wight, 2003).

These issues may concomitantly contribute to incomplete emptying of the breast, interfering with the supply-demand mechanism of breast milk production. Left unchecked, the phenomenon of insufficient milk supply ultimately ensues and infants who are exclusively, or mostly, breastfed may experience significant morbidities related to inadequate caloric intake. Unfortunately, this cascade of events typically transpires with the onset of lactogenesis II—copious milk production occurring 2 to 3 days postbirth (Meier, Furman, & Degenhardt, 2007), after the late preterm infant with no immediate health concerns has been discharged to home.

3.4.4.2 Mother-related barriers-preterm and term populations

Although developmental immaturities of the infant likely play a significant role in late preterm breastfeeding difficulties, breastfeeding itself is a complex, reciprocal activity between the infant and mother. The maternal component of the issue has not yet been examined in depth, except to note that there may be difficulty in establishing breastfeeding due to maternal conditions causing or associated with the preterm birth. For example, type I diabetes, obesity, Cesarean sections, and pregnancy-induced hypertension may delay lactogenesis II (Hartmann & Cregan, 2001; Rasmussen, Hilson, & Kjolhede, 2001; Sozmen, 1992; Wight, Morton, & Kim, 2008). Infections, multiple births, and medications used to treat some of these conditions (e.g., antibiotics, labor analgesia/anesthesia) may lead to postpartum separation of mother and infant, preventing early breastfeeding establishment (Wight et al.).

There are numerous studies generalized to premature and low-birth-weight infants describing maternal perceptions of breastfeeding. These qualitative analyses describe feelings of disparity between breastfeeding expectations and reality (Sweet, 2008), objectification of breast milk (Sweet, 2006), concerns regarding inadequate milk volume and composition (Callen, Pinelli, Atkinson, & Saigal, 2005; Kavanaugh, Mead, Meier, & Mangurten, 1995), a duty versus reciprocal breastfeeding viewpoint (Flacking, Ewald, Nyqvist, & Starrin, 2006; Flacking, Ewald, & Starrin, 2007), and the act of breastfeeding as providing a claim on the infant and validating maternal identity (Kavanaugh, Meier, Zimmermann, & Mead, 1997). As a result of significant research in this area, evidence-based interventions for providing breastfeeding support in the neonatal intensive care unit have been delineated (Meier & Brown, 1996).

Maternal anxiety, stemming from an early or traumatic birth and/or the fragility of a preterm infant, has also been cited in the preterm literature as a contributor to breastfeeding

failure. Specifically, anxiety has been implicated in the delay of lactogenesis II, though the pathophysiology of this process remains somewhat obscure (Chen, Nommsen-Rivers, Dewey, & Lonnerdal, 1998; Hartmann & Cregan, 2001; Neville & Morton, 2001). Some have postulated a negative effect of psychological stress on pulsatile oxytocin release, possibly modulated by opiate activity, which subsequently inhibits the milk ejection reflex and contributes to poor establishment of milk supply (Dewey, 2001; Lau, 2001; Ueda, Yokoyama, Irahara, & Aono, 1994). This process is supported by at least one randomized controlled trial involving 65 breastfeeding mothers of premature infants, which found that an audiotape of relaxation and visual imagery techniques listened to every other day for a week in resulted in 63% more milk yield in the treatment group compared to the control group, as measured in a single pumping 1 week later (Feher, Berger, Johnson, & Wilde, 1989).

Numerous studies of term infants have also demonstrated a negative association between anxiety and breastfeeding—revealing that the existence of postpartum anxiety independently accounts for breastfeeding non-initiation and early breastfeeding cessation (Britton, 2007; Papinczak & Turner, 2000; Ystrom, Niegel, Klepp, & Vollrath, 2008). In one study (Taveras et al., 2003), insufficient milk was the most frequently cited reason for early breastfeeding cessation, and lack of confidence in ability to breastfeed doubled the odds of breastfeeding discontinuation at 2 weeks postpartum (OR=2.8, 95% CI [1.02, 7.6]).

Other barriers to breastfeeding within the general population have been elucidated within the literature. These include competing work/school obligations, inadequate or conflicting breastfeeding information from health care providers (O'Campo, Faden, Gielen & Wang, 1992), lack of breastfeeding support from significant others (Arora, McJunkin, Wehrer, & Kuhn, 2000),

breastfeeding discomfort (Taveras, et al., 2003), and early use of pacifiers and breast milk supplementation (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003).

3.4.5 Current guidelines

Despite the paucity of evidence, several publications exist that provide suggestions, guidelines, and frameworks for breastfeeding support among late preterm mother-infant dyads. These include the AWHONN Near-Term Infant Initiative, which describes a conceptual framework incorporating family role, care environment, nursing care, and infant physiologic-function status in optimizing the health of late preterm infants (Medoff-Cooper, Bakewell-Sachs, Buus-Frank, Santa-Donato, & Near-Term Infant Advisory Panel, 2005). The initiative includes both patient and healthcare provider breastfeeding guidelines.

Walker (2008) and Meier et al. (2007) described the effects of common late preterm morbidities on breastfeeding and provided best practice suggestions for breast milk supplementation and maintenance of the maternal milk supply. Engle et al. (2007) proposed specific criteria for discharge of late preterm infants who are breastfeeding, including 24 hours of successful feeding, formal evaluation of breastfeeding documented at least twice daily by trained caregivers, a feeding plan, and conduct of a risk assessment for development of severe hyperbilirubinemia. Wight (2003) additionally recommended a multidisciplinary discharge plan, including lactation consultation and pediatrician follow-up within 24 to 48 hours, and administrative considerations, including a written hospital breastfeeding policy, in caring for the breastfed late preterm infant. Smith, Donze, and Schuller (2007) suggested many of the same measures but also recommended home visits by a lactation consultant until the infant reaches 40 weeks corrected age.

Perhaps the most comprehensive guidelines come from The Academy of Breastfeeding Medicine (2008), who recommended inpatient and outpatient directives. These include a late preterm hospital breastfeeding order set and pathway, weight loss classifications warranting consideration for supplementation, formal lactation consultation within 24 hours of delivery, follow-up within 48 hours of hospital discharge, and weekly weight checks through 40 weeks corrected age. Although these protocols reflect best practice based on the state of the science of breastfeeding in the late premature period, most are based upon expert opinion and breastfeeding patterns in the general preterm population. See Table 7 for a summary of common guidelines.

3.5 GAPS IN KNOWLEDGE AND FUTURE RESEARCH DIRECTIONS

Infants born in the late premature period remain a largely understudied group. These infants appear to have poorer rates of breastfeeding initiation and duration compared to term (and possibly earlier preterm) infants, and those who are breastfed appear more vulnerable to significant morbidity. The scope and causes of substandard breastfeeding rates and outcomes among late preterm infants remain uncertain, however.

Discrepancies in definitions of breastfeeding and late prematurity, as well as differing breastfeeding measurement periods are problematic in quantifying breastfeeding rates and synthesizing the morbidity literature. In addition, the reviewed studies delineating breastfeeding morbidity rely on large retrospective chart reviews. In these analyses, the longest follow-up examining morbidity and mortality data is 28 days postpartum (with the exception of the Bhutani and Johnson study 2006), and in all cases breastfeeding is vaguely defined as any breastfeeding at hospital discharge. Likewise, the majority of the late preterm literature reporting breastfeeding

initiation and duration define breastfeeding in a dichotomous "any/none," or occasionally "exclusive/any/none," format, disregarding the dose-dependent effect of breastfeeding on infant health outcomes.

To create comparable outcomes and synthesize findings, future analyses of breastfeeding within the late preterm population should consider the following: (a) standard definitions of late prematurity as 34 0/7 to 36 6/7 weeks gestation; (b) consistency in reporting degrees of breastfeeding, such as those recommended by Labbok and Krasovec (1990) (e.g., exclusive, token, etc.); (c) clarification of breastfeeding status to include provision of expressed breast milk; (d) examination of breastfeeding and associated morbidity extended to 6 to 12 months postpartum, as the minimum time recommended by the American Academy of Pediatrics for breastfeeding exclusivity and continuation, respectively (Gartner et al., 2005); and (e) utilization of large, national data sets reporting breastfeeding rates with the potential to link these to infant health outcomes (particularly infant mortality, which is difficult to study owing to low incidence within individual studies).

Benefits of breast milk and breastfeeding in the late preterm population require empirical corroboration and comparison with advantages documented in term and earlier preterm populations. Although research clearly demonstrates an inverse relationship between gestational weeks and health benefits of breastfeeding, current analyses generally indicate increased risk inherent in exclusive breastfeeding among late preterm infants. As noted, this is likely due to breastfeeding process factors, rather than breast milk composition. Thus, there is a need for future analyses that consider breastfeeding benefits and morbidity/mortality within the late preterm population accounting for breastfeeding support, length of postpartum hospitalization, NICU admittance (which may confer additional breastfeeding support), and supplementation

with expressed breast milk, as is standard practice in most NICUs and among early preterm infants.

Evidence suggesting that the current late preterm breastfeeding support is ineffective is provided by Escobar and colleagues (2005, 2006), who report an ostensibly protective effect of NICU admission on morbidity among breastfed late preterm infants—suggested to be due to the provision of additional guidance and breastfeeding support inherent in the NICU milieu. The finding is strengthened by Colaizy and Morriss (2008), who reported higher breastfeeding rates among late preterm infants admitted to the NICU as compared to the well-baby nursery. Similarly, in the only RCT found on breastfeeding interventions within the late preterm population, breastfeeding infants 35 to 37 6/7 weeks gestation who were discharged early and received home support from a certified lactation consultant had higher rates of exclusive breastfeeding at 5 to 12 days postpartum as compared to a control group receiving standard care (73.3% vs. 67.7%), though the sample was very small and results not statistically significant (McKeever et al., 2002).

Another gap in knowledge concerns the interplay of neonatal, maternal, social, and system factors contributing to late preterm breastfeeding failure. There is a need to more closely examine breastfeeding outcomes considering late preterm physiological maturity and health status, hospital routines and policy, timing and content of discharge and follow-up, the quality of the maternal/infant relationship, familial and cultural breastfeeding expectations, and other maternal physiological and psychological factors.

In particular it is unknown whether the same perceptions, anxieties, and resultant effects on breastfeeding observed among mothers of term and early preterm infants exist for mothers of late preterm infants. It may be hypothesized that maternal anxiety, thought to interfere with

breast milk production, increases exponentially with the precariousness of the infant's medical condition and degree of prematurity. However, a recent prospective cohort study of 116 premature infants found that higher maternal perception of child vulnerability (as measured by the Vulnerable Child Scale) was predicted by maternal anxiety but not associated with neonatal illness severity factors, including gestational age, birth weight, or length of mechanical ventilation (Allen et al., 2004). Likewise, it is acknowledged that the mother/premature relationship is complex, in that mothers of medically-fragile infants may be more responsive to their infants than mothers of nonchronically ill premature infants (Holditch-Davis, Cox, Miles, & Belyea, 2003) and that increased stress related to caring for a premature infant is associated with more positive maternal involvement (Holditch-Davis, Schwartz, Black, & Scher, 2007).

Breastfeeding (and breast milk provision) evidence-based guidelines for late preterm mother/infant dyads are currently lacking. To develop sound policy and recommend specific institutional and discharge guidelines for breast milk feeds within this vulnerable group (e.g., pumping recommendations, follow-up care, indications for supplementation), additional research on breastfeeding outcomes in concordance with the above factors is imperative.

3.6 IMPLICATIONS FOR PRACTICE

It is paramount that obstetric/neonatal nurses are aware of the increased risks to which breastfed late preterm infants are prone. Extra vigilance should be exercised in terms of monitoring and screening for hyperbilirubinemia and poor milk transfer. These observations should be documented regularly and systematically, that any departures from baseline may be recognized and treated rapidly. Additionally, it is the health care provider's responsibility to advocate for

appropriate care for the breastfeeding late preterm mother/infant dyad, including lactation consultation, no early discharges, and appropriately tailored discharge instructions.

Hospital units might also consider forming committees or appointing staff responsible for policy development and review of current practices relative to the care of breastfed late preterm infants. It is vital that these parties regularly review current literature and institute a system for incorporating policy updates, as the evidence for best practice in this area is rapidly evolving.

3.7 CONCLUSIONS

The number of infants born in the late preterm period is increasing more rapidly than within any other gestational cohort. These infants have unique, often unrecognized, medical vulnerabilities that predispose them to high rates of morbidity and hospital readmissions. In particular, breastfeeding complications have emerged as a preeminent health concern for late preterm mother/infant dyads.

To improve breastfeeding initiation and continuation rates and infant health outcomes, clinicians must recognize and address the late preterm breastfeeding paradox. It is imperative that health care providers understand and communicate the overwhelming short- and long-term benefits of breast milk and breastfeeding as opposed to formula feeding among preterm infants yet remain vigilant for evidence of poor breast milk transfer and infant problems related to poor intake. As current guidelines recommend and limited research suggests, mothers of late preterm infants should receive qualified, extended lactation support, frequent follow-up, and possibly delayed hospital discharges. In addition, supplementation with expressed breast milk will likely be necessary for a period of time.

Further research exploring causes of poor breastfeeding establishment and associated outcomes among late preterm mother/infant dyads is warranted. These preliminary analyses will be vital in informing subsequent randomized-controlled breastfeeding intervention trials and evidence-based guidelines.

3.8 ACKNOWLEDGEMENT

Funded by National Institute of Nursing Research grant 1F31NR011562.

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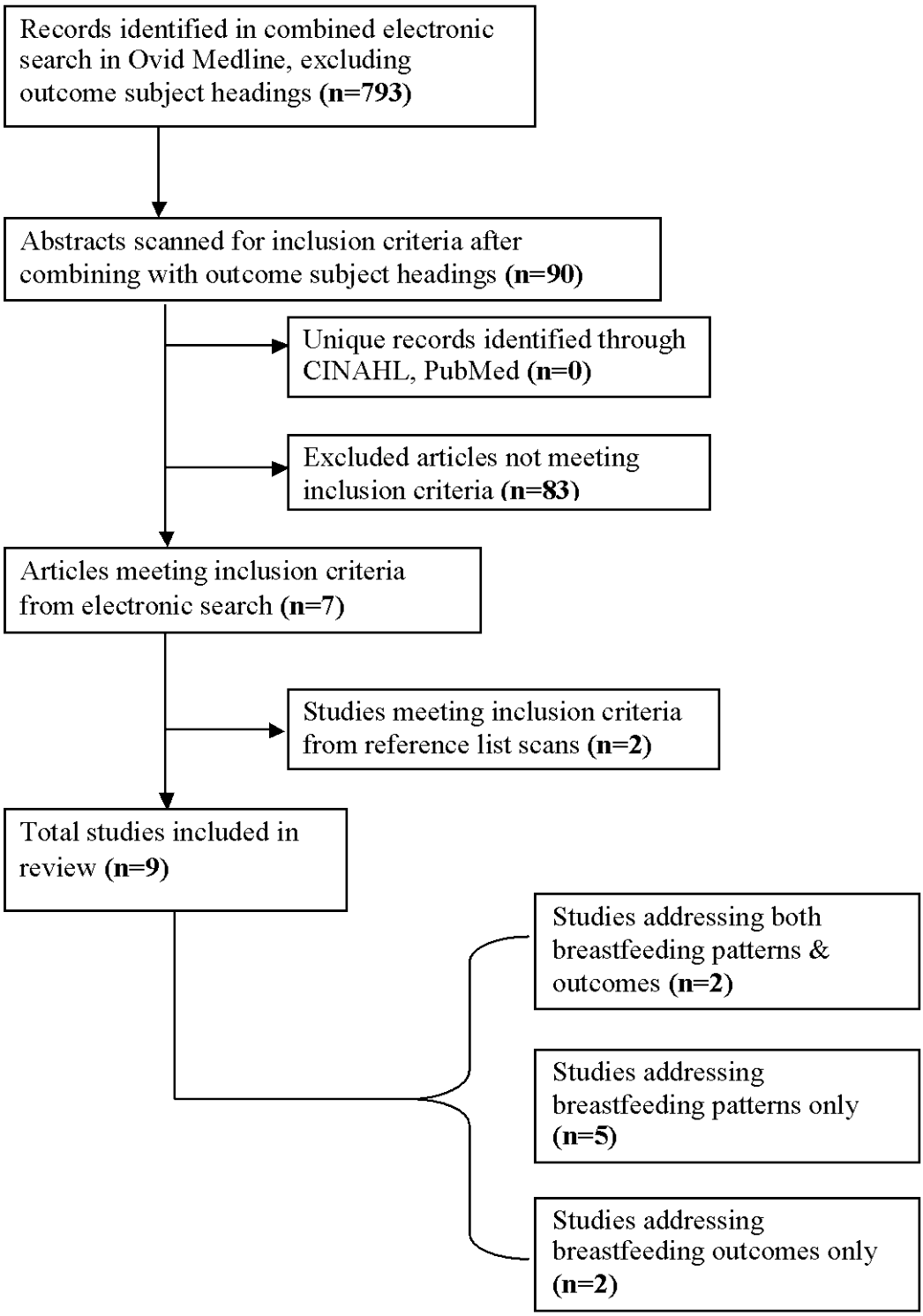

Figure 1. Flowchart of search strategy and study selection

Table 5. Morbidity and re-hospitalizations among late preterm breastfed infants

Reference/ Design	Study Purpose	Sample	Results/Effect Sizes Specific to Breastfeeding Morbidity	Limitations	Recommendations
Tomashek et al. (2006) Retrospective chart review U.S.	Evaluate differences in hospital readmissions & observational stays between FTIs and LPIs	24,320 FTIs (≥ 37 wks gest.) and 1,004 LPIs (34-36 6/7 wks gest.) discharged < 2 days pp	Breastfed LPIs compared to breastfed FTIs: **aRR 1.8 (1.2-2.6)** for observational stay *or* hospital readmission **aRR 2.2 (1.5-3.2)** for hospital readmission aRR 1.3 (0.6-2.9) for observational stay	Breastfeeding status defined only at time of birth certificate completion Unable to link all readmissions and birth records Secondary data sources Exclusion of multiples	Individualized discharge instructions and close follow-up for breastfed LPIs Research to establish discharge & follow-up guidelines for breastfed LPIs
Shapiro-Mendoza et al. (2006) Retrospective chart review U.S.	Compare hospital readmissions and observational stays (i.e., morbidity) & mortality between healthy LPIs with/out risk factors	9,552 "healthy" vaginally-delivered infants 34-36 6/7 wks gest.	Overall neonatal morbidity among breastfed LPIs, compared to non-breastfed LPIs: **aRR 1.65 (1.33-2.04)** * Mortality statistics not calculated due to low incidence	Breastfeeding status defined only at time of birth certificate completion Unable to link 23% of re-hospitalizations to birth records Secondary data sources Exclusion of multiples	Closer hospital monitoring & follow-up of breastfed LPIs, especially with risk factors, including: Asian/Pacific Islander heritage, firstborn status, labor and delivery complications
NO EXCLUSIVE CATEGORY FOR INFANTS 34 0/7-36 6/7 WEEKS GESTATION					
Wang et al. (2004) Retrospective chart review U.S.	Test hypothesis that NTIs have more medical problems pp than FTIs	120 NTIs (35-36 6/7 wks gestation) & 125 FTIs (≥ 37 wks gest.) *~80% breastfeeding rate*	Discharge delay due to "poor feeding:" NTIs: 75.9%; FTIs 28.6%: NTIs compared to FTIs, calculated **OR 7.9 (1.2-49.9), p = 0.029**	Gestational classification of NTI differs from LPI No objective identification of breastfeeding status or success at time of discharge Secondary data sources	Ongoing breastfeeding assistance and support for NTIs Early supplementation with expressed breast milk or formula, if indicated Close observation for common NTI feeding complications; consider longer pp hospitalizations

Bhutani & Johnson (2006) Retrospective review U.S.	Comparison of etiology and clinical outcomes between LPIs and FTIs with a diagnosis of kernicterus or extreme hyperbilirubinemia	96 FTIs (≥ 37 wks gest.) and 29 LPIs (35-36 6/7 wks gest.) part of Pilot Kernicterus Registry *"Nearly all" LPIs breastfeeding*	Severe posticteric sequelae: LPIs: 82.7%; FTIs: 70.8% **($p < 0.01$)** "Unsuccessful lactation experience" most common risk factor for hazardous hyperbilirubinemia in LPIs	Sample not inclusive of full late preterm period No distinction among breastfed/non-breastfed LPI infants; breastfeeding in term infants not addressed "Unsuccessful lactation experience" not defined	Assessment of pre-discharge hyperbilirubenemia risk; follow-up within 24-48 hrs for LPIs Family-centered care streamlined between hospital & pediatrician office Accurate, precise, universally available hyperbilirubinemia measures

Key for Tables 5 & 6: *Significant findings and non-U.S. study settings are bolded. Abbreviations: LPI= late preterm infant; NTI= near term infant; PTI= preterm infant; FTI= full-term infant; EBF= exclusively breastfed; PBF= partially breastfed; pp= postpartum; wks gest= weeks gestation; hrs= hours; aOR= adjusted odds ratio; parenthesized numbers indicate a 95% confidence interval*

Table 6. Initiation, duration, and exclusivity of breastfeeding among late preterm mother-infant dyads

Reference/ Design	Study Purpose	Sample	Results/Effect Sizes Specific to Breastfeeding Patterns	Limitations	Recommendations
Tomashek et al. (2006) See Table 5	See Table 5	See Table 5	Breastfeeding at hospital discharge: LPIs: 59.3% (n= 592) FTIs: 69.4% (n= 16,864) LPIs compared to FTIs, calculated **OR 0.64 (0.56-0.73)**	See Table 5	See Table 5
Shapiro-Mendoza et al. (2006) See Table 5	See Table 5	See Table 5	LPIs breastfeeding at hospital discharge: **70.0%** (n = 6,651)	See Table 5	See Table 5
NO EXCLUSIVE CATEGORY FOR INFANTS 34 0/7-36 6/7 WEEKS GESTATION					
Merewood et al. (2006) Retrospective chart review U.S.	Compare breastfeeding initiation rates among preterm and term infants	67,884 singleton births between 24-42 wks gestation	Rates of breastfeeding initiation: 24-31 wks gest.: 62.9% 32-36 wks gest.: 70.1% 37-42 wks gest.: 76.8% "Older preterm" (32-36 6/7 wks gest.) as compared to FTI (37-42 wks gest.): **aOR 0.73 (0.68-0.79)**	No exclusive LPI category Self-report of breastfeeding status via single, double-barreled question Some factors not controlled for (e.g., infant morbidity) Exclusion of multiples Secondary data sources	Provision of additional knowledge, support, and equipment (e.g., breast pumps) for breastfeeding preterm dyads Research investigating breastfeeding practices or interventions for all gestational ages should consider maternal birthplace and race
Colaizy & Morriss (2008) Retrospective review of survey data U.S.	Test hypothesis that NICU admission reduces breastfeeding in U.S. infants	29,940 NICU-admitted infants part of 2000-2003 PRAMS survey	Infants 32-< 35 wks gest., NICU-admitted (n = 4949) vs. non-admitted (n = 467): *Ever breastfed:* 70.2% vs. 55.3% (***p* < 0.01**) *Breastfed > 4 wks pp:* 49.1% vs. 35.1% (***p* < 0.01**)	No exclusive LPI category Self-report of all data	Further research investigating factors within the NICU environment that are associated with successful breastfeeding initiation and continuation, especially among LPI (35-<38 wks gest.)

			<u>Infants 35-< 38 wks gest. NICU-admitted (n = 8159) vs. non-admitted (n = 9601):</u> *Ever breastfed:* 68.7% vs. 64% (***p* < 0.01)** *Breastfed > 4 wks pp:* 47.6% vs. 43.5% (***p* < 0.01)** Compared to infants ≥38 wks gest., breastfeeding > 4 wks pp: **OR 0.87 (95% CI 0.78-0.97)** infants 32-<35 wks gest. **OR 0.78 (95% CI 0.73-0.83)** infants 35-<38 wks gest. *(lowest OR of any gestational cohort, including infants < 32 wks)*		
Donath & Amir (2008) Population-based cohort study **Australia**	Investigate effect of gestation on initiation and duration of breastfeeding	3,600 singleton infants in Australia	NTI (35-36 6/7 wks gest.) breastfeeding rates & aOR's compared to infants ≥ 40 wks gest: Initiation: 88.2% aoR 0.64 (0.35-1.18) 6 months pp: 41.2% **aOR 0.51 (0.34-0.76)** **Lower rates for NTIs than for any other gestational age (e.g., ≤34 wks, ≥37 wks)*	No category inclusive of full late preterm period May not be representative of U.S. rates Exclusion of multiples Significance/effect size not reported for NTI compared to early PTI	Individualized assessment and discharge planning for infants of 35-36 gestational weeks to improve chances of successful breastfeeding Need for awareness among clinicians that infants less than 40 weeks gestation (even 37-39 weeks) may be less likely to achieve successful breastfeeding
Wooldridge & Hall (2003) Ex post facto descriptive correlational	Describe breastfeeding patterns of moderately preterm infants over 4 wks pp	66 infants 30-35 6/7 wks gest. from 53 mothers in Canada	According to feeding diaries, rate of breastfeeding exclusivity: 1 wk pp: 60.6% 4 wks pp: 59.1% Rate of exclusive & "primary" breastfeeds at breast increased	No exclusive LPI category May not be representative of U.S. rates Small sample size, convenience sampling Possible rate inflation due	Establishment of adequate milk supply before hospital discharge in moderately preterm mother-infant dyads More research examining breastfeeding patterns and best practices among moderately

Canada			steadily over 4 wks pp: 3% to 23% (exclusive); 18% to 27% (primary) Little variability in rates of breastfeeding exclusivity over 4 wks pp when breastfeeds not necessarily at breast	to breastfeeding experience of research assistants 40% of sample was twins; non-comparable to other included studies Effect sizes/significance not reported	preterm twins; more clinical breastfeeding support for mothers of twins
McKeever et al. (2002) Randomized controlled trial **Canada**	Compare effects of breastfeeding support in hospital & home settings on breastfeeding outcomes and satisfaction in FTIs and NTIs	75 FTIs (≥38 wks) and 37 NTIs (35-37 6/7 wks gest.) breastfeeding at hospital discharge	Breastfeeding exclusivity (past 24 hrs) at 5-12 days pp in standard care group: NTIs: 67.7% (n=12) FTIs: 73.5% (n=34) NTIs compared to FTIs, calculated OR 0.72 (0.17-2.98)	No exclusive LPI category Very small sample of NTIs Short follow-up period Inclusion criteria requiring breastfeeding at discharge may inflate exclusivity rate May not be representative of U.S. rates	Awareness that many NTIs require supplemental feeding after discharge, contributing to decreased breastfeeding exclusivity in this grp Research to determine optimal healthcare setting, frequency, and duration of support for breastfeeding mothers Healthcare policies to ensure availability of skilled, in-home lactation support for all breastfeeding mothers

Table 7. Summary of common breastfeeding recommendations for late preterm infants

	Clinical Review/Expert Opinion						**Data-based Studies**								
Recommendations	Smith et al. (2007)	Walker (2008)	Wight (2003)	ABM (2008)	Engle et al. (2007)	Meier et al. (2007)	Bhutani & Johnson (2006)	Merewood et al. (2006)	McKeever et al. (2002)	Wang et al. (2004)	Tomashek et al. (2006)	Donath & Amir (2008)	Shapiro-Mendoza et al. (2006)	Wooldridge & Hall (2003)	Colaizy & Morriss (2008)
Immediate STS care, 24-hr rooming-in	*	*	**	**											
Football or cross-cradle positioning		*				*									
Pediatrician follow-up 24-28 hrs post-discharge, then frequently thereafter	*	*	*	*	*		*								
Hyperbilirubinemia risk assessment & monitoring	*	*	*	*	*		*			*			*		
Clinician/parental education & awareness re: increased lactation risk & normal LPI breastfeeding patterns	*		*	*	*	*		*	*			*			
Repeated, documented breastfeeding observations in-hospital	*	*		*	*										
Specific d/c criteria (e.g., established milk supply, 24 hrs successful feeding, etc.)			*		*									*	
Early use of interventions if not breastfeeding effectively (e.g., double electric pump, nipple shields, SNS)	*	*	*	*		*		*	*	*					
D/C feeding plan (written, individualized), evidence-based hospital pathway	*	*	**	**	*						*	*			
Close monitoring of output & weight pre/post-d/c (e.g., home test weights)	*	*	*	*		*							*		
Streamline care among HCPs pre/post-d/c	*		*	*			*								
Professional, experienced lactation support (e.g., lactation consultant) pre/post-d/c	*		*	*					*						
Further research re: optimal breastfeeding support, interventions, and discharge criteria									*		*				*

** = endorsement of 1st or only recommendation; **= endorsement of both 1st and 2nd recommendation; Abbreviations: STS= skin to skin; LPI= late preterm infant; D/C= discharge; SNS= supplemental nursing system; HCP= health care provider; ABM= The Academy of Breastfeeding Medicine*

4.0 MANUSCRIPT #2: PREVALENCE AND PREDICTORS OF EARLY BREASTFEEDING AMONG LATE PRETERM MOTHER-INFANT DYADS

4.1 COVER LETTER TO JOURNAL EDITOR

November 7, 2011

Dear Editors and Reviewers,

Please consider the attached manuscript, "Prevalence and Predictors of Early Breastfeeding among Late Preterm Mother-Infant Dyads" for publication in the Journal of Public Health and Epidemiology. This paper describes prevalence of breastfeeding initiation and factors impacting early breastfeeding in a population-based sample of late preterm mother-infant dyads. Jill Radtke is serving as the first and corresponding author. Please feel free to contact her with any questions.

Regards,

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4.2 ABSTRACT

Although late preterm infants (LPIs), 34 0/7-36 6/7 weeks gestation, are reported to have suboptimal rates of breastfeeding, there is a lack of quantitative evidence concerning trends and factors impacting breastfeeding within this population. This study examined the prevalence of and social, medical, and system-level variables impacting breastfeeding initiation within a Pennsylvania population-based cohort of late preterm mother-infant dyads. Though LPI breastfeeding initiation increased significantly from 2003-2009 ($p<0.001$), the 2009 prevalence

at 61.8±1.1% remains well below rates in term infant populations and national standards. Binary logistic regression results indicated that interactions involving sociodemographic variables, including marital status, age, race/ethnicity, education, parity, WIC, and smoking status were among the most significant factors associated with LPI breastfeeding initiation ($p<0.05$). Univariately, our findings are similar to those reported in preterm and term populations, but the interaction terms suggest that certain, unexpected demographic groups be prioritized for breastfeeding support resources and further analysis. More research is indicated to understand the effect of modifiable psychosocial factors on late preterm breastfeeding initiation, duration, and exclusivity.

4.3 INTRODUCTION

Breast milk is widely recognized as the optimal form of nutrition for infants of all gestational ages (Gartner et al., 2005). However, the most dramatic health benefits related to breastfeeding likely exist among premature infants (Callen & Pinelli, 2005; Henderson, Anthony, & McGuire, 2007). In comparison to formula-feeding, breastfeeding in premature infants has been linked to improved gastrointestinal, immunological, circulatory, cognitive, neuro-motor, and psychosocial outcomes (Adams-Chapman, 2006; Barradas, Fonseca, Guimaraes, & Lima, 2006; Britton, Britton, & Gronwaldt, 2006; Callen & Pinelli; Dodd, 2005; Lucas, Morley, Cole, & Gore, 1994; Rao, Hediger, Levine, Naficy, & Vik, 2002; Simeoni & Zetterstrom, 2005). Unfortunately, prevalence of breastfeeding in late preterm infants (LPIs), born at 34 0/7-36 6/7 weeks gestation, has been cited well below rates in term populations, and occasionally, earlier preterm groups

(Radtke, 2011). This trend is concerning, as LPIs comprise the largest segment of premature births in the U.S. (Martin et al., 2010).

Both trends and causes of subpar breastfeeding initiation, duration, and exclusivity (i.e., provision of only breast milk) within the late preterm population have not been adequately investigated. Multiple and inter-related infant, maternal, and system factors have been implicated in poor LPI breastfeeding duration and exclusivity statistics. For example, the physiologic immaturity of LPIs in terms of state regulation, suck-swallow-breathe coordination, and oro-motor tone can lead to problems with latching on and achieving a consistent, effective suck pattern that permits adequate milk transfer. LPIs are also at risk for medical complications related to prematurity, such as hypothermia, hypoglycemia, and sepsis. These conditions, whether confirmed or suspected, may lead to early mother-infant separation (e.g., use of isolettes, NICU admission) and/or formula supplementation, threatening the early breastfeeding relationship and establishment of milk supply (Committee on Obstetric Practice, 2008; Medoff-Cooper, McGrath, & Bilker, 2000; Meier, Furman, & Degenhardt, 2007; Wight, 2003). In addition, LPI mothers may have medical issues related to the preterm birth, such as type I diabetes, obesity, and pre-eclampsia. These conditions may contribute to delayed lactogenesis II (onset of copious milk production) or necessitate medications or IV fluids that compound infant lethargy at breast and maternal breast edema, leading to problems with coordinated sucking and latching, respectively (Hartmann & Cregan, 2001; Rasmussen, Hilson, & Kjolhede, 2001).

Understanding the impact of these and other possibly yet unexplored factors on LPI breastfeeding duration and exclusivity is important for the development of interventions within this special population. However, it is critically important to first establish which variables impact (and in what manner) early, or in-hospital breastfeeding initiation in the LPI population.

Indeed, these factors should inform which demographic groups, individual characteristics, and medical practices are targeted for breastfeeding improvement. In addition, because national and state-level breastfeeding prevalence data specific to LPIs are not routinely reported, the scope of the LPI breastfeeding problem is only vaguely defined within the larger population.

The purpose of this analysis, using Pennsylvania birth registry data, was two-fold: 1) to describe the current 2009 rate and temporal trends (2003-2009) in LPI breastfeeding initiation; and 2) to develop a predictive model for LPI breastfeeding initiation (or early breast milk provision) in 2009 accounting for social, medical, and system-level variables. To the authors' knowledge, influences on LPI breastfeeding initiation have not been previously analyzed utilizing a population-based dataset permitting control of multiple covariates and confounders.

4.4 METHODS

4.4.1 Study design

This cross-sectional analysis examined breastfeeding prevalence among LPI mothers (n=62,451) and their infants (n=68,886) 2003-2009, and the latter was compared to moderately preterm (30 1/7-33 6/7 weeks gestation; n=17,325) and term infants (≥ 37 weeks gestation; n=870,034) in the same time period. The study also utilized logistic regression to determine the association of system/provider, infant, and maternal sociodemographic and medical factors with breastfeeding initiation in late preterm mother-infant dyads for year 2009 (n=7,012). All variable data were obtained from a de-identified electronic birth certificate file prepared by the Pennsylvania Department of Health, Bureau of Health Statistics and Research after IRB approval.

Predictor variables for inclusion were chosen based upon birth registry availability of frequently cited and suspected influential factors in breastfeeding initiation within the general and late preterm infant populations, respectively. After discussion and consensus among all authors, 25 variables were included in the initial screening procedure. Maternal variables examined included age, pre-pregnancy body mass index (BMI), birth country, smoking during pregnancy, marital status, level of education, Hispanic ethnicity, race, history of prematurity, history of infertility treatment, Medicaid status, parity, WIC recipient status, and diabetic status (gestational and pre-pregnancy type I and II). Infant variables examined included gender, birth weight, weeks of completed gestation, NICU admission, and plurality. System or obstetric practice variables included delivery attendant, receipt of first trimester prenatal care, use of anesthesia during labor, induction or augmentation of labor, and route of delivery. Due to excessive missing data or categorical outliers, some variables of interest were retained for descriptive purposes only.

Pennsylvania birth certificate data are compiled via electronic transfer from health care providers, whose procedures for data collection may vary, to the Bureau of Health Statistics and Research. The outcome variable—breastfeeding initiation, is recorded post-delivery by medical staff on a worksheet that asks the question, “Is the newborn being breastfed?” Pennsylvania specifies that this answer is based on the provider’s observation of breastfeeding, but it does not dictate when this should be assessed (Chapman, Merewood, Ackatia Armah, & Pérez-Escamilla, 2008; A. Farrell, Pennsylvania Department of Health, personal communication).

Gestational age is assessed by the birth attendant and defined as his or her final estimation of gestation, based on all perinatal factors and assessments, but *not* the neonatal exam, date of last menstrual period, or date of the infant’s birth. In general, the other variables included

in this analysis are abstracted from the medical record post-delivery, based either upon maternal self-report to the medical provider or the medical provider's observations (A. Farrell, Pennsylvania Department of Health, personal communication). At least one study suggests that birth record data are relatively reliable for variables pertaining to labor outcomes, obstetric and maternal history, and infant-related variables, but less reliable for variables involving maternal comorbidities and obstetric complications (DiGiuseppe, Aron, Ranbom, Harper, & Rosenthal, 2002).

4.4.2 Predictive model sample

Because a relatively "healthy" LPI sample capable of receiving breast milk feeds was desired, infants and mothers with significant morbidity or factors demonstrated to preclude or seriously hinder breastfeeding initiation were excluded from the predictive model (n=414). Mothers were excluded based on documentation of any of the following variables, relevant to the birth admission: ruptured uterus, unplanned hysterectomy or other operation, and admission to the intensive care unit. Infants were excluded if any of the following conditions were documented: anencephaly, seizure or serious neurologic dysfunction, congenital heart disease, gastroschisis, omphalocele, congenital diaphragmatic hernia, down syndrome (suspected or karyotype confirmed), chromosomal disorder (suspected or karyotype confirmed), cleft lip and/or palate, pending adoption, 5-minute Apgar score < 3, and assisted ventilation for > 6 hours. Although no extremely low birth weight infants (ELBW; <1000 grams) were included, seven VLBW (very low birth weight; <1500 grams) infants were were part of the final sample; these infants' weights tended to cluster closely around the 1500 gram mark, and they had a breastfeeding rate of 62%, suggesting that they were capable of receiving breast milk feeds.

To avoid violating the independence of observations assumption in a de-identified dataset, only year 2009 data from singleton or first-born multiple infants were utilized. Cases with missing data on variables of interest were eliminated after it was determined that missingness occurred in a random pattern. For univariate outliers in infant birth weight (n=2) and maternal age (n=28), score alterations were executed. When determined to be part of the study population, categorical outliers were collapsed where possible (e.g., maternal education) and eliminated (e.g., birth country) when not possible. Eighteen cases determined to be multivariate outliers using a Malhalanobis' distance procedure were dropped from the analysis. To ensure a representative sample, a sensitivity analysis was conducted by comparing the logistic regression results with and without these outliers. The final regression sample included 7,012 mothers of "healthy" singleton, or first-born mutiple, infants.

4.4.3 Analysis

Annual proportions (2003-2009) of breastfeeding initiation were calculated for late preterm, moderately preterm, and term infants to permit comparisons by year and gestational age category. Proportions were further broken down for LPI mother-infant dyads by gestational week (e.g., 34, 35, 36 weeks) and plurality (e.g., infant part of singleton or multiple gestation).

For year 2009, descriptive statistics were compiled examining breastfeeding initiation in relation to the various predictor variables. To determine differences in breastfeeding initiation in both continuous and categorical predictor variables, binary logistic regression was used to obtain unadjusted odds ratios (uOR) and 95% CIs (Table 8).

These initial, univariate logistic regression models were also utilized as a first step in developing the breastfeeding initiation predictive model. Those variables with likelihood ratio

chi-square and Wald statistic p-values ≤0.25 were included in multivariate modeling (n=13), which involved the following sequential steps: 1) Examination of a "saturated" model (all variables simultaneously) and retention of variables with Wald statistic p-values <0.25 (n=10); 2) Verification of the assumptions of logistic regression within the saturated model ("maternal age" violated the linearity in the logit assumption and was thus log base-10 transformed); 3) Exploration of all first-order interactions among remaining predictor variables (to capture non-additivity) and retention of significant interaction terms ($p<0.05$; n=7); 4) Using an all-subsets regression approach, analysis of competing regression models, including all combinations of main effect variables and interactions terms, for improvement in fit statistics (e.g., likelihood ratio chi-squares, chi-square goodness of fit tests, Wald statistics); 5) Within the final "best fit" model, examination of residuals, deviance statistics, influential observation statistics, and classification tables. The final model specifies adjusted odds ratios (aORs) and 95% CIs for the most significant predictor variables.

4.4.4 Power calculation

A power calculation determined that the smallest detectable odds ratio (OR) for categorical and continuous predictors within the logistic regression was 1.22 and 1.10, respectively, (predicting breastfeeding initiation;$1-\beta=0.90$; α two-tailed=0.05; n=7,012; $R^2=0.35$; $p_0=0.618$). These odds ratios reflect small, but still clinically meaningful values.

4.5 RESULTS

4.5.1 Sample

Characteristics of the final sample are displayed in Table 8. The majority of mothers were non-Hispanic White non-smokers, with at least a high school diploma (largest proportion were college graduates). Most mothers also had a vaginal delivery, prior live births, no history of prematurity, and no labor induction or augmentation. Index infants were most often singletons and 36 weeks gestation. Infant gender, WIC status, labor anesthesia, and marital status were more equally split within the sample. Average birth weight was above the low birth weight criterion of 2500 grams and was significantly higher among those initiating breastfeeding (2667.5±467.9 grams versus 2616.5 ±468.2 grams, $p<0.001$). Median maternal age was also significantly higher among those initiating breastfeeding (29±5 years versus 27±5 years, $p<0.001$).

Descriptive variables not included in the regression procedure indicated a sample with maternal median BMI of 24.4, which approached the upper boundary of normal (normal BMI: 18.5-24.9). Additionally, the majority of mothers were U.S.-born, had the index infant delivered by a medical doctor, did not have pre-pregnancy or gestational diabetes, did not have a history of infertility treatment, and did not receive first trimester prenatal care (though missingness was over 30% of cases for this variable). A large proportion of the sample was also receiving Medicaid (36.9%).

4.5.2 Temporal trends

Rates of LPI breastfeeding initiation increased significantly each year from 2003-2009 (uORs >1, p<0.001), except in 2004 (uOR 1.05, 95% CI: 0.99-1.11, p=0.13). Compared to mothers of 34 week infants, mothers of 35 and 36 week infants were significantly more likely to initiate breastfeeding in years 2003-2009 (uOR 1.08, 95% CI: 1.03-1.13, p<0.01; uOR 1.14, 95% CI: 1.09-1.19, p<0.001, respectively). Despite this difference and more dramatic improvements in breastfeeding initiation noted among 34 week LPIs from 2003-2009, there was no interaction effect of birth year with gestational week (except for 36 week infants in 2009; aOR 0.83, 95% CI: 0.70-0.99, p=0.04). See Table 9 and Figure 2.

Compared to mothers of singletons, mothers of late preterm multiples were significantly more likely to initiate breastfeeding 2003-2009 (uOR 1.17, 95% CI: 1.11-1.23, p<0.001), but there were no interaction effects of plurality with birth year. Likewise, there were no interactions of plurality with gestational age 2003-2009 (Table 9).

Breastfeeding initiation rates increased significantly among all gestational ages from 2003-2009 (p<0.001). Though rates increased most dramatically from 2003-2009 in moderately preterm infants (12.6%), compared to LPIs (7.7%) and term infants (7.4%), the difference was non-significant (p>0.05). Compared to LPIs, breastfeeding initiation in cumulative years 2003-2009 was significantly greater among term infants (uOR 1.44, 95% CI:1.42-1.46, p<0.001) and significantly lower among moderately preterm infants (uOR 0.85, 95% CI: 0.82-0.88, p<0.001). In 2009 in Pennsylvania, the breastfeeding initiation rates for moderately preterm, late preterm, and term infants, unadjusted for control variables or plurality, were 60.7%, 62.0%, and 70.1%, respectively (Table 10). The 2009 rate of breastfeeding initiation among mothers of LPIs, adjusted for plurality, was 61.8±1.1%.

4.5.3 Predictive model

uORs and 95% CIs for breastfeeding initiation relative to each predictor variable are provided in Table 8. Variables found to be highly non-significant ($p>0.25$), and thus eliminated from multivariate modeling included infant gender, route of delivery, labor induction or augmentation, and infant plurality. Unadjusted variables that were positively associated with breastfeeding initiation included higher education, increasing maternal log age, increasing birth weight, "other" racial classification (e.g., Asian), being married, and labor anesthesia ($p<0.01$). Being of Hispanic ethnicity and greater gestational age also tended to be positively associated with the outcome variable ($p=0.25$). Unadjusted variables found to be negatively associated with breastfeeding initiation included being a WIC recipient, Black race, smoking during pregnancy, parity, and a history of prematurity ($p<0.001$). Infant NICU admission also tended to be negatively associated with the outcome variable ($p=0.09$).

The saturated model included 13 main effect variables. Predictors found to be highly non-significant in this model ($p>0.25$) and excluded from further analysis included previous preterm birth, infant birth weight, and gestational age. The final "best fit" model included 2 main effect variables and 7 significant interaction terms (Table 11). There were no large residuals or influential cases. A sensitivity analysis including the multivariate outliers produced the same final model, though indices of fit (e.g., log likelihood, pseudo-R^2) were slightly worse. The final model correctly classified more cases than any other model (69.4%) and better classified those breastfeeding (84%) than those not initiating breastfeeding (44.6%).

In the final model, labor anesthesia remained positively associated with breastfeeding initiation (aOR 1.18, 95% CI: 1.06-1.32; $p<0.01$), while smoking during pregnancy remained negatively associated with breastfeeding initiation (aOR 0.58, 95% CI: 0.50-0.66; $p<0.001$).

WIC was involved in four of the seven significant interactions. A negative association with breastfeeding initiation was noted for WIC x married and WIC x increasing log age (aORs ≤0.75; p≤0.04). WIC x Hispanic ethnicity and WIC x Black race were both positively associated with breastfeeding initiation (aORs ≥1.38; p≤0.03).

Marital status was involved in three significant interactions, including WIC. Married x NICU admission and married x increasing educational level were both negatively associated with breastfeeding initiation (aORs ≤0.75; p≤0.04). Log age was involved in two significant interactions. Increasing log age and both WIC and parity were negatively associated with breastfeeding initiation (aORs ≤0.29; p≤0.05).

4.6 DISCUSSION

4.6.1 Sample

To the authors' knowledge, this analysis is the first to examine the impact of various sociodemographic and practice variables on LPI breastfeeding initiation, inclusive of multiple gestation infants, within a population-based sample. Sample characteristics, including infant gender, distribution of gestational age, ethnicity, education, age, parity, marital status, and Medicaid status were very similar to another population-based analysis of LPIs without major medical issues (Shapiro-Mendoza et al., 2006). The current sample had more Black and U.S. born mothers, however. Infant birth weight was comparable to two other population-based studies involving LPIs (Tomashek et al., 2006) and near-term infants (35-36 6/7 weeks gestation) (Wang, Dorer, Fleming, & Catlin, 2004). The majority of sample LPIs were singletons, delivered

vaginally without labor augmentation or induction. This is consistent with research that reports that nearly half of all LPIs are delivered as a result of spontaneous labor (Reddy, Ko, Raju, & Willinger, 2009). The 2009 rate of maternal LPI breastfeeding initiation in this sample at 61.8±1.1% is about 10% lower than rates reported in another population-based analysis examining healthy LPIs (Shapiro-Mendoza et al.). This may reflect the lower overall rates of breastfeeding initiation in Pennsylvania, which was 63.8% in 2007 (Centers for Disease Control and Prevention, 2010a). Together, these comparisons support the relative representativeness of this sample of LPIs within Pennsylvania and the larger U.S.

4.6.2 Temporal trends

As expected due to issues with infant maturity in coordinating and tolerating at-breast feeds, rates of breastfeeding among LPIs were lower than those among term infants within the sample, but higher with increasing gestational week and higher than those of moderately preterm infants. Interestingly, some authors have reported lower rates of breastfeeding initiation and continuation among LPIs as compared to earlier preterm infants, speculated to be due to extra vigilance and support of breast milk feeds in the NICU, where early preterm infants outnumber LPIs (Colaizy & Morriss, 2008; Donath & Amir, 2008). In the current study, however, this was not the case; there was also a borderline *negative* effect of NICU admission on breastfeeding initiation within the saturated model and within an interaction in the final model. This supports findings by Merewood and colleagues (2006) and the intuitive reasoning that increasing gestational age confers a biological advantage in coordinating the neurologically complex activity of breastfeeding and tolerating oral breast milk feeds. Likewise, it may suggest that mothers of infants of increasing gestational age are more supported in their breastfeeding efforts, that NICU

breastfeeding support varies significantly among institutions and/or regions, and/or the reported NICU breastfeeding benefit is more visible in breastfeeding continuation than initiation.

The increasing trend in breastfeeding initiation among all gestational ages from 2003-2009 reflects several national breastfeeding movements that became prominent within the decade, for example the Breastfeeding Friendly Hospital Initiative (Baby-Friendly USA, 2010), Healthy People 2010 breastfeeding goals (U.S. Department of Health and Human Services, 2000), and the Blueprint for Action on Breastfeeding (Department of Health and Human Services, 2000). The more dramatic increases in breastfeeding initiation seen among early preterm infants and mothers of 34 week infants may be due to research demonstrating the overwhelming health benefits of breast milk for premature infants (Callen & Pinelli, 2005; Henderson et al., 2007).

The higher rate of breastfeeding initiation observed among mothers of late preterm multiples compared to singletons is noteworthy. Conflicting research reports positive (Killersreiter, Grimmer, Buhrer, Dudenhausen, & Obladen, 2001), negative (Wooldridge & Hall, 2003), and no effects (Geraghty, Khoury, & Kalkwarf, 2005; Lau, Hurst, Bums, & Schanler, 2004; Zachariassen et al., 2010) of preterm plurality on rates of breastfeeding or breast milk provision. The literature suggests that breastfeeding premature multiples may be curtailed by infant or maternal comorbidities (Donovan et al., 1998). Alternatively, breastfeeding may be unaffected or increased due to greater milk volumes (Gromada & Spangler, 1998) and high rates of breast milk pumping among mothers of multiples (Geraghty et al.). Because very few studies examining preterm breastfeeding include or differentiate among multiples, drawing comparisons in the LPI population is difficult.

4.6.3 Predictive model

The final model indicated that sociodemographic factors, including marital status, education, parity, race, log age, WIC, and smoking status were among the most influential variables impacting LPI breastfeeding initiation. The importance of sociodemographic characteristics in early breastfeeding behavior is consistent with research in general and earlier preterm populations (Mitra, Khoury, Hinton, & Carothers, 2004; Ryan & Zhou, 2006; Scott & Binns, 1999; Zachariassen, et al., 2010). However, while most of these unadjusted variables were associated with breastfeeding initiation in the expected direction (e.g., positive association with markers of higher social status, including married, educated, non-smoker; negative association with factors typically associated with lower breastfeeding rates in the general population, including Black race and WIC) (Centers for Disease Control and Prevention, 2010b), the multivariate analysis revealed that these variables were involved in several significant, counterintuitive interactions with each other. For example, univariately, being married and increasing education were both strongly associated with breastfeeding initiation, but their interaction had a negative impact. Similarly, being a WIC recipient was negatively associated with breastfeeding initiation in the univariate analysis, but its interactions with other negatively-associated variables (Black race, Hispanic ethnicity) were positive, and its interactions with positively-associated variables (log age, married) were negative. Finally, given the strongly positive univariate associations of both log age and married (uORs $\geq$3.01, $p<0.001$), their negative interactions with parity and NICU admission (respectively) were also somewhat surprising.

These findings suggest that early LPI (and possibly more general) breastfeeding behavior is a complex phenemenon, heavily influenced by non-modifiable sociodemographic factors in a

non-additive manner. This complexity is supported by at least one study, which found a similar reversal in the effect of race on preterm and term infant breastfeeding initiation when comparing univariate and multivariate results (Merewood, Brooks, Bauchner, MacAuley, & Mehta, 2006). However, this study did not examine interaction terms, and because interactions are not routinely measured or reported in other infant populations, it is unclear how, or if, their influence differs for non-LPI infants.

It is difficult to speculate on the causes of some of these interactions without a basis for comparison in other populations and the likely influence of unmeasured, confounding variables. For example, variables such marital status, parity, and WIC may be proxy factors for employment, income, and additional home/childcare responsibilities. Highly educated, married women are likely to have more prestigious careers and higher incomes, possibly translating to more work-related barriers and less economic incentive to breastfeed. This trend may be particularly true among women with NICU-admitted LPIs, who do not initiate breastfeeding or experience early breastfeeding difficulties related to infant medical/developmental barriers. Likewise, women of increasing parity (likely associated with age to a point), may abandon or never begin breastfeeding, owing to a combination of additional childcare responsibilities and unanticipated early breastfeeding problems out of line with prior breastfeeding experiences and the "term" LPI appearance. Conversely, mothers in racial and ethnic minorities in WIC, who are likely to have the lowest average household incomes (Connor et al., 2010), may choose to begin breastfeeding due to the WIC economic benefits (e.g., supplementary food packages), lack of gainful employment (i.e., more time and closer proximity to infant for breastfeeding), or influence of WIC breastfeeding promotions targeted at minorities (Pennsylvania Department of Health & Maternal and Child Health, 2011; Ryan, Wenjun, & Acosta, 2002). While the abstract

nature of these interactions do not support specific breastfeeding interventions within the LPI population, they do indicate that practitioners should exercise caution in applying broad sociodemographic labels to interpret LPI (or general) breastfeeding behavior and that certain "combination demographics" be considered in the design of future LPI breastfeeding research (with adequate sample sizes), promotion efforts, and hospital support services.

In addition to the interaction terms, both labor anesthesia and smoking in pregnancy were independently significant in the final model ($p \leq 0.01$). The positive association of anesthesia with breastfeeding (aOR 1.18, 95% CI: 1.06-1.32) was somewhat unexpected, as research in general infant populations indicates no effect (Uppal & Young, 2010; Wilson et al., 2009) or a negative effect—due to mild infant sedation (Bick, MacArthur, & Lancashire, 1998; Jordan, Emery, Bradshaw, Watkins, & Friswell, 2005) of epidurals and other labor anesthesia on breastfeeding initiation. This finding warrants further investigation, especially since type and dose of anesthesia were not specified. In contrast, the negative association of smoking with breastfeeding initiation (aOR 0.58, 95% CI: 0.50-0.66) is consistent with findings in other infant populations (Amir & Donath, 2002; Bailey & Wright, 2011; Di Napoli, Di Lallo, Pezzotti, Forastiere, & Porta, 2006). Because research suggests that smokers are often unsupported in their breastfeeding efforts and perceive significant infant breastfeeding risks, like other women, mothers of LPIs should be encouraged to engage in cessation efforts, but educated that not breastfeeding while smoking is a greater infant health risk than smoking while breastfeeding (Goldade et al., 2008).

Interestingly, many practice and infant-related variables, including cesarean section deliveries, labor induction/augmentation, earlier gestational age, prior premature birth, plurality, and lower birth weight were non-significant in the univariate and/or multivariate analyses.

Research has suggested a negative association of all these factors with early breastfeeding behavior (Callen & Pinelli, 2005; Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003; Donath & Amir, 2008; Donovan, et al., 1998; Evans, Evans, Royal, Esterman, & James, 2003; Hall et al., 2002; Nagy, Orvos, Pal, Kovacs, & Loveland, 2001). Yet, a similar study in a younger preterm population found many of the same factors to be non-significant in initial breastfeeding when considering sociodemographic factors (Zachariassen et al., 2010).

4.6.4 Strengths and limitations

A major strength of this analysis was the large, population-based sample, permitting control of multiple covariates and examination of interactions among variables. The analysis was also strengthened by differentiating among infants part of single and multiple gestations. Conversely, the study design was weakened by non-inclusion of more modifiable predictor variables cited as influential in other infant populations, including: self-efficacy, anxiety, and significant other support (Britton, 2007; Dennis, 2006); competing work and family demands; inadequate or conflicting hospital breastfeeding support (Dennis, 2006); and early formula supplementation (Dewey et al., 2003). Similarly, we were unable to fully compare our model of LPI breastfeeding initiation to research in other infant groups due to non-inclusion of interaction terms in these studies. Despite this, we believe that the examination of interactions permits a more comprehensive understanding of breastfeeding behavior as a complex social and biologically influenced phenomenon.

A major limitation of this study is that the outcome variable—breastfeeding initiation—could not be verified as collected at a uniform point or in a standard manner (e.g., who observes breastfeeding and what constitutes “breastfeeding”) due to the generalized instructions part of the

Pennsylvania birth registry. In addition, the outcome variable did not account for breastfeeding exclusivity, which is an arguably more important indicator in breastfeeding promotion efforts. Indeed, breastfeeding initiation was the only initiative achieved as part of the Healthy People 2010 breastfeeding goals (Centers for Disease Control and Prevention, 2010c). To take advantage of a potentially very rich, population-based data source and to achieve more conclusive analyses, like others (Chapman et al., 2008; Navidi, Chaudhuri, & Merewood, 2009), we suggest that state birth registries streamline how breastfeeding initiation is assessed and expand to include breastfeeding exclusivity data. Currently, state breastfeeding data may be collected at time of discharge or at any time during the birth hospitalization. Breastfeeding may also be posed as a question of maternal intention, actual initiation, or infant feeding method—all divergent concepts (Chapman et al.).

We would also suggest that future breastfeeding research expand to include younger "term" infants (e.g., 37-38 gestational weeks). Some research suggests that full neurological maturity and coordinated breastfeeding is not achieved until approximately 39-40 weeks gestation (Kinney, 2006), predisposing earlier term infants to poorer rates of breastfeeding initiation and duration (Donath & Amir, 2008).

4.7 CONCLUSIONS

Late preterm infants comprise the largest segment of preterm births in the U.S. and experience suboptimal breastfeeding rates, despite increased potential for benefit from breastfeeding compared to term infants. Identifying factors that influence early, in-hospital breastfeeding among late preterm mother-infant dyads serves as a starting point for targeted breastfeeding

interventions and provides a basis for research investigating breastfeeding duration and exclusivity, modifiable barriers to breastfeeding, and confounding variables. With the caveat that additional research is warranted to confirm and expand upon these new findings, our analysis suggests that efforts to increase early breastfeeding within the LPI population might be especially focused on the following groups: 1) women with at least one prior child; 2) mothers who are married and educated; 3) married women with NICU-admitted infants; 4) non-traditional WIC recipients (non-minority, older, married); and 5) smokers.

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Table 8. Late preterm infant and mother sample characteristics associated with breastfeeding initiation for year 2009

Variable	N and % of full sample (n=7,012) with characteristic	% Breastfeeding	uOR and 95% CI for Breastfeeding Initiation	p-value
Marital Status				<0.001
Not married	3109 (44.3)	48.6	1.0	
Married	3903 (55.7)	74.0	3.01 (2.73-3.33)	
Education				<0.001
Less than high school	1101 (15.7)	43.7	1.0	
High school graduate	2047 (29.2)	52.0	1.40 (1.20-1.62)	<0.001
Some college	1292 (18.4)	63.9	2.28 (1.93-2.68)	<0.001
College graduate	2572 (36.7)	78.9	4.83 (4.15-5.62)	<0.001
Hispanic Ethnicity				0.25
Not Hispanic	6405 (91.3)	62.5	1.0	
Hispanic	607 (8.7)	64.9	1.11 (0.93-1.32)	
Race				<0.001
White	4999 (71.3)	64.0	1.0	
Black	1291 (18.4)	54.1	0.66 (0.59-0.75)	<0.001
Other	722 (10.3)	69.5	1.28 (1.09-1.52)	<0.01
Maternal Age (log_{10}[years])	7012		17.04 (10.36-28.03)	<0.001
Smoking				<0.001
No smoking	5510 (78.6)	68.6	1.0	
Smoking	1502 (21.4)	41.3	0.32 (0.29-0.36)	
Parity				<0.001
No prior live births	2873 (41.0)	69.0	1.0	
Prior live births	4139 (59.0)	58.4	0.63 (0.57-0.70)	
History of Prematurity				<0.001
No previous preterm birth	6303 (89.9)	63.4	1.0	
Previous preterm birth	709 (10.1)	56.7	0.76 (0.65-0.88)	
WIC Benefits				<0.001
Not receiving	4093 (58.4)	70.2	1.0	
Receiving	2919 (41.6)	52.3	0.47 (0.42-0.51)	
Anesthesia				<0.001
No labor anesthesia	2262 (32.3)	58.5	1.0	
Labor anesthesia	4750 (67.7)	64.8	1.30 (1.18-1.44)	

Induction/Augmentation				0.79
Neither	4520 (64.5)	62.6	1.0	
Either	2492 (35.5)	63.0	1.01 (0.92-1.12)	
Route of Delivery				0.95
Vaginal	4242 (60.5)	62.8	1.0	
Cesarean section	2770 (39.5)	62.7	1.00 (0.90-1.10)	
Infant Gender				0.70
Female	3385 (48.3)	63.0	1.0	
Male	3627 (51.7)	62.5	0.98 (0.89-1.08)	
Birth Weight (kilograms)*	7012		1.26 (1.14-1.40)	<0.001
Gestational Age (weeks)				0.25
34	1039 (14.8)	60.6	1.0	
35	1876 (26.8)	63.8	1.14 (0.98-1.34)	0.10
36	4097 (58.4)	62.8	1.10 (0.95-1.26)	0.19
NICU Admission				0.09
No admission	5156 (73.5)	63.3	1.0	
Admission	1856 (26.5)	61.1	0.91 (0.82-1.01)	
Infant Plurality				0.73
Singleton	6216 (88.6)	62.7	1.0	
Multiple	796 (11.4)	63.3	1.03 (0.88-1.20)	
¥ Birth Country				<0.001
Non-U.S.	570 (8.1)	80.2	1.0	
U.S.	6196 (88.4)	61.6	0.40 (0.32-0.49)	
¥ Pre-pregnancy BMI	6699			
¥ Medicaid				<0.001
Non-recipient	4252 (60.6)	71.8	1.0	
Recipient	2586 (36.9)	48.6	0.37 (0.34-0.41)	
¥ Pre-pregnancy Diabetes				0.13
No diabetes	6889 (98.2)	62.9	1.0	
Diabetes	123 (1.8)	56.1	0.76 (0.53-1.08)	
¥ Gestational Diabetes				0.36
No diabetes	6536 (93.2)	62.6	1.0	
Diabetes	476 (6.8)	64.7	1.10 (0.90-1.33)	
¥ First Trimester Prenatal Care				<0.001
Non-receipt	1711 (24.4)	57.6	1.0	
Receipt	3365 (48.0)	67.5	1.53 (1.35-1.72)	
¥ History of Infertility Treatment				<0.001
No infertility treatment	6798 (96.9)	62.3	1.0	
Infertility treatment	214 (3.1)	81.8	2.73 (1.93-3.88)	

ɣ **Delivery Attendant**				
MD	5793 (82.6)	62.5	1.0	
DO	745 (10.6)	59.6	0.89 (0.76-1.03)	0.12
CNM/CM	433 (6.2)	69.7	1.38 (1.12-1.71)	<0.01
Other midwife	19 (0.3)	84.2	3.20 (0.93-10.99)	0.07
Other	21 (0.3)	76.2	1.67 (0.70-5.25)	0.20

*Calculations based on "healthy" LPI sample; uOR=unadjusted odds ratio; CI=confidence interval; MD= Medical Doctor; DO= Doctor of Osteopathy; CNM= Certified Nurse Midwife; CM=Certified Midwife; BMI= body mass index; Unable to compute uOR for BMI, as it violated assumption of linearity in the logit and was not amenable to transformation; *birth weight transformed to kilograms to achieve meaningful OR. ɣ indicates variables not included in the regression model.*

Table 9. Percentages of mothers of late preterm infants initiating breastfeeding by gestational week, year, and plurality

Year																					
Gest wks	2003			2004			2005			2006			2007			2008			2009		
	S	M	T	S	M	T	S	M	T	S	M	T	S	M	T	S	M	T	S	M	T
34	48.8 *1128*	57.1 *191*	50.0 *1319*	52.3 *1198*	52.6 *215*	52.4 *1413*	54.9 *1249*	57.5 *186*	55.3 *1435*	52.1 *1306*	58.9 *207*	53.1 *1513*	53.5 *1258*	62.8 *207*	54.8 *1465*	57.5 *1311*	58.3 *223*	57.6 *1534*	60.5 *1132*	64.0 *214*	61.1 *1346*
35	52.6 *1980*	59.9 *272*	53.5 *2252*	55.0 *2163*	56.2 *283*	55.2 *2446*	55.5 *2195*	60.7 275	56.1 2470	55.6 *2219*	60.1 291	56.1 2510	55.4 2289	66.9 299	56.7 2588	58.2 2313	58.9 309	58.3 2622	61.6 1934	64.3 272	62.0 2206
36	55.5 *4299*	55.1 *365*	55.5 *4664*	55.5 *4789*	61.8 *414*	56.0 *5203*	57.1 4759	61.7 *410*	57.5 5169	57.7 *4773*	64.4 427	58.3 5200	58.2 4794	57.7 423	58.1 5217	59.3 4794	63.8 389	59.6 5183	61.7 4279	64.5 417	61.9 4696

Gest wks= gestational week of infant; S= mothers of singleton infants; M= mothers of multiple infants; T= total mothers; numbers in plain text represent percentages of mothers initiating breastfeeding; numbers in italics indicate total mothers for a particular category; rates unadjusted infant/maternal morbidity.

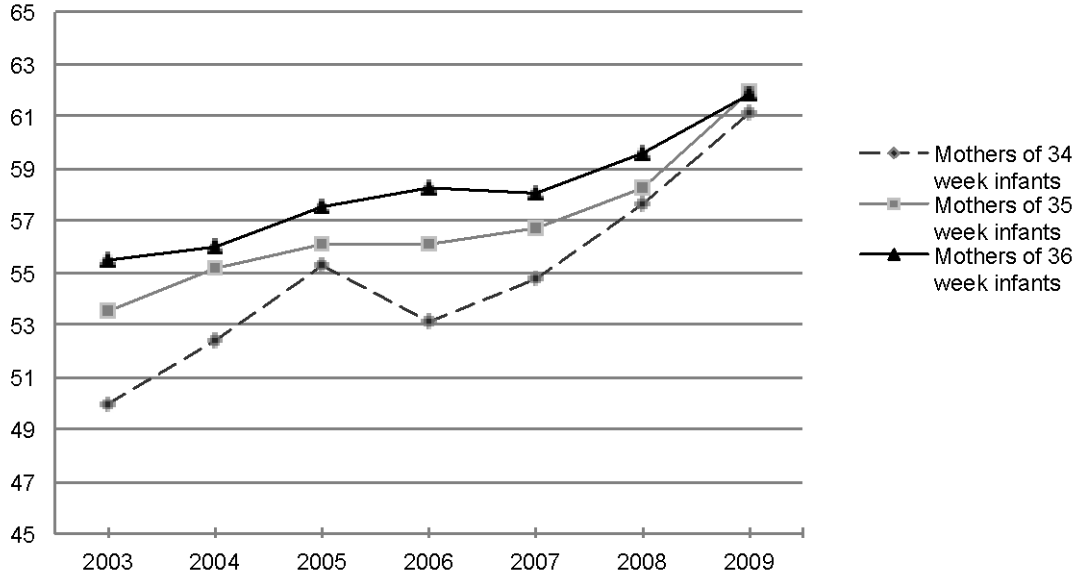

Figure 2. Percentages of mothers of LPIs (singletons and multiples) initiating breastfeeding by year and gestational weeks, adjusted for plurality

Table 10. Percentages of infants initiating breastfeeding by gestational age and year

	Year						
Gestational Age	2003	2004	2005	2006	2007	2008	2009
Moderately Preterm (30-33 weeks)	48.1 *2350*	51.1 *2489*	53.1 *2475*	52.9 *2527*	53.5 *2597*	55.2 *2564*	60.7 *2323*
Late Preterm (34-36 weeks)	**54.3** *9093*	**55.4** *9991*	**57.0** *9964*	**57.3** *10164*	**57.5** *10220*	**59.0** *10282*	**62.0** *9172*
Term (≥ 37 weeks)	62.7 *120873*	63.6 *121571*	65.1 *123433*	66.1 *126657*	66.8 *128511*	67.8 *129487*	70.1 *119502*

Plain text numbers indicate percentages of infants breastfeeding at hospital discharge; numbers in italics represent total infants, breastfed and non-breastfed; rates adjusted for neither maternal/infant morbidity nor plurality.

Table 11. Final model for 2009 LPI breastfeeding initiation

Variable/Interaction	aOR and 95% CI (Breastfeeding Initiation)	p-value
Married	4.79 (3.35-6.84)	<0.001
Hispanic	0.94 (0.63-1.41)	0.77
WIC Benefits	5.07 (0.92-27.90)	0.06
Labor Anesthesia	1.18 (1.06-1.32)	<0.01
Smoking during Pregnancy	0.58 (0.50-0.66)	<0.001
Parity (prior live births)	6.72 (1.38-32.72)	0.02
NICU Admission	1.00 (0.84-1.18)	0.97
Maternal Age (log10[years])	2.02 (0.64-6.43)	0.23
Education		<0.001
Less than high school	1.0	
High school graduate	1.67 (1.38-2.03)	<0.001
Some college	2.72 (2.16-3.42)	<0.001
College graduate	3.70 (2.77-4.94)	<0.001
Race		0.01
White	1.0	
Black	0.92 (0.74-1.16)	0.48
Other	1.69 (1.17-2.42)	<0.01
Married x Education		<0.001
Less than high school	1.0	
High school graduate	0.53 (0.37-0.75)	<0.001
Some college	0.38 (0.26-0.56)	<0.001
College graduate	0.46 (0.31-0.68)	<0.001
Married x WIC	0.75 (0.57-0.98)	0.04
Married x NICU	0.79 (0.62-0.99)	0.04
Hispanic x WIC	2.11 (1.24-3.59)	<0.01
WIC x Race		0.02
White	1.0	
Black	1.38 (1.03-1.84)	0.03
Other	0.69 (0.42-1.14)	0.15
Maternal Age (log10[years]) x WIC	0.29 (0.09-0.99)	0.04
Maternal Age (log10[years]) x Live Births	0.20 (0.07-0.61)	<0.01

5.0 MANUSCRIPT #3: "HELLO, ARE YOU ALIVE?!": THE INTERPLAY OF EXHAUSTION, UNCERTAINTY, HOPE AND DISAPPOINTMENT IN MOTHERS BREASTFEEDING LATE PRETERM INFANTS

5.1 COVER LETTER TO JOURNAL EDITOR

May 9, 2012

Dear Dr. Annandale,

Please consider the attached manuscript, "Hello, are you alive?: Tales of exhaustion, uncertainty, hope and disappointment in mothers breastfeeding late preterm infants," for publication in the Social Science & Medicine. This paper reports the primary findings of a grounded theory study examining breastfeeding establishment among mothers of late preterm infants. To our knowledge, there are no other studies examining the maternal perspective of breastfeeding within this vulnerable group. Please feel free to contact me with any questions. We look forward to hearing from you.

Regards,

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5.2 ABSTRACT

Poor breastfeeding outcomes in the late preterm population have been attributed to inadequate breast milk transfer stemming from infant physiological immaturities. However, breastfeeding is more than a biological phenomenon, and it is unclear how mothers of late preterm infants (LPIs) manage contextual factors that may also impact the breastfeeding course. This study sought to examine breastfeeding establishment over a 6-8 week period among 10 late preterm mother-infant dyads. Grounded theory methods, incorporating several data collection techniques, were utilized. We found that breastfeeding in the LPI population was a fluctuating, cascade-like progression of trial and error, influenced by a host of contextual factors and events and culminating with breastfeeding continuation (with or without future caveats regarding breastfeeding duration or exclusivity) or cessation. The trajectory was explained by the basic psychosocial process *Weighing Worth against Uncertain Work*, which encompassed the tension between breastfeeding motivation, the intensity of breastfeeding work, and ambiguity

surrounding infant behavior and feeding cues. Several sub-processes were also delineated: *Playing the Game*; *Letting Him be the Judge vs. Accommodating Both of Us*; and *Questioning Worth vs. Holding out Hope*. If valid, our theoretical model indicates that mothers of LPIs require early, extended, and intensive breastfeeding support that emphasizes management strategies and the connection between infant prematurity and observed behaviors.

5.3 INTRODUCTION

The research documenting the nutritional, immunological, and developmental advantages of breastfeeding, particularly among infants born prematurely, is significant and compelling (Callen & Pinelli, 2005; Henderson, Anthony, & McGuire, 2007; Ip et al., 2007). It is concerning, then, that infants born in the late preterm period (34 0/7-36 6/7 weeks gestation) experience suboptimal breastfeeding rates and a high incidence of breastfeeding-associated morbidity, presumably related to insufficient breast milk intake (Radtke, 2011). Considering that these infants comprise ~70% of preterm births in the U.S., their poor breastfeeding outcomes constitute a public health issue (Martin et al., 2010).

Unrecognized or poorly managed physiologic immaturities, which often belie a "term" appearance, have been implicated in late preterm infant (LPI) breastfeeding difficulties. These immaturities are manifested in poor regulation of sleep-wake states, uncoordinated sucking and latching, and decreased oro-motor tone, all of which contribute to unsustained at-breast feeds and insufficient breast milk transfer (Meier, Furman, & Degenhardt, 2007; Wight, Morton, & Kim, 2008). Consistent with this basic view of the problem, current evidence-based late preterm guidelines, based largely on clinical experience and expert opinion, address breastfeeding mainly

from a physiological standpoint (Association of Women's Health, 2010; The Academy of Breastfeeding Medicine, 2011). Yet, breastfeeding remains an extremely complex psychosocial, as well as biological process, mutually directed by mother and infant. Thus, in order to design LPI breastfeeding interventions with practical relevance, research considering the maternal perspective, environmental context, and individual idiosyncrasies is necessary.

5.4 THE STUDY

5.4.1 Design

The purpose of this study was to describe the process of breastfeeding establishment among late preterm mother-infant dyads. Our philosophical orientation and methodological processes were informed by constructivist grounded theory, which posits theory development as a context-dependent co-creation of reality between participants and researcher (Charmaz, 2004).

5.4.2 Setting and sample

After Institutional Review Board approval, participant recruitment occurred in the maternity wards and NICU in a large tertiary care maternity hospital in Pittsburgh, Pennsylvania, USA over a one year period from 2011-2012. The recruitment hospital typically delivers over 10,000 infants per year, accounting for 45% of the births in the county. During the data collection period, the hospital was actively working on attaining Breastfeeding-Friendly status, a prestigious designation indicating a hospital’s commitment to supporting breastfeeding mothers

(Baby-Friendly USA, 2010). The hospital's 2011 rate of breastfeeding initiation was 72%, slightly below the national rate of 74.6% during the same year (Centers for Disease Control and Prevention, 2011).

Postpartum women were eligible for study participation if they were English-speaking, at least 18 years old, had delivered an infant between 34 0/7 and 36 6/7 weeks of gestation, and intended to breastfeed or provide breast milk to their infant. Dyads were excluded from the study if they had conditions that precluded or were anticipated to significantly complicate breastfeeding (e.g., HIV-positive status, major infant congenital anomalies). Medical records of patients admitted to the maternity ward were screened for eligibility, and potential participants were approached for enrollment by the first author, who also worked as a staff nurse on the maternity unit but did not care for any study patients. Eligible mothers were purposefully selected for variability in parity, gestational age, race, and maternal age. As the study progressed, theoretical sampling aimed for variability in infant neonatal intensive care unit (NICU) admission, prior breastfeeding experience, and nature of early breastfeeding management.

The final study sample included 10 maternal participants and their 12 infants. At birth, six infants were 36-37 weeks gestation, three were 35-36 weeks gestation, and one was <35 weeks. Birth weights ranged from 2210-3440 grams, and four infants were <2500 grams. There were eight male infants and four females, and two sets of twins. Two infants were admitted to the NICU (not twins) during the birth hospitalization. All infants experienced one or more health issues associated with prematurity, including hyperbilirubinemia, hypoglycemia, respiratory distress or infection, bradycardia, and reflux. Three infants, including a set of twins, were re-hospitalized with viral respiratory illnesses several weeks post-birth. None of those rehospitalized had a prior NICU admission.

Mothers ranged in age from 21-41, with a mean age of 31. There were two non-Hispanic black women; the remaining participants were Caucasian. Seven were married, and seven were college-educated. Two were WIC recipients. Five mothers were primiparas. Participants with other children had at least three months breastfeeding experience, and three mothers had previously breastfed a preterm infant. Four mothers had a cesarean birth, and several had pregnancy- or other health-related complications, including gestational diabetes, type II diabetes, and hypertension. One dyad was discharged from the hospital early (48-hours status-post cesarean birth).

5.4.3 Data collection

Serial, semi-structured interviews were the main source of study data. Interviews generally occurred during the postpartum hospitalization (1-2 days post-birth), at 1 week, 2 weeks, and 6-8 weeks postpartum. In total, 39 interviews were conducted. Interviews ranged from 10 to 65 minutes in length.

Participants were invited to participate in several additional, exploratory forms of data collection as a means to achieve methodological triangulation. These optional methods included breastfeeding email or audio "diaries" and video-recording with stimulated-recall interviewing. The latter method, designed to elicit deeper participant self-review and reflection (Busse & Ferri, 2003), encompassed participants' audio-recorded reactions and responses to interview questions as their video-recorded breastfeeding footage (from preceding interview) was viewed. While no participants attempted audio diaries, five completed one or more email diaries and two took part in video reviews. These supplemental data sources were analyzed similar to interview data and served to enrich, confirm, and clarify participants' thoughts and emergent themes.

5.4.4 Data analysis

Data analysis proceeded concurrently with data collection. All data were professionally transcribed and reviewed for accuracy by the first author. Transcripts were first "open coded," which consisted of a detailed segment-by-segment analysis of all salient processes and concepts and assignment of a label as close to participants' actual words as possible. Initial coding progressed to focused coding, which synthesized similar, frequently used initial codes. Naturally and simultaneously, codes were organized into more abstract categories, which took into account the fit of concepts into the developing theoretical framework. Certain categories held particular explanatory power and connectedness to other categories and were interwoven, along with theoretical memos, into a framework that included participants' thoughts and words, as well as the authors' interpretations. As a final step, the theoretical framework was refined and differentiated from extant theories and concepts in the literature. Though presented linearly, this process was an abductive endeavor, relying heavily on the technique of constant comparison (Charmaz, 2000, 2006; Morse et al., 2009). Multiple qualitative analysis techniques (e.g., matrix development, diagramming, interview summaries, dimensional analysis—identification of attributes, antecedents and consequences (Kools, McCarthy, Durham, & Robrecht, 1996)) assisted in the development of the model, and analysis decisions were discussed, validated, and expanded in weekly meetings with senior authors (SMC and MBH) and a qualitative analysis workgroup.

5.5 FINDINGS

Breastfeeding establishment among late preterm mother-infant dyads was a complex, tenuous process in flux. It was characterized by a bifurcated, cascade-like progression of infant physiological issues and maternal reactions, initial and continued management strategies, secondary issues dependent upon management, and, finally, breastfeeding cessation or continuation. For some participants, continued breastfeeding came with caveats impacting the exclusivity or long-term duration of nursing (e.g., return to work). All participants followed one of three general paths (see Figures 3 and 4), determined by the continuation of positive (n=4) or negative (n=3) breastfeeding strategies, or correction of initial negative strategies (n=3). Women who could not, or did not, compensate for poor early breastfeeding management were those who ceased breastfeeding before or shortly after study participation. A constellation of contextual factors and events were pivotal to the entire trajectory and major determinants in management decisions.

Late preterm breastfeeding establishment was not simple or straightforward. Participants who ultimately stopped breastfeeding (n=3; range: 4 weeks-2.5 months) experienced an emotional "rollercoaster," involving brief periods of hope, in which their milk supply or at-breast feeds seemed to improve, amidst a downward spiral of ineffective at-breast feeds, formula supplementation, decreasing milk supply, more formula supplementation, and insufficient time and energy to incorporate breastfeeding activities into daily life. Likewise, mothers who eventually achieved success in breastfeeding (n=7) also experienced multiple setbacks in their breastfeeding journey, including periods when their infants were supplemented with formula against their desires and "getting" breastfeeding took longer than expected.

A core social-psychological process was identified from the data: *Weighing Worth against Uncertain Work*. This explanatory process entailed how participants managed the tension between the value they placed on breastfeeding and the perceived mental and physical stamina necessary for breastfeeding success, whilst definitive or consistent signs of milk availability and transfer, as well as infant feeding and satiety cues remained elusive. Three sub-processes in the trajectory, entailing how mothers thought about and dealt with breastfeeding over time, were also delineated: 1) "Playing the game," 2) "Letting him be the judge vs. accommodating both of us," and 3) "Questioning worth vs. holding out hope."

5.5.1 Worth

"Worth" encompassed a mother's motivation to breastfeed or provide breast milk to her infant. For almost all participants, this was a relatively enduring concept, influenced by her cumulative life experiences and therefore often established prior to the birth. Although most participants cited awareness of a wide range of breastfeeding benefits, two distinct groups of women emerged. The first and the large majority of participants were those who identified breastfeeding as central to their role as a mother. For these women, breastfeeding "wasn't even a question." It was seen as a "responsibility" to one's children and "what being a mom is all about." These mothers cited infant immunologic, cognitive, and developmental benefits, as well as bonding, or their connection to their baby, as primary reasons they chose and continued to breastfeed.

The second group of women (n=2) was motivated to breastfeed by convenience, guilt, and/or maternal benefits. In general, mothers of the second type exhibited a laid-back attitude toward breastfeeding success and goals.

For me, I think it's just because I did with the other two. It's not like I ever planned on, with any of them, it was just…I did with my first, and so once you do it with one, I think you feel you should with all of them.

5.5.2 Uncertain work

Uncertain work was conceptualized as the non-reciprocal effort put forth by the mother to achieve breastfeeding success, while her infant was "not willing to work," "not trying," "lazy," "not interested," or wouldn't "contribute." Work was time and energy-intensive, often consisting of multiple strategies to encourage the infant to nurse at breast, for example using nipple shields or dripping formula onto the breast, followed by formula supplementation and/or breast pumping.

…It feels like I'm non-stop moving. And, a lot of the time it is with feeding him. It's like, it'll take about an hour just between getting everything ready [including breast pump, formula supplement] and [breast]feeding him on top of it.

[Pumping is] the last thing on my mind after, like, trying to get him to eat for an hour. I don't want to spend, like, another 15 minutes having to pump…

The work was characterized as uncertain, as infant behavior, particularly related to decreased responsiveness, made determination of milk transfer and identification of satiety and feeding cues difficult.

Keeping her interested in the breastfeeding and making sure that she is getting enough milk [is a challenge], because she falls asleep sometimes halfway through feedings and I have to keep waking her up… my main concern is like that she needs to get enough…

It is definitely easier with the formula just because [the twins] have been eating about two ounces or so with the formula…[with breastfeeding], I mean I still kind of question: like, are you really done? Was that really enough? Did you really get enough? Maybe…And if I'm really not sure sometimes I will still get a bottle out and do some formula just to make sure that their bellies are full.

Mothers also worried about whether their infant's behavior was a sign of a more serious problem.

> *I guess I just wasn't prepared for [infant's sleepiness], and everyone's like, 'Oh, be thankful,' and I'm like, I'm only thankful if it's normal and it's OK. If that's dangerous for him to be sleeping…[or] if it's a sign of like—I don't know why I was thinking 'brain'-is his brain not developed? Like why in the world is he just sleeping so much?*

5.5.3 Weighing worth against uncertain work

As they navigated through the breastfeeding trajectory, participants' ideals in caring for their infants (worth) were tempered by the reality of day-to-day breastfeeding under less than ideal circumstances (work). This balance was in almost constant fluctuation, as circumstances changed, infants matured, and management strategies evolved. In general, when difficulties continued without abatement, the worth of breastfeeding was called into question. Participants with prior breastfeeding experience, however, were able to justify the initial uncertainty, time investment, and lack of enjoyment derived from early nursing as temporary.

> *It's like a process, with everything that I have to do to nurse. I kinda see it as, 'This is what it takes to do what I need to do,'…It's only probably going to be temporary, so let's work through this so that we can accomplish our goal, which is getting him to latch on and not having to take so many bottles…I don't think that this is gonna be a permanent situation. He can only get better with time, so I'm just patiently waiting for him to make the adjustment. He's getting there…I mean I think it's definitely rewarding to breastfeed. It's a lot of hard work, but I just see it as…in a few short months everything is going to be changed, so, I try not to let what's going on right now affect me.*

Women who were highly motivated to breastfeed and considered breastfeeding integral to their maternal identity were willing to go to great lengths to make breastfeeding successful. For example, despite stalled or slow progress with infants latching or staying on breast, some participants diligently continued at-breast attempts at each feeding, followed by supplementation

via bottle and pumping to increase or maintain milk supply. However, negative management strategies, often implemented by primiparas early to save time or energy (e.g., pumping less frequently), were corrected late, and these mothers experienced extreme disappointment and frustration as milk supply dropped and their infants continued to have difficulty nursing.

> *And then when I was still pumping for 40 minutes and got half an ounce, or not even enough to cover the bottom of the bottle. I was just hopeless. It was hard for me to stop, because I was thinking I've ruined everything. But it was so little milk, it was frustrating….So I did stop at about the end of August.*

Alternatively, mothers who were motivated to breastfeed by convenience or guilt were willing to put in breastfeeding "work" initially, but were more amenable to modifying breastfeeding goals as secondary issues or contextual factors became more evident and problematic.

> *I mean, I'm going to [breastfeed], you know, as long as I can, but there have been some changes just as far as family things that are going on, and my life's going to get much more complicated in the next few days…[my nieces] will be [living with me], and [they] will be able to help me more, if the babies are bottle-fed. They can, kind of help and take some of that away with…the more time that I'll need for [my nieces], but less time with the feedings then…*

5.5.4 Playing the game

Playing the game comprised the guesswork that went into managing early breastfeeding. At this stage, which tended to last until 39-40 weeks corrected gestational age, all mothers perceived their infants to have one or more issues that complicated sustained at-breast feeds, including decreased wakefulness, difficulty latching/staying on breast, inability to coordinate sucking, or hypoglycemia that required formula supplementation. These issues led to concern over whether infants were "getting enough" breast milk, especially as some participants experienced delayed lactogenesis II (i.e., onset of copious milk production 2-3 days post-birth). At the same time,

first-time mothers and mothers of twins felt overwhelmed with the time demands and "learning" associated with breastfeeding. Participants exuded anxiety, fear, and frustration as they struggled to make sense of their infant's behavior and establish successful breastfeeding.

> *At first, it was one of the most frustrating things…I'm like, 'I don't know why they told us we had to feed you when you're not eating. What's going on?'*

> *I mean, it was borderline scary for me because I'm like, 'Hello, are you alive!? Like, I have cold rags on you, I have no clothes on you, and you are not responding to me!'…Those first two weeks were probably the most challenging. And I think having a newborn, those are your challenging weeks anyhow, but that was, like, a different challenge for me because it was, like, just everything from scary to frustrating to, 'How do I do this?' Like, you know, he needs to eat. I know he needs to gain weight, but he's not waking up, you know? So again, it was new to me…*

Breastfeeding was described as a "trial and error" process or "game," and infants' behaviors related to physiologic immaturity (e.g., overstimulation and shut down behavior after difficulty at breast) were often misinterpreted as intentional acts, personality traits, or simply part of the "individual" breastfeeding experience. At the extreme, some mothers did not acknowledge the infant's prematurity status at all, citing the infant's "term" weight or negligible proximity to 37 weeks. Infants were described as "faking it," and "tricking" their mothers, as they acted hungry or "interested," but fell asleep or "refused" to stay on breast.

> *He'll fake like he's asleep. He'll get so mad that he just lays there and acts like he's asleep, and then after a few minutes, he's like, 'Okay, I know that she's gonna give me the bottle any minute now,' and then he'll wake up and he'll just start crying all over again because he's hungry. He's so smart that it's just like, 'Wow, I can't believe this is happening.' It's weird.*

> *I mean, it's still day-by-day with the whole bottle, like, after I breastfeed for the 20 minutes. I don't know what's gonna make me feel more comfortable knowing how much he's getting from me. I don't know. I guess it's just a game that you're gonna have to play, a time game. Maybe have to start breastfeeding longer to see if he'll get more that way, drink less bottle…all trial and error.*

> *He always latches on very well. He just doesn't stay awake…he just kind of hangs out [on the breast]. We call it the baby bar, and it's like happy hour. He's just kind of hanging on and not really doing much of anything.*

For some, the expected bonding, or connection to their infant through breastfeeding in this period was delayed as a result of decreased infant responsiveness and interaction during nursing.

> *[The connection between breastfeeding and bonding] is different since he's not in that sleepy mode. Before I don't even know if I saw it more as, like, nurturing. I'm just like, 'This is just what I'm to do. He just needs to be held.' He was supposed to still be inside of me, so of course I loved holding him then, but now I feel like it's more of like a bonding…In the beginning, you're like, 'I'm just trying to nurse this thing to life.' I feel like it's dead, and I am trying to nurse it to life.*

> *I know a lot of women enjoy breastfeeding because it bonds them and things like that. I can't say that I am doing it for that reason or not because it really hasn't been a bonding experience. Because he's really not…he's sleeping.*

These early issues were dealt with in a manner detrimental or protective to breastfeeding success, marked by accounting for the supply-demand principle of breast milk production (e.g., milk expression at regular intervals) and continued determination and attempts of at-breast feeds. Techniques to keep the infant awake at breast (e.g., undressing, touching infant's chin, feet) were employed with mixed results. Some mothers began to wake the infant ahead of time to fit in more frequent feedings, while some started feeding diaries, used breast compressions to increase milk transfer during feedings, or attempted nipple shields to attain a sustained latch. In the absence of definitive signs of satiety, infant weight-gain was the ultimate barometer against which these at-breast efforts were measured (which, dependent upon outcome, provided relief or further angst). Some mothers remained uncomfortable or impatient with at-breast feeds and gravitated toward strategies that minimized time and energy demands, while permitting visual confirmation of the volume of milk ingested (e.g., bottle-feeding with formula, expressed breast milk, or a combination of the two).

[Bottle-feeding is] a lot faster and easier…it's better for him, too. I mean, I don't know. Probably a breast would be better—a little bit more connection or something, but this way it's faster and [he] still gets breast milk at least, yeah…So I'm really happy. At least he gets what he needs instead of formula.

[I give him bottles rather than breastfeed] just so that it could be as fast and efficient as possible so that I can get a solid few hours of sleep [before going into work]… whenever I attempt to breast feed him and then bottle feed him and then change his diaper it's a good 45-minute process. So in the middle of the night, if it's three o'clock in the morning and I can narrow that down to like 15 minutes between a bottle-feeding and a diaper change that would be a lot better… it's just easier for everybody I think, unless he's doing well on the breast. If he's doing well and can eat in 15 minutes then that's ideal but if he keeps up with this napping on the breast it's tough…

Primiparas without prior breastfeeding experience and knowledge sometimes employed "shortcuts." This preserved the goal to breastfeed only temporarily, as breast milk supply eventually dropped.

So [pumping] a couple times a day, it's perfect, you know? Even if he's not eating from nipple, just [breast milk] from the bottle, I'm happy with that. Better than with nothing at all…Because I have [enough breast milk] for like three bottles, so I can pump like every six hours.

5.5.5 Questioning worth versus holding out hope

When poor breastfeeding management continued, the women experienced secondary issues including "nipple confusion" (latch difficulties, presumably due to the infant "getting used to" bottle nipples or flow) and difficulty maintaining their milk supplies. Typically at this point—when the success of breastfeeding was threatened, help was sought in earnest and mothers who were highly motivated to breastfeed were willing to go to extremes to make breastfeeding work. They sought help from multiple sources (including pediatricians, friends, and lactation consultants), used the Internet to find causes of and solutions to their breastfeeding difficulties, and devoted additional time to breastfeeding. However, the effort was often too late. While participants had brief periods of hope with improved infant latching or slight increases in milk

supply, the trajectory followed a downward trend. Mothers became weary seeing little success in terms of milk output, and had increasing difficulty justifying the work of breastfeeding. Remarkably, however, two participants continued to vacillate between giving up and hope for eventual success until their milk supplies were all but gone.

> *It doesn't help encourage me to continue to pump as frequently, because I'm not getting enough to make it--not that it doesn't make a difference, 'cause I know it does. I know any [breast milk] is good, but…yeah, sometimes it's not even half an ounce. Last night [I pumped] half an ounce from one side, and maybe a quarter of an ounce from the other side. And it's just, "Okay, well I'll give them what I can," but…it's just… not really picking up…Everybody keeps telling me a lot of that is just 'cause they're not directly nursing, and that would help with production, but I can't get them to directly nurse, so. I mean, I want it to work. I still really want it to work, but I think just 'cause I know it's what's best for them. I really want them to-even if they're not doing it maybe the most efficient way [at breast], but it means that they're at least getting something…So I'm really hoping that now that it's past six weeks that…I haven't completely failed with it. That there still is some kind of hope to make it work.*

> *Like, yesterday was a half ounce when I was pumping altogether. It's just frustrating. I don't even know if was worth it to do it…But I have to [continue], because I want to give him that. You know, it's still good…What I get, I give it to him because it's still there…even if it's a little bit. Still good for his body or something…*

One participant, who initially identified breastfeeding as central to her identity as a mother, ceased breastfeeding at 2 ½ weeks. Her statements and general demeanor signified defeat and denial of the original worth she attached to breastfeeding.

> *Pumping became too much of a hassle. I mean he wasn't latching on, and I didn't think he would…It sucks that he didn't really latch on and I didn't really produce much, but…like I said before, with the whole bonding thing, I just, it seems the same to me whether it's breastfeeding or bottle-feeding because he's still, you know, in your arms and…he's still close to you and everything like that. I don't see the difference. And that was one of the main reasons why I wanted [to breastfeed].*

5.5.6 Letting him be the judge versus accommodating both of us

On the other hand, as initial infant wakefulness issues resolved, mothers with positive continued breastfeeding management wrestled with the dialectic relationship between their needs and the

breastfeeding demands of the infant. At this stage, infants were feeding often, but inefficiently, at the same time other life responsibilities began to consume more time and attention. Mothers described infants as "constantly" breastfeeding, or "hanging out" on the breast for extended periods doing "mini-feeds." Although they desired more predictable feeding schedules and considered imposing feeding "limits" on their babies, the threat of "going back to square one" with breastfeeding difficulties loomed large. Ultimately, those who perceived breastfeeding as central to their maternal identity and had once experienced a major threat to breastfeeding success resolved to let their infants' control the nursing relationship for the foreseeable future.

> *But again I'm probably lax on [a feeding schedule] right now just because it's like, 'Okay, you want to eat? I'll still continue to put weight on you right now,' but eventually, hopefully, gradually getting out of that.*

> *I think, right now, with her size, I'm going to let her eat when she wants to, but probably within the next week or so I'm gonna try to put her on a schedule…so I've been trying to let her be the judge of it, and once she gets used to eating…and she already has started to. And I think I will definitely put her on a schedule, cause I'm gonna have to [think about] the other children's' schedules.*

> *… I had to do so much to get her to want to breastfeed. And now she's doing so great at it, but now she's like eating too much, and the schedule part [is] the most challenging. To get her on a routine. So it could accommodate both of us.*

Typically by the last interview at 6-8 weeks, mothers who fell into this category reported improved infant efficiency in breastfeeding. However, these participants continued to experience conflict between other responsibilities and the time demands inherent in breastfeeding; this was particularly troublesome during "the overnight," when infants were perceived to be more alert and active. For some, especially among mothers in whom breastfeeding was not part of their maternal identity, these issues led to imposing caveats on continued breastfeeding, including plans for future formula supplementation.

5.5.7 Intervening and contextual factors

A plethora of external events, personal circumstances, and thought processes shaped by individual experiences became major influences on the late preterm breastfeeding process. These factors impacted how mothers thought about breastfeeding, managed issues, and ultimately, whether breastfeeding continued. Factors were categorized as: 1) intervening events, which were more isolated in nature; and 2) contextual factors, which were considered preexisting or enduring variations among participants.

5.5.7.1 Intervening factors

Intervening factors included hospital policy and practices, breastfeeding support from healthcare providers and others, and "trigger" events. Mothers were differentially affected by delivery timing (e.g., season, time of day) in terms of availability of hospital breastfeeding assistance. In addition, a stricter hospital-wide hypoglycemia protocol went into effect several months into data collection, which resulted in more liberal formula supplementation. Cultural differences between the NICU and well-baby units also presented as issues. For example, nursing staff in the NICU reinforced maternal confidence in breastfeeding through their comparisons of breastfeeding progress to more premature and sick infants, positing LPIs as the breastfeeding "stars" of the NICU.

> *I was surprised…with how well he's learning how to latch on and everything like that. [He's] a fast learner…Just like all the nurses say, he's feisty, very feisty. They said that usually, like, the premature babies are usually just tired, just laying there, not really doing much, with this one, he was just active.*

NICU staff were perceived to be more knowledgeable and supportive of breastfeeding, compared to the nurses in the well-baby nursery.

> *Because he wasn't in my room at all I really didn't get any [breastfeeding] feedback or help or anything like that. I mean if I had a question I'm sure that they would have answered but the NICU nurses were my 'go-to' team. But my [postpartum] nurses in my room didn't really address the issues at all.*

Breastfeeding timing and measurement of feeding volumes were more tightly regulated in the NICU, however. Although mothers did not perceive this as problematic at the time, it seemed to reinforce a bottle-feeding mentality and led to palpable discomfort in transitioning to at-breast feeds.

> *They [NICU] like to do the feeding every three hours, and it seems like he's getting hungry every two. But…it's their protocol. So he gets a little fussy like about…either a half an hour or hour before his next feeding.*

Healthcare providers, including pediatricians, lactation consultants, nurses, and obstetricians, were extremely influential in how breastfeeding evolved for LPI dyads. Their availability, accessibility, perceived interest, and provision of accurate information were highly variable, but figured prominently in how mothers viewed and managed breastfeeding. After hospital discharge, remarkably few mothers understood which practitioners were knowledgeable about breastfeeding and who to consult for help. Most often, these mothers became self-reliant, accessing information on the Internet or reaching out to trusted family or friends who had breastfed. Rarely were mothers given "warning signs" of what to expect with breastfeeding a premature infant, and routine breastfeeding follow-up post-discharge was virtually non-existent. At some point, most participants did consult the pediatrician about breastfeeding, who was perceived as available and convenient, but whose breastfeeding knowledge was often questionable.

> *Well [the pediatrician] asked me if she was still breastfeeding, and I told him, 'Yeah.' He's like, 'Well keep doing it,' I guess 'cause she had gained enough weight. At this point, if I were to get any type of lactation support, it would be because I went out and got it. So it's not like they are gonna come knock on my door and be like, 'Hey, how's she doing?' So I haven't tried to get any help.*

Trigger events were perceived by participants to mark the beginning of breastfeeding difficulties. For two mothers, the trigger event was supplementation with formula in the hospital for actual or borderline hypoglycemia. Although these mothers felt formula was necessary to correct the hypoglycemia issue, they were frustrated that nurses did not help them "troubleshoot" at-breast feeds. Later, both mothers attributed issues with latching on, or "nipple confusion" to early supplementation. Other trigger events included a circumcision (n=1) and a re-hospitalization, which were blamed for ensuing infant latch problems.

5.5.7.2 Contextual factors

Prior breastfeeding experience was the single most influential factor impacting the late preterm breastfeeding trajectory. Experience conferred an advantage in that mothers were aware of the temporary nature of breastfeeding issues, understood the concept of supply and demand, and took early measures to protect their milk supplies. Experienced mothers were also more aware of breastfeeding resources and were less overwhelmed with learning the basics of infant care and breastfeeding, on top of breastfeeding a less-responsive infant. In fact, all of the mothers who eventually "gave up" were first-time mothers. The importance of experience in breastfeeding perseverance was voiced by almost all multiparas.

> *I just think that with [my oldest son] and [middle son], just how different they were. Just the idea that they're all different, so I don't get as frustrated as I think I would if I didn't have the other ones…to know that, ok, so maybe this isn't just me, and eventually she'll catch on, kind of thing. So I think that's been helpful, just having other experiences, and not just her.*

Other contextual factors included managing the breastfeeding time commitment along with other responsibilities, such as childcare, career, and school; social/personal issues, including familial support, attitude toward breastfeeding difficulties, and relationship stressors (e.g., one participant attributed milk supply problems partly to stress associated with legal issues involving

an ex-spouse); special circumstances inherent in breastfeeding twins, including exhaustion and coordinating feedings; and prematurity issues, including breastfeeding unpreparedness (delivery occurring prior to "reading the baby books") and failure to make a conscious connection between prematurity status and infant behavior.

5.6 DISCUSSION

We found breastfeeding within the late preterm population to be a volatile and labor-intensive process, characterized by the coexistence of preterm obstacles and a "term"-oriented environment. The misalignment between breastfeeding expectations and experiences led to anxiety, fatigue, and mismanagement of issues. Mothers struggled to balance life responsibilities (e.g., careers, children), while also dealing with "preterm" concerns related to uncertain breastfeeding progress, muted feeding cues, and lack of reciprocity within the breastfeeding relationship (Bernaix, Schmidt, Jamerson, Seiter, & Smith, 2006; Flacking, Ewald, & Starrin, 2007). Unlike the more transient nature of breastfeeding issues noted in term dyads (Brandon et al., 2011) and more intensive, structured breastfeeding guidance typical within preterm populations in the NICU (Aagaard & Hall, 2008; Lupton & Fenwick, 2001), our work suggests that the LPI breastfeeding trajectory follows a less tightly regulated, more convoluted path, commencing in the hospital and continuously evolving up to, and sometimes beyond, 6-8 weeks postpartum.

The multifaceted social, psychological, and biological nature of breastfeeding, coupled with the unique circumstances among late preterm mother-infant dyads, defied easy classification of our findings into existing theoretical models, such as the Theory of Planned

Behavior or Self-Efficacy Theory. The Sense of Coherence Theory (Thomson & Dykes, 2011) provided a fit with the study's central themes of uncertainty, work, and worth, with its equitable treatment of "comprehensibility," "manageability," and "meaningfulness" in management of life stressors. However, in its simplicity, this model does not adequately capture the complexity of the LPI breastfeeding process. Perhaps most closely aligned with our model, both Wight (2003) and Meier and colleagues (2007) depict breastfeeding risk in the late preterm population as a negative cascade involving infant physiological issues, delayed lactogenesis II (associated with pregnancy or delivery complications), decreasing milk supply, and increasing formula supplementation, which compromise breastfeeding success. We feel that our model expands upon these representations by offering insight into maternal thought processes, individual variations, timing, and circumstances leading to both success and failure scenarios.

The concepts of uncertainty, work, and worth in breastfeeding are not new. The literature is rife with accounts describing the emotional fall-out, guilt, and despair when women's expectations and motivation to breastfeed based on the "naturalness" of breastfeeding, the desire to "be a good mother," or to "do what's best for the baby," clash with the unmanageable and "surprising" demands, intensity, and "workload" that breastfeeding entails (Burns, Schmied, Sheehan, & Fenwick, 2009; Larsen, Hall, & Aagaard, 2008; Schmied & Barclay, 1999). Uncertainty in these accounts encompasses the unsettling nature of at-breast feeding when volume of milk transfer is not readily visible. For mothers of preterm infants, uncertainty also centers around perception of inadequate milk supply and the infant's prognosis (Bernaix, Schmidt, Jamerson, Seiter, & Smith, 2006; Flacking, Ewald, Nyqvist, & Starrin, 2006). Burns et al. (2009) describes a scientific discourse of breastfeeding to which women are subjected, prescribing a "right way" that breastfeeding mechanics and outcomes should be measured (e.g.,

weight gain, milk volume). This reinforces women's distrust of their bodies and discomfort with relying on infant satiety cues to ensure adequate nourishment, often leading to formula supplementation and early breastfeeding cessation (Kirkland & Fein, 2003). In our sample, the tension between uncertainty, motivation, and breastfeeding work seemed to be amplified, as LPI mothers operated under the auspices of a "normal" breastfeeding experience, including lack of forewarning of potential issues by medical personnel and abbreviated breastfeeding support, while managing intense, seemingly inexplicable infant breastfeeding behavior related to prematurity. Health care providers (HCPs), particularly nurses and pediatricians, were disturbingly complicit in the process, as most participants encountered outdated, incorrect, and conflicting breastfeeding advice, as well as perceived lack of interest in "troubleshooting" breastfeeding issues.

The lack of consistency in infant trajectory by gestational week, but fairly uniform improvement in wakefulness by 38-39 weeks of corrected gestation, was striking. These findings concur with literature noting attainment of system maturity around 39 weeks of gestation, despite the unpredictable nature of the late preterm course (Kinney, 2006). Thus, our findings support the movement toward no elective deliveries before 39 weeks and the need to investigate "early term" (37-38 weeks gestation) breastfeeding establishment, as well.

Our theoretical model indicates several areas for possible intervention. Interventions should ideally commence in-hospital, prior to the onset of the negative breastfeeding management cascade and irrevocable loss of milk supply. Both LPI mothers and health care providers (HCPs) should be educated on expected infant behavior, basic breastfeeding interventions, and available breastfeeding support resources. It is crucial that health care providers make repeated and sincere attempts to solidify the connection between infant behavior,

physiological prematurity, and the high likelihood for problems compromising milk supply, especially for mothers who may have "term" expectations based on infant weight or gestational age close to 37 weeks. For care providers uncomfortable or unqualified to provide breastfeeding support for this population, referrals should be made to skilled lactation consultants with experience supporting mothers of premature infants. Considering the decreased suction pressures exerted by LPIs at breast, limiting their capacity to transfer adequate milk volumes and maintain an adequate maternal milk supply (Medoff-Cooper, McGrath, & Bilker, 2000), early breast milk expression should be considered for all LPI mothers, regardless of how breastfeeding seems to be progressing. Continued milk expression might also be considered, as the "snacking" behavior observed among some study participants was likely influenced to some degree by compromised infant milk extraction.

LPI mothers and HCPs should be particularly cognizant of the risk-benefit ratio of formula supplementation. Research has shown that even small amounts of formula can drastically alter the normal gastrointestinal flora of an infant (Bullen, Tearle, & Stewart, 1977), posing a substantial threat to the premature immune system. In addition, supplementation via bottle may be particularly problematic in the neurologically immature LPI population in terms of "imprinting" a suck style or higher milk flow expectation that impedes the transition to at-breast feeds (Abouelfettoh, Dowling, Dabash, Elguindy, & Seoud, 2008; Neifert, Lawrence, & Seacat, 1995). Indeed, participants in our study had extended struggles with "nipple confusion."

The balance between work and worth should also be considered in LPI breastfeeding support. Our results indicate that mothers who are extremely committed to breastfeeding may be amenable to more intensive interventions—for example, providing formula via supplemental

nursing systems[1] to reduce the risk of later nipple confusion. First-time LPI mothers, possibly at exponentially greater risk for breastfeeding failure, may benefit from more intensive breastfeeding support as well, including "the basics" left uncovered before an unexpected delivery. The "NICU effect" we observed in terms of greater satisfaction with breastfeeding support among mothers with NICU-admitted infants certainly supports the need for more thorough, longitudinal breastfeeding support in the LPI population.

Because our sample was recruited from a single hospital system in one region, it is possible that our findings may not be applicable within other settings. The NICU culture, healthcare system characteristics, and available breastfeeding support are likely to differ considerably at different places in different times. Although our sample is representative of the geographical area, the hospital patient population available during data collection, and the demographics most likely to breastfeed, our findings may not reflect the experiences of less educated, more culturally-diverse women and infants younger than 35 gestational weeks.

Our multiple data collection methods revealed some discrepancies between maternal memory and real-time interview data. Though a natural reflection of how information is processed over time and represented to others (Sandelowski, 1993), these inconsistencies required some form of action or resolution. When they occurred, clarification was sought, which sometimes led to even deeper reflection and understanding. When the discrepancy persisted, real time event data were considered "correct."

A final limitation involved the length of follow-up. At the final interview (6-8 weeks postpartum), several participants anticipated modifying breastfeeding based on return to work, familial demands, or new information received from HCPs. After IRB re-approval, an attempt

[1] Device consisting of a bottle or similar vessel attached to a long, thin tube, which opens onto the nipple. Typically utilized to encourage at-breast feeding or deliver supplemental nourishment without an artificial teat.

was made to re-contact all participants, via mail, at 4-6 months to ascertain breastfeeding outcome. To date, eight mothers have been contacted, but only five have provided responses. In order to understand the longer-term late preterm breastfeeding experience, then, we recommend that future studies consider extended follow-up periods, reliant on interviews or other methods convenient to participants, rather than non-incentivized mailed questionnaires.

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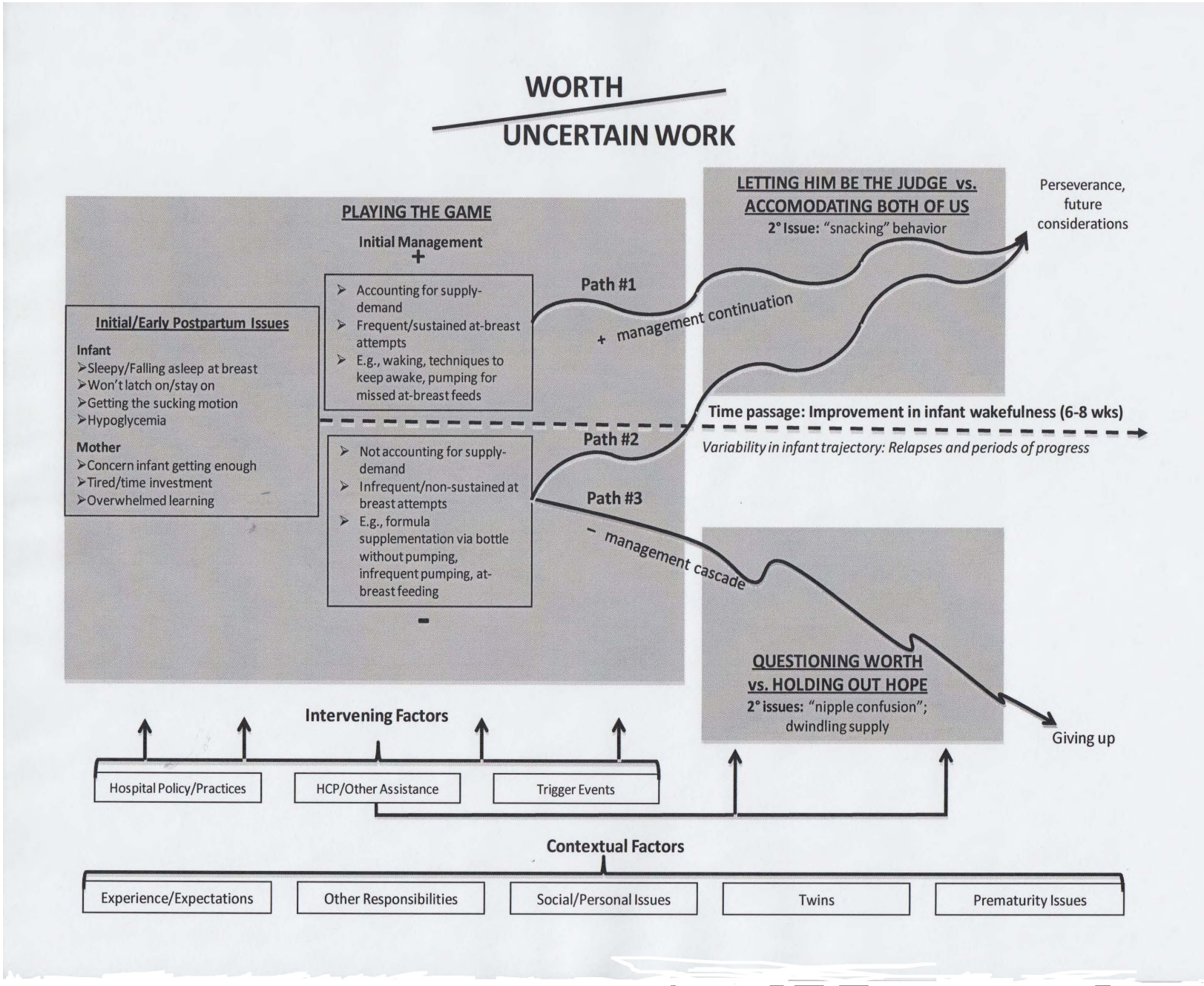

Figure 3. Theoretical model of late preterm breastfeeding establishment

CASE 1: POSITIVE INITIAL AND CONTINUED MANAGEMENT

"Lauren," a 31 year-old multipara, initially felt relaxed and confident breastfeeding her son, "Austin," born at 36 1/7 weeks gestation. Two days after coming home from the hospital, however, she had difficulty in keeping Austin awake at breast. She panicked that something was wrong with her son and worried that she would "lose [her] milk supply." She began to pump after feedings, kept a feeding diary, and continued at-breast feeding attempts every 2-3 hours, setting an alarm. Austin's breastfeeding behavior continued unpredictably, and at the follow-up pediatrician appointment, he had lost weight. Lauren instituted a weekend "feeding frenzy," recommended by the pediatric nurse, in which Austin was consistently woken for breastfeeding every 1.5 hours. The following Monday, he had gained weight. At 39-40 weeks corrected gestation, Lauren noticed considerable improvement in wakefulness, but struggled with "where to draw the line," as she felt Austin was almost constantly "snacking" at breast. Although she desired a more predicable feeding schedule, she acquiesced to let Austin feed as often as he wanted, since he was still so "young." Around 8 weeks, Lauren confirmed Austin was becoming more efficient at breastfeeding, and she intended to continue breastfeeding indefinitely.

CASE 2: NEGATIVE INITIAL, POSITIVE CONTINUED MANAGEMENT

"Anne" a 32 year-old multipara delivered "Carson" at 36 5/7 weeks gestation. Carson experienced in-hospital issues of sleepiness at breast and borderline hypoglycemia, which "required" formula supplementation. Despite Anne's request for a breast pump, none were available on the unit, and Carson was fed formula for several days. At home, Carson's wakefulness improved, but he "refused" to latch onto breast, despite continued attempts. Anne was worried about Carson's presumed "nipple confusion" and losing her milk supply, but remained optimistic. She began to pump diligently, and provided expressed breast milk via bottle. After three weeks of difficulty, Anne consulted with a hospital-based lactation consultant, who recommended a nipple shield to assist with latching. The nipple shield proved successful. After six weeks, Carson was exclusively breastfeeding without the nipple shield and Anne no longer needed to pump breast milk.

CASE 3: INITIAL AND CONTINUED NEGATIVE MANAGEMENT

"Sophie," a 34 year old primipara, delivered "Oliver" at 36 6/7 weeks gestation. During the postpartum hospitalization and for several days at home, Oliver was "too sleepy" to sustain a latch, so Sophie gave formula at the nurses' suggestion without initiating breast milk expression. After continued difficulty, Sophie contacted a lactation consultant at one week postpartum, who provided a nipple shield (for "flat" nipples) and ordered a breast pump. Sophie was happy to discover that she only needed to pump a few times per day to provide all the milk Oliver was consuming. She ceased at-breast feeding, as pumping and feeding breast milk by bottle was faster and easier. Within a week, however, Sophie's milk supply was dropping, and she needed to give increasing amounts of formula to keep Oliver satisfied. At the lactation consultant's suggestion, she re-attempted at-breast feeds and more frequent pumping, but had limited success. At her 6-week obstetrician appointment, Sophie asked about a medication to increase milk supply she had read about online, but was erroneously told it "didn't exist." As a last-ditch effort, Sophie re-contacted the lactation consultant, who recommended "power pumping" (pumping frequently for short periods). This was briefly successful in increasing supply, but Sophie later reported that progress stalled. Frustrated and hopeless, she "gave up" breastfeeding at 2 ½ months.

Figure 4. Case summaries

APPENDIX A

PARTICIPANT BACKGROUND DEMOGRAPHICS, OBSTETRICAL AND BREASTFEEDING HISTORY

Participant ID:
Date form initiated:

Participant Background Demographics, Obstetrical & Breastfeeding History

Note: To be abstracted from the medical chart or administered verbally (adapting language/clarifying where appropriate)

Demographics

Age in years:

Date of birth (dd/mm/yy):

Occupation:

Marital Status (married/single/divorced/widowed):

Race (American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White; Other):

Ethnicity (Hispanic or Latino, Not Hispanic or Latino):

WIC benefits (yes/no):

Smoking (history, with pregnancy, current, # of cigarettes or PPD):

Highest level of education (high school diploma, GED, some college, college grad, etc.):

Obstetrical History

Date & time of index infant birth:

G/P/T/P/A/L (Gravida, Para, Term, Preterm, Abortions, Living):

Ages of prior children:

Any complications during pregnancy (e.g., preeclampsia, gestational hypertension, gestational diabetes, preterm labor):

Breastfeeding History

Number of children for whom breastfeeding was attempted:

Duration (months/days) for each breastfeeding attempt (any breast milk):

Duration (months/days) for each breastfeeding attempt (exclusive breastfeeding):

Current Birth

Type of delivery (Cesarean-section or vaginal):

Onset of labor (natural or induced):

Anesthesia during labor (general, epidural, natural, other):

Complications during labor and delivery or postpartum (e.g., forceps delivery, vacuum extraction, emergency Cesarean-section, postpartum hemorrhage, infant resuscitation, use of Pitocin before/after delivery):

Obstetric caregiver (e.g., midwife, MD):

Continuity of nurse caregivers in hospital (number of different nurses each day/night?):

Infant

Weeks gestation at delivery:

Weight (grams and lbs.) & length (cm & inches) (at delivery and at d/c):

Birth injuries (e.g., cephalhematoma, fractured clavicle, palsies):

Genetic abnormalities/deformities:

Other illnesses/abnormalities:

Apgar Scores (1 min/5 min):

Type of admission (NICU or well-baby nursery):

If admitted to NICU, length of NICU stay:

Blood glucose values during admission:

Bilirubin values (TCB, direct blood draws) during admission:

Lactation consult completed or ordered during admission (yes/no/dates):

APPENDIX B

MEDICAL CHART INFANT FEEDING AND OUTPUT ABSTRACTION FORM

Participant ID:

Medical Chart Infant Feeding & Output Abstraction Form

(To be completed for each day of infant birth hospitalization)

Date & Infant Age	Time	LATCH Score & Comments	Minutes Breastfeeding	Supplementation Type	Supplementation Volume

U=unobserved/unassisted breastfeeding
O=observed breastfeeding session
DOD=day of discharge

Infant Output

Date	Time	Void	Stool

APPENDIX C

CURRENT BREASTFEEDING STATUS WORKSHEET

Participant ID:
Date and Interview #:
Days Postpartum:
Age of Infant (months/days):

Current Breastfeeding Status/Definition Worksheet

(To be completed at each contact point)

1. **FULL**

   Exclusive

   Almost exclusive (vitamins/minerals/water/given infrequently)

2. **PARTIAL**

   High (>80%)

   Medium (20-80%)

   Low (<20%)

3. **TOKEN** *(minimal/occasional/irregular breastfeeds)*

1. ***Frequency (approximate # of feedings in 24 hrs or per day/night)***

2. ***Duration (average duration of 1 feed)***

3. ***Intervals (longest time between 2 feeds)***

4. ***Use of pacifiers/artificial nipples (yes/sometimes/never)***

5. ***Percentage of feeds as expressed breast milk***

6. ***Type/timing/amount of other feeds***

7. ***Other influences (e.g., time of day, other children, infant/mother conditions)***

APPENDIX D

ORIGINAL INTERVIEW GUIDE

Date:
Participant ID:
Days postpartum:
Infant age (months/days):

Interview Guide

Grand Tour Question: I am interested in learning about your experiences with your new baby who was born slightly early. I especially want to know your thoughts about breastfeeding.

Initial Interview

Decision

Tell me about how you came to the decision to breastfeed or to provide breast milk for your new baby.

Probes

1. Did anyone or anything influence your decision? In what way?
    a. Parenting books/internet sites?
    b. Other media?
    c. Acquaintances/relatives?
2. How have your family and friends either supported or not supported your decision?
    a. What did they say/do?
3. How has your doctor or the baby's pediatrician either supported or not supported your decision?
    a. What did he or she say/do?
4. What is your prior experience with breastfeeding?
    a. Have you breastfed other children? If so, how did those experiences go?

b. Have others' breastfeeding stories or your own observations impacted your decision to breastfeed? If so, how?

Process

Tell me about your first few attempts at breastfeeding, or pumping and providing breast milk. How has it gone?

Probes

1. How has breastfeeding thus far been different from, or similar to, your expectations or prior experiences with breastfeeding?
2. Describe the first time you put your baby to breast or pumped breast milk and gave it to the baby.
    a. When did this occur?
    b. How did it unfold?
    c. How did you feel about it?
3. Describe how breastfeeding or pumping has progressed since the first feed.
    a. Is there a feeding schedule? How was this decided?
    b. What has made it easier? Harder?
        i. Is it dependent upon certain times of the day or certain circumstances? Describe this.
    c. What has breastfeeding assistance in the hospital been like?
        i. How have any of the following people helped or hindered breastfeeding?
            1. Nurses?
            2. Doctors?
            3. Lactation consultants?

4. Have there been times when you supplemented the baby with a bottle or didn't feed from the breast?

    a. Did you use your breast milk, formula, or another substance (e.g., water) during these times?

    b. How was this decided?

    c. Who decided?

5. What problems have you had? (ONLY use the following as a probe if no response: Mothers report some common breastfeeding problems. I'll name some, and you tell me if you've experienced any of them: latching-on problems, the baby is fussy during feeding, the baby is lazy or sleepy, not having enough breast milk, a fragile or sick baby, not feeling well or taking medications that interfere with breastfeeding, wanting to know how much breast milk the baby gets, nipple tenderness, breasts being too full or engorgement, and feeling worn out or exhausted.)

    a. How were/are these managed?

    b. Who/what helped?

    c. What didn't help?

Mother-Role

1. How does your experience with breastfeeding so far compare with your picture of motherhood ?

    a. How is it different/same as you thought it might be?

Subsequent Interviews

Decision to Continue

What do you think are the reason(s) that you have continued to breastfeed?

Probes

1. How have other obligations and activities factored into **your decision** to continue or modify breastfeeding/pumping? *(may directly follow-up with #4 "Process," below)*
2. What did, or do, you see as benefits of continuing to breastfeed/provide breast milk?
3. What did/do you see as disadvantages or obstacles in continuing to breastfeed or provide breast milk?

(Also utilize same probes as in initial interview topic, "Decision," with the exception of #4)

Process

I am wondering how breastfeeding/pumping has gone since the last time we've spoken. Could you tell me about that?

Probes

1. How does breastfeeding/pumping in the hospital compare with breastfeeding or pumping at home?
2. How has breastfeeding/pumping changed since last time we've spoken?
    a. Easier? How so?
    b. Harder? How so?
3. Is there a feeding schedule? How was this decided?
4. How have you balanced other obligations and activities with breastfeeding/pumping?
    a. How do you feel about breastfeeding/providing breast milk in public or outside the home? How would/do you manage this?
    b. Describe a typical day breastfeeding/pumping and feeding.
5. How do others in your household or family (e.g., spouse, other children) impact or respond to your breastfeeding/pumping?

a. Describe any emotional support offered/opposition encountered.

b. Describe any practical support offered/opposition encountered.

6. Have you sought additional assistance or advice regarding breastfeeding/pumping? If so, how has this impacted breastfeeding?

   a. From the pediatrician?

   b. From a lactation consultant?

   c. Others?

7. What do you expect in terms of any changes in the future that will impact your ability to breastfeed/pump?

   (Also utilize probes #1,4,5 from initial interview topic, "Process")

Mother-Role

Describe how breastfeeding fits into your idea of mothering or caring for your baby at this point.

(Utilize same probes as in initial interview, under interview topic, "Mother-Role," modifying tense accordingly)

APPENDIX E

ADDENDUM INTERVIEW ITEMS, ADDED 8/30/11 BASED ON THEMES IDENTIFIED IN PRELIMINARY ANALYSES

1. When did you first notice the sleepiness/decreased responsiveness? When do you think it resolved?

2. What kind of issues would prompt you to seek out help for breastfeeding? What are you, or would you, decide to deal with on your own?

3. What kinds of pediatrician advice do you follow? Not follow? –in r/t breastfeeding. What factors into your decision to modify their advice?

4. How do you feel you were prepared/unprepared to deal with how breastfeeding is going right now? Or to deal with the problems you're facing?

5. What do you think are the signs that your baby is "getting enough"?

6. Some participants have distinguished between mother and infant breastfeeding problems.

7. For you, what, what do you see as problems with breastfeeding r/t to your infant? What problems do you see as related only to you?

8. What would you do differently or the same looking back on your breastfeeding experience thus far?

9. What advice would you give to someone going through the same breastfeeding situation?

10. What are your long term plans for breastfeeding?

11. What would be your deal-breaker for continuing to breastfeed?

12. What would an intervention to help mothers in your situation look like? Involve?

APPENDIX F

INSTITUTIONAL REVIEW BOARD APPROVALS

F.1 INITIAL APPROVAL

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Jill Radtke, BSN, RN

From: Sue Beers, PhD , Vice Chair

Date: 12/3/2009

IRB#: PRO09090221

Subject: Study of Late Preterm Breastfeeding Establishment and Processes

---

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:
45 CFR 46.110.(6, 7).

The IRB has approved the waiver for the requirement to obtain informed consent to use protected health information to identify potential research subjects.

This study is supported by the following federal grant application(s):
1F31NR011562-01 Breastfeeding the Late Preterm Infant: A Grounded Theory Study

Approval Date: 12/2/2009
Expiration Date: 12/1/2010

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

F.2 LATEST RENEWAL/APPROVAL

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Jill Radtke
From: Sue Beers, PhD , Vice Chair
Date: 9/19/2011
IRB#: REN11080010 / PRO09090221
Subject: Study of Late Preterm Breastfeeding Establishment and Processes

---

Your renewal for the above referenced research study has received expedited review and approval from the Institutional Review Board under:
45 CFR 46.110.(6)
45 CFR 46.110.(7)

Please note the following information:

Approval Date: 9/15/2011
Expiration Date: 9/14/2012

This study is supported by the following federal grant application:
1F31NR011562-01 Breastfeeding the Late Preterm Infant: A Grounded Theory Study

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month** prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

F.3 MODIFICATION APPROVAL TO RE-CONTACT PARTICIPANTS

University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Jill Radtke
From: Christopher Ryan, PhD, Vice Chair
Date: 10/17/2011
IRB#: MOD09090221-03 / PRO09090221
Subject: Study of Late Preterm Breastfeeding Establishment and Processes

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The University of Pittsburgh Institutional Review Board reviewed and approved the requested modifications by expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110.

Modification Approval Date: 10/17/2011
Expiration Date: 9/14/2012

For studies being conducted in UPMC facilities, no clinical activities that are impacted by the modifications can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

APPENDIX G

CONSENT FORMS

G.1 ORIGINAL CONSENT FORM

University of Pittsburgh

School of Nursing

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Study of Late Preterm Breastfeeding Establishment and Processes

PRINCIPAL INVESTIGATOR: Jill Radtke, BSN, RN
University of Pittsburgh School of Nursing
311 Victoria Building, Pittsburgh, PA 15261
Telephone: 724-622-6371

CO-INVESTIGATORS:

Susan Cohen, DSN, APRN, FAAN
Associate Professor
University of Pittsburgh
Telephone: 412-624-5345

Susan Albrecht, PhD, RN, FAAN
Professor and Associate Dean
University of Pittsburgh
Telephone: 412-624-2403

Mary Beth Happ, PhD, RN, FAAN
Professor
University of Pittsburgh
Telephone: 412-624-2070

Debra Bogen, MD
Associate Professor of Pediatrics and Psychiatry
University of Pittsburgh
Telephone: 412-692-6000

Sandra Founds, CNM, FNP, PhD
Assistant Professor
University of Pittsburgh
Telephone: 412-624-3822

Source of Support: Breastfeeding the Late Preterm Infant: A Grounded Theory Study, (NINR) National Institute of Nursing Research (1F31NR011562-01)

What is informed consent?

The following information describes the purpose, procedures, risks, benefits, and requirements of participating in this research study. Signing this form indicates that this information has been explained to you, any questions have been answered, and you agree to participate in the study with your infant. The process of reading and signing this form is called informed consent.

Why is this research being done?

The purpose of this study is to learn more about breastfeeding and the relationship between mothers and their infants who were born slightly premature ("late preterm"). Research has shown that breastfeeding a premature infant has different challenges than breastfeeding an infant who is born at term. We think that there may be unique challenges in breastfeeding a late preterm infant that are not seen with preterm or term infants.

Who is being asked to take part in this research study?

You and your baby are being asked to be in this research study because your baby is considered "late preterm" (34-36 weeks of gestation) and you intend to breastfeed. Approximately 10-18 breastfeeding mothers and their late preterm infants will take part in this study.

What is involved?

(1) If you agree to take part in this study with your baby, the researcher will meet with you once during your hospitalization to talk to you about your breastfeeding experience. The interview will occur in a private meeting space on the hospital unit or in your hospital room, wherever you feel most comfortable. It will be arranged at a time convenient for you and should last one hour or less.

(2) The researcher will review your/your baby's hospital records and record information related to your reproductive health history, the birth, your baby's health, and your baby's feedings.

(3) The researcher will make arrangements with you for additional interviews about breastfeeding based on the needs of the study and your availability. These interviews will generally be scheduled 1 week, 2 weeks, and 6-8 weeks after your baby's birth and should last 1 hour or less. These interviews will occur at a time and in a location convenient for you, such as your home. You are encouraged to bring your baby to the interviews and breastfeed if you feel comfortable doing so. At all interviews, the researcher will make observations and take notes about the interview process, setting, and other activities going on during the interview.

(4) All interviews will be audio-recorded and your words typed and used as part of the study data. Audio-recording is used to assure an accurate record of your words and the interviewer's questions. It is the best way to record all of the conversation and allows the interviewer to focus on what you are saying instead of trying to remember or write every word. Your name will not be used on the audio file or in the typed transcript. After the recording is typed, the audio file will be destroyed.

(5) You also have the *option* to participate in emailing the researcher about your breastfeeding experiences, having one or more breastfeeding sessions video-recorded (video-recording will occur before, during, or after an interview) with the opportunity to view and comment on the video at the next interview, and/or self audio-recording your thoughts as you breastfeed your baby. These additional options will allow the researcher to have more detailed information about the breastfeeding process. You may chose not to participate in the options, but still participate in the study.

(6) The number and timing of emails and audio-recorded breastfeeding sessions is up to you. If you chose to audio-record your thoughts during breastfeeding, you will be provided with a digital audio-recorder. The researcher will transfer each audio file to a password-protected, encrypted computer file during your next scheduled interview. At the end of your study participation, the researcher will collect the audio-recorder back from you. All audio-recorded sessions will be transcribed without any identifiable information, and the audio files stored without identifiable information. Emails will be copied into a Word document, saved without identifiable information, and the original email deleted immediately.

If you chose to have breastfeeding sessions video-recorded, the researcher will set up a small camera on a tripod while you breastfeed your baby in a private location, such as your home. You will be able to interact with the researcher and/or your baby as you breastfeed. You may also ask the researcher to leave during the video-recording. At the next interview session, the researcher will bring the video for you to watch. As you view the video, you will be encouraged talk about that breastfeeding session, and your comments will be audio-recorded and transcribed. The video and audio recordings resulting from the video portion of the study will be stored indefinitely without identifiable information in a locked file cabinet in a locked room.

Your participation in the study should last approximately 6-8 weeks.

What are the possible risks and discomforts of this study? There are no risks in being observed or interviewed, with the exception that you may be uncomfortable recalling difficult breastfeeding experiences. The researcher will stop the interview at any time if you become uncomfortable. You may also stop the interview at any time.

The risks in being video-recorded for this study are that your/your infant's face and your breasts will likely be seen on the video, you/your infant could possibly be identified on the videos, or you may feel uncomfortable being video-recorded breastfeeding. Your breasts will be blurred on the video if it is not critical to evaluate some aspect of breastfeeding. You may also decline to have your videos stored for future research or research presentations. You may stop a video-recording at any time. You may also decline to participate in any video-recording for the study.

It is possible, but unlikely, that your voice may be identifiable as part of the audio-recording in this study. You may decline participation in self audio-recording your thoughts on breastfeeding and/or audio-recorded responses to video viewing, but all interviews will be audio-recorded. Any identifiable information discussed on the audio-recordings will be deleted, and you may

choose to have audio file information destroyed after transcription. Audio files of interviews will automatically be destroyed after transcription.

It is possible, but unlikely, that your emailed breastfeeding experiences may be visible over the internet. Precautions will be taken to minimize a breach of confidentiality by saving your emails as text documents only, deleting the email upon receipt along with any identifiable information within the email, and emptying the computer's "trash can" after deleting an email. You may decline to participate in the emailing portion of the study.

All of your research records will be coded to minimize potential risks of confidentiality breaches.

Will I benefit from taking part in this study? There will probably not be any direct benefits to you or your baby from being in this study. However, you may enjoy speaking about your breastfeeding experience and relationship with your new baby. Additionally, your participation may help us understand more about breastfeeding issues with late preterm infants in order to improve breastfeeding support in the future.

Will anyone know that I am taking part in this study? All study records pertaining to you and your baby's involvement in this study will be kept strictly confidential. All study data, including video and audio files, will be assigned an individual pseudonym (made-up name). Your real name will not be written on any papers, forms, or video/audio-files used in this study, with one exception. We will keep a master file linking your pseudonym with your name in a single form in a password-protected, encrypted computer file. All video and audio files will be stored only as digital (no hard copies, including CD's or VHS tapes), password-protected encrypted files and kept within a locked file cabinet within a locked room at the University of Pittsburgh. Video and audio files will be stored for a minimum of 7 years and may be stored indefinitely in this same area. The Principal Investigator assumes overall responsibility for control over this storage area.

You will not be identified by name in any publication or presentation of research results unless you give the researcher permission to do so. No one will have access to any papers, videos, or audio-recordings except for the research team on this and any related projects. If you give your permission, the information collected in this study, including the video-recordings may be used by other secondary investigators after any information that might link you to the study information has been removed.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this study? No, there will be no costs to you or your insurance provider for being in this study.

Will I be paid for participating in this study?
You will receive a gift worth $5 for the first interview, $5 for the second interview, $10 for the third interview, $15 for the fourth interview, $10 for any additional interviews, plus a gift worth $5 if you participate in any email journaling, videotaping, or self audio-recordings. The number of interviews is based upon the needs of the study and the Principal Investigator's and your availability.

Is my participation in the study voluntary? Yes! Your/your infant's participation in this study is completely voluntary. You may refuse to take part in it or you may stop participating at any time, even after signing this form. Your/your infant's medical care will be the same whether or not you participate in this study, and your decision will not affect your/your infant's relationship with the University of Pittsburgh, Magee Women's Hospital of UPMC, or the University of Pittsburgh Medical Center.

If I agree to take part in the study, can I be removed from the study without my consent? If you stop breastfeeding, your participation in the study will be discontinued. However, the researcher may schedule a final interview after you decide to stop breastfeeding to ask you about stopping.

How do I get more information?

If you have further questions about your participation in this study, you may contact the Principal Investigator, Jill Radtke, at the number listed on the front page of this form. If you have any questions about your rights as a research subject, please contact the Human Subject Protection Advocate, IRB Office (1-866-212-2668). You may refuse to participate or you may withdraw from this study at any time without affecting your relationship with or treatment at University of Pittsburgh and University of Pittsburgh Medical Center. You will receive a copy of this consent form.

VOLUNTARY CONSENT

(Please check boxes, and place your initials on the lines to indicate your agreement with the statements.)

□ All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-888-212-2668).

___ I agree to participate in the breastfeeding self audio-recordings. I understand that any identifiable information on the recordings will be deleted, and that these audio-recordings will be destroyed after transcription if I so request it (optional).

___ I agree to participate in the email portion of this study. I understand that any identifiable information in the emails will be deleted upon receipt of the email by the Principal Investigator (optional).

___ I agree to participate in the video-recorded breastfeeding portion of this study. I understand my breast will be blurred in order to protect my privacy at my request after I view the videos and complete the audio-recorded review with the Principal Investigator. My audio files in response to the videos will be destroyed after transcription if I request it (optional).

___ I give my permission to have my video-recorded breastfeeding sessions stored after I view them and complete the audio-recorded review with the PI. I understand that these video-recordings may be used by other researchers in an unidentifiable manner for research related to breastfeeding in late preterm infants (optional).

___ I give permission to use the video-recordings for educational or research presentations or publications. My breasts and/or face may be blurred for this purpose if I request it (optional).

□ By signing this form, I agree to participate and have my infant participate in this research study. A copy of this consent form will be given to me.

Maternal Subject Name	Maternal Subject Signature	Date/Time

Infant Subject Name

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-mentioned maternal participant and I have discussed the potential benefits and possible risks of study participation. Any questions about this information have been answered.

Investigator Name	Investigator Signature	Date/Time

G.2 LATEST CONSENT FORM

University of Pittsburgh

School of Nursing

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Study of Late Preterm Breastfeeding Establishment and Processes

PRINCIPAL INVESTIGATOR: Jill Radtke, BSN, RN
University of Pittsburgh School of Nursing
311 Victoria Building, Pittsburgh, PA 15261
Telephone: 724-622-6371

CO-INVESTIGATORS:

Susan Cohen, DSN, APRN, FAAN
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Professor and Associate Dean
University of Pittsburgh
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Mary Beth Happ, PhD, RN, FAAN
Professor
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Debra Bogen, MD
Associate Professor of Pediatrics and Psychiatry
University of Pittsburgh
Telephone: 412-692-6000

Sandra Founds, CNM, FNP, PhD
Assistant Professor
University of Pittsburgh
Telephone: 412-624-3822

Source of Support: Breastfeeding the Late Preterm Infant: A Grounded Theory Study, (NINR) National Institute of Nursing Research (1F31NR011562-01); Sigma Theta Tau International (Eta Chapter)

What is informed consent?

The following information describes the purpose, procedures, risks, benefits, and requirements of participating in this research study. Signing this form indicates that this information has been explained to you, any questions have been answered, and you agree to participate in the study with your infant. The process of reading and signing this form is called informed consent.

Why is this research being done?

The purpose of this study is to learn more about breastfeeding and the relationship between mothers and their infants who were born slightly premature ("late preterm"). Research has shown that breastfeeding a premature infant has different challenges than breastfeeding an infant who is born at term. We think that there may be unique challenges in breastfeeding a late preterm infant that are not seen with preterm or term infants.

Who is being asked to take part in this research study?

You and your baby are being asked to be in this research study because your baby is considered "late preterm" (34-36 weeks of gestation) and you intend to breastfeed. Approximately 10-18 breastfeeding mothers and their late preterm infants will take part in this study.

What is involved?

(1) If you agree to take part in this study with your baby, the researcher will meet with you once during your hospitalization to talk to you about your breastfeeding experience. The interview will occur in a private meeting space on the hospital unit or in your hospital room, wherever you feel most comfortable. It will be arranged at a time convenient for you and should last one hour or less.

(2) The researcher will review your/your baby's hospital records and record information related to your reproductive health history, the birth, your baby's health, and your baby's feedings.

(3) The researcher will make arrangements with you for additional interviews about breastfeeding based on the needs of the study and your availability. These interviews will generally be scheduled 1 week, 2 weeks, and 6-8 weeks after your baby's birth and should last 1 hour or less. These interviews will occur at a time and in a location convenient for you, such as your home. You are encouraged to bring your baby to the interviews and breastfeed if you feel comfortable doing so. At all interviews, the researcher and student assistant (if available) will make observations and take notes about the interview process, setting, and other activities going on during the interview.

(4) All interviews will be audio-recorded and your words typed and used as part of the study data. Audio-recording is used to assure an accurate record of your words and the interviewer's questions. It is the best way to record all of the conversation and allows the interviewer to focus on what you are saying instead of trying to remember or write every word. Your name will not be used on the audio file or in the typed transcript. After the recording is typed, the audio file will be destroyed.

(5) You also have the ***option*** to participate in emailing the researcher about your breastfeeding experiences, having one or more breastfeeding sessions video-recorded (video-recording will occur before, during, or after an interview) with the opportunity to view and comment on the video at the next interview, and/or self audio-recording your thoughts as you breastfeed your baby. These additional options will allow the researcher to have more detailed information about the breastfeeding process. You may chose not to participate in the options, but still participate in the study.

(6) The number and timing of emails and audio-recorded breastfeeding sessions is up to you. If you chose to audio-record your thoughts during breastfeeding, you will be provided with a digital audio-recorder. The researcher will transfer each audio file to a password-protected, encrypted computer file during your next scheduled interview. At the end of your study participation, the researcher will collect the audio-recorder back from you. All audio-recorded sessions will be transcribed without any identifiable information, and the audio files stored without identifiable information. Emails will be copied into a Word document, saved without identifiable information, and the original email deleted immediately.

If you chose to have breastfeeding sessions video-recorded, the researcher will set up a small camera on a tripod while you breastfeed your baby in a private location, such as your home. You will be able to interact with the researcher and/or your baby as you breastfeed. You may also ask the researcher to leave during the video-recording. At the next interview session, the researcher will bring the video for you to watch. As you view the video, you will be encouraged talk about that breastfeeding session, and your comments will be audio-recorded and transcribed. The video and audio recordings resulting from the video portion of the study will be stored indefinitely without identifiable information in a locked file cabinet in a locked room.

(7) Because we have observed that breastfeeding is still changing for some participants after 6-8 weeks, we are seeking your feedback on several additional questions related to your breastfeeding experience approximately 4-12 months after your initial interview. These questions should take approximately 5-10 minutes to complete, and you may answer as few or as many questions as you wish. You may mail or email written responses, or if you prefer, you may request a phone or in-person interview with the Principal Investigator to complete this portion of the study. Participation in this follow-up is **optional**; you may choose not to participate (simply by not returning the mailed questions to the researcher) and still participate in the main study.

What are the possible risks and discomforts of this study? There are no risks in being observed or interviewed, with the exception that you may be uncomfortable recalling difficult breastfeeding experiences. The researcher will stop the interview at any time if you become uncomfortable. You may also stop the interview at any time.

The risks in being video-recorded for this study are that your/your infant's face and your breasts will likely be seen on the video, you/your infant could possibly be identified on the videos, or you may feel uncomfortable being video-recorded breastfeeding. Your breasts will be blurred on the video if it is not critical to evaluate some aspect of breastfeeding. You may also decline to have your videos stored for future research or research presentations. You may stop a video-recording at any time. You may also decline to participate in any video-recording for the study.

It is possible, but unlikely, that your voice may be identifiable as part of the audio-recording in this study. You may decline participation in self audio-recording your thoughts on breastfeeding and/or audio-recorded responses to video viewing, but all interviews will be audio-recorded. Any identifiable information discussed on the audio-recordings will be deleted, and you may choose to have audio file information destroyed after transcription. Audio files of interviews will automatically be destroyed after transcription.

It is possible, but unlikely, that your emailed breastfeeding experiences may be visible over the internet. Precautions will be taken to minimize a breach of confidentiality by saving your emails as text documents only, deleting the email upon receipt along with any identifiable information within the email, and emptying the computer's "trash can" after deleting an email. You may decline to participate in the emailing portion of the study.

All of your research records will be coded to minimize potential risks of confidentiality breaches.

Will I benefit from taking part in this study? There will probably not be any direct benefits to you or your baby from being in this study. However, you may enjoy speaking about your breastfeeding experience and relationship with your new baby. Additionally, your participation may help us understand more about breastfeeding issues with late preterm infants in order to improve breastfeeding support in the future.

Will anyone know that I am taking part in this study? All study records pertaining to you and your baby's involvement in this study will be kept strictly confidential. All study data, including video and audio files, will be assigned an individual pseudonym (made-up name). Your real name will not be written on any papers, forms, or video/audio-files used in this study, with one exception. We will keep a master file linking your pseudonym with your name in a single form in a password-protected, encrypted computer file. All video and audio files will be stored only as digital (no hard copies, including CD's or VHS tapes), password-protected encrypted files and kept within a locked file cabinet within a locked room at the University of Pittsburgh. Video and audio files will be stored for a minimum of 7 years and may be stored indefinitely in this same

area. The Principal Investigator assumes overall responsibility for control over this storage area.

You will not be identified by name in any publication or presentation of research results unless you give the researcher permission to do so. No one will have access to any papers, videos, or audio-recordings except for the research team on this and any related projects. If you give your permission, the information collected in this study, including the video-recordings may be used by other secondary investigators after any information that might link you to the study information has been removed.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this study? No, there will be no costs to you or your insurance provider for being in this study.

Will I be paid for participating in this study?
The study consists of four interviews, and total compensation for study completion is $80, plus a package of infant diapers if you participate in any email journaling, videotaping, or self audio-recordings. You will receive a cash card worth $10 for each of the first three interviews and a cash card worth $50 for the fourth interview. If additional interviews are scheduled, you will receive a $10 cash card for each additional interview. The number of interviews is based upon the needs of the study and the Principal Investigator's and your availability.

Is my participation in the study voluntary? Yes! Your/your infant's participation in this study is completely voluntary. You may refuse to take part in it or you may stop participating at any time, even after signing this form. Your/your infant's medical care will be the same whether or not you participate in this study, and your decision will not affect your/your infant's relationship with the University of Pittsburgh, Magee Women's Hospital of UPMC, or the University of Pittsburgh Medical Center.

If I agree to take part in the study, can I be removed from the study without my consent? If you stop breastfeeding, your participation in the study will be discontinued. However, the researcher may schedule a final interview after you decide to stop breastfeeding to ask you about stopping.

How do I get more information?

If you have further questions about your participation in this study, you may contact the Principal Investigator, Jill Radtke, at the number listed on the front page of this form. If you have any questions about your rights as a research subject, please contact the Human Subject Protection Advocate, IRB Office (1-866-212-2668). You may refuse to participate or you may withdraw from this study at any time without affecting your relationship with or treatment at University of Pittsburgh and University of Pittsburgh Medical Center. You will receive a copy of this consent form.

VOLUNTARY CONSENT

(Please check boxes, and place your initials on the lines to indicate your agreement with the statements.)

! All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-888-212-2668).

__ I agree to participate in the breastfeeding self audio-recordings. I understand that any identifiable information on the recordings will be deleted, and that these audio-recordings will be destroyed after transcription if I so request it (**optional**).

__ I agree to participate in the email portion of this study. I understand that any identifiable information in the emails will be deleted upon receipt of the email by the Principal Investigator (**optional**).

__ I agree to participate in the video-recorded breastfeeding portion of this study. I understand my breast will be blurred in order to protect my privacy at my request after I view the videos and complete the audio-recorded review with the Principal Investigator. My audio files in response to the videos will be destroyed after transcription if I request it (**optional**).

__ I give my permission to have my video-recorded breastfeeding sessions stored after I view them and complete the audio-recorded review with the PI. I understand that these video-recordings may be used by other researchers in an unidentifiable manner for research related to breastfeeding in late preterm infants (**optional**).

__ I give permission to use the video-recordings for educational or research presentations or publications. My breasts and/or face may be blurred for this purpose if I request it (**optional**).

! By signing this form, I agree to participate and have my infant participate in this research study. A copy of this consent form will be given to me.

Maternal Subject Name	Maternal Subject Signature	Date/Time

Infant Subject Name

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-mentioned maternal participant and I have discussed the potential benefits and possible risks of study participation. Any questions about this information have been answered.

Investigator Name	Investigator Signature	Date/Time

G.3 ADDENDUM CONSENT

University of Pittsburgh

School of Nursing

ADDENDUM

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Study of Late Preterm Breastfeeding Establishment and Processes

PRINCIPAL INVESTIGATOR: Jill Radtke, BSN, RN
University of Pittsburgh School of Nursing
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CO-INVESTIGATORS:

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University of Pittsburgh
Telephone: 412-624-5345

Susan Albrecht, PhD, RN, FAAN
Professor and Associate Dean
University of Pittsburgh
Telephone: 412-624-2403

Mary Beth Happ, PhD, RN, FAAN
Professor
University of Pittsburgh
Telephone: 412-624-2070

Debra Bogen, MD
Associate Professor of Pediatrics and Psychiatry
University of Pittsburgh
Telephone: 412-692-6000

Sandra Founds, CNM, FNP, PhD
Assistant Professor
University of Pittsburgh
Telephone: 412-624-3822

Source of Support: Breastfeeding the Late Preterm Infant: A Grounded Theory Study, (NINR) National Institute of Nursing Research (1F31NR011562-01); Sigma Theta Tau International (Eta Chapter)

EXTENSION OF STUDY:

You were recently a participant in a research study to investigate breastfeeding establishment among moms of late preterm infants. Because we are seeing that breastfeeding is still changing for some of our participants after the study ends (about 6-8 weeks after giving birth), we are seeking your feedback on several additional questions. The questions are related to your breastfeeding experience *after* your study participation ended. These questions should take approximately 5-10 minutes to complete, and you may answer as few or as many questions as you wish. You may mail or email written responses, or if you

prefer, you may request a phone or in-person interview with the Principal Investigator to complete this portion of the study. There is no financial compensation for taking part in this additional study activity. The possible risks of participation include the following: 1) you may feel uncomfortable recalling difficult breastfeeding experiences. If you become uncomfortable, you may choose not to complete the questions; 2) it is possible, but unlikely, that a breach of confidentiality could occur (e.g., if you choose to email your answers, it is possible that it may be visible over the internet). Please note that any information generated from your participation will be kept confidential; all data will stored in a de-identified format as either a password-protected electronic file or a hard copy in a locked drawer within a locked room at the University of Pittsburgh. There are probably no direct benefits of participation, but your participation may help us understand more about breastfeeding issues with late preterm infants in order to improve breastfeeding support in the future.

RIGHT TO NON-PARTICIPATION

You may choose not to participate from this research study simply by not signing and returning this form. Your/your infant's medical care will be the same whether or not you participate in this study, and your decision will not affect your/your infant's relationship with the University of Pittsburgh, Magee Women's Hospital of UPMC, or the University of Pittsburgh Medical Center.

****

VOLUNTARY CONSENT

I understand all of the above information and all of my questions have been answered. I understand that any future questions I have about this research will be answered by the investigator(s) listed on the first page of this addendum to the consent document at the telephone number(s) listed. Any questions I have about my rights as a research subject will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to continue to participate in this research study.

_____ _____

Subject Signature **Date**

INVESTIGATOR'S CERTIFICATION

I certify that I have answered any questions and addressed any concerns about the information contained in this form to the individual above.

_____ _____

Investigator's Signature **Date**

APPENDIX H

PERMISSION TO REPRINT MANUSCRIPT #1

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jurisdiction of such court, waives any objection to venue in such court and consents to service of process by registered or certified mail, return receipt requested, at the last known address of such party.

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