

Reliability of the Preterm Infant Breastfeeding Behavior Scale (PIBBS)
for the Late Preterm Infant Population

by

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ABSTRACT

Late preterm infants (LPIs), born between 34 and 37 weeks gestation, are at risk for a myriad of health conditions related to neuro-muscular and physiologic immaturity. However, relative stability allow many of these infants to avoid care in specialty nurseries and discharge home with their mothers after birth. Due to underlying immaturity, feeding difficulty is the most common issue LPIs experience, resulting in early breastfeeding cessation, increased risk for secondary diagnoses, and hospital readmission. The purpose of this study was to assess early breastfeeding behavior of LPIs, including testing inter-rater reliability of an assessment tool and the feeding patterns of infants over time. An extensive review of breastfeeding assessment tools resulted in the selection of the Premature Infant Breastfeeding Behavior Scale (PIBBS) based on its reliability and validity in the preterm infant population. A convenience sample of LPI dyads was recruited and used to conduct inter-rater reliability testing of PIBBS. A longitudinal one-group non-experimental study was used for observational follow-up. A strong statistical agreement of PIBBS scores occurred between mothers and a healthcare professional (Cohen's kappa values of items ranged from .776 to 1.000, $p = <.001$). Participants continued using the PIBBS tool after hospital discharge until their infants expected due dates (40 weeks adjusted age). *T*-test analyses were conducted to examine changes in scores over time indicating increase in item scores ($p = .003 - .193$). PIBBS appears to be a valid and reliable tool to assess breastfeeding among LPI dyads. Incorporation of PIBBS into a comprehensive plan of care could better support and protect breastfeeding among the LPI population.

DEDICATION

This effort is dedicated to the thousands of mothers who have struggled to breastfeed their late preterm babies without the full understanding and support needed to navigate the nuances of subtle prematurity. Being a mother is notoriously difficult. Breastfeeding can add another layer to the complexities of motherhood. Additional issues of prematurity only make the complexities more profound. Breastfeeding mothers of late preterm infants are warriors of their own variety.

The participants of this study allowed me into their lives during a sacred and vulnerable time. They expressed feelings of uncertainty, fear, and worry as they learned to care for and breastfeed their late preterm babies. This work is dedicated specifically to the 23 women who allowed me space in their lives and agreed to help other families in the future through the outcomes this study may produce. I am deeply honored and grateful to have known them and have offered any amount of help and encouragement.

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TABLE OF CONTENTS

	Page
LIST OF TABLES.....	vii
LIST OF FIGURES.....	viii
CHAPTER	
1 INTRODUCTION.....	1
Background.....	2
The Problem.....	3
Significance.....	4
Conceptual Framework.....	6
Purpose.....	9
Research Questions.....	9
2 REVIEW OF LITERATURE.....	10
Issues of Maturation.....	10
LPI Feeding Guidelines.....	13
Breastfeeding Assessment Tools.....	14
Eliminated Tools.....	23
Tool Selection.....	26
Conclusions.....	31
3 METHODOLOGY.....	33
Design.....	33
Setting.....	33

CHAPTER	Page
Sample.....	34
Human Subjects Protection.....	34
Measures.....	35
Data Collection Procedures.....	36
Planned Analyses.....	39
4 DATA ANALYSIS AND RESULTS.....	42
Description of Sample.....	42
Inter-rater Reliability.....	45
Survey Items for Quality Improvement.....	51
5 DICUSSION.....	52
Sample Characteristics.....	53
PIBBS Usefulness.....	56
Implications.....	61
Limitations.....	62
Considerations.....	63
Conclusions.....	64
REFERENCES.....	65
APPENDIX	
A DEMOGRAPHIC DATA COLLECTION.....	80
B PRETERM INFANT BREASTFEEDING BEHAVIOR SCALE	83
C MATERNAL SELF-REPORT SURVEY.....	85

APPENDIX	Page
D RECRUITMENT LETTER.....	87
E CONSENT FORM.....	89
F HIPPA AUTHORIZATION FORM.....	93
G CONTACT INFORMATION FORM.....	96
H PARTICIPANT BOOKLET.....	98
I CONTACT SCRIPT.....	105

LIST OF TABLES

Table	Page
1. Interpretation of Cohen’s Kappa Statistic.....	40
2. Maternal Characteristics of the Sample	44
3. Infant Characteristics of the Sample	45
4. Inter-rater Timepoint 1	46
5. Inter-rater Timepoint 2	47
6. Feeding Activity During First Assessment	48
7. Feeding Method at the First At-home Score	49
8. Feeding Method at the Last At-home Score	49
9. Difference in PIBBS Scores from First At-Home Score to Last.....	50

LIST OF FIGURES

Figure	Page
1. Conceptual Framework for Optimizing Health for Near-Term Infants	74
2. Reimagined conceptual framework	75
3. Reimagined conceptual framework: Focused concepts for study	75
4. Participant contact algorithm	76
5. Feeding activity at first assessment	77
6. Feeding type at the first at-home timepoint	78
7. Feeding type at the last at-home timepoint (40 weeks adjusted age).....	7

CHAPTER 1

Introduction

Human milk is widely recognized as the optimal nutrition for infants and breastfeeding as the normative means of infant feeding (Chantry, Eglash, & Labbok, 2015; American Academy of Pediatrics [AAP], 2012). Human milk provides nutrients and immune protective agents for better acute and long-term health outcomes as compared to artificial human milk (AAP, 2012). As women navigate the process of breastfeeding challenges may arise such as learning the mechanics and rhythms of breastfeeding, milk production, avoidance or resolution of pain, and influencing social dynamics. The infant's level of participation, readiness, and maturation may either ease or complicate the experience.

Late preterm infants (LPIs), born between 34 weeks and completion of 36 weeks gestation, often lack the strength, coordination, and stamina necessary for effective breastfeeding, as compared to full term infants born after 37 weeks gestation (Dimitriou et al., 2010; Hallowell & Spatz, 2012; Kardatzke, Rose, & Engle, 2017). Due to biologic and physiologic immaturity, LPIs are at higher risk of morbidity and mortality when compared to full term infants (Hamilton, Martin, Osterman, & Curtin, 2015; Kardatzke et al., 2017). Risks such as jaundice, hypoglycemia, and slowed neurological development are potentially reduced or eliminated by the components of human milk (Hamilton et al., 2015; Kardatzke et al., 2017). Additionally, inherent developmental maturation challenges of LPIs may be improved with the muscle conditioning gained through the act of breastfeeding (Hamilton et al., 2015; Kardatzke et al., 2017). However, little is known about LPI breastfeeding effectiveness (actual transfer of milk from the breast) and

feeding development. LPIs compose a bridge population between full term and preterm sharing characteristics of each group: size and relative stability of term infants and neuromuscular and physiologic immaturity of preterm infants. As applied to breastfeeding, LPIs may show strong initial breastfeeding effort with a wide latch to the breast yet not create the force of oral vacuum necessary to transfer milk. Effectiveness of breastfeeding effort may vary considerably feeding-to-feeding and day-to-day. Therefore, a tool is needed to accurately assess breastfeeding effectiveness for this specific population. Breastfeeding assessment tools have been developed and validated for term and preterm populations in an effort to provide objective assessment of breastfeeding effectiveness. However, no tool has been tested specifically for the LPI population. The Preterm Infant Breastfeeding Behavior Scale (PIBBS) was developed and validated for preterm infants in the neonatal intensive care unit (NICU; Hedberg Nyqvist et al., 1999). Considering aspects for preterm infant feeding behavior and maturation, PIBBS may also be appropriate for use with the LPI population. The purpose of this study was to test reliability of the PIBBS tool for late preterm infants not receiving care in the NICU.

Background

Human milk is known to reduce acute and long-term health risks. During the immediate post-birth period, human milk provides all the nutrition and hydration required for physiologic stabilization (American Academy of Pediatrics [AAP], 2012). Due to issues of maturation, LPIs are at two to three times greater risk for hypoglycemia than full term infants (Horgan, 2015). Human milk stabilizes newborn blood sugar preventing hypoglycemia decreasing or eliminating the need for formula supplementation (Tozier, 2013). Similarly, hyperbilirubinemia (jaundice) is diagnosed in 25.2% of LPIs prior to

hospital discharge after birth (Dimitriou et al., 2010). Nine to eleven human milk feedings in the first 24 hours after birth can reduce the risk of jaundice below 1% (Yamauchi & Yamanouchi, 1990). Therefore, ensuring human milk intake by LPIs may significantly reduce the incidence of hypoglycemia and jaundice.

Due to the neuromuscular immaturity of LPIs, the risk of ineffective breastfeeding and milk transfer is significant (Dimitriou et al., 2010; Hallowell & Spatz, 2012; Kardatzke et al., 2017). Compromised oral muscular coordination and rapid loss of stamina creates a negative cycle of decreasing milk transfer at the breast. Feeding efforts are potentially misread with assumption that the LPI is adequately breastfeeding or the LPI is placed on a routine plan for supplementation without assessment of each feeding. Ideally, supplementation is provided with the mother's own expressed milk or donor human milk; however, if these are not available, formula is often given thereby increasing the health risks inherent with formula (Bartick and Reinhold, 2010). Accurate assessment of effective breastfeeding is essential to help ensure milk transfer is occurring on a feeding-by-feeding basis.

The Problem

Effective breastfeeding, the infant's independent ability to transfer full feeds of milk directly from the breast, may not consistently occur for weeks after birth (Lennon, 2011; Meier, Wright, & Engstrom, 2013; Radtke Demirci, Happ, Bogen, Albrecht, & Cohen, 2012). Hospital care guidelines recommend LPIs discharge no sooner than 48 hours after birth (Boies, Vaucher, & the Academy of Breastfeeding, 2016; Association of Women's Health, Obstetric and Neonatal Nurses [AWHONN], 2010; Lennon, 2011; Engle et al., 2007; National Perinatal Association [NPA], 2013). Therefore, it may be

assumed that LPIs leave the hospital not able to breastfeed effectively. Having a defined plan inclusive of a feeding assessment tool could help mothers' make feeding decisions and progress toward meeting their breastfeeding goals.

Currently no tool has been specifically tested to assess breastfeeding effectiveness with late preterm infants outside of specialty care nurseries. Breastfeeding assessment tools have either been tested for the full term population or preterm population receiving care inside a NICU. The Preterm Breastfeeding Behavior Scale (PIBBS) provides assessment of preterm breastfeeding maturation and effectiveness (Hedberg Nyqvist, Sjödnén, & Ewald, 1999). However, PIBBS has been validated only for preterm infants, all infants less than 37 weeks gestation, receiving care within the NICU. LPIs demonstrate characteristics of the general preterm population yet are often cared for as term infants. Therefore, testing the appropriateness of this tool for the late preterm population may provide health professionals and mothers a means for feeding-by-feeding assessment and evolving feeding plan.

Significance

Approximately 10% of all births in the United States (U.S.) are preterm with delivery prior to 37 weeks gestation (Hamilton et al., 2015). Of the general preterm population, 71.3% are infants born during the late preterm period (Hamilton et al., 2015). The U.S. has the highest number of late preterm birth compared to other high-income countries (Delnord & Zeitlin, 2018). Although about half of preterm deliveries are due to unknown causes, clinical risk factors include; previous preterm or early term (birth at 37 or 38 weeks gestation) delivery, multiple fetal pregnancy, infection, inflammation, hypertension, vascular disease or disorder, diabetes, shorten cervix, and placental

complication (Delnord & Zeitlin, 2018). As results from perinatal science have led to a decrease in the number of early preterm deliveries, birth during the late preterm period has increased, resulting in LPIs currently being the fastest growing preterm cohort (Hamilton et al., 2015).

Infants born four to six weeks early face a myriad of physiological risks. Before discharge from the birth hospitalization, 30.1% of LPIs receive a medical diagnosis secondary to prematurity (Dimitriou et al., 2010; Kardatzke et al., 2017). LPIs are four times more likely to be diagnosed with one medical condition and 3.5 times more likely to receive two diagnoses than their full term counterparts (Dimitriou et al., 2010; Kardatzke et al., 2017). This increased risk for morbidity is potentiated by their gestational age: 59.7% at 34 weeks, 38.2% at 35 weeks, and 16.8% at 36 weeks (Dimitriou et al., 2010). Despite health risks, the majority of LPIs (64.3%) are stable enough to remain with their mothers in postpartum units after birth discharging home together (Boyle et al., 2015). Yet, hospital readmission rates range from 3.6% to 8.9% for LPIs compared to 2.0% to 3.7% for term infants (Moyer et al., 2014; Slimming, Einarsdottir, Srinivasjois, & Leonard, 2014; Tomashek et al., 2006).

LPIs are at risk for feeding difficulty and early breastfeeding cessation (Horgan, 2015; Shannon et al., 2007). Feeding difficulties were found in 60.7% of 35 week LPIs ($n = 183$) and 50.0% of 36 week LPIs ($n = 156$) (Hellmeyer et al., 2012). Longer gestational age provides further neuromuscular development in utero; thus, the rate of feeding difficulties dropped dramatically to 29.1% for infants born at 37 weeks ($n = 189$) demonstrating the maturational significance of each gestational week (Hellmeyer et al., 2012). In a study comparing feeding patterns of early preterm (25 to 34 weeks gestation)

($n = 319$) to LPIs ($n = 571$), LPIs demonstrated similar feeding dysfunction as did the early preterm cohort (DeMauro, Patel, Medoff-Cooper, Posencheg, & Abbasi, 2011). The parents of the LPI cohort reported similar oral motor dysfunction and feeding avoidance behavior to the early preterm cohort (DeMauro et al., 2011). Feeding dysfunction improved over time for both cohorts and was not strongly correlated with readmission or subspecialty visits (DeMauro et al., 2011). Yet, LPIs ($n = 1,860$) had less than half the odds of being exclusively breastfed at one week of age when compared to term infants (AOR 0.38 [95% CI 0.23-.065]) (Goyal, Attanasio, & Kozhimannil, 2014). As LPI feeding effectiveness may oscillate between feedings due to instability of coordination and stamina, mothers and health care professionals may benefit from an organized method of feeding assessment.

Conceptual Framework

The Association of Women's Health, Obstetrics, and Neonatal Nursing (AWHONN) developed a conceptual framework to guide the general care of late preterm infants (Medoff-Cooper, Bakewell-Sachs, Buus-Frank, & Santa-Donato, 2005). The conceptual model placed the general LPI healthy outcome at the center of four contributing concepts: physiologic functional status, family role, care environment, and nursing care practices (Figure 1; Medoff-Cooper et al., 2005). The healthy outcome was defined as the medical stability required for hospital discharge with efforts made to minimize the risk of readmission (Medoff-Cooper et al., 2005). Physiologic functional status was defined as the physiologic and functional state of the neonate as influenced by gestational age, prenatal health and history, method of delivery, and quality of care (Medoff-Cooper et al., 2005). The family role was defined as the extent to which the

LPI's family is involved in the infant's care (Medoff-Cooper et al., 2005). The care environment was defined as the geographic location of care and the social, cultural, political, and economic context influencing the care to the LPI (Medoff-Cooper et al., 2005). Nursing care practices were defined as the nature and quality of LPI care by a registered or advanced practice nurse (Medoff-Cooper et al., 2005). The model considered the general care of LPIs as one aimed toward "health promotion, health maintenance, and health restoration" (Medoff-Cooper et al., 2005).

A reconceptualized model is offered here with a breastfeeding focus (Figure 2). The concepts of nursing care and the care environment remain the same as the AWHONN model. In the conceptual framework for exclusive breastfeeding of the LPI, the operational definitions of all other concepts are redefined.

Physiological functioning provides a starting point for nursing care, feeding evaluation, and development of a feeding plan. Maturation variation occurs with each week of gestational growth compounded by variation among individual neonates; therefore, feeding readiness and physiologic stability provide the starting concept.

The family role is clarified in this model to refer to only the breastfeeding mother. The breastfeeding mother is the only person with the infant for every feeding at the breast and one to assess the effectiveness of each feeding. Therefore, this concept is renamed "maternal care."

A healthy outcome is redefined as the achievement and maintenance of exclusive breastfeeding. Due to physiologic immaturity, the LPI is often not prepared to accomplish effective breastfeeding consistently, resulting in an unpredictable process vacillating between effective and ineffective breastfeeding effort. Therefore, the ultimate marker of a

healthy outcome, as it relates to feeding effort, is the achievement of sustained exclusive breastfeeding.

The redefined model diagram is a quasi-linear progression (Figure 2). The concepts within the conceptual framework flow from left to right starting with the physiological functioning of the LPI moving into overlapping concepts of nursing care practices, maternal care, and the care environment. Each of these has overlapping influence over the other. The level, quality, and quantity of nursing care influences maternal perception and expectations regarding the care for her LPI. Maternal motivation and the sense of priority given to engagement of the breastfeeding plan may be affected by the degree to which the nurse is quick or slow to educate the mother about the LPI feeding process. Nursing care practices and the care environment are reciprocally influential. The nursing care practices can guide the development of hospital policy and procedure and vice versa. Similarly, the quality of nursing care has the potential of continuing established culture or evolving the care culture to reflect current research standards. The mother influences nursing care practices through her receptiveness or resistance. The nature of the care environment, albeit supportive of breastfeeding or dependent on formula, influences both the nursing care and the maternal/family role. Braiding together nursing care, maternal care, and the care environment forms a potential path toward exclusive breastfeeding as a healthy outcome.

This study focused on the intersection of nursing care practices and maternal care where initiation and support of breastfeeding exists (Figure 3). Appropriate LPI feeding support depends on the how quickly, accurately, and consistently education is provided by nurses. Concurrently, effective feeding will hinge on on how ready and receptive the

mother is to accept the education and engaging in a feeding plan. A breastfeeding assessment tool may help both nurses and mothers better understand LPI feeding behavior and guide feeding decisions.

Purpose

The purpose of this study was to assess early breastfeeding behavior of late preterm infants using the Preterm Infant Breastfeeding Behavioral Scale (PIBBS).

Research Questions

The research questions for this study were:

1. What is the inter-rater reliability of PIBBS assessment scores of LPIs between mothers and a health professional?
2. How are the actual feeding patterns of LPIs reflected in their PIBBS scores?
3. How do PIBBS scores at the first at-home timepoint compare to those at the last at-home timepoint (40 weeks adjusted age)?

CHAPTER 2

Review of Literature

A review of literature was conducted to discover the issues of late preterm maturation related to feeding, what is known about breastfeeding in the LPI population, and an evaluation of established breastfeeding assessment tools. Electronic databases including CINAHL, ERIC, JSTOR, PubMed (Medline), PsycInfo, and Web of Science were searched to retrieve English language studies published between 2007 and 2017 and seminal articles. The indexed subject headings searched: *Breastfeeding, late preterm, near term, and breastfeeding/feeding assessment tools.*

Issues of Maturation

The multifaceted aspects of neurophysiological immaturity of LPIs manifest commonly as feeding difficulties, respiratory disorders, thermoregulation, hypoglycemia, and hyperbilirubinemia (Hellmeyer et al., 2012; Kalyoncu, Aygun, Cetinoglu, & Kucukoduk, 2010; Raju, Higgins, Stark, & Leveno, 2006). The following is an exploration of late preterm maturation as described in the academic literature.

Neurology. Late gestation is a critical period of brain growth and development; nearly 50% of cortical growth occurs between 34 and 40 weeks gestation with a 5-fold increase in white brain matter during this period (Horgan, 2015; Hallowell & Spatz, 2012). An immature nervous system leads to poor state regulation resulting in rapid fluctuations between overstimulation and sleep cycles (Horgan, 2015; Shannon, O'Donnell, & Skinner, 2007). These fluctuations interrupt feeding effort and disallow for sustained feeding behavior (Horgan, 2015; Hallowell & Spatz, 2012).

Hypoglycemia. LPIs are at two to three times greater risk for hypoglycemia than full term infants (Horgan, 2015). Nearly 9% of LPIs are diagnosed with hypoglycemia prior to birth discharge (Dimitriou et al., 2010). Hellmeyer et al. (2012) found hypoglycemia in 50.8% of 35 week LPIs ($n = 183$) and 59.6% of 36 week LPIs ($n = 156$). Interwoven elements contribute to hypoglycemia including feeding difficulty, poor intake, hepatic glycogenolysis, adipose lipolysis, ketogenesis, hormonal regulation and gastrointestinal immaturity (Engle et al, 2007; Horgan, 2015). Hospital interventions often include recurrent formula supplementation in addition to efforts at breastfeeding and/or human milk feeding.

Hyperbilirubinemia. Jaundice in LPIs is often more severe and prolonged than for term infants (Engle et al., 2007; Horgan, 2015). Hyperbilirubinemia was diagnosed in 25.2% of LPIs ($N = 548$) prior to birth discharge (Dimitriou et al., 2010). The incidence of hyperbilirubinemia is dependent on gestational age. Jaundice is diagnosed in 41.0% of 35 week LPIs ($n = 183$) and 26.3% of 36 week LPIs ($n = 156$) (Hellmeyer et al., 2012). Hepatic immaturity, feeding difficulties, decreased intake, and slow gastrointestinal motility are contributors (Horgan, 2015). LPIs were found to be two times more likely to have significantly elevated bilirubin levels at five and seven days after birth than term infants (Engle et al., 2007). Bilirubin is excreted via urine and stool; therefore, ensuring effective breastfeeding is crucial (NPA, 2013). Increased risks of feeding difficulty in the LPI population, may result in repeated supplementation as an immediate intervention, yet doing so contributes to difficulty or inability to establish breastfeeding.

Respiratory and thermoregulation. Respiratory distress has been found in 25.4% of LPIs ($N = 548$) (Dimitriou et al., 2010). LPIs are less able to clear amniotic

fluid after birth resulting in increased risks for respiratory distress, tachypnea, apnea, and mechanical ventilation than full term infants (Engle, Tomashek, & Wallman, 2007; Escobar, Clark, & Greene, 2006; Horgan, 2015; Kalyoncu et al., 2010). Breathing is more vital for infant survival than is eating; therefore, any respiratory distress interferes with feeding effort and effective transfer of milk at breast.

Six percent of LPIs ($N = 548$) were diagnosed with hypothermia prior to birth discharge (Dimitriou et al., 2010). Hellmeyer et al. (2012) found hypothermia in 41.5% of 35 week LPIs ($n = 183$) and 48.1% of 36 week LPIs ($n = 156$). Hospital intervention for hypothermia ranges from skin to skin contact between mother and infant to separation of the dyad while the infant is transferred to a nursery to spend time under a radiant warmer. Often hypothermia is considered a symptom of hypoglycemia and supplementation is provided as a treatment (Engle, Tomashek, & Wallman, 2).

Feeding maturation. Little is known about the breastfeeding process and development of LPIs. Suck and swallow studies to determine the adequacy of oral function have been done via bottle-feeding only. Rhythmic compression bursts are present at 34 weeks, as evidenced by pressure monitoring studies (Lau, Alagurusamy, Schanler, Smith, & Shulman, 2000), and oral suction develops between 36 and 38 weeks gestation; however, these oral motor activities are not yet coordinated (Lau et al., 2000). The physiological immaturity of LPIs puts them at risk for breastfeeding challenges (Hellmeyer et al, 2012; Kalyoncu, Aygun, Cetinoglu, & Kucukoduk, 2010; Raju, Higgins, Stark, & Leveno, 2006). Treatment of physiologic complications often involves feeding practices and/or separation of infant from mother that will further compromise the establishment of effective breastfeeding. Variables of feeding difficulty are clinically

useful to identify and explain the feeding challenges of LPIs. An orchestra of neurologic and muscular actions must harmonize for an infant to produce effective breastfeeding actions and behaviors. An evaluation of bottle-fed preterm infants ($n = 48$), revealed that any degree of prematurity resulted in shorter sucking bursts, longer resting pauses, and decreased coordination resulting in decreased milk transfer (Lau et al., 2000).

The intersection of breastfeeding and late preterm maturation has not been fully investigated. LPI feeding development has been predominantly studied with only bottle-fed infants (Adamkin, 2006; Lau, et al. 2000). Researchers exploring feeding difficulty have not clearly defined “difficulty” or identified the method of difficulty evaluation (DeMauro, Patel, Medoff-Cooper, Posencheg, & Abbasi, 2011; Medoff-Cooper, 2012; Radtke Demirci, Happ, Bogen, Albrecht, & Cohen, 2012). More research is needed to discover the breastfeeding challenges and maturational development of LPIs.

LPI Feeding Guidelines

Clinical care guidelines have been developed to improve breastfeeding and health outcomes (Boies, Vaucher, & the Academy of Breastfeeding, 2016; AWHONN, 2010; Lennon, 2011; Shannon, O’Donnell, & Skinner, 2007; Meier, Furman, & Degenhardt, 2007; Meier, Wright, & Engstrom, 2013; Engle et al., 2007; NPA, 2013; Walker 2008; Wright, 2003). The guidelines of the Academy of Breastfeeding Medicine (ABM), the National Perinatal Association (NPA), and Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) provide comprehensive feeding guidelines.

Care guidelines during the birth hospitalization include extended skin-to-skin contact and rooming in with mom when appropriate to encourage frequent breastfeeding (AWHONN, 2010; Boies et al., 2016). Specific feeding guideline range from

breastfeeding ad libitum (Boies et al., 2016) to feeding at three-hour intervals, supplemental feedings when appropriate (e.g., hypoglycemia, excessive weight loss), and maternal use of a breast pump if supplementation is required (AWHONN, 2010; Boies et al., 2016; NPA, 2013). To assess effectiveness of feeding, the ABM suggest the use of a valid and reliable instrument (Boies et al., 2016).

Breastfeeding Assessment Tools

A review of the general breastfeeding literature was conducted for all established breastfeeding assessment tools. Due to the dynamic nature of breastfeeding and the wide range of variation among women and infants, multiple tools have been developed. Thirteen tools were discovered. When determining the appropriate tool for use with the LPI population, six tools met the purpose of this study and were considered. Seven tools were not aligned with the purpose of the study and, although discussed below, were eliminated from consideration. The instruments are discussed in chronologic order of publication, as each was developed and refined progressively.

Infant Breastfeeding Assessment Tool. The Infant Breastfeeding Assessment Tool (IBFAT), designed for use by both mothers and health caregivers to (a) assess infant readiness to breastfeed, (b) infant rooting, (c) latching, (d) sucking, and (e) maternal satisfaction with the feeding (Matthews, 1988; Matthews, 1993). Infant readiness to breastfeed is assessed as spontaneous feeding effort (score of three), need for mild stimulation (score of two), need for vigorous stimulation (score of one), and inability to rouse infant (score of zero; Matthews, 1988). The author did not provide definitions of mild and vigorous stimulation. Infant rooting is assessed as spontaneous and immediate infant mouth opening with stimulation (score of three), rooting after prompting (score of

two), depressed rooting with stimulation (score of one), and no rooting regardless of stimulation (score of zero; Matthews, 1988). Latching is scored as spontaneous and immediate (score of three), latching after three to ten minutes of stimulation (score of two), latching after ten minutes of stimulation (score of one), no latch achieved (score of zero; Matthews, 1988). Infant sucking is assessed as “sucked well” (score of three), “sucked fairly well” with intermittent burst requiring stimulation (score of two), “sucked poorly” short sucking burst and/or weak suck (score of one), and no observable infant sucking (score of zero; Matthews, 1988). Maternal satisfactions with the feeding is scored as “very please” (score of three), “pleased” (score of two), “fairly pleased” (score of one), “not pleased” (score of zero; Matthews, 1993). Original instrument testing was with full term health infants only ($N = 60$). Inter-rater reliability between mothers and observers demonstrated 91% agreement (Matthews, 1988).

Riordan and Koehn (1997) tested IBFAT for reliability and validity ($N = 13$). Using Spearman correlation coefficients, estimates of inter-rater agreement ranged from 0.27 to 0.69 (Riordan & Koehn, 1997). Although indicating some agreement between raters, scores fell below the 0.80 cut off to indicate stability (Polit & Beck, 2012, pp. 331-333). However, Altuntas et al. (2014) also tested reliability and validity ($N = 46$) with different findings. Spearman correlation coefficients for summary IBFAT scores of inter-rater agreement were 0.90 to 0.95 demonstrating stability of the instrument (Altuntas et al., 2014).

Schlomer et al. (1999) tested the IBFAT tool for predicting maternal satisfaction and breastfeeding problems ($n = 15$). A positive correlation was found between IBFAT scores and maternal satisfaction at both 12 hours and one week postpartum and found

negative correlations between IBFAT scores and breastfeeding problems at the same time intervals ($r = -0.083, p = 0.769$; $r = -0.489, p = 0.064$; Schlomer et al., 1999).

Furman and Minich (2006) validated IBFAT for use with very low birth weight infants (birth weight of 1.5 kilograms or less) at 35 weeks corrected age ($N = 119$). Prefeed and postfeed weights were taken to correlate IBFAT scores to actual milk intake volumes (Furman & Minich, 2006). IBFAT scores were significantly correlated with human milk intake ($r = 0.651, p = .001$) and duration of feeding ($r = 0.559, p = .001$; Furman & Minich, 2006). Authors found IBFAT sucking scores were correlated with percent of time with sucking bursts ($r = 0.632, p = .001$; Furman & Minich, 2006). Multiparity or previous breastfeeding experience was not found to influence IBFAT scores (Furman & Minich, 2006).

Mother-Baby Assessment. The Mother-Baby Assessment (MBA) tool is meant to direct the education given by health professionals and resulting documentation (Mulford, 1992). MBA evaluates five components of the breastfeeding process with each component having a maternal and infant aspect: (a) signaling, (b) positioning, (c) fixing/latching, (d) milk transfer, and (e) ending (Mulford, 1992). Signaling describes the first steps to indicate a feeding will occur (Mulford, 1992). The maternal aspect of signaling includes picking the baby up, waking the baby, and responding to the infant's cues (Mulford, 1992). The infant aspect of signaling includes movement, rooting, and crying (Mulford, 1992). Positioning describes the alignment of the mother's and infant's bodies to allow for breastfeeding (Mulford, 1992). Maternal positioning includes sitting or reclining, the use of pillows, and how she holds the infant (Mulford, 1992). Infant positioning includes the movements of head, neck, and oral cavity to prepare for contact

with the breast (Mulford, 1992). Fixing occurs when the infant latches to the breast (Mulford, 1992). The mother's fixing involves holding the breast, expressing milk, and breast compression once the baby latches on (Mulford, 1992). Infant fixing involves the latch and initiation of suck bursts with pausing phases (Mulford, 1992). Milk transfer describes the act of breastfeeding when the infant receives milk after maternal milk release (Mulford, 1992). The maternal aspect of milk transfer includes the effective ejection of milk from the breast as indicated by a sense of thirst, uterine cramping, breast softening, and drowsiness (Mulford, 1992). Infant indications of milk transfer include audible swallowing, visual nutritive suck pattern, relaxation of extremities, and drifting to sleep (Mulford, 1992). Finally, ending indicates the conclusion of the feeding (Mulford, 1992). Maternal aspects of ending include softened breasts and an absence of nipple tenderness (Mulford, 1992). Infant indications of feeding end are spontaneous detachment from the breast and readiness for age-appropriate activity such as sleep or play (Mulford, 1992).

Scoring of the MBA is done using a simple grid. For each of the five components, the observer marks a plus sign (+) if the behavior is present, a zero (0) if it is not, and a check mark if help was provided (Mulford, 1992). Each plus sign is given one point for a possible total of ten; five possible points for mother and five possible points for infant (Mulford, 1992). A score of three or lower indicates either mother or infant was not ready for the feeding although the other may have been (Mulford, 1992). A score of four and five indicates skill building but not effective breastfeeding (Mulford, 1992). A score of six to eight may indicate possible milk transfer (Mulford, 1992). A score of nine to ten indicates breastfeeding effectiveness with minimal to no help (Mulford, 1992).

Riordan and Koehn (1997) tested the MBA for reliability and validity ($N = 13$). Using Spearman correlation coefficients, estimates of inter-rater agreement ranged from 0.33 to 0.66 (Riordan & Koehn, 1997). Although indicating some agreement between raters, scores fall below the 0.80 cut off to indicate stability (Polit & Beck, 2012). However, Altuntas et al. (2014) also tested reliability and validity ($N = 46$) with different findings. Spearman correlation coefficients for summary MBA scores of inter-rater agreement were 0.81 to 0.88 demonstrating stability of the instrument (Altuntas et al., 2014).

LATCH. The LATCH assessment tool provides a systematic and standardized method for nursing documentation to guide consistent breastfeeding evaluation and education (Jensen, Wallace, & Kelsay, 1994). Each letter in the LATCH acronym represents an individual component to be evaluated (Jensen et al., 1994): “L” notes how well the baby latches to the breast, “A” notes the absence or presence of audible swallowing, “T” notes the mother’s nipple type (e.g. flat, inverted), “C” notes the mother’s breast and nipple comfort per maternal report, and “H” notes the level assistance the mother requires in holding or positioning her baby at the breast. The caregiver observes a dyad breastfeeding and scores each component (Jensen et al., 1994). Five key breastfeeding components are assigned a numerical score (0, 1, 2) for a total possible score of 10. Each score is added together for an overall score that breastfeeding session. A score of 9 or 10 indicates the dyad requires minimal to no assistance. Conversely, scores of 0 or 1 indicate the need for full assistance and education. Low scores in each area will provide focus for the caregiver’s intervention.

LATCH reliability and validity was tested ($N = 13$) by Riordan and Koehn (1997). Using Spearman correlation coefficients, estimates of inter-rater reliability ranged from 0.11 to 0.46 (Riordan & Koehn, 1997). Although some agreement is indicated between rater, scores are well below 0.80 to indicate stable reliability (Polit & Beck, 2012).

Schlomer, Kemmerer, and Twiss (1999) found a positive correlation between LATCH scores and maternal satisfaction ($n = 15$). Additionally, LATCH scores were negatively correlated with breastfeeding problems at both 12 hours and one week postpartum (Schlomer et al., 1999).

Riordan, Bibb, Miller, and Rawlins (2001) examined reliability and validity of the LATCH tool as a predictive tool for breastfeeding duration. Full term, healthy infants ($N = 127$) were observed breastfeeding by lactation consultant at 24 to 72 hours after birth and followed up at eight weeks of age (Riordan et al., 2001). Women with high LATCH scores after birth (9.3 ± 0.9) were correlated with continued breastfeeding at six weeks ($p < .05$; Riordan et al., 2001). Construct validity was determined using Spearman correlations (Riordan et al., 2001). Total LATCH scores were positively correlated with breastfeeding duration at six weeks ($n = 128$, $r = .26$, $p = .003$; Riordan et al., 2001). A cutoff score of seven rendered the highest sensitivity (97.7%) with a very low specificity (26.3%) when measured at 16 to 24 hours after birth (Kumar, Mooney, Wieser, & Havstad, 2006). However, the authors found with a LATCH score of nine at 16 to 24 hours after birth mothers were 1.7 times more likely to be breastfeeding at six weeks (Kumar et al., 2006).

Altuntas et al. (2014) also tested reliability and validity ($N = 46$). Spearman correlation coefficients for summary LATCH scores of inter-rater agreement were 0.85 to 0.91 demonstrating stability of the instrument (Altuntas et al., 2014).

Lau, Htun, Lim, Ho-Lim, and Klainin-Yobas (2016) tested the full five-item LATCH tool against a four-item version ($n = 907$). The four-item version removed maternal report of comfort (“C”) due to the relative subjective nature of the item (Lau et al., 2016). The Cronbach’s alpha for the five-item tool was 0.70 and for the four-item tool 0.74 (Lau et al., 2016). Among vaginally delivered women ($n = 669$) the five- and four-item tools demonstrated acceptable sensitivities (94% and 95% respectively), low specificity (0% and 2%), low positive predictive values (25% each), and negative predictive values (20% and 47%; Lau et al., 2016). Among women delivered via cesarean section ($n = 238$) the five- and four-item LATCH tools rendered satisfactory sensitivity (93% and 98% respectively), low specificity (4% and 9%), low positive predictability (41%), and negative predictability (65% and 75%; Lau et al., 2016). This analysis indicated the four-item tool to a more reliable and valid tool as compared to the five-item LATCH instrument (Lau et al., 2016).

Premature Infant Breastfeeding Behavior Scale. The Premature Infant Breastfeeding Behavior Scale (PIBBS) was developed and validated for the assessment of breastfeeding maturation among infants born at 35 weeks gestation or less (Hedberg Nyqvist et al., 1999). Six components are assessed by PIBBS: (a) rooting, (b) areola grasp, (c) latching and maintaining latch, (d) sucking, (e) longest sucking burst, and (f) swallowing (Hedberg Nyqvist et al., 1999). Rooting is scored zero to two: (0) did not root, (1) showed some rooting behavior, and (2) showed obvious rooting behavior

(Hedberg Nyqvist et al., 1999). Areola grasp is scored zero to three: (0) none, (1) the mouth only touched the nipple; (2) the whole nipple, not the areola; (3) the nipple and some of the areola (Hedberg Nyqvist et al., 1999). Latching and maintaining latch is scored zero to three: (0) did not latch at all, (1) latched for five minutes or less, (2) latched for six to ten minutes, (3) latched for 11 to 15 minutes (Hedberg Nyqvist et al., 1999). Sucking is scored zero to four: (0) no sucking or licking; (1) licking but no sucking; (2) single sucks, occasional short bursts (two to nine sucks); (3) repeated short bursts, occasional long burst (ten sucks or more); (4) repeated long burst (more than two bursts; Hedberg Nyqvist et al., 1999). The longest sucking burst for the feeding session is scored from one to six: (1) one to five consecutive sucks, (2) six to ten consecutive sucks, (3) 11-15 consecutive sucks, (4) 16-20 consecutive sucks, (5) 21-25 consecutive sucks, (6) 26 or more consecutive sucks (Hedberg Nyqvist et al., 1999). Swallowing is scored zero to two: (0) swallowing was not noticed, (1) occasional swallowing was noticed, (2) repeated swallowing was noticed (Hedberg Nyqvist et al., 1999). Nutritive sucking (transfer of milk) was considered to have occurred with a pre- and post-feeding weight increase of five grams or more (Hedberg Nyqvist et al., 1999).

Mothers and trained observers performed PIBBS assessment to test for inter-rater reliability (Hedberg Nyqvist et al., 1999). A sample of 4,321 feedings was assessed using the PIBBS tool with infants ranging from 26 to 35 weeks gestation (Hedberg Nyqvist et al., 1999). Observers assessed 348 feedings from the same infant sample (Hedberg Nyqvist et al., 1999). Inter-rater results between mothers and observers were 89-97% (kappa value range of 0.77 to .94; Hedberg Nyqvist et al., 1999). Inter-rater results

between two observers were 83-90% (kappa value range of 0.68-0.84; Hedberg Nyqvist et al., 1999).

Mother-Infant Breastfeeding Progress Tool. The Mother-Infant Breastfeeding Progress Tool (MIBPT) evaluates the mechanics of breastfeeding (e.g. position and latch) while incorporating key maternal and infant behaviors (Johnson, Mulder, & Strube, 2007). The tool involves eight items: (a) maternal response to infant cues, (b) maternal breastfeeding attempt at least every three hours (c) infant latch with wide oral gape, (d) infant nutritive sucking pattern, (e) maternal ability to independently position infant at breast, (f) maternal ability to independently latch baby, (g) no nipple trauma, and (h) mother without negative comments regarding feeding (Johnson et al., 2007). Tool testing included late preterm infants as a cohort often cared for by their mothers in the postpartum units and discharged home with their mothers (Johnson et al., 2007).

Inter-rater agreement ($n = 62$) for MIBPT ranged from 79.0% to 95.1% (Johnson et al., 2007). Rater assessment of maternal responsiveness to feeding cues, feeding timing, and nutritive sucking patterns demonstrated over 90% inter-rater agreement (Johnson et al., 2007). Assessment of independent maternal positioning and latching demonstrated more than 80% inter-rater agreement (Johnson et al., 2007). The presence of maternal nipple trauma produced 79% inter-rater agreement (Johnson et al., 2007).

Bristol Breastfeeding Assessment Tool. The Bristol Breastfeeding Assessment Tool (BBAT) was created by combining elements of the LATCH and IBFAT tools to create an instrument sensitive enough to determine changes in breastfeeding at different time points and before and after procedures such as frenectomy (Ingram, Johnson, Copeland, Churchill, & Taylor, 2015). The tool originally consisted of five components:

(a) positioning, (b) attachment, (c) sucking, (d) swallowing, and (e) comfort (Ingram et al., 2015). Positioning is measured by observing the infant side-lying against the mother's body, lined up with nose at mother's nipple, and maternal confidence with infant handling (Ingram et al., 2015). Attachment is observed as spontaneous infant rooting, quick latch with wide oral gape, and infant ability to maintain the latch (Ingram et al., 2015). Sucking is observed as an effective suck pattern of faster and slower suck bursts with resting pauses (Ingram et al., 2015). Swallowing is determined by audible swallowing with visual smooth jaw movement (Ingram et al., 2015). Finally, comfort is measured by maternal report of breast and nipple comfort and a visual assessment for skin trauma (Ingram et al., 2015). Each component has a possible score of two with a total summary score of ten (Ingram et al., 2015).

The tool was tested with 206 feedings at the breast from 48 mother-infant dyads (Ingram et al., 2015). Internal consistency for the original five-item instrument rendered a Cronbach's alpha score of 0.558 (Ingram et al., 2015). The authors then removed the fifth item, comfort, for the final four-item tool with a Cronbach's alpha of .668 (Ingram et al., 2015). When testing the tool at two time intervals, five days and eight weeks after birth, BBAT demonstrated a *p* Value (via Mann Whitney test) of 0.02 indicating strong sensitivity of the instrument (Ingram et al., 2015).

Eliminated Tools

Seven breastfeeding and feeding assessments were eliminated from consideration for this study due to a lack of reliability and/or validity testing or emphasized placed only maternal factors. Below is a review of the tools with rationale for elimination.

Potential Early Breastfeeding Problem Tool. The Potential Early Breastfeeding Problem Tool (PEBPT) was designed to identify prenatal and perinatal risk factors for compromised breastfeeding outcomes (Kearney, Cronenwett, & Barrett, 1990). PEBPT assesses for variables such as maternal depression, breast infection, and maternal tiredness as potential factors in breastfeeding cessation (Kearney et al., 1990). Additionally, PEBPT allows for bottle supplementation beginning at two weeks without considering doing so as a contributing factor of breastfeeding cessation (Kearney et al., 1990). As these factors are not aligned with the aims of this study, PEBPT been eliminated from further consideration.

Systematic Assessment of the Infant at Breast. The Systematic Assessment of the Infant at Breast (SAIB) evaluates four elements: (a) alignment, (b) areolar grasp, (c) areola compression, and (d) audible swallowing (Shrago & Bocar, 1990). Although SAIB provides comprehensive guidance for evaluation and teaching of effective breastfeeding, it does not provide a scoring system and has not been tested for reliability. Therefore, SAIB has been eliminated from further consideration for this study.

Neonatal Oral-Motor Assessment Scale. The Neonatal Oral-Motor Assessment Scale (NOMAS) was designed to provide a detailed evaluation of infant suck pattern through jaw and tongue movement evaluation (Palmer, Crawley, & Blanco, 1993). NOMAS provides questions used to measure 13 characteristics of jaw movement and 13 characteristics of tongue movement (Palmer et al., 1993). The observer rated each characteristic as normal, disorganized, or dysfunctional (Palmer et al., 1993).

Palmer et al. (1993) determined inter-rater reliability ($N = 35$) as 80% for 17 of the 26 items; however, the NOMAS tool was eliminated for this study as it evaluates oral-motor function while bottle-feeding only.

Breastfeeding Evaluation and Education Tool. The Breastfeeding Evaluation and Education Tool (BEET) was designed as a one-page handout for parent reference and to guide care givers in the development of a prenatal breastfeeding class (Tobin, 1996). BEET does not provide a scoring system, therefore, has not been tested for reliability. Consequently, BEET has been eliminated as an option for this research.

Lactation Assessment Tool. The Lactation Assessment Tool (LAT) was designed as an instrument to prevent and correct the cause of sore nipples (Blair, Cadwell, Turner-Maffei, & Brimdyr, 2003). LAT emphasizes position, latch, and nipple trauma (Blair et al., 2003). Since it cannot be said that every LPI mother experiences sore nipples or that sore nipples are the root cause of LPI feeding issues, LAT was eliminated from further consideration for this study.

Early Feeding Skills. The Early Feeding Skills assessment tool (EFS) is a 36 item observational tool to determine infant feeding readiness and oral skill maturation (Thoyre, Shaker, & Pridham, 2005). Oral feeding readiness is measured by the infant's ability to align the body and demonstrate feeding cues (Thoyre et al., 2005). Oral feeding skill is measured by four main components: (a) ability to remain engaged in the feeding, (b) organization of oral-motor functioning, (c) coordination of swallowing and breathing, and (d) maintenance of physiological stability (Thoyre et al., 2005). Feeding recover is measured by state of alertness and oxygen saturation (Thoyre et al., 2005). Although the

variables of this tool are appropriate for the LPI population, the tool is based completely on bottle-feeding and has, therefore, been eliminated as an option for this study.

Breastfeeding Assessment Score. The Breastfeeding Assessment Score (BAS) identifies maternal risk factors leading to early breastfeeding cessation (Raskovalova et al., 2015). Five variables are measured: (a) maternal age, (b) previous breastfeeding experience, (c) latching difficulty, (d) breastfeeding intervals, and (e) number of bottles used in the hospital (Raskovalova et al., 2015). These variables are not in line with the aims of this study; therefore, BAS was not considered for this study.

Tool Selection

Following an evaluation of breastfeeding assessment tools in the literature, PIBBS was determined to fit the purpose of this study best, as the PIBBS scale takes into consideration issues of feeding immaturity (Hedberg Nyqvist et al., 1999). Specific indications of length of sucking bursts and evidence of milk transfer are as relevant measures for the LPI population as for younger preterm populations. Hedberg Nyqvist et al. (1999) additionally tested reliability between observers and mothers. Anticipating continued feeding complications beyond the hospital stay, a tool designed for maternal use may provide guidance through the breastfeeding development process. The tool's author, Kerstin Hedberg Nyqvist, granted permission to use PIBBS in this study.

Development of the PIBBS tool began with discovery of feeding maturation observable in infants born between 31 and 37 weeks gestation (Hedberg Nyqvist, Rubertsson, Ewald, & Sjöden, 1996). An initial assessment scale of maturational steps was field tested with full term ($n = 12$) and preterm infants ($n = 23$; Hedberg Nyqvist et al., 1996). Modifications were made based on maternal input (Hedberg Nyqvist et al.,

1996). Four experts provided face validity; one dietician, the chairperson of the Swedish La Leche League, and two nurse midwives (Hedberg Nyqvist et al., 1996).

The tool was initially tested with 34 infants admitted to a nursery or NICU (Hedberg Nyqvist et al., 1996). Gestational ages included less than 33 weeks to greater than 37 weeks gestation (Hedberg Nyqvist et al., 1996). Inter-rater reliability was tested between the first and second authors rendering acceptable agreement (kappa values ranging from 0.64 to 1.00; Hedberg Nyqvist et al., 1996). Inter-rater reliability between each observer and mother ranged between kappa values of 0.27 (fair) and 0.86 (excellent; Hedberg Nyqvist et al., 1996). After further modification, the tool was retested as described above. Inter-rater agreement between two observers was 83-90% (kappa value range of 0.68-0.84; Hedberg Nyqvist et al., 1999). Inter-rater agreement between mothers and observers was 89-97% (kappa value range of 0.77 to 0.94; Hedberg Nyqvist et al., 1999).

PIBBS has been used in four studies and two dissertations (Hedberg Nyqvist, & Ewald, 1999; Hedberg Nyqvist, Färnstrad, Eeg-Olofsson, & Ewald, 2001; Abouelfetoh, Dowling, Dabash, Elguindy, & Seoud, 2008; Holsti, Oberlander, & Brant, 2011; Gides Radzyminski, 2001; Phalen, 2003). Hedberg Nyqvist, and Ewald (1999) used PIBBS to explore the relationship between specific infant and maternal factors on the development of preterm infant breastfeeding behavior. An observational, prospective analytical cohort design was used with a convenience sample included 71 infants born at or earlier than 35 weeks (Hedberg Nyqvist & Ewald, 1999). Infant factors measured were the gestational age at birth, blood culture results, birth weight, gender, lowest hemoglobin level, bottle feeding, oxygen treatment, Theophylline treatment, and ventilator support (Hedberg

Nyqvist & Ewald, 1999). Maternal factors included education level, previous breastfeeding experience, and tobacco use (Hedberg Nyqvist & Ewald, 1999). Maternal-infant separation was also considered as an independent variable (Hedberg Nyqvist & Ewald, 1999). The best PIBBS performance was defined as achieving the highest score in each of the six tool factors (Hedberg Nyqvist & Ewald, 1999). The researchers found the longer gestation and/or higher birth weight rendered best PIBBS performance within the first four weeks after birth. Gestational age did not remain a factor in achieving best PIBBS performance for those infants who remained in hospital for five weeks or longer possibly due to interference of greater morbidity (Hedberg Nyqvist & Ewald, 1999). An unexpected finding was that short gestation contributed to best performance in latch, sucking/swallowing, and full breastfeeding by 32 to 37 weeks adjusted age (Hedberg Nyqvist & Ewald, 1999). The researchers concluded maturation at birth was not an indicator for breastfeeding effectiveness but rather length of learning and breastfeeding practice (Hedberg Nyqvist, & Ewald, 1999).

Infant oral movement was evaluated during breastfeeding using electromyographic (EMG) data to further validate the PIBBS tool (Hedberg Nyqvist, Färnstrad, Eeg-Olofsson, & Ewald, 2001). A convenience sample ($N=26$) was used with infants born earlier than 37 weeks gestation (Hedberg Nyqvist et al., 2001). The EMG probe detected the strength and frequency of sucking bursts and swallowing activity during breastfeeding (Hedberg Nyqvist et al., 2001). EMG data and PIBBS scores had strong agreement (kappa values ≥ 0.75 , 85-89%, $r = 0.88-0.92$; Hedberg Nyqvist et al., 2001).

PIBBS was used in a quasi-experiment study to compare breastfeeding outcomes of LPIs who were cup fed with those who were bottle-fed (Abouelfetoh, Dowling, Dabash, Elguindy, & Seoud, 2008). PIBBS scores indicated the maturational development of breastfeeding skills over a six-week period (Abouelfetoh et al., 2008). PIBBS was used to answer the authors' second research question: "Do premature infants supplemented by cup during hospitalization demonstrate more mature breastfeeding behavior at 1, 2, 3, 4, 5, and 6 weeks after discharge when compared to premature infants supplemented by bottle?" (Abouelfetoh et al., 2008). The study consisted of 60 LPIs born between 34 and 37 weeks gestation (Abouelfetoh et al., 2008). The sample size was determined by a power analysis using a medium effect size and a power of 80% (Abouelfetoh et al., 2008). Cup feeding was positively correlated with higher PIBBS scores at all data points (Abouelfetoh et al., 2008). PIBBS was designed as six individual factors without cumulative scoring (Hedberg Nyqvist, et al., 1999); however, cumulative PIBBS scores were used without discussion of rationale or explanation of cut off points.

Researchers developed a randomized clinical trial to measure the effect of breastfeeding on neonatal pain (Holsti, Oberlander, & Brant, 2011). A sample of 57 preterm infants, born between 30 and 36 weeks gestation, were randomly assigned into two groups: those breastfed during a blood draw procedure and those given a pacifier (Holsti et al., 2011). Infant pain was measured with the Behavioral Indicators of Infant Pain (BIIP; Holsti et al., 2011). PIBBS assessed breastfeeding before the procedure and 24 hours after (Holsti et al., 2011). A paired t-test assessed differences in the two sets of PIBBS scores (Holsti et al., 2011). Pearson correlations evaluated relationships between BIIP, PIBBS, and infant heart rate (Holsti et al., 2011). Infant pain was measured with

the Behavioral Indicators of Infant Pain (BIIP; Holsti et al., 2011). The authors found the higher the PIBBS score the lower the BIIP score; therefore, it was surmised that infants with mature breastfeeding behavior would benefit from the intervention (Holsti et al., 2011).

The PIBBS tool, along with other instruments, was used to measure the differences in term infant breastfeeding behavior following birth with either no pain medication or epidural containing bupivacaine and fentanyl (Gides Radzyski, 2001). Power analysis indicated sample sizes of 26 for each group (Gides Radzyski, 2001). A final sample of 56 dyads was recruited, 28 had medicated deliveries and 28 were not medicated (Gides Radzyski, 2001). All participants were described as term, although specific gestational ages were not reported. PIBBS was conducted at the first feeding after delivery and at 24 hours (Gides Radzyski, 2001). Modifications were made for the use of the tool to fit the aims of the study (Gides Radzyski, 2001). Asking the mothers to complete a hand-written assessment with the first feeding was determined not to be feasible; therefore, the researcher completed the tool then verbally asked mothers if they agreed (Gides Radzyski, 2001). The second PIBBS assessment was conducted in the same manner 24 hours later (Gides Radzyski, 2001). No significant differences were found in PIBBS scores between groups at either first feeding or 24 hours later (Gides Radzyski, 2001). A limitation identified was mothers' inability to understand the scale factors; however, the tool was not used as it had been designed (Gides Radzyski, 2001).

PIBBS was tested to predict milk intake in preterm infants (Phalen, 2003). A prospective, cross-sectional, descriptive correlational design was developed with a power

analysis that determined a sample size of 44 would be sufficient for an effect size of .50 (Phalen, 2003). The researcher then obtained a convenience sample of 50 infants born less than 37 weeks gestation and admitted to NICU (Phalen, 2003). Inter-rater reliability testing between the researcher and two internationally board certified lactation consultants (IBCLCs) demonstrated substantial agreement ($\kappa = 0.73, p = .01$) and between researcher and mother a slight agreement of ($\kappa = 0.14$; Phalen, 2003). To determine the relationship between PIBBS scores and actual milk intake, Phalen (2003) used cumulative PIBBS scores (zero to 20) with the higher the score indicating the more efficient the feeding. Phalen (2003) found 26.4% of infants with scores between seven and sixteen had a milk volume intake of zero and 60 milliliters. The other 73.6% of infants had scores of 17 to 20 with a range of milk volume intake from zero to 60 milliliters (Phalen, 2003). Scores lower than 17 demonstrated low milk volume intake (Phalen, 2003). Scores between 17 and 20 demonstrated high variability of intake (Phalen, 2003). Correlation between PIBBS scores and milk intake was statistically significant but with low magnitude of the correlation ($r = 0.48, p = .01$; Phalen, 2003). Phalen concluded PIBBS did not predict adequate milk intake and cumulative scores could not be used; however, the study added information regarding inter-rater reliability therefore contributing to the selection of PIBBS for this study.

Conclusions

LPIs are a high-risk cohort for ineffective breastfeeding and early breastfeeding cessation leading to secondary health complications. Although the physiologic causes have been identified, feeding maturation and progression toward effective breastfeeding has not been fully investigated. Additionally, LPI feeding patterns are known to fluctuate

in efficiency due to changes in state regulation, muscular development, stamina, and breastfeeding practice time; however, a tested approach to assess LPIs toward independent effective breastfeeding has not been tested. Finally, no tool has been tested to assess breastfeeding effectiveness in the LPI population. A reliable instrument for the late preterm population would provide means to better understand late preterm breastfeeding maturation and create the foundation for an approach to assist LPIs toward breastfeeding efficiency. Therefore, testing an assessment instrument was the focus of this study.

CHAPTER 3

Methodology

Design

A longitudinal one-group observational non-experimental design was used to assess the inter-rater reliability agreement of mothers and a healthcare professional during hospitalization. Based on the initial PIBBS validation study design (Hedberg Nyqvist et al., 1999), this study extended the reliability testing to the late preterm infants outside of the NICU setting. The study period began during the birth hospitalization, continued beyond discharge, and concluded on the infant's expected due date (40 weeks adjusted age).

Setting

Participants were recruited from three urban hospitals within the same hospital system located in a major metropolitan area of the southwest region of the US. The Joint Commission (TJC) credentialed all three hospitals as level three perinatal care facilities. TJC issued a core measure in 2014 calling for the achievement of 70% exclusive human milk feeding for all healthy full term infants meeting broad inclusion criteria (TJC, 2012). Maternal and infant policies and practices developed to meet the core measure were also supportive of breastfeeding/human milk feeding of all infant cohorts. The number of LPIs born at these facilities was approximately 8% of all births thus mirroring national statistics. All maternity nurses in the hospital system were trained in basic breastfeeding assistance and lactation management at the time of hire and by continuing annual education. The hospital system followed established national standards of care for LPIs as delineated by the American Academy of Pediatrics and the National Perinatal

Association (AAP, 2012; NPA, 2013) through hospital policy and standing provider orders.

Sample

A convenience sample comprised of LPIs born between 34 weeks and 0 days and 36 weeks and 6 days was recruited for a period of four months: February through May 2018. The mothers provided consent for their infants' participation as well as their own. Infant inclusionary criteria were: (a) singleton birth with a five minute APGAR of seven or greater, and (b) infants' birth weight appropriate for gestational age. Maternal inclusion criteria included: (a) maternal age of 18 years of age or older, (b) English speaking and literate, and (c) mothers who expressed intention to breastfeed upon admission to labor and delivery. Weight appropriate for gestation age was defined as: Females 1700 – 3300 grams and males 1800 – 3700 grams (Olsen, Groveman, Lawson, Clark, & Zemel, 2010). Exclusionary criteria were those situations shown to inhibit effective breastfeeding: (a) newborns with congenital anomalies, (b) newborn admission into neonatal intensive care or other situations of long-term separation, (c) maternal pregestational diabetes, (d) maternal illicit drug or tobacco use, (e) maternal psychiatric illness, or (f) intrapartum administration of magnesium sulfate (Horgan, 2015; Hellmeyer et al., 2012; Kalyoncu et al., 2010).

Human Subjects Protection

Approval from the university Institutional Review Board (IRB) was obtained prior to participant recruitment and data collection. The university and hospital system maintain a reciprocal agreement requiring IRB approval from only the university's IRB. The researcher met in-person with all potential participants while in hospital. The

purpose and details of this project were presented and interested participants were enrolled. Participation was voluntary and participants could withdraw at any time without consequence. No foreseeable risk was associated with this study.

Measures

Demographic. Maternal demographic information was collected either from the maternal and infant electronic medical records (EMR) or from maternal interview (Appendix A). Variables were parity, previous breastfeeding experience, and mode of current delivery. Infant demographic variables were date and time of birth, and gestational age. At the end of the study, the IRB approved an addendum to the consent form for the collection of additional demographic data. With participant consent, the investigator returned to the electronic patient health records to gather the following variables: Marital status (married or not married), education (no high school diploma, high school diploma, some college, college diploma, graduate degree), ethnicity (Hispanic or not), race (Caucasian, black, Asian, Native American), maternal age, insurance (commercial, Medicaid, or self-pay), and history of preterm delivery.

Instrument. Multiple copies of the PIBBS tool were provided to each participant in the form of a booklet for use during the data collection period (Appendix B).

Maternal survey. On the mother's due date, participants completed a self-report survey (Appendix C). The survey included data about breastfeeding exclusivity (feeding directly from the breast), human milk supplementation, formula supplementation, and the mother's impression of PIBBS usefulness. Completion of the survey marked the end of each participant's data collection.

Data Collection Procedures

Recruitment. Participant contact followed a delineated algorithm to ensure protection of all participants (Figure 4). Prior to the initiation of recruitment, the researcher met with Internationally Board Certified Lactation Consultants (IBCLCs) at all participating hospitals to discuss the purpose and methods of the study. When an IBCLC identified a late preterm breastfeeding family during the normal course of their work, the IBCLC provided the mother with a recruitment letter (Appendix D). By signing the letter, the mother gave permission for the release of her name and hospital location to the investigator. At earliest availability, the researcher met with the interested mother in person.

Upon meeting, the researcher described the study and participation requirements. If the mother wished to join the study, a written consent form (Appendix E) and Health Insurance Portability and Accountability Act (HIPPA) form (Appendix F) was presented and explained verbally. The mother was given time to read the consent and HIPPA forms to decide on participation. The researcher provided photocopies of the signed consent and HIPPA forms to the participant while retaining the originals. With signed consent, the researcher verified inclusion and exclusion criteria and collected demographic information either through the EMR or maternal interview (Appendix A). Once a participant was determined to meet the criteria of the study, her enrollment was confirmed, and study materials were given.

Also provided during this meeting was a contact information form (Appendix G). The participant provided her name, contact information, and preferred mode of contact.

The researcher completed this form by writing in dates of contact following hospital discharge. The participant received a photocopy of this form, as well.

Each case was assigned a unique study code number for data analysis. Only the researcher had access to the master list of participants' names and associated study code numbers. The researcher stored digital files on a password-protected computer in a secured and locked office at all times. Any hard copy was kept in a locked filing cabinet within the secured office for the duration of the study. The researcher transcribed demographic data onto data collection forms. Each data form was given a code numbers matching the same participant PIBBS booklet code number. Once collected, the data were entered into SPSS version 25 for analysis.

In-hospital data collection. After enrollment in the study, the participant received a booklet (Booklet A) containing scale definitions, instructions, and multiple copies of the PIBBS tool (Appendix H). At the bottom of each PIBBS tool, the participant recorded the ultimate composition of the feeding: Exclusive breastfeeding, breastfeeding plus supplementation of expressed milk, breastfeeding plus supplementation of formula, breastfeeding plus supplementation of both expressed milk and formula, or exclusive formula. Each document within the booklet was discussed and explained. The researcher ensured participant comprehension. At the next breastfeeding opportunity, the researcher and participant conducted the first PIBBS observation together (henceforth referred to as Timepoint 1) each scoring independently.

Both participant and researcher recorded PIBBS scores by hand on preprinted PIBBS forms. PIBBS was intended to teach mothers how to assess breastfeeding effectiveness; therefore, participants were given feedback about PIBBS observation

immediately after the feeding. If ineffective breastfeeding (no evidence of milk transfer) was observed, the researcher immediately contacted the registered nurse or IBCLC for follow up.

The participants were encouraged to utilize the PIBBS assessment found in her booklet with subsequent feedings, but at least once, until meeting with researcher the next day (prior to hospital discharge). Upon second meeting with the researcher, the participant and researcher conducted their second PIBBS observation together (henceforth referred to as Timepoint 2). At this time, Booklet A was collected to retain inter-rater data.

Post-discharge data collection. Data collection continued after hospital discharge until the infant's expected due date (40 weeks adjusted age). The participant was given an at-home data collection booklet, Booklet B (Appendix H), and encouraged to continue completing the PIBBS tool, at least once a week until the infant's expected due date. The Booklet B contained definitions, instructions, and copies of the PIBBS tool, and an area to document feeding information at the bottom of each PIBBS, as in Booklet A. Additionally, Booklet B included a survey for completion on the last day of study participation. A prepaid envelope was provided to return Booklet B at the end of data collection.

In an effort to support study participation, the researcher contacted each participant on the day the infant would have achieved the next week of gestation. For instance, if the infant was born at 36 weeks and two days, the researcher would contact the mother five days after birth when the infant would have been 37 weeks gestation. This time point was selected to replicate the original inter-rater reliability study (Hedberg

Nyqvist et al., 1999) and to assist in the evaluation of PIBBS score as a week-to-week progression. The second at-home contact occurred at the infants next week and continued at each week marker until the infant reached 40 weeks adjusted age.

The researcher conducted each telephone, text, or email interaction as scripted to determine progress of PIBBS scores and use (Appendix I). Any response from the participant indicating the need for lactation or breastfeeding support was referred to a community resource.

The final contact point occurred when the infant reached the expected due date. The researcher asked the participant to complete the last PIBBS assessment and the survey found at the back of the booklet (Appendix C). The participant was encouraged to return the completed PIBBS booklet in the prepaid envelope at this time.

The researcher attempted to contact each participant a maximum of three times at each data point. The participant was considered to have withdrawn from the study when contact could not be made after the third attempt. Twenty-three mothers enrolled in the study. By the first at-home contact point, 20 (86.9%) participants responded. At the second at-home contact point, 19 (82.6%) participants responded. At the third at-home contact point, 17 (73.9%) participant responded. At the fourth at-home contact point, 10 (43.5%) participants responded. Ten participants completed data collection and returned Booklet B to the investigator.

Planned Analysis

Prior to study initiation data analysis procedures were planned to answer the research questions.

Research question #1: What is the inter-rater reliability of PIBBS assessment scores of LPIs between mothers and a health profession? Inter-rater reliability was determined by Cohen's kappa analysis with a 95% Confidence Interval. Cohen's kappa is the standard statistical procedure to measure the degree of agreement between two or more raters using an ordinal categorical scale (Laerd Statistics, 2018). Each PIBBS item was analyzed comparing participant's score with the investigator's score, using the SPSS crosstabs command for computing Cohen's kappa (Laerd Statistics, 2018). This procedure provided the kappa value and *p*-value of each PIBBS item. The percentage of agreement was determined via SPSS frequency analysis of score differences for each PIBBS item. The interpretation of kappa scores followed defined parameters (Table 1) as presented by Laerd Statistics (2018) and McHugh (2012).

Table 1

Interpretation of Cohen's Kappa Statistic

Kappa value	Level of agreement
0 - .20	None
.21 - .39	Minimal
.40 - .59	Weak
.60 - .79	Moderate
.80 - .90	Strong
Above .90	Almost perfect

Research question #2: How are the actual feeding patterns of LPIs reflected in their PIBBS scores? Survival analyses were planned to assess the time to an event (exclusive breastfeeding) using weeks of progression as the outcome variable and each individual PIBBS item. In total, six models were planned to explore survival success: (a) rooting, (b) areola grasp, (c) latching and maintaining latch, (d) sucking, (e) longest sucking burst, (f) swallowing (Hedberg Nyqvist et al., 1999). Repeated measures ANOVA were planned to determine the difference between related means over multiple time points (Lærd Statistics, 2017). A model was to be created to determine if scores changed over time on weekly basis and if scores progressed toward PIBBS excellence (i.e. highest item achievement on each PIBBS Likert subscale) of each of the six items (Lærd Statistics, 2017). Due to the small sample size and high attrition rate for this study, the analysis was not possible. As an alternative, frequency statistics were conducted to explore recorded feeding patterns over the duration of the study.

Research question #3: How do PIBBS scores at the first at-home timepoint compare to those at the last at-home timepoint (40 weeks adjusted age)? Data were analyzed with paired *t*-tests to compare PIBBS scores at the first at-home timepoint and at 40 weeks adjusted age. Differences in scores were evaluated to determine if changes in PIBBS item scores occurred with maturation.

CHAPTER 4

Data Analysis and Results

Description of Sample

A total of 42 mothers were approached and asked to participate in the study. Ten declined participation and nine initially expressed interest but declined prior to enrollment. Twenty-three mothers enrolled and provided inter-rater data prior to hospital discharge. After hospital discharge, 10 participants completed the at-home data collection.

Sample selection criteria provided the sample parameters. All 23 infants were born during late preterm gestation (34 weeks and 0 days and 36 weeks and 6 days) and remained with their mothers from birth until discharge. All infants were singletons with a five-minute APGAR of seven or greater. All infants' birth weight was appropriate for gestational age (females 1700 – 3300 grams and males 1800 – 3700 grams). All mothers were 18 years of age or older, English speaking and literate, and expressed intention to breastfeed upon admission to labor and delivery.

Maternal demographics (Table 2) included age, education, ethnicity, race, insurance provider, parity, previous preterm birth, previous breastfeeding experience, and method of delivery. The mean age of maternal participants was 31.43 years (SD 6.0) with ages ranging from 21 to 41 years. Nearly a third (30.4%) of participants held a college diploma. The labels contained within the EMR limited race identification: 10 (43.5%) of participants identified as white, four (17.4%) as Asian, and two (8.7%) as black or African American. Approximately a third (30.4%) of the sample was identified as Hispanic ethnicity (Table 2). As a proxy for socio-economic status, insurance provider

was collected and coded as: Commercial insurance, Medicaid, or self-pay. The majority (65.2%) of participants had commercial insurance policies and the remaining (34.8%) had a Medicaid plan. There were no self-paying participants in this study. Eight (34.8%) participants were primiparas. Of the multiparous participants, five (21.7%) had delivered a preterm infant prior to this pregnancy and more than half (56.5%) reported having some previous breastfeeding experience. Most (73.9%) participants gave birth vaginally.

Table 2

Maternal Characteristics of the Sample: n = 23

Characteristic	n (%)	Mean \pm SD
Age		31.43 \pm 6.0
Education		
No high school diploma	1 (4.3)	
High school diploma	6 (26.1)	
Some college	5 (21.7)	
College diploma	7 (30.4)	
Graduate diploma	4 (17.4)	
Race		
White	10 (43.5)	
Black/African American	2 (8.7)	
Asian	4 (17.4)	
Hispanic	7 (30.4)	
Insurance		
Commercial	15 (65.2)	
Medicaid	8 (34.8)	
Parity		2.26 \pm 1.7
Previous preterm birth	5 (21.7)	
Previously breastfed	13 (56.5)	
Cesarean Section	6 (26.1)	

Infant demographics included gestational age at delivery and gender (Table 3). Six (26.1%) infants were born at 35 weeks gestation and 17 (73.9%) infants were born at 36 weeks gestation. The modal gestational age was 36 weeks and 4 days (26.1% of the sample). Eleven (47.8%) infants were female and 12 (52.2%) were male.

Table 3

Infant Characteristics of the Sample: n = 23

Characteristic	n (%)	Mean \pm SD
Gestational age		36.3 \pm 0.4
35 weeks	6 (26.1)	
36 weeks	17 (73.9)	

Inter-rater Reliability

Research question #1: What is the inter-rater reliability of PIBBS assessment scores of LPIs between mothers and a health professional? Inter-rater reliability was tested at two different time points, the first within 24 hours of birth (Timepoint 1) and the second between 24 and 48 hours after delivery (Timepoint 2). Due to discharge timing, 11 (47.8%) of the 23 participants were not available for the second inter-rater test. The six PIBBS items were scored independently as the tool does not use cumulative scoring.

Timepoint 1. Twenty-three dyads provided inter-rater data at the first timepoint (Table 4). Five of the six PIBBS items demonstrated almost perfect agreement. Kappa values for the degree of rooting effort, the length of time the infant remained latched, the degree of sucking effort were all 1.000 ($p = <.001$) and 100% agreement. Latching effort had a kappa value of .938 ($p = <.001$) and 95.7% agreement. Observed infant swallowing

had a kappa value of .929 ($p = <.001$) and 95.7% agreement. The longest sucking burst had strong agreement with a kappa value of .871 ($p = <.001$) and 91.3% agreement.

Overall, each item of the PIBBS tool had a strong to almost perfect agreement.

Table 4

Inter-rater Timepoint 1 (n = 23)

PIBBS Item	Kappa	<i>p</i> -value	Percentage agreement (%)
Rooting effort	1.000	<.001	100
Latch effort	.938	<.001	95.7
Staying latched	1.000	<.001	100
Sucking effort	1.000	<.001	100
Longest sucking burst	.871	<.001	91.3
Swallowing	.929	<.001	95.7

Timepoint 2. Eleven dyads provided inter-rater data at the second timepoint (Table 5). At this timepoint, only one item, the length of time the infant remained latched, had almost perfect agreement with a kappa value of 1.000 ($p = <.001$) and 100% agreement. Four of the six items had strong agreement: Rooting effort, latch effort, sucking effort, and observed swallowing. The degree of rooting effort had a kappa value of .843 ($p = <.001$) and 90.9% agreement. The infant's latching effort had a kappa values of .857 ($p = <.001$) and 90.9% agreement. Sucking effort had a kappa value of .871 ($p = <.001$) and 90.9% agreement. Observed swallowing had a kappa value of .857 ($p = <.001$) and 90.9% agreement. The length of the longest sucking burst had moderated

agreement with a kappa value of .776 ($p = <.001$) and 81.8% agreement. Although scores show wider variation at the second timepoint, the level of agreement remains acceptable.

Table 5

Inter-rater Timepoint 2 (n = 11)

PIBBS Item	Kappa	<i>p</i> -value	Percentage agreement (%)
Rooting effort	.843	<.001	90.9
Latch effort	.857	<.001	90.9
Staying latched	1.000	<.001	100
Sucking effort	.871	<.001	90.9
Longest sucking burst	.776	<.001	81.8
Swallowing	.857	<.001	90.9

Research question #2: How are the actual feeding patterns of LPIs reflected in their PIBBS scores? Due to the small sample size of participants collecting at-home data ($n = 10$) and the extremely small number of exclusive breastfeeding participants at the end of the study ($n = 1$), PIBBS scores could not be analyzed to determine changes breastfeeding success over time.

To explore changes in feeding patterns during the study, frequency statistics were conducted for the ten participants completing at-home data collection (Tables 6-8 and Figures 5-7). The number of breastfeeding sessions (without supplementation) increased over time from 20% within 48 hours of birth to 40% at the infants' 40 weeks adjusted age. The number of formula supplementation was higher at the first at-home data

collection timepoint compared to in hospital (formula supplementation included combined breastfeeding with formula supplementation, breastfeeding with supplementation of both mother’s own milk (MOM) and formula, and feeding with only formula), increasing from 40% to 60% at the first at-home timepoint (breastfeeding with formula supplementation). By 40 weeks adjusted age, formula supplementation was down to 20% (combined breastfeeding with supplementation of both MOM and formula and breastfeeding with formula only supplementation).

Table 6

Feeding Activity During First Assessment (n = 10)

Feeding	n (%)
No feeding	4 (40)
Breastfed only	2 (20)
Breastfed with formula	1 (10)
Formula fed only	2 (20)
Breastfed with both MOM and formula	1 (10)

Note. ‘No feeding’ was a data collection point off the infant’s determined feeding schedule. Assessment was conducted to prevent loss of data and to ensure maternal confidence in using the PIBBS tool. MOM = mother’s own milk

Table 7

Feeding Method at the First At-home Score (n = 10)

Feeding	n (%)
Breastfed with MOM	4 (40)
Breastfed with formula	6 (60)

Note. MOM = mother's own milk

Table 8

Feeding Method at the Last At-home Score (n = 10)

Feeding	n (%)
Breastfed only	4 (40)
Breastfed with MOM	4 (40)
Breastfeeding with formula	1 (10)
Breastfeeding with both MOM & formula	1 (10)

Note. MOM = mother's own milk

At the conclusion of the study when each infant had reached 40 weeks adjusted age, 90% ($n = 9$) were both breastfeeding and bottle-feeding. Only one (10%) of the infants was exclusively breastfeeding. Of the nine who were bottle feeding in addition to breastfeeding, 33% ($n = 3$) used only human milk, 33% ($n = 3$) used mostly human milk but some formula, 22% ($n = 2$) used some human milk but mostly formula, and 11% ($n = 1$) only formula. After leaving the hospital, 80% ($n = 8$) gave formula while 20 % ($n = 2$) did not. Participants were not asked to explain their feeding decisions.

Research question #3: How do PIBBS scores at the first at-home timepoint compare to those at the last at-home timepoint (40 weeks adjusted age)? Comparison of

breastfeeding behavior between the first at-home timepoint and the 40 week adjusted age assessment was tested using a paired *t*-test (Table 9). The difference in scores were evaluated to determine if a significant change in PIBBS items, development of breastfeeding behaviors, had occurred. No significant difference was found for rooting effort ($M = -.30, SD = .67, p = .193$), latch effort ($M = -.20, SD = .42, p = .168$), or observed swallowing ($M = -.50, SD = .71, p = .052$). There was a significant difference in scores for staying latched ($M = -1.0, SD = .82, p = .004$), sucking effort ($M = -.90, SD = .74, p = .003$), and longest sucking burst ($M = -1.40, SD = 1.07, p = .003$).

Table 9

Difference in PIBBS Scores from First At-Home Score to Last

PIBBS	Mean	SD	95% CI of the differences		<i>t</i>	df	<i>p</i>
			Lower	Upper			
Rooting effort	-.30	.67	-.78	.18	-1.41	9	.193
Latch effort	-.20	.42	.13	.10	-1.50	9	.168
Staying latched	-1.0	.82	.26	-.42	-3.87	9	.004
Sucking effort	-.90	.74	.23	-.37	-3.86	9	.004
Longest sucking burst	-1.40	1.07	.34	-.63	-4.12	9	.003
Swallowing	-.50	.71	.22	.01	-2.24	9	.052

Note: Significance was 2-tailed

Survey Question for Quality Improvement

To inform quality improvement and usefulness of the instrument in practice, participants were asked how useful they found the PIBBS tool in assessing breastfeeding effectiveness. A Likert-like scale was used and provided answers included “very helpful,” “kind of helpful,” “neutral,” “not very helpful,” and “not helpful at all.” Eight of participants (80%) found the tool very helpful and two (20%) described the tool as “kind of helpful.”

CHAPTER 5

Discussion

Anatomic and physiologic prematurity of LPIs increase the risk for morbidity and mortality. Researchers have reported strong evidence of a relationship between human milk and a reduction in the incidence of poor health outcomes among LPIs (Chantry, Eglash, & Lobbok, 2015; AAP, 2012). Issues of maturation and feeding readiness, however, may delay or inhibit exclusive breastfeeding. Accurate interpretation of feeding behaviors and breastfeeding effectiveness can be challenging, as LPIs present more like term than preterm infants in size and gross physiologic stability; yet, they are often unable to consistently demonstrate efficient breastfeeding behaviors. If ineffective breastfeeding effort is not detected, LPIs may experience excessive weight loss, hypoglycemia, jaundice, and readmission to hospital. Ineffective milk transfer may cause maternal complications of severe engorgement and reduced milk production. A reliable feeding assessment tool could provide mothers a guide when determining breastfeeding effectiveness and making feeding decisions.

The purpose of this study was to investigate the use of the PIBBS in the late preterm population. Strong agreement occurred with inter-rater reliability testing between mothers and a healthcare professional. Mothers found the tool helpful as they continued to use the tool once discharged from the hospital. Although low recruitment and high attrition provided limited data for inference about feeding progress, PIBBS was an appropriate tool for objective evaluation at each feeding.

Sample Characteristics

Recruitment for this convenience sample was limited by geography and exclusion criteria. The sample was recruited from only one metropolitan area within a southwest US city. A greater geographical reach for recruitment may provide data that could better generalize to LPI dyads in any environment. Exclusion criteria were determined based on previous research within the general and breastfeeding LPI literature and previous PIBBS research (Horgan, 2015; Hellmeyer et al., 2012; Kalyoncu et al., 2010; Olsen et al., 2010; Hedberg Nyqvist et al. 1996; Hedberg Nyqvist et al., 1999). The most common reasons for recruitment exclusion were women who were non-English speaking or had received intrapartum magnesium sulfate. The investigator was only English speaking and literate. Future research should include translation of PIBBS into other languages.

The investigator observed many LPI dyads were excluded from study participation due to the use of intrapartum magnesium sulfate (MgSO_4). To maintain pregnancy for a longer gestation, MgSO_4 is used to slow smooth muscle contraction preventing seizure activity when pre-eclampsia exists and uterine contractions during preterm labor (ACOG, 2016; Alonso et al., 2018). Although research is needed to confirm that, MgSO_4 may cause a reduction of contraction of milk ejection from the breast. Smooth muscles line the alveoli of breast glandular tissue. A medication, such as MgSO_4 , could slow breast alveoli muscle contractility resulting in decreased milk transfer and reducing the volume of infant milk intake. Therefore, issues of maturation could be further compromised by inhibited maternal milk let-down. However, evidence to support this does not currently exist. Further, intrapartum MgSO_4 delivered to the fetus via the placenta is retained in the newborn after delivery (Alonso et al., 2018). Transfer of

MgSO₄ is associated with infant respiratory depression, hypotonia, and hyporeflexia each additionally inhibiting effective breastfeeding behavior (Alonso et al., 2018). Due to these considerations, women receiving intrapartum MgSO₄ were excluded from this study; however, future research is needed to explore the incidence of MgSO₄ among late preterm deliveries and the effect of intrapartum MgSO₄ on breastfeeding effectiveness in the LPIs.

The majority of participants had at least some college education and were of higher socio-economic status (SES) as inferred by their private insurance provider. For decades, national breastfeeding data have indicated that women who are college educated and of high SES are more likely to exclusively breastfeed (CDC, 2017; Heck, Braveman, Cubbin, Chavez, & Kiely, 2006; Hirschman & Butler, 1981; Jackson & Johnson, 2017; Ryan, 1997). Researchers have suggested the more educated the mother is, the more likely she is to have received health promotion information and attend prenatal breastfeeding classes (Heck et al., 2006; Jackson & Johnson, 2017). Women of lower SES may not have access to health promotion information (Jackson & Johnson, 2017). Additionally, food that is inexpensive is often of low nutritional quality potentially disallowing appreciation of nutrition as a priority (Jackson & Johnson, 2017). Participation in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) may receive free formula resulting in decreased exclusive breastfeeding (Jackson & Johnson, 2017). Whatever the underlining influences, the trends continue.

The majority of participants were white followed by Hispanic, Asian, and Black or African American. This demographic distribution was not representative of national or local statistics, thus indicating a skewed sample. CDC data indicate Asian women have

the highest rates of breastfeeding followed in order by white women, Hispanic women, Black women (CDC, 2017). According to state census data and reflective of data of the three participating hospitals more than 50% of the state population is white (non-Hispanic), over 30% is Hispanic or Latino, and around 5% black or African American (United State Census Bureau, 2018). The study sample may have been skewed by the influences of education and SES as they intersect with race and ethnicity. Additionally, the lack of a Spanish language version of study material may have prevented more Hispanic mothers from participation. Race and ethnicity as they relate to late prematurity has not been well researched. Shapiro-Mendoza et al. (2006) found Asian/Pacific Islander mothers were more at risk for delivering during late preterm. Radtke Demirci, Sereika, and Bogen (2013) found over two-thirds of the LPI mothers ($n = 7,012$) were white. Future research exploring race and ethnicity, as it is associated with later preterm delivery would provide a deeper understanding about this population.

Multiparity increases the risk of preterm delivery (Delnord & Zeitlin, 2018; Wheeler, Maxson, Truong, & Swamy, 2018). In this study, similar findings were revealed, as participants had a mean parity of 2.26 ($SD 1.7$).

Nearly three-quarters of the participating infants were born at 36 weeks gestation. Researchers have found infants born at 36 weeks to be the largest subgroup in the LPI cohort (Shapiro-Mendoza et al., 2006; Radtke Demirci, Sereika, & Bogen, 2013; Delnord & Zeitlin, 2018). Many of the 35-week LPIs that initially met inclusion criteria became ineligible, as they were eventually admitted into the NICU after birth. PIBBS was validated and shown to be reliable for clinicians and mothers in the NICU (Hedberg Nyqvist et al., 1999). The purpose of this study was to evaluate the use of PIBBS outside

of the NICU; therefore, admission into the NICU was an exclusion criterion. The rate of NICU admissions for infants born at 35 weeks is nearly double the rate of those born at 36 weeks (Horgan, 2015). Just one week of continued gestation has a tremendous influence on maturation and readiness for extrauterine life.

All hospitals involved in this study observe the National Perinatology Association guidelines of a minimum 24-hour NICU admission for infants born less than 35 weeks gestation; therefore, no infants born at 34 weeks were included in this study.

PIBBS Usefulness

Research question #1: What is the inter-rater reliability of PIBBS assessment scores of LPIs between mothers and a health professional? Each item of the PIBBS tool tested with strong agreement between mother and a health care professional. Original reliability testing was conducted for use with all preterm infants inside the NICU setting (Hedberg Nyqvist & Ewald, 1999). This study supports the use of PIBBS for the late preterm cohort outside of the NICU where infants receive less rigorous monitoring by health professionals. Mothers are held more responsible for infant feeding outside of the NICU and therefore must learn quickly how to effectively feed her infants. PIBBS can provide a more objective means of observing and interpreting breastfeeding behavior.

The lowest kappa scores at both timepoints was a count of the longest sucking burst. Sucking motions are often quick as the infant stimulates milk let-down then slows once milk is being transferred (Watson Genna, 2017). A mother, when she is potentially exhausted and receiving pain medication during the early postpartum period, may count movements differently compared to an experienced clinician. To determine the cause of

the discrepancy, study design would need to include interviews with participants regarding the decision making for each item.

Overall, PIBBS was reliable as an assessment tool for maternal evaluation of their LPI feeding behavior. The reliability and usefulness of PIBBS assisted mothers of LPIs to make feeding decisions regarding breastfeeding effectiveness and the need for supplementation. Many mothers had prepared themselves for the birth of a full-term infant. When birth unexpectedly occurs four to six weeks early, mothers need to readjust their understanding and expectations of their infant's behavior. As feeding readiness and states of wakefulness oscillate throughout the day and over weeks, anticipating actual feeding effectiveness can be frustrating (Radtke Demirci et al., 2012). PIBBS may provide an objective means for feeding evaluation while parents are navigating the waters between expectations and reality. Few researchers have used PIBBS. This may speak to the general lack of priority given to breastfeeding for preterm infants. Incorporating PIBBS into standard care of late preterm infants may produce overall improved breastfeeding rates and health outcomes. Since transfer of milk during breastfeeding cannot be easily measured or seen, the process requires trust from both the mother and the clinician. PIBBS can contribute to building maternal trust in the breastfeeding process.

Research question #2: How are the actual feeding patterns of LPIs reflected in their PIBBS scores? Although there was insufficient data to answer the question, some important findings did emerge. The number of breastfeeding sessions without supplementation increased over time by 20% indicating improvement in breastfeeding from birth to 40 weeks adjusted age. Helping families to understand that achievement of

exclusive breastfeeding is a process rather than something to be achieved immediately after birth, could protect breastfeeding long term. The data reflect the recording of one feeding of the mother's choice once a week. If data were collected each day or each feeding, patterns and trends may be more conclusive; however, this is potentially impractical. Given the high volume of tasks involved in the care of a new baby, the emotional workload, and accompanying physical recovery from birth there is little energy or time to spare for a mother of a newborn.

The use of MOM for supplementation increased from 10% to 50% (combining only MOM supplementation and MOM with formula) while formula use decreased. Supplementation of any kind is commonly required for LPIs due to immature feeding patterns and behaviors (DeMauro et al., 2011; Medoff-Cooper, 2012; Radtke Demirci et al., 2012). Shorter periods of wakefulness, weaker oral strength, and lower levels of stamina as compared to full term infants, makes effective milk transfer during breastfeeding every feeding questionable (Adamkin, 2006; DeMauro et al., 2011; Lau, et al. 2000; Medoff-Cooper, 2012; Radtke Demirci et al., 2012; Watson Genna, 2017). Supplementation is necessary during these feeding to prevent adverse outcomes (Boies et al., 2016; AWHONN, 2010; Engle et al., 2007; NPA, 2013). In the immediate postpartum period, colostrum can be difficult to express in volumes large enough for full supplementation often requiring the use of formula if pasteurized donor milk or peer shared milk is not available. With the onset of the copious milk supply and continued milk expression, MOM becomes more available for supplementation. Maternal dedication to providing human milk is evident in this study with the increase in MOM for supplementation over the duration of data collection. Anticipating the likely need for

supplementation clinicians should encourage early and frequent milk expression by hand expression and/or the use of an electric breast pump. Hospital policies should make donor milk available for this population to uphold the use of human milk as a priority and support best health outcomes.

As an unexpected finding of the study, only one participant was exclusively breastfeeding at 40 weeks adjusted age. It was not within the scope of this study to ask participants what their barriers to exclusive breastfeeding were; however, social contextual factors abound (i.e., returning to work or the care of other children). Barriers to exclusive breastfeeding in the term and preterm populations have been well studied. Future research is needed to discover the barriers specific to the LPI cohort. As the conceptual framework for this study hypothesized, LPI breastfeeding progress is multifaceted with contributing factors from the infant, mother, nursing care practices, and care environment. Considerably more research is needed to gain a fuller understanding of the confounding variables preventing or delaying exclusive breastfeeding among LPI dyads.

Although the duration of continuous breastfeeding practice and neuro-muscular development is not known for the achievement of effective breastfeeding, it may be suggested that exclusive breastfeeding in the LPI population will take at least the time needed to achieve 40 weeks adjusted age (four to six weeks). By four to six weeks postpartum, life situations, such as returning to work or caring for older children, may make the effort of breastfeeding and pumping overwhelming for LPI mothers. The oscillating nature of the LPI breastfeeding process, rather than a predictable linear progression, may lead mothers to question the worth of the effort (Radtke Demirci et al.,

2012). Multiple confounding factors may contribute to a mother's decision to discontinue breastfeeding before the infant reaches the maturational readiness for the full work of exclusive breastfeeding. Exploring how to better support this vulnerable dyad population while simultaneously supporting the lives they lead could transform breastfeeding outcomes.

Mothers are more likely to exclusively breastfeed if they feel their obstetrician and/or pediatrician are supportive of their effort (Ramakrishnan, Oberg, & Kirby, 2013). However, many women have reported receiving little to no breastfeeding education from medical providers (Stolzer & Hossain, 2014). Encouragement, discouragement, or apathy from family practitioners, obstetricians, and pediatricians influence families' feeding decisions either toward breastfeeding or away (Stolzer & Hossain, 2014). Four (17.4%) participants in this study were told by their pediatric providers that the reflux their infants were experiencing was due to human milk allergy. No evidence currently supports the existence of a human milk allergy; however, reflux related to prematurity is a known condition within the general preterm population (Eichenwald, 2018). Research is needed on the incidence and presentation of reflux in LPIs to enable the provision of anticipatory guidance. Further, providers need general breastfeeding education to prevent knowledge gaps from being a barrier to achievement of maternal breastfeeding goals.

Research question #3: How do PIBBS scores at the first at-home timepoint compare to those at the last at-home timepoint (40 weeks adjusted age)? A significant difference was found for the PIBBS items of staying latched, sucking effort, and the longest sucking bursts. As neurologic development continues for LPIs in the extrauterine environment, progression of breastfeeding behavior may be attributed, at least in part, to

maturation (Horgan, 2015; Hallowell & Spatz, 2012). Breastfeeding practice also may speed the achievement of optimal PIBBS scores. Future research is needed to explore the influence of the number of times each day infants are put to breast and the duration of each breastfeeding session. If practice speeds maturation, educating and encouraging families to practice every feeding may quicken the time needed to achieve exclusive breastfeeding and possibly increase milk production volume.

Implications

The process of breastfeeding is often challenging but rarely static. As mother and infant traverse the dynamic path of breastfeeding, the influences of maternal motivation and self-efficacy; social, political, and cultural contributors; and family support or the lack of add complexity to the already delicate situation. When the infant is born during late preterm, issues of maturation further complicate the multifaceted process. A general lack of breastfeeding knowledge has been identified as a barrier to breastfeeding duration (USDHHS, 2011). LPI parents need a program, inclusive of multiple teaching modalities, to provide education and encouragement for navigating the vacillating progression of LPI breastfeeding. Teaching modalities may include written material, verbal instruction, pictures and imagery, and digital outreach (text messaging and/or downloadable application). Several participants indicated how having contact with the investigator provided the motivation to continue breastfeeding or pumping or delay transition to formula feeding. Incorporating PIBBS into an education program has the potential of supporting maternal breastfeeding goals and infant sucking skills. Future research is needed to test the effectiveness of a comprehensive patient education program with a structured outpatient follow up program on achievement of breastfeeding exclusivity and

duration. Qualitative research following the implementation of such a program could serve evaluate effectiveness and usefulness, while identifying additional breastfeeding barriers and other nuanced considerations for LPI dyads.

Limitations

High attrition is not unusual for longitudinal studies with many authors reporting attrition rates between 30 and 70% (Gustavson, von Soest, Karevold, & Roysamb, 2012). Likewise, there was a 43.5% attrition rate during this study. Participant loss jeopardizes the validity of study findings and appropriateness of generalization to the LPI population (Given, Keilman, Collins, & Given, 1990; Polit & Beck, 2017). Replication of this study is needed with a larger sample size to ensure results are representative of LPI dyads. Revised communication and collaboration strategies with participants may serve to decrease attrition (Given et al., 1990). With a small sample size, no generalization is possible.

Recruitment was limited by the dependence on hospital lactation consultants at each facility to identify and approach potential participants then communicate with the investigator in a timely manner. IBCLCs at participating facilities admitted to sometimes being too busy to discuss the study with potential participants or simply forgetting about the study. This study design provided only one investigator for the study going to multiple facilities which resulted in missed recruitment opportunities. Replication of this study would benefit from at least two investigators or, ideally, at least one at each facility. Recruitment was further limited by the timeframe of the study. Four months was dedicated to recruitment with consideration for timely data collection and evaluation.

Considerations

Repeating inter-rater testing with a larger sample size and more than one investigator would provide definitive data for usefulness in guiding feeding decisions. An evaluation of the effect of intrapartum MgSO₄ on LPIs in general and their breastfeeding behaviors, in particular, would provide a better understanding and the foundation for education in this cohort of LPI dyads. Additionally, validation research of PIBBS translation into Spanish and other languages will allow for cross-cultural reliability testing.

Research is needed to explore the influence of a comprehensive LPI education package and follow up care program. The program could include an education packet describing normal feeding patterns and behaviors of LPIs, PIBBS tools, and weekly contact with a lactation consultant. Exploring the outcomes of such a program could help further the standard of care for LPIs and improve health outcomes. Qualitative investigation of LPI dyads navigating through a postpartum care program would further inform the effectiveness of the program and quality improvement.

The methodology of this study did not contain a qualitative component; however, breastfeeding is inherently qualitative. Each contact timepoint provided space for participants to ask questions and discuss their breastfeeding experiences. Stories were told of issues of latch, infant sleepiness, and the stress of breastfeeding over pumping and bottle-feeding expressed milk. Some mothers also discussed using alternative feeding products, i.e. nipple shields, supplemental nursing systems, and bottles. General and specific health concerns were discussed, most commonly infant reflux, medical diagnosis of infant milk protein allergy, and maternal milk production. A qualitative analysis of the

LPI breastfeeding experience with PIBBS could identify additional barriers and further education needs.

Conclusions

Breastfeeding behavior of late preterm infants can oscillate day to day and week to week. Unlike other preterm infants, the relative size and stability of LPIs allows them to stay with their mothers after birth. Yet any level of prematurity can prevent immediate effective breastfeeding behaviors. PIBBS is a reliable tool for the LPI population providing an objective means of maternal evaluation of feeding quality. Incorporating PIBBS into standard breastfeeding education could allow for better support toward achievement of maternal breastfeeding goals.

When an infant is born four to six weeks early, feeding maturation skills must be developed in the extrauterine environment where other infant and maternal/caregiver influences may change the course of feeding progression. The introduction of alternative feeding methods, the degree of practice time at the breast, tolerance of feeding frustrations by both mother and infant, separation of mother from infant, and other innumerable determinants may delay or disallow exclusive breastfeeding. However, the use of PIBBS within the context of a purposefully designed and operationalized LPI education program initiated at birth and continued until the expected due date may go far to protect, promote, and support breastfeeding.

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*Figure 1. Conceptual Framework for Optimizing Health for Near-Term Infants. Adapted from Medoff-Cooper, B., Bakewell-Sachs, S., Buus-Frank, M.E., & Santo-Donato, A. (2005). The AWHONN near-term infant initiative: A conceptual framework for optimizing health of the near-term infant. *Journal of Obstetrics, Gynecology, and Neonatal Nursing*, 34(6), 666-671.*



Figure 2. Reconceptualized framework.

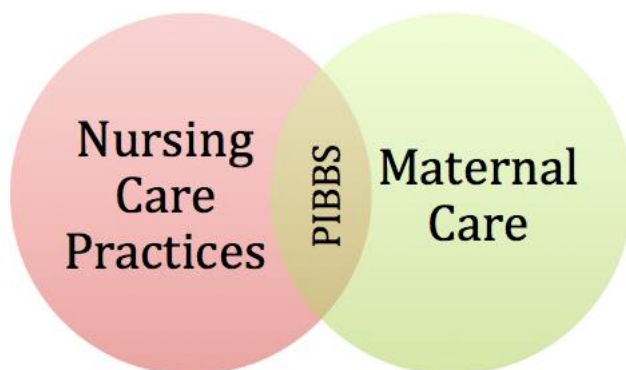


Figure 3. Reconceptualized framework: Focused concepts for study.

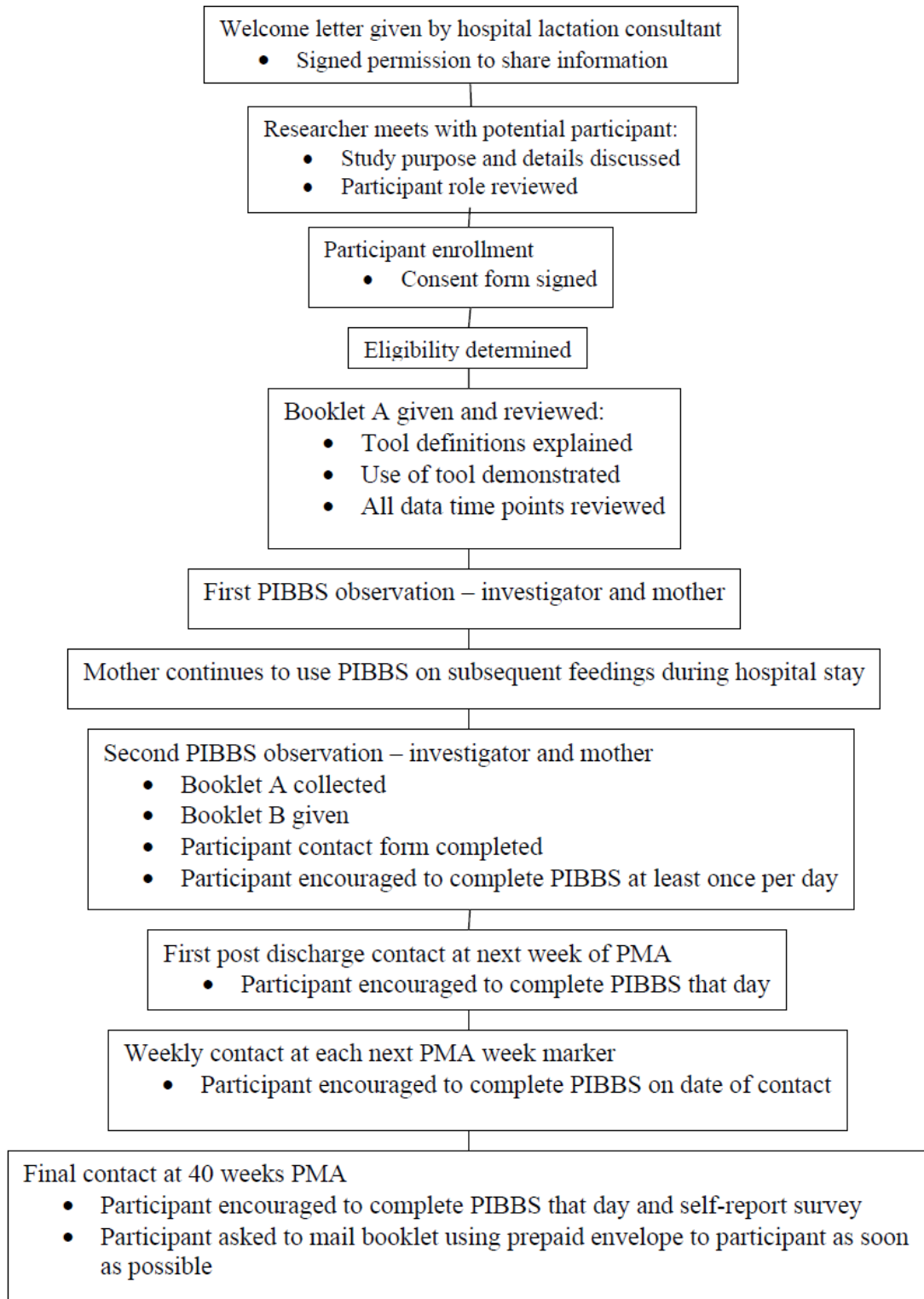


Figure 4. Participant contact algorithm.

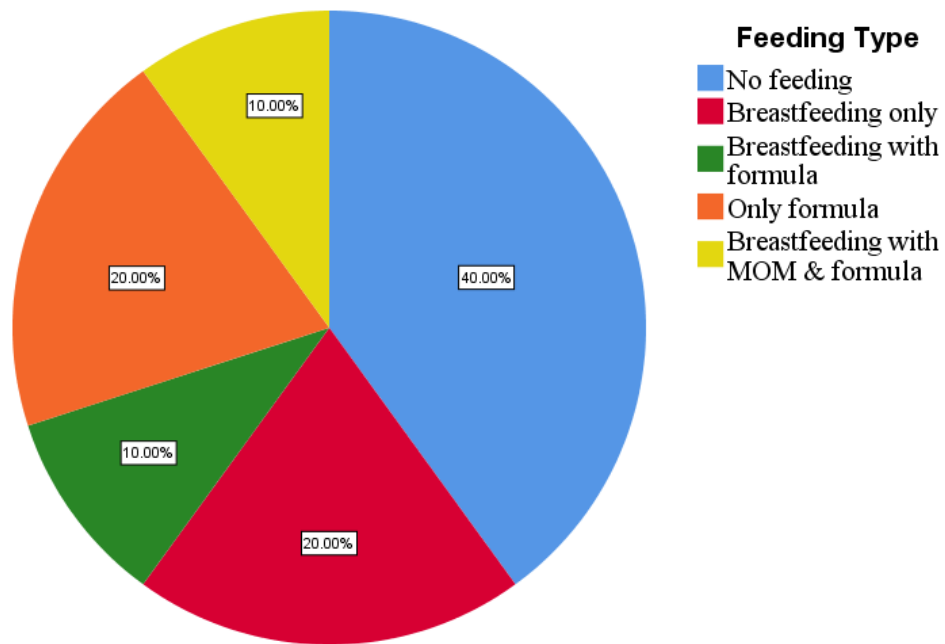


Figure 5. Feeding activity at first assessment. Percentage of feeding by each feeding type. ‘No feeding’ was a data collection point off the infant’s determined feeding schedule. Assessment was conducted to prevent loss of data and to ensure maternal confidence in using the PIBBS tool. MOM = mother’s own milk.

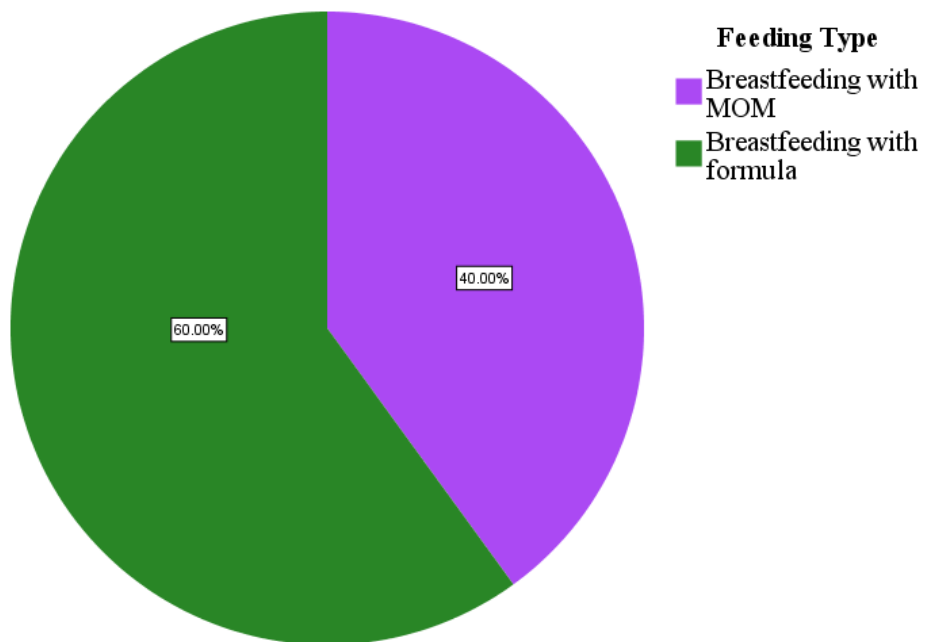


Figure 6. Feeding type at the first at-home timepoint. Percentage of feeding by each feeding type. MOM = mother's own milk.

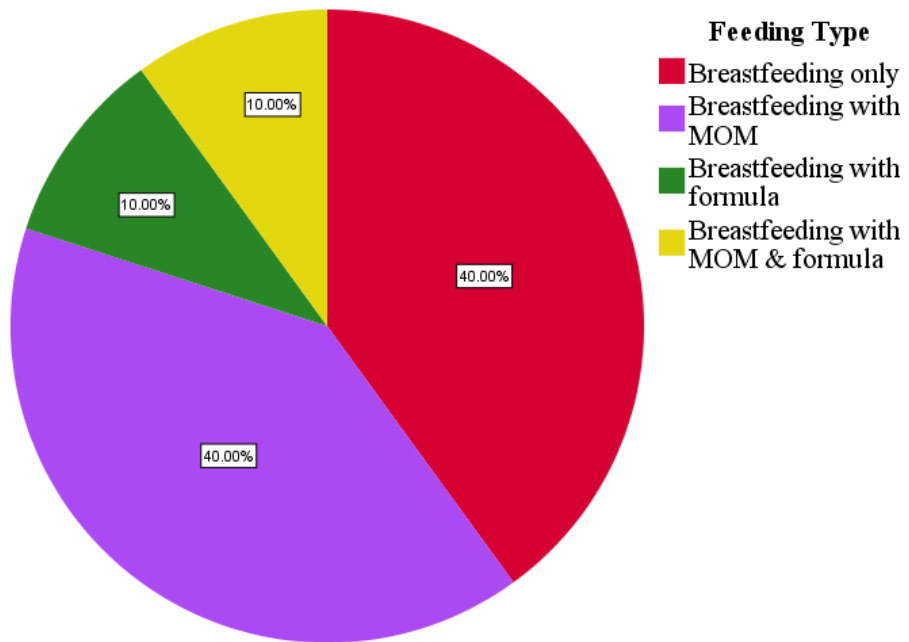


Figure 7. Feeding type at the last at-home timepoint (40 weeks adjusted age). Percentage of feeding by each feeding type. MOM = mother's own milk.

APPENDIX A
DEMOGRAPHIC DATA COLLECTION

Demographic Data Collection Form

- Check for inclusion criteria
 - Maternal
 - 18 years of age or older
 - English speaking and literate
 - Expressed intent to breastfeed upon admission to labor and delivery
 - Infant
 - Singleton
 - APGAR at 5 minutes: ≥ 7
 - Birth weight WNL for LPI
Female: 1700-3300 grams
Male: 1800-3700 grams

- Check for exclusion criteria
 - Maternal
 - Pre-gestational diabetes
 - Illicit drug use or tobacco use
 - Psychiatric illness
 - Intrapartum use of magnesium sulfate
 - Infant
 - Congenital anomalies
 - Admission to NICU
 - Other long term separation

Demographic information from EMR

Maternal parity _____
Previous breastfeeding experience _____
Mode of delivery _____
Date & time of delivery _____
Gestational age at delivery _____
Due date _____
Baby's name _____

Demographic Data Collection Form cont.

Marital status: Not married _____ Married _____

Education: No high school _____
High school diploma _____
Some college _____
College diploma _____
Graduate degree _____

Hispanic ethnicity: No _____ Yes _____

Race: White _____
Black/African American _____
Asian _____
Native American _____

Maternal age _____

Insurance provider: Commercial _____
Medicaid _____
Self-pay _____

History of preterm delivery: No _____ Yes _____

APPENDIX B

PRETERM INFANT BREASTFEEDING BEHAVIOR SCALE

Item	Baby behavior	Score
Rooting	No rooting.....	0
	Some rooting behavior.....	1
	Obvious rooting behavior.....	2
Latch	None, only touches the nipple.....	0
	Only part of the nipple.....	1
	The whole nipple, but not the areola.....	2
	Wide latch, all of nipple and as much areola as possible.....	3
Staying latched	No latch at all.....	0
	Latched on for ≤ 5 minutes.....	1
	Latched on for 6-10 minutes.....	2
	Latched on for $\geq 11-15$ minutes.....	3
Sucking	No sucking at all.....	0
	Licking motion but no sucking.....	1
	Short sucking bursts (2-9 sucks).....	2
	Repeated short sucking bursts and/or occasional long bursts (≥ 10 sucks).....	3
	Repeated (≥ 2) long sucking bursts (≥ 10 sucks).....	4
Longest sucking bursts	1-5 consecutive sucks.....	1
	6-10 consecutive sucks.....	2
	11-15 consecutive sucks.....	3
	16-20 consecutive sucks.....	4
	21-25 consecutive sucks.....	5
	≥ 26 consecutive sucks.....	6
Swallowing	No swallowing noticed.....	0
	Occasional swallowing.....	1
	Repeated swallowing.....	2

APPENDIX C
MATERNAL SELF-REPORT SURVEY

Breastfeeding progress at this time	I am exclusively breastfeeding	I am both breastfeeding and bottle feeding	I am exclusively bottle feeding		
If bottle-feeding at this time, what is in the bottle?	My expressed breast milk	Mostly my breast milk, but sometimes formula	Sometimes my breast milk, but mostly formula	Only formula	
Did you need to give formula after you left the hospital	No	Yes			
If YES, were you able to stop giving formula after you left the hospital	No	Yes			
How useful was the PIBBS tool in assessing how well your baby was breastfeeding	Very helpful	Kind of helpful	Neutral	Not very helpful	Not helpful at all

APPENDIX D
RECRUITMENT LETTER



Hello!

You have made a wonderful decision to breastfeed your baby. Your milk and breastfeeding are so important for both you and your baby's health.

A baby born 4 to 6 weeks early (late preterm), needs time to grow and develop breastfeeding skills. In the meantime, it may be challenging to breastfeed. Our research team is conducting a study to determine the best way for parents and health care providers to understand how to make breastfeeding as easy as possible for these early babies.

Angela Lober, the researcher, would like to come speak with you face-to-face to explain the study. If you choose to participate in the study, you and Angela will follow guidelines about how to assess how well your baby is breastfeeding. After talking with Angela, you may choose to join the study or not to participate. Participation is voluntary. The decision is yours and will have no affect on the medical care you receive.

If you are interested, please sign below. Your name and hospital room number will be passed on to Angela and she will contact you very soon.

Thank you for your time.

Angela Lober, PhD(c), RN, IBCLC
Doctoral Candidate at
Arizona State University College of Nursing and Healthcare Innovation
550 North 3rd Street, Phoenix, AZ 85004

I am interested in talking to Angela Lober about the above described research.

Signature

Printed name

Date

Hospital _____ Room number _____

APPENDIX E
CONSENT FORM



Title of research study: Reliability of the Preterm Infant Breastfeeding Behavior Scale (PIBBS) for the Late Preterm Infant Population

Investigators:

Dr. Pauline Komnenich, PhD, RN and Angela Lober, PhD(c), RN, IBCLC

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are the mother of a late preterm baby. Mothers who are 18 years of age and older and have chosen to breastfeed are eligible to participate.

Why is this research being done?

Babies born between 34 and 37 weeks gestation are sleepy, need time to grow, and are often have difficulty breastfeeding well – at least at first. Having a way to understand how to make breastfeeding easier and assess if your baby is getting enough milk while breastfeeding may ease worry and facilitate further lactation help.

How long will the research last?

We ask you to participate until you reach your expected due date. For instance, if your baby was born at 36 weeks, you will remain in the study for 4 weeks.

How many people will be studied?

We expect about 75 mom/baby dyads will participate in this research study.

What happens if I say yes, I want to be in this research?

You are free to decide whether you wish to participate in this study. You will meet with one of the primary investigators, Angela Lober, who will review all details with you. She will check your medical record for information about your labor and birth. She will also record the baby's weight and gestational age.

Once you are enrolled, you will receive a booklet with study information and Ms. Lober will explain how to use it. Copies of a breastfeeding assessment scale (Preterm Infant Breastfeeding Behavior Scale [PIBBS]) will be included. PIBBS will be used throughout the study to assess individual breastfeeding sessions. This assessment scale takes about 5 minutes to complete. During your hospital stay, you will be taught how to use this scale and asked to score two breastfeeding sessions with Angela using the scale. You will take a study booklet home with you.

You will be asked to continue using the PIBBS at least once a week until your baby's due date. Angela will contact you by phone call or text once a week until your due date. You will receive a schedule of when to expect these calls, which can be arranged around your schedule.

What happens if I say yes, but I change my mind later?

You can leave the research at any time by letting Ms. Lober know you want to do. Leaving the study will not affect your medical care.

Is there any risk to being in this study?

There are no foreseeable risks to participating in this research.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning how to know if your baby is effectively breastfeeding and when to seek help from a breastfeeding expert.

What happens to the information collected for the research?

Only the research team will have access to your information. Your information and study material will be given a code number. Your name or any other personal identifiers will not be attached to the information collected. No personal information will be shared in any written work or presentation that may come from this study. All data is grouped so individuals will not be identifiable.

However, we cannot promise complete secrecy. Organizations that may inspect and copy your information include the University board that reviews research who want to make sure the researchers are doing their jobs correctly and protecting your information and rights.

Who can I talk to?

If you have questions, concerns, or complaints, talk to the research team:

Dr. Pauline Kommenich, Dr. Joan Dodgson, and Dr. Lesly Kelly

This research has been reviewed and approved by the Social Behavioral IRB.

You may email at research.integrity@asu.edu if:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Your signature documents your permission to take part in this research.

Signature of participant –
signature also provided consent for infant participation

Date

ADDENDUM

I acknowledge the collection of the additional demographic information which includes my marital status, education, ethnicity/race, age, insurance (commercial, AHCCCS, or self-pay), and history of preterm birth. I give permission for the researcher to access that information from the medical record. I understand that the information will remain anonymous and maintained as confidential.

Your signature documents your permission to provide this information.

Signature of participant

Date

Printed name of participant

APPENDIX F
HIPPA AUTHORIZATION FORM



HIPAA AUTHORIZATION FORM

Protocol Title/ASU HS #: Reliability of the Preterm Infant Breastfeeding Behavior Scale (PIBBS) for the Late Preterm Infant Population

Principal Investigator: Dr. Pauline Komnenich & Angela Lober, PhD(c), RNC, IBCLC

AUTHORIZATION TO COLLECT, USE, AND SHARE HEALTH INFORMATION FOR RESEARCH

By law, researchers must protect the privacy of health information about you. This form and the attached research consent form need to be kept together.

We are asking you to take part in the research described in the attached consent form. The researchers are not authorized to collect any health information about you unless that information is described in the consent form that you sign.

What is “health information”?

As used in this form, the phrase “health information” includes:

- Health information that identifies you.
- Information about you that is created during the research study. This might include the results of tests or exams that become part of the study records.
- Information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, diagnostic and medical procedures and your medical history.

The specific information that will be collected in this research is:

- Date and time of infant birth
- Type of delivery: vaginal or c-section
- Gestational age of infant at birth
- Number of previous pregnancies
- Previous breastfeeding experience

For you to be in this research, we need your permission to collect and share this information.

Who will see the health information collected in this research?

If you agree to participate, you are giving permission for the researchers to share your health information with the following people and groups:

- Anyone listed in the informed consent document as a person or group that you agree may receive information about you,
- Anyone listed in a separate authorization for release of medical records or information that is signed by you,

- People at ASU who help with the research,
- Review boards and others who watch over the safety, effectiveness, and conduct of the research.
- Other researchers when a review board approves the sharing of the health information.
- Your health insurer if they are paying for care provided as part of the research study.
- Others, if the law requires.

The researchers cannot control what any of these persons or groups may do with the information they receive about you and the privacy of your information may no longer be protected by federal privacy rules after it is disclosed to them.

What if you don't want to participate in the research?

You do not have to sign this permission (“authorization”) form if you do not want to be in the research. If you do not sign, then you will not be allowed to participate in the study. If you decide not to sign, it will not result in any penalty or loss of benefits to which you are entitled.

If you sign this form and then change your mind later, and do not want us to use and share your health information, you will need to send a letter to the researcher at the address listed on the attached consent form. The letter will need to say that you have changed your mind and do not want the ASU researcher to collect and share your health information. The researcher may still use the information they have already collected.

Will you get to see the health information collected about you?

If you wish, you will have access to health information about you that is created during the study.

If you have any questions, please contact the researcher listed on the attached consent form. You may also call the ASU Office of Research Integrity and Assurance at 480-965-6788 with questions about the research use of your health information. Your researcher will give you a signed copy of this form.

I agree to the collection, use, and sharing of my health information for purposes of this research study. This permission will not expire unless you tell the researchers in writing that you have changed your mind and no longer want to participate.

Signature of participant

Date

Printed name of participant

APPENDIX G

CONTACT INFORMATION FORM



Contact Information

Mom's first name: _____

Phone number: _____

Email address: _____

Preferred method of contact:

- Phone: call
- Phone: text
- Email

Baby's name: _____

Adjusted gestational age of baby at first home contact: _____

Contact schedule: _____

APPENDIX H

PARTICIPANT BOOKLET

Late Preterm
Breastfeeding
Notebook



Preterm Infant Breastfeeding Behavior Scale
Booklet

Dear Study Participant,

Thank you for participating in this study. Late preterm infants are often born not completely ready to do the work of breastfeeding. With time and practice, breastfeeding will improve.

The purpose of this study is to test a breastfeeding assessment tool for use with late preterm infants. The tool may help determine the effectiveness of breastfeeding at each feeding. This tool is called the Preterm Breastfeeding Behavior Scale (PIBBS) and it takes about 5 minutes to complete.

This booklet contains copies and instructions of the PIBBS form. The researcher will go over the form, how to use it, and answer all your questions.

Your personal information will not be shared with anyone. Your booklet and the baby's feeding information will not include any information that could identify you. Your participation is voluntary and you can leave the study at anytime. However, the information you provide may help to make a difference in the breastfeeding experience of many late preterm infants to come.

Thank you again for being a part of this study.

Sincerely,

Angela Lober, RNC-MNN, IBCLC

Cell # --- --- ----

Email: AngelaLober@asu.edu

You will be asked to participate in the following ways:

1. On the first day, review the booklet with the researcher. You and the researcher will observe your baby breastfeeding and use the tool together.
2. You will be asked to complete the tool with each feeding during your hospital stay or as often as possible. The more the better.
3. The researcher will meet with you again on the second day before you go home. You will observe another breastfeeding session with the researcher and complete the PIBBS tool again.
4. The researcher will then give you a new booklet. Also included will be a prepaid envelope to return the booklet at the end.
5. You will be asked to complete a PIBBS tool as often as possible until your baby's due date.
6. From this point, the researcher will contact you, either call or text (your choice), each week on the day your baby would have been the next week's gestation. She will ask you how you are doing with the tool and remind you to complete the tool at least once that day.
7. On your baby's due date, the researcher will contact you for the final time. She will ask you to complete the last PIBBS form that day and the survey at the end of the booklet.
8. Once you are done, place the booklet in the prepaid envelope and drop it in the mail. If it is easier for you, scan your PIBBS pages and email them to the researcher instead.

The PIBBS item definitions

Rooting: The baby's mouth is wide-open and/or bringing hand to mouth. The baby moves her head side to side. She tries to suck on her hand or other object around her face.

Some rooting: Shows one or more sign of rooting, but may not be eagerly done.

Obvious rooting: Shows rooting by both opening mouth and turning head from side to side.

To encourage rooting: Unswaddle baby and place skin to skin. Lightly touch the corner of the baby's mouth, lips or cheeks. Express breast milk to provide drops to baby.

Latch: How wide is the latch? Do you notice the baby is able to take in part of the nipple, the whole nipple, both the nipple and the part of the areola?

Staying latched: Does the baby suck when latched? Does he stay latched or come on and off? Do you need to re-latch?

Record the longest period of time, in minutes, that your baby stayed latched on until his mouth relaxes and he lets go.

Sucking: The baby makes movements with the mouth and tongue to while latched. You may feel the suck or see movements of her mouth, cheek, or jaw.

Licking: The baby licks and makes light sucking movements, but does not latch. He may lick the milk from the breast and swallow without sucking at all.

Short sucking bursts: A single suck up to 9 consecutive sucks on the longest burst.

Long sucking bursts: 10 or more consecutive sucks.

Repeated long sucking bursts: 2 or more consecutive long bursts.

To encouraged suck: Repeated breast compression (gentle pressure down and toward the baby, hold for a few seconds, release, repeat), massage the arm, apply gentle pressure to the soft space behind the tip of the chin.

Record the longest sucking burst from 1 to 30 sucks. A pause between bursts is the lack of sucking for 2 seconds or longer.

Swallowing: You may hear swallowing or only see movements of the baby's jaw and throat. The sucking rhythm may change from rapid to slow and regular.

General behavior: What does your baby look like as she while at the breast?

1. Closed eyes, no active movement
2. Closed eyes, active movement in arms, legs, or torso
3. Open eyes, active movement in arms, legs, or torso
4. Drowsy: semi-dozing look with half-open eyes, opened eyes momentarily and closed them again, only minimum active movement
5. Open eyes, did not seem to have visual contact with you or at anything else, dazed look (seems to look through rather than at anything), minimum active movements
6. Eyes wide open with tense look, minimum active movements
7. Open eyes, seemed to focus attention on something, looked calm or satisfied, a minimum active movement
8. Cries or audibly fussy

Sometimes it is hard to clearly see different behaviors in preterm babies. Behaviors last for a short time and change rapidly.

Breast milk transfer: The first few days after birth, uterine cramping will indicate milk letdown. Also you may notice swallowing motion in your baby's jaw and throat. As the milk volume increases, you may feel tingling or a warm sensation inside the breast as the milk releases.

To encourage milk transfer: Repeated breast compression (gentle pressure down and toward the baby, hold for a few seconds, release, repeat)

Breastfeeding session: A period when the baby has some kind of oral contact with the breast, no matter if she shows any activity while at breast or not.

If the baby shows some kind of activity toward the breast, takes a pause of 30 minutes or more, then begins a new period of activity, this will be recorded as a new breastfeeding session.

Adapted from: Hedberg Nyqvist, K., Rubertsson, C., Ewald, U., & Sjöden, P. (1996). Development of the Preterm Baby Breastfeeding Behavior Scale (PIBBS): A study of nurse-mother agreement. *Journal of Human Lactation*, 12(3), 207-219.

Date _____ Time _____

Preterm Infant Breastfeeding Behavior Scale

Item	Baby behavior	Score
Rooting	No rooting.....	0
	Some rooting behavior.....	1
	Obvious rooting behavior.....	2
Latch	None, only touches the nipple.....	0
	Only part of the nipple.....	1
	The whole nipple, but not the areola.....	2
	Wide latch, all of nipple and as much areola as possible.....	3
Staying latched	No latch at all.....	0
	Latched on for ≤ 5 minutes.....	1
	Latched on for 6-10 minutes.....	2
	Latched on for $\geq 11-15$ minutes.....	3
Sucking	No sucking at all.....	0
	Licking motion but no sucking.....	1
	Short sucking bursts (2-9 sucks).....	2
	Repeated short sucking bursts and/or occasional long bursts (≥ 10 sucks).....	3
	Repeated (≥ 2) long sucking bursts (≥ 10 sucks).....	4
Longest sucking bursts	1-5 consecutive sucks.....	1
	6-10 consecutive sucks.....	2
	11-15 consecutive sucks.....	3
	16-20 consecutive sucks.....	4
	21-25 consecutive sucks.....	5
	≥ 26 consecutive sucks.....	6
Swallowing	No swallowing noticed.....	0
	Occasional swallowing.....	1
	Repeated swallowing.....	2

How did this feeding go?

Only breastfeeding Both breastfeeding and expressed breast milk
 Both breastfeeding and formula Only formula

Hedberg Nyqvist, K.H., Sjöden, P., & Ewald, U. (1999). The development of preterm infants' breastfeeding behavior. *Early Human Development, 55*, 247-264.

APPENDIX I
CONTACT SCRIPT

“Hello. This is Angela from ASU with the PIBBS breastfeeding tool. How are you doing with the PIBBS tool? Would you complete one today if you have not already? Do you have any questions?”