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UNIVERSITY OF SAN DIEGO

IN-HOSPITAL FACTORS ASSOCIATED WITH SUPPLEMENTATION
AMONG HEALTHY, FULL-TERM, BREASTFED INFANTS

by

Jodi Kae O'Brien

A dissertation presented to

THE FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
BETTY AND BOB BEYSTER INSTITUTE FOR NURSING RESEARCH,
ADVANCED PRACTICE, AND SIMULATION

In partial fulfillment of the requirement for the degree

DOCTOR OF PHILOSOPHY IN NURSING

May 2016

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DOCTOR OF PHILOSOPHY IN NURSING

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In-Hospital Factors Associated with
Supplementation among Health, Full-term
Breastfed Infants.

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Abstract

Background: Formula supplementation of healthy, term, breastfed infants born to mothers who plan to exclusively breastfeed persists at high rates, in spite of global reduction efforts. The identification of modifiable risk factors for supplementation and effective nursing care for successful breastfeeding is understudied.

Purpose: This study aimed to better understand the obstetrical, hospital, and nursing factors associated with supplementation during the hospital stay. The aims were: (1) examine the relationships between aspects of hospital care of infants who are supplemented compared to infants exclusively breastfed and (2) determine what in-hospital risk factors increase the odds of formula supplementation among a sample of breastfeeding infants.

Methods: This was a retrospective analysis of prospectively collected data from the electronic medical record. The cohort was a 25% random sampling of term, healthy, singleton infants born to mothers planning exclusive breastfeeding at a large tertiary hospital between January and June 2015. Adjusted odds ratios and 95% confidence intervals was calculated using logistic regression.

Results: Total sample was 1,023 with 222 (22%) supplemented. Most of the women were primiparous (88%) and 69% experienced a vaginal birth. Less than 50% of infants, reportedly initiated breastfeeding in the first hour after birth. If first breastfeed was after one hour, odds of supplementation increased to 1.42 (1.02, 1.96) Infants born to multiparous mothers had an OR 3.01 (1.95, 4.64) and similar odds were observed for women with a cesarean. Infants born during the evening hours had twice the odds of being supplemented compared to those born 6 am to noon (OR 2.10; 95% CI 1.30, 3.09).

No other birth time periods showed a statistically significant increase. Mother-infant dyads who experienced a lactation consultation were more than three times as likely to be supplemented (OR 3.08 [1.88, 5.03]).

Conclusions: Hospital policy to support attempts or initiation of breastfeeding in the first hour of life may help to reduce the odds for formula supplementation. Reducing the percentage of cesareans among healthy, women with uncomplicated pregnancies, may decrease odds for formula supplementation. The effect of the breastfeeding experience with the first birth on subsequent births needs more study.

Dedication

This endeavor would not have been possible, first and foremost, without the support of my husband, family, and close friends. This dissertation is dedicated to my parents, who I inherited my thirst for knowledge from and to my children, Aiden, Mi-Cha, and Turi, who have been my constant source for motivation towards my desire to be better, everyday.

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I would like to thank my committee members, Dr. Cynthia D. Connelly and Dr. Debra Poeltler. Dr. Connelly, thank you for helping to shape my research, from conception to completion, and for the emotional support. I would like to thank Dr. Poeltler who not only was a constant source of encouragement, but a true mentor in every sense of the word.

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Chapter I

Introduction

Endorsement of exclusive breastfeeding as the best feeding method by leading authorities (American Academy of Pediatrics, 2012; WHO, 2014), has not been enough to help frontline nurses in their support of breastfeeding mothers. Efforts in achieving the breastfeeding goals of hospitals seeking Baby-Friendly (Baby-Friendly USA, 2010) designation have not matched the outcomes indicating that breastfeeding in the immediate postpartum period is poorly understood. The evidence supports all infants be exclusively breastfed for the first 6 months of life yet, currently 19% of breastfeeding newborns are supplemented with formula during the first 2 days of hospital stay (United States Department of Health and Human Services [USDHHS], 2010) in spite of supplementation being a known predictor of breastfeeding cessation (Alikasifoğlu et al., 2001; Black, et al., 2008; Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003; Parry, Ip, Chau, Wu, & Tarrant, 2013; Semenic, Loiselle, & Gottlieb, 2008). This data combined with the known health risks of formula underscore the importance in understanding the reasons for non-medically indicated, in-hospital formula supplementation of breastfeeding infants.

Challenge

Currently, more than half of all infants in the U.S. receive formula supplementation prior to 3 months of age with only 19% of all infants breastfeeding exclusively at 6 months. In response to this major health concern, the *Healthy People 2020* initiative includes the goals to reduce formula supplementation in the first 2 days of life to 10%, increase the number of infants exclusively breastfed at 3 months to 44%, and

25.5% at 6 months (CDC, 2014). The Joint Commission for hospitals accreditation has also ramped up efforts to improve breastfeeding with the inclusion of a breastfeeding core measure (United States Breastfeeding Committee, 2013). These efforts coupled with hospitals around the globe adopting Baby-Friendly standards to support breastfeeding have achieved some success but have not translated to optimal breastfeeding outcomes, as supplementation among healthy breastfed infants persists.

Some hospitals have seen marked improvements in exclusive breastfeeding rates with the implementation of Baby-Friendly standards. However, a number of hospitals report modest improvements with overall mixed breastfeeding outcomes with persistent problems in breastfeeding duration, as evidenced by the publically reported national breastfeeding data. This suggests the pursuit of breastfeeding goals is being thwarted by factors that are poorly understood.

Even less is understood about in-hospital factors directly affecting breastfeeding in part due to limitations of the type of factors that have been investigated. All breastfeeding patterns in the hospital and nurse factors contributing to in-hospital formula supplementation among healthy, breastfeeding infants have not been identified. Much of breastfeeding research has investigated factors that promote exclusive breastfeeding, as well as maternal and infant characteristics associated with formula supplementation and its effects on breastfeeding duration and cessation.

Background

Some women choose formula supplementation in lieu of, or in addition to breast feedings during the hospital stay. By some approximations, 10% of mothers upon admission disclose of their plan *not* to breastfeed. However, the majority of women on

hospital admission report an intent to exclusively breastfeed in their infant feeding plan (Lutsiv et al., 2013) yet a quarter of all women succumb to exclusive formula supplementation for their infants after initiating breastfeeding for a variety of reasons, and as a result fail to fulfill their intention to exclusively breastfeed (Declercq, Labbok, Sakala, & O'Hara, 2009). Consequentially, these infants do not meet the recommended six-month standard for exclusive breastfeeding, are deprived of the full health benefits provided by breast milk, and are subject to the myriad of health risks associated with artificial formula (Collaborative Group on Hormonal Factors in Breast Cancer, 2002). Consequently, health risks are posed to both the mothers and their infants who are fed formula. Few non-modifiable factors have been identified that are strongly related to formula supplementation during the hospital stay. Influences of the hospital environment, including hospital practices not supportive of breastfeeding and discretionary supplementation, continue to jeopardize the health of mothers, their infants, and our community. The adoption of hospital policy which supports exclusive breastfeeding and restricts unnecessary supplementation is backed by robust evidence. However, current exclusive breastfeeding rates continue to be far from national goals, suggesting such policies fail to fully address: clinical barriers to breastfeeding, potential gaps in translating evidence into competent care at the bedside, and/or the complexity of assessing and modifying a human behavior.

The attainment of breastfeeding goals has been centered on efforts to promote breastfeeding as the most favorable feeding choice for infants and mothers. Recently, breastfeeding promotional efforts have shifted from a traditional health-benefit approach towards a preventative model to raise awareness of health risks associated with formula

(Berry, & Gribble, 2008). This has included many hospitals' adoption of routine provision of health risk education for mothers who choose formula supplementation. This change in view was generated by research that has not only identified the health risks associated with formula supplementation for infants and hazards for mothers who do not exclusively breastfeed, but also the protective effects of breastfeeding for both (Horta, Bahl, Martines, & Victora, 2007).

Much of breastfeeding research has sought to identify perinatal risk factors for formula supplementation including maternal and infant characteristics associated with formula supplementation, prenatal, and postnatal support. This focus has revealed non-modifiable characteristics including but not limited to, maternal education, gestational age, and infant gender, associated with formula supplementation. Several other factors amenable to intervention include lack of Baby-Friendly Health Initiative (BFHI) standards, breastfeeding social support, and a mother's returning to work.

Shift in Breastfeeding Support

The identification of factors known to be associated with in-hospital formula supplementation has created a significant shift in breastfeeding support representing a pivotal change from traditional breastfeeding promotion. Baby Friendly Hospital Initiative's *Ten Steps to Successful Breastfeeding* (Baby-Friendly USA, 2010) emphasizes the feeding cues of the infant as a central tenet to breastfeeding exclusivity, an improvement to breastfeeding support offered prior to 1991 when there was either a recommendation to feed based on a prescriptive number of times per 24 hours or lack of a recommended frequency. This attention to infant and maternal behavior has reinforced the complexity of synchronous factors of breastfeeding. While the focus of this study is

not on the BFHI standards, themselves, it is important to note successful breastfeeding initiation and sustainment in the hospital requires early mother and infant bonding, accurate maternal interpretation of an infant's feeding readiness behavior, and direct nurse-observation, which sets the stage for future health and well-being of both infant and mother. This emphasis on infant readiness implies breastfeeding is a complex set of activities which may explain why evaluation and prediction of breastfeeding success has proven to be challenging for both mothers and clinicians whose definition of success may also differ.

Baby-Friendly Hospital Initiative standards and evaluation criteria include guidelines for optimal in-hospital breastfeeding support shown to be effective in raising the rate of exclusively breastfeeding infants. While the biggest improvement of breastfeeding success as a result of BFHI standards has been an increase in breastfeeding initiation, significant gains in breastfeeding duration have not been seen during either the hospital stay or later in the postpartum period through the recommended six months.

Gaps in the Literature

Much of the research on reasons for formula supplementation has focused on prenatal education and postpartum (after a mother leaves the hospital) support, non-modifiable maternal and infant characteristics, and removal of in-hospital barriers to breastfeeding, such as lack of rooming-in policies. Unknown are specific breastfeeding characteristics (including the mother's response to infant feeding cues during breastfeeding episodes and time of first breastfeed), hospital influences (time of birth, timing of first supplementation, and length of stay) and nursing interventions addressing the mother-infant breastfeeding interaction Latch, Audible swallowing, Type of nipple,

Comfort, Hold (LATCH) scores and types of nursing interventions ordered for suboptimal breastfeeding assessments). Even less is known about the relationship between the nurse and the breastfeeding mother and infant and in particular, whether or not nurses themselves, or the care they provide, is associated with in-hospital formula supplementation among breastfeeding infants.

Significance

The ambiguity of in-hospital breastfeeding patterns, the hospital birth characteristics, and the nurse's role in the assessment and interventions for breastfeeding mother-infant dyad warrants research into the relationship of these factors and in-hospital, formula supplementation. These aspects of the breastfeeding interaction, hospital environment, and nurse influences on breastfeeding remain less explored in the literature. Investigation of these factors may help to identify aspects of breastfeeding support not previously known.

Purpose

The purpose of this study was to examine in-hospital factors including infant breastfeeding characteristics, aspects of the hospital stay, and nursing factors among breastfeeding infants who were supplemented with formula during the hospital stay. Previous studies have explored predictive factors of formula supplementation have not thoroughly studied these factors as essential to breastfeeding success in the immediate (hospital stay) postpartum period. Identifying risk factors for supplementation is the first step in designing appropriate policy and interventions to modify exposure to risk factors and mitigating potential effects of modifiable risks. Parity alone is a predictor of formula supplementation and will be addressed in Chapter 2. Unknown is the relationships

between the proposed investigational factors and primiparous versus multiparous mothers. This study proposed breastfeeding attributes, characteristics of being born in the hospital, and nursing factors are associated with unnecessary formula supplementation of breastfed infants born to both primiparous and multiparous mothers. This dissertation's objective in answering the following research questions were met through two aims.

Research Questions

Among infants born in a 6-month timeframe at a Southern California women's hospital:

1. Are there significant differences by maternal age, obstetric factors, infant factors, and an order for lactation consultant between those infants who are supplemented and those who are not?
2. What obstetric, breastfeeding characteristics, and hospital factors, including nurse factors, increase the odds for formula supplementation among this cohort of breastfeeding infants?

Specific Aims

Aim 1:

Examine the relationships between aspects of the hospital delivery of infants who are supplemented compared to infants exclusively breastfed among a cohort of breastfeeding infants born to mothers who delivered in a women's hospital in Southern California.

Aim 2:

To identify in-hospital risk factors that increase the odds of formula supplementation among a sample of breastfeeding infants.

Conceptual Framework

Ajzen's (1991) proposed Theory of Planned Behavior (TPB), an adaptation of the earlier Theory of Reasoned Action (TRA) (Fishbein and Ajzen, 1975) is particularly relevant to understanding influences, specific to a healthy behavior such as breastfeeding. The concept of beliefs linked to behavior is central to the theory. Variability in the expected outcome, in this case, exclusive breastfeeding is function of a women's intent to breastfeed which is mediated both by internal and external beliefs.

In applying this theory, a woman's intent to breastfeed is seemingly moderated by three domains of interconnected beliefs: 1) a mother's attitude toward breastfeeding-an iterative set of opinions or general feelings about breastfeeding, and is predicted by the mother's beliefs or what she holds as truth about breastfeeding and about breastfeeding outcomes leveraged by her individual, familial, and cultural determinants; 2) a mother's subjective norm-her unique perception about what people generally think she should do with respect to breastfeeding is predicted by normative beliefs, what she believes the in-hospital or locally accepted breastfeeding standards to be; and 3) perceived behavioral control-a mother's perceptions about being able to manage the act of breastfeeding, predicted by her perception about the ability to manage specific factors necessary for performance of breastfeeding, e.g., interpreting and responding to infant's behavior. Considering a mother's intent to breastfeed has been shown in the literature to be influenced by hospital factors, it is logical that her intent and breastfeeding success is influenced in ways not yet investigated. A woman's breastfeeding outcome may be predicated by influences within the hospital stay that compete with and commonly override her plan to exclusively breastfeed. During the hospital stay a mother and her

breastfed infant are subject to hospital influences including hospital routines, aspects of individual breastfeeding episodes, and characteristics of the nurses not accounted for with breastfeeding policy and standards of practice. Figure 1 represents a diagram of a mother's intent to breastfeed and the associated factors that may negatively or positively influence her ability to carry out her breastfeeding plan modeled after TPB [Ajzen, (1991)].

Figure 1. Applying Planned Behavior and the Parent-Child Interaction Model to a Mother's Intent to Breastfeed and Nurse-managed Maternal-Infant Feeding

The Parent-Child Interaction Model (PCI) (Barnard, 1979) later modified to become the Barnard Model, is also in explaining breastfeeding outcomes. This theory not only highlights the hospital environmental influence on breastfeeding, but the importance

of the nurse's role in the support of the maternal-infant breastfeeding interaction. The PCI model supports this parent-infant interaction changes over time and emphasizes maternal response to infant cues.

The Barnard Model incorporates the care provider, the nurse, into the maternal and infant interaction. Barnard (1979) asserts the nurse's involvement in the early establishment of the mother-infant bond is essential to improving outcomes. Barnard's theory supports the nurse's focus on fixing and intervening once breastfeeding problems have occurred thwarts breastfeeding and the maternal-infant interaction. A nurse's direct involvement in the evolving maternal-infant interaction and breastfeeding should be focused on preventative measures in reducing health and psychosocial risks associated with formula supplementation and assuring adequate opportunity for bonding and early breastfeeding initiation in the immediate postpartum period. The theory also supports the perception that hospital environmental factors are as varied as the individual nurses but the adaptability of mother, infant, and nurse is more modifiable than the previously identified predictors of exclusive breastfeeding

It is logical to suggest while there may be multiple influential factors that shape a women's breastfeeding intent as implied by the Theory of Planned Behavior, it is more humanistic to argue breastfeeding is more than a behavior or performance or an activity-it is the foundation of a maternal-infant relationship best explained by the Theory of Parent-Child Interaction. This interaction is meaningful and requires guidance and protection by the nurse as patterns for the future maternal-infant bond are being set in the early postpartum period.

Implications

The hospital environment, where 98.6% of all infants get their start in life, has a significant influence on maternal and infant interaction and bonding (Martin, Hamilton, Osterman, Curtin, & Mathew, 2015). Breastfeeding represents a dynamic interaction requiring the establishment of maternal and infant communication. The literature supports breastfeeding infants are more vulnerable to formula supplementation during specific times during the hospital stay. This is especially true during the night time when lactation specialists are not available and infants and mothers are most prone to disruptive sleep patterns. Understanding obstetrical factors, aspects of the hospital stay, and nursing care that increase risk for formula supplementation is essential in shaping appropriate policy and best practice for the care of maternal-infant dyads in the immediate postpartum period through time of discharge. Nursing as a health profession, is charged with the care and protection of those in their care (ANA, 2012), as well as the prevention of adverse health outcomes. Nurses are obligated to preserve an infant's inherent need to breastfeed. This study aims to understand how these factors may be related to breastfeeding outcomes, towards the goal of identifying better ways of supporting women and their infants in this critical time.

Chapter II

Review of the Literature

A 2011 Centers for Disease Control and Prevention (CDC) report showed 78% of U.S. hospitals do not limit formula supplementation among healthy breastfeeding infants. Only 7.9% of the U.S. hospitals classified as very large, where more than 5,000 infants get their start in life, limit hospital use of breastfeeding supplements (CDC, 2011), representing a considerable health concern. Ninety-nine percent of all births in the US occur in the hospital setting (Hamilton, 2015) with an estimated 24% of newborns being supplemented (CDC, 2013) before 2 days of age. Examining in-hospital reasons for supplementation that fall outside of the medical indication category, is imperative to reaching the *Healthy People 2020 Initiative*, aimed at reducing the number of infants supplemented in the first 2 days to 10%. Understanding these reasons may help in the endeavor to increase the total number of mothers exclusively breastfeeding at 3 months to 44.3% and 25.5% of mothers at 6 months (USDHHS, 2010).

Early formula supplementation is a known predictor of early breastfeeding cessation (Alikasifoğlu et al., 2001; Dewey et al., 2003; Parry, et al., 2013; Semenik et al., 2008). Tarrant and colleagues (2011) found in-hospital exclusive breastfeeding was protective against early breastfeeding cessation at less than 8 weeks. Research also supports formula supplementation may precede and predict breastfeeding resulting in a reduction of mothers exclusively breastfeeding throughout the hospital stay and beyond (Demirtas, 2012).

Nationwide, hospitals seek to adopt the best practice standards from Baby-Friendly USA Inc., the accrediting body for the (BFHI) (United Nations International

Children's Emergency Fund [UNICEF], 2015) in the United States. Originally launched by WHO and UNICEF in 1991, the BFHI included the original *Ten Steps to Successful Breastfeeding*, as a comprehensive roadmap to mitigate formula supplementation and improve the health of mothers and newborns. This plan served to help institutions become centers of breastfeeding support (UNICEF, 2015). When implemented collectively, these ten steps improve exclusive breastfeeding rates. Among the ten steps, is step number 6, *give newborn infants no food or drink other than breast milk, unless medically indicated*. Step 1, stipulates hospitals have policies to support breastfeeding care inclusive of step 6. However, as identified in the Guidelines and Evaluation Criteria for Baby-Friendly USA, the minimal standard of care for a hospital demonstrating adherence to Step 1 indicates a mechanism be in place for monitoring feeding policies as on-going quality improvement procedure, yet no prescriptive guidelines exist as to how to address less than optimal breastfeeding rates. Additionally, for organizations seeking Baby-Friendly designation, implementing Step 6 includes meeting criteria that, among audited infants' records, at least 80% must indicate exclusive breastfeeding at time of discharge. This audit does not sample from records of infants born to mothers who request for formula supplementation or the infants supplemented for medical reasons, an estimated 70% of all infants supplemented. While not explicitly stated, there is no maximum allowed ratio or percentage for mothers requesting formula indicating a weakness in the policy which may partially explain failure of facilities to fully carry out the BFHI guidelines and achieve the seemingly elusive breastfeeding goals. Several studies seek to identify in-hospital practices associated with the supplementation of

breastfeeding infants, regardless of Baby-Friendly accreditation, to determine why supplementation persists outside of medical necessity.

The original Step 4 of *The Ten Steps to Successful Breastfeeding*, authored by WHO and UNICEF's BFHI, specified, *help mothers initiate breastfeeding within a half-hour of birth* (UNICEF, WHO, 1992). This Step is now interpreted as: *place babies in skin-to-skin contact with their mothers immediately following birth for at least an hour. Encourage mothers to recognize when their babies are ready to breastfeed and offer help if needed*. This departure, from the original intent to support early initiation, is based on evidence that the practice of skin-to-skin is essential for newborn auto-regulation. This recent revision has yet to translate to steep improvements in early initiation and breastfeeding exclusivity.

Many studies have examined both maternal and infant characteristics associated with in-hospital formula supplementation. Researchers have studied non-modifiable characteristics such as maternal age, education, income level, and breastfeeding intent and their effects on outcome variables of exclusive breastfeeding or lack thereof. Additionally, infant characteristics such as birth weight and gender have also been examined. All of these maternal and infant characteristics are known predictors of formula supplementation, and consequently are not the focus of this study. In line with the intent of this study, the purpose of this review of the literature is to evaluate studies relevant to this study's aims, which explore in-hospital factors and nurse factors associated with in-hospital supplementation of breastfed infants among both primiparous and multiparous mothers. Articles were included if they investigated any of these factors with a focus on term, healthy infants. If studies included preterm infants or those

admitted to the NICU, the review focused on the results relevant to the sub-population of term infants.

Search Strategies

The search included published literature included in PubMed, Ovid, Cochrane Library, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases to identify studies examining hospital factors associated with in-hospital formula supplementation. The search was carried out using the key words *breastfeeding*, *supplementation*, *LATCH score* and Medical Subject Headings (MeSH) *breast feeding*, *infant formula*, and *baby formula* as words in the major subject heading. Only studies in the English from 2000 and 2015 were considered for this review. The reference lists of each study were manually examined for additional studies which met the review's focus. Only those that addressed breastfeeding patterns and in-hospital practices namely nurse factors associated with in-hospital supplementation were included. Studies that met these criteria and also evaluated primiparous and/or multiparous were considered for review.

Study Selection

The following summary includes studies related to in-hospital formula supplementation of healthy, full-term infants for non-medical reasons. Hospital factors, breastfeeding patterns, and the nurse's role and the implications on in-hospital formula supplementation were addressed. Findings are organized according to key hospital factors.

Review Findings

Definitions

Exclusive breastfeeding, as defined by WHO is no food or drink, not even water, except breast milk (including donor milk) for 6 months of life, but allows the infant to receive oral rehydration solution(ORS) drops and syrups (vitamins, minerals and medicines) (WHO, 2014). While an exact dose-response is unknown for optimal infant health outcomes, authorities agree exclusivity in the first 6 months offers optimal health benefits for mother and infant.

Hospital Factors

(Night) Time Phenomenon. Of babies born in the hospital, two studies reported that babies born at night were at increased risk for formula supplementation. Gagnon et al. (2005) conducted a mixed method study using secondary data from a randomized control trial of postpartum care of 564 mother-infant pairs born to mothers who delivered in a Canadian teaching hospital and focused interviews with 38 of the hospital's perinatal nurses. Hazard ratio curves showed infants born between 1900 and 0300 have a higher risk of early supplementation at less than 6 hours of age compared to those born in the morning (0300 to 1100). However, infants born between 0300 and 1100 had an increased risk of supplementation around 8 hours of age compared to those born in the afternoon. By 10 hours of age, the time of birth had no effect of risk of supplementation. Combining the results, the authors concluded the highest risk time of day to be supplemented, regardless of time of birth, was between 1900 and 0900. The study did not control for, or perform separate analyses by, parity with one-third of the sample being primiparous.

Additionally, mother-infant pairs were excluded if birth was by cesarean, limiting generalizability of the results to only vaginal births.

Another U.S. study conducted a retrospective, cohort study of 302 maternal-infant dyads at two different hospitals within the same hospital system using two different time periods. Infants born between 2200 and 0900, were twice more likely to be supplemented than infants born during the day [OR = 1.99, CI 1.19, 3.37] (Grassley, Schleiss, Bennett, Chapman, & Lind, 2014). Infants were also at highest risk of being supplemented at night between the hours of 1900 and 0900. Of the 38% of healthy infants that were supplemented ($n = 114$), an alarming 85% were supplemented for reasons other than medical indication or for unknown reason (reason was not documented). While the authors reported that discharge day and time of birth were significant predictors of supplementation, it is unclear as to whether or not they adjusted for known confounders including parity, infant gender, and mode of birth because neither unadjusted or adjusted relative risks were reported. A limitation of this study is the fact that the author reported the data was collected from two time periods, exactly two years apart. Investigating these factors and controlling for confounders would provide a better estimate of the association between these factors and supplementation. This sampling aspect may have influenced the outcome and further limiting the validity. Additionally, nursing interventions and breastfeeding factors were not explored highlighting a need for investigation of such.

Gagnon, Leduc, Waghorn, Yang, and Platt (2005) investigated data occurring from 1997 to 1998 and Grassley and colleagues (2014), from 2007 to 2009. Not surprising is the similarity in findings given the two studies investigated similar maternal and infant characteristics. Neither study investigated LATCH scores or nursing factors

associated with supplementation. No information was provided to indicate if the birth settings from either study were Baby-Friendly. These reasons point to the need for further investigation these factors of both hospitals that have Baby-Friendly status and those hospitals that do not.

Timely Initiation of Breastfeeding vs. skin-to-skin

The recommended Baby-Friendly standard supportive of skin-to-skin as a replacement for initiating breastfeeding within the first hour after birth (Baby-Friendly USA, 2012) may not adequately address the inherent need for breastfeeding to occur in the first hour of life. Early initiation of breastfeeding is associated with higher longer-term exclusive breastfeeding rates (Debes, Kohli, Walker, Edmond, & Mullany, 2013). While skin-to-skin has many benefits for the infant, such as temperature and respiratory regulation, and was also shown to allow infants to demonstrate unfettered early breastfeeding cues (Moore, Anderson, Bergman, & Dowswell, 2012; Widstrom, Lilja, Aaltomaa-Michalias, Dahllöf, Lintula, & Nissen, 2011) breastfeeding initiation in the first hour was not directly investigated as the outcome. A national survey of mother's in-hospital birth experiences conducted in 2012 documented less than half of mothers said they held their babies in their arms for most of the first hour of birth (Declercq, Sakala, Corry, Applebaum, & Herrlich, 2013). Of those who did, 30% of the babies were wrapped in blankets, instead of being skin-to-skin. These are exemplars of the lack of inconsistency in maternal-infant contact in the first hour and the under-investigated correlation between contact and optimal early breastfeeding initiation.

A cross-sectional study which included structured interviews with 192 Turkish primiparous mothers who delivered in a Baby-Friendly hospital found infants breastfed

within 1-2 hours were almost three times more likely to experience breastfeeding problems than mothers who breastfed within a half hour of birth (OR 2.89, CI 0.75-11.077) (Demirtas et al., 2012). This finding did not reach statistical significance, probably secondary to the fact supplementation in the hospital was forbidden and the percentage of infants supplemented was 9.9%. This low supplementation rate may be partially explained by discharge occurring at or less than 24 hours after birth and did not include cesarean delivered infants. Including cesarean deliveries would have likely produced a higher overall supplementation rate since a greater percentage are not breastfed within 1 hour due to hospital practices associated with cesareans which are not conducive to routine skin-to-skin and commonly delay the first breastfeed.

Grassley and colleagues (2014) found exclusively breastfed infants were significantly younger at first breastfeed than infants who received formula (mean age = 1.7 vs. 3.03 hours, $p = 0.048$). This finding is not surprising since this study, unlike the study of Turkish mothers, included both primiparous and multiparous mothers, vaginal and cesarean births, and a study site lacking Baby-Friendly designation.

The national *Listening to Mothers II* survey reported hospital staff-assisted breastfeeding initiation was significantly associated with the likelihood of achieving intention to exclusively breastfeed at 1 week (adjusted odds ratio [AOR] = 6.3; 95% CI 1.8, 21.6) (Declercq, Sakala, Corry, & Applebaum, 2007). Abstaining from unnecessary supplementation among primiparous and multiparous mothers resulted in a 4.4 times and 8.8 times likelihood of achieving breastfeeding exclusivity at 1 week postpartum respectively [(AOR = 4.4; 95% CI 2.1, 9.3); (AOR = 8.8; 95% CI 4.4, 17.6)]. This data provides evidence in support of modifications to current policy that permits allowable

exceptions to breastfeeding and adoption of tighter regulations to reduce supplementation.

These findings were substantiated with data supplied in the follow up survey, *Listening To Mothers III* survey (Declercq, Sakala, Corry, Applebaum, & Herrlich, 2013). Of mothers ($n=1364$) planning to exclusively breastfeed, 81% reported hospital staff helped them get started when they (mother and infant) were ready, but only 20% were exclusively breastfeeding at 6 months. This indicates that while hospitals have seen some success with helping to initiate breastfeeding, there is a sharp decline across the postpartum period including the hospital stay and beyond.

Parry and colleagues (2013) conducted a multicenter, longitudinal, prospective study of 1,417 infants born to Chinese mothers who intended to breastfeed in Hong Kong between 2006 and 2007. The study employed both chart review and telephone follow-up at multiple points from the infant's birth to 12 months of age. While none of the hospitals in Hong Kong were Baby-Friendly at the time, the authors recognized the 82.5% supplementation rate among all newborns in the hospital before 48 hours was a significant health concern. The detrimental effects of routine in-hospital supplementation is compounded by the study's results that showed two-thirds of all mother infant dyads experienced a delay in breastfeeding initiation outside the recommended standard of 1 hour. Breastfeeding in the delivery room was associated with lower odds of being supplemented (OR = 0.55; 95% CI 0.33, 0.89) prior to discharge or within 48 hours of birth, the study criteria for supplementation., but feeding information was not gathered through time of discharge for those infants who stayed beyond 48 hours. It is unclear why the authors chose the cutoff point of 48 hours, instead of time of hospital discharge to

evaluate breastfeeding outcomes given that feeding patterns are not stagnant and do change over time. The cut-off may have been decided based on publically reported breastfeeding rates that are measured in the first two days. Breastfeeding data through time of discharge may have resulted in even less infants exclusively breastfeeding. The generalizability of this study's results was limited to the first 48 hours postpartum and to hospitals that are not Baby-Friendly. While the supplementation rate reported by these researchers (as compared to other similar studies) may be partially explained by cultural aspects, it is more likely, as the authors point to, that traditional hospital practices including a lack of nursing breastfeeding support, and lack of Baby-Friendly policies, are likely explanations.

Length of Stay

The data from the two studies reporting on median age of first supplementation, 12 hours and 8.4 hours (Gagnon, et al. 2005; Grassley et al., 2014) indicates the first 12 to 24 hours is a high risk time for supplementation. A reported 38% of newborns ($n = 302$) in the first study and 48% in the second ($n = 564$) were supplemented in the hospital. Grassley and colleagues (2014) also found the odds of supplementation doubled for each day an infant spent in the hospital, subsequent to the first 24 hours. Research has shown unnecessary supplementation continues after discharge from the hospital as a result of breastfeeding experiences during the hospital stay. Although the characteristics of breastfeeding associated with supplementation are poorly understood, the findings presented by this study's authors also indicate in-hospital factors are overriding the mother's intent to breastfeed and promote tolerance of a behavior (supplementation

without medical indication) that provokes or breeds a lack of confidence in a woman's ability to breastfeed.

Parity

Biro, Sutherland, Yelland, Hardy, and Brown (2011) conducted a population-based survey in 2007 of 4,085 Australian mothers at 6 months postpartum to investigate in-hospital feeding factors associated with formula supplementation. Among infants who were breastfed, those born to primiparous mothers were at greater odds of being supplemented compared to multiparous mothers (adj. OR = 2.16; 95% CI 1.76-2.66). While the authors' descriptive approach to characterize women surveyed was informative, the characteristics were not inclusive of factors directly related to, and preceding, supplementation including assessment of breastfeeding episodes or interventions to address breastfeeding problems. While the authors cite known infant supplementation predictors related to infant behavior, no such data was collected or reported to help explain potential associations with supplementation. The only infant characteristics examined were infant's birth weight and special care nursery admission. With infants weighing less than 2500 grams and those admitted to the special care nursery being at more than twice the risk for supplementation, ([AOR 2.02; CI 1.3-3.15] and [2.72 CI 2.19-3.30]) respectively compared to those of average birth weight and not admitted to the special care nursery.

In a similar study, Chantry, Dewey, Pearson, Wagner, and Nommsen-Rivers (2014), prospectively followed a diverse group of 393 primiparous women, to investigate in-hospital breastfeeding practices and feeding practices up to 60 days postpartum. All women delivered in a setting that had reportedly adopted Baby-Friendly policies.

However, the percentage of first-time mothers of infants who were supplemented was nearly half (47%), more than double the percentage reported by Biro and colleagues (2011) whose study reported data from approximately the same time period. This disparity may be partially explained by the Australian hospitals having Baby-Friendly designation and those from the U.S. study only having policy reportedly consistent with Baby-Friendly standards.

In a third study, Sutherland, Pierce, Blomquist, and Handa, (2012) conducted a longitudinal cohort study to investigate maternal characteristics predictive of breastfeeding duration and success among 812 primiparous and multiparous women who gave birth in a large private hospital in suburban Maryland. The study began in 2008 and is on-going. Results revealed increasing birth order was associated with supplementation. The adjusted odds for a woman who did not initiate breastfeeding with a second birth, was almost twice that observed for first birth (OR = 1.83, 95% CI 1.42, 2.35). A mother's likelihood of initiating breastfeeding decreased with births subsequent to the first and a mother's breastfeeding experience with her first baby predicted her likelihood of breastfeeding success with future babies. Multiparous mothers who initiated breastfeeding early during the hospital stay and were successful at breastfeeding with their first baby (95%) were highly likely to initiate breastfeeding with their second baby (96%). A limitation of Sutherland and colleagues' study (2012) was they only captured the experience of women who returned to the same hospital for subsequent births and therefore, these women may be different from women who are more mobile or choose alternative birth settings for subsequent births. Additionally, little is known about breastfeeding factors, time of birth, breastfeeding support, and whether or not

supplementation differed between primiparous mothers and multiparous mothers during the hospital stay. This study of breastfeeding across a woman's childbearing years highlights the importance of the breastfeeding experience among infants born to primiparous mothers and its potential to have longer term consequences for subsequent infants born to these mothers.

Breastfeeding Patterns

No studies were found in the literature that sought to investigate specific aspects of the hospital breastfeeding routine and its effect on supplementation as a primary research aim. Few studies included breastfeeding characteristics as part of their primary investigation. One study reported the nurses' report of breastfeeding problems experienced by mothers who were supplemented included infant behavior, insufficient milk supply, and maternal fatigue (Gagnon et al., 2005). No information was provided about how the actual suckling process was evaluated by the nurses limiting the use of this information.

Demirtas (2012) found breastfeeding problems among primiparous mothers were significantly predictive of supplementation during the hospital stay. The problems cited included poor latch and (maternal) perceived insufficient milk supply. In spite of the author's report of the study site being Baby-Friendly, no empirical method was reported as a measure of breastfeeding success, thereby limiting the interpretation of the results.

Another study investigated maternal-reported reasons for in-hospital formula supplementation including: poor infant breastfeeding behavior along with poor latch, and poor milk transfer, and infant not ready to feed as reasons for formula supplementation associated with mixed feedings (both breast and formula) by day 60 (Chantry et. al.,

2014). Predictors for supplementation were not identified through modeling, but were investigated based on the infant breastfeeding assessment tool (IBFAT) scores of these primiparous mothers. Grassley and colleagues (2014) examined specific breastfeeding factors, including total minutes spent breastfeeding and number of feeds in the first 24 hours of the hospital. They found exclusively breastfed infants, breastfed more times (8.65 vs. 6.60 times, $p < 0.001$) and for more minutes (150 vs. 106 minutes, $p < 0.001$) than those who were supplemented (Grassley, et al., 2014). Since these variables were not measured through the entire hospital stay, it is unknown how these outcomes might have changed after 24 hours. A limitation of this study was the evaluation of breastfeeding factors for the first 24 hours only, thereby limiting the generalizability of the results given what is known about the increasing supplementation rate through the hospital stay.

Nurse's Role

Research evidence suggests decreased success of mothers exclusively breastfeeding throughout their hospital stay is influenced by the nurses caring for them, especially in hospitals without Baby-Friendly designation. Within hospitals that are not Baby-Friendly, high supplementation rates not only reflect weak breastfeeding policy but serve as a proxy of nursing care and practice that is below the BFHI standard. Hospitals that either have Baby-Friendly designation or have policies reflective of Baby-Friendly standards, demonstrate nursing care and supplementation rates closer to the national goals (Abrahams & Labbok, 2009). The disparity between a mother's intent to breastfeed and fulfillment to do so, may be partially explained by the mismatch between nurses' breastfeeding knowledge, attitudes, and practice in hospitals without Baby-Friendly

policy compared to nurses practicing in hospitals with Baby-Friendly policy. Weddig, Baker & Auld's (2011) qualitative study's findings from interviews with postpartum nurses revealed an exclusive breastfeeding policy promotes breastfeeding knowledge which in turn translates to best practice. Another significant finding of this study indicated nurses understand the importance of assessing breastfeeding with direct observation but the policy may not be clear as to how to best document their findings or how to teach parents about infant physiologic feeding cues. Given these findings, it is logical to postulate with enhancements to current Baby-Friendly policy specific to the evaluation of feeding and the documentation of support provided by the nurse for suboptimal LATCH scores, improvements in feeding outcomes may be improved and it is more likely mothers may successfully breastfed through their hospital stay and beyond.

Support provided by the individual nurses may vary depending on a number of factors. Demirtas (2012) investigated the nursing support received by breastfeeding mothers in a Baby-Friendly hospital through structured interviews. One indicator of suboptimal nursing support that predicted supplementation was the unavailability of nurses during actual breastfeeding session, (OR 3.44, 95% CI 1.06-11.18). This finding reinforces previous findings that nurses' direct observation of feedings with policy supporting empirical evaluation of feedings and will further mitigate unnecessary supplementation.

Assessment of Breastfeeding

While Pereira de Souza, Alves, Rodrigues, Branco, de Oliveira Lopes, and Souza Barbosa, (2015) did not evaluate the LATCH assessment score directly, they did report

the nursing strategy for assessing a mother's understanding of breastfeeding knowledge though direct observation of breastfeeding episodes was a way to ensure breastfeeding success and respond to potential breastfeeding obstacles. Kumar, Mooney, Wieser, and Havstad (2006), found nurses' use of the LATCH score was a predictor of breastfeeding success at 6 weeks postpartum. The authors reported that women with a LATCH score of 9 or above at 16-24 hours, were 1.7 times more likely to be breastfeeding 6 weeks out. This study highlights the importance of the LATCH in describing the in-hospital breastfeeding process. However, as noted by the study authors, hospital discharge for healthy mother and infant dyads is the traditional norm, thereby emphasizing the need to evaluate LATCH scores in association with breastfeeding exclusivity during the hospital stay as a means to predict breastfeeding success through admission and respond to those at risk more efficiently.

Summary

These studies identify or highlight several limitations in the way hospital factors have been investigated relative to in-hospital supplementation. All of these studies were observational in nature with few incorporating qualitative components, thereby making it difficult to identify all of the variables that could affect or explain differences in breastfeeding outcomes. Current in-hospital supplementation rate and lack of exclusive breastfeeding at time of discharge reflect this and the hospital's inability to adequately support individual mothers' breastfeeding needs regardless of BFHI designation. Observational studies continue to be a preferred methodological approach given the convenience and resources required to do so. However, while a potential limitation of this proposed study may be the data set itself, investigating breastfeeding patterns including

LATCH scores, hospital factors, and nursing interventions with predictive modeling is something not done previously.

A gap in the literature lies in modifiable hospital practices and routines of care that are not favorable to breastfeeding. Recent studies have identified in-hospital barriers to successful breastfeeding, such as mother and infant separation and allowing distribution of formula samples, and have evaluated interventions to address these barriers with modest increases to supplementation rates. Even among mothers who gave birth in hospitals where at least 6 of the 10 BFHI Ten Steps were 13 times more likely to be breastfeed at 6 weeks (DiGirolamo, Grummer-Strawn, & Fein, 2008), indicating while supplementation persists in many hospitals and birthing centers, mothers can successfully fulfill their goal to breastfeed when a concerted effort is made to help them.

Studies by Grassley et al. (2014) and Gagnon et al. (2005) both suggested factors related to breastfeeding behavior and maternal and clinician response may be factors underlying supplementation. Moreover, all of the foundational documents to support exclusive breastfeeding created by the WHO (1991), American Academy of Pediatrics (2012), and the Joint Commission (n.d.) indicate a mother's preference to not breastfeed should be honored. Policy at this level translates into a variety of ways at the bedside when clinicians are tasked with helping a mother make an informed decision about breastfeeding when a mother's requests formula

A limitation in past research attempting to identify in-hospital factors associated with formula supplementation is the fact the majority have been observational studies. While this study is observational, the aim to investigate hospital and breastfeeding factors, including the nurses' influence, has not been previously studied. Specifically, this

proposed study setting has seemingly implemented the *Ten Steps to Successful Breastfeeding* underscoring the importance of ensuring maternal and infant outcomes of the highest standard. Additionally, the nurses' role in the literature has been highly undervalued and under-investigated with regard to breastfeeding support. Professional nurses adhere to standards of care consistent with optimal health outcomes and strive to reach health outcomes targets. Understanding our role as nurses in helping women fulfill their feeding plans is a universal concern.

Chapter III

Methodology

Purpose

The purpose of this study was to better understand in-hospital factors including obstetrical characteristics, aspects of the hospital stay, and nursing factors associated with formula supplementation among breastfeeding infants, during the hospital stay. Gaining an understanding of these in-hospital factors will help to identify infants at risk factors for formula supplementation. Identifying infants with risk factors who may not have been previously classified as at risk, will likely increase breastfeeding duration through the hospital stay, by recruiting appropriate resources and spurring hospital policy amendments. In this chapter a description of the design, sample, data collection, and analytic techniques is described. The protection of human subjects and study limitations is also addressed.

Specific Aims

Primary Aims:

Aim 1: Examine the relationships between aspects of the hospital delivery of infants who are supplemented compared to infants exclusively breastfed among a cohort of breastfeeding infants born to mothers who delivered in a women's hospital in Southern California.

Aim 2: To identify in-hospital risk factors that increase the odds of formula supplementation among a sample of breastfeeding infants.

Research Questions

Question 1:

Are there significant differences by maternal age, obstetric factors, infant factors, and an order for lactation consultant between those infants who are supplemented and those who are not?

Question 2:

What obstetric, breastfeeding characteristics, and hospital factors, including nurse factors, increase the odds for formula supplementation among this cohort of breastfeeding infants?

The purpose of investigating these questions is to describe breastfeeding characteristics and hospital factors associated with both medically and non-medically indicated formula supplementation of healthy, term, breastfed infants.

Assumptions

There are modifiable breastfeeding characteristics and aspects of the hospital stay associated with and increase the odds of formula supplementation not previously examined. Breastfeeding problems, as identified with the breastfeeding patterns and LATCH scores, indicate nurses are not tailoring their education and interventions appropriately according to Kreuter, Lukwago, Bucholtz, Clark, & Sanders-Thompson, (2003) theory of intervention tailoring, resulting in formula supplementation. Clinical nurses are the first line of breastfeeding support for mothers and arguably have their own supplementation rate because of differences in breastfeeding knowledge, attitudes and practice.

Study Design

A prospective cohort study design was used to address both aims. This study cohort included all mother-dyad pairs who delivered at the designated hospital and met study inclusion criteria during a pre-specified period of time. The sample was obtained with an initial request from the perinatal download database (PDD) using the inclusion criteria identified. This dataset was then supplemented by manual data extraction from the electronic medical record (EMR).

Manual extraction was necessary to collect LATCH scores and missing data for time of first supplemental feed. During manual data extraction, inclusion criteria were verified and if this data indicated that subjects did not meet study inclusion criteria, they were excluded.

Sample and Setting

The setting for this study was a non-profit Southern California hospital for women and infants in an urban metropolitan area. This over 200 bed hospital provides obstetrical and acute gynecological care for women across the lifespan and also houses a Level III neonatal intensive care unit (NICU). The hospital has affiliations with the many private obstetrical group practices. During the timeframe of this study, the hospital was in the late stages of seeking official Baby-Friendly designation by Baby-Friendly USA, with a designated multidisciplinary task-force orchestrating the application process. Evaluation of the breastfeeding dyad and documentation of breastfeeding and infant characteristics were in the process of being standardized and adopted in preparation for the Baby-Friendly application. While steady gains in exclusive breastfeeding had been achieved for this hospital, supplementation, both medical and non-medical, continued.

Nearly all mothers admitted to this hospital reported the intent to exclusively breastfeed as their feeding plan. An average length of stay in this hospital is 2-3 days, for an uncomplicated vaginal delivery, and 3-4 days for a cesarean delivery. On average, 61% of women are exclusively breastfeeding at time of discharge. This setting was selected because of the diverse population served by this hospital and the large annual volume of deliveries. The hospital is charged with the care and health promotion of members of the surrounding community, underlining the importance for the hospital to have the highest standards of maternity care.

Breastfeeding Hospital Policy

Labor and delivery and postpartum registered nurses are required to follow hospital policies that reflect local and international professional guidelines in the care of mother and infant dyads in the postpartum period during the hospital stay (Simpson, 2013; UNICEF & WHO, 1989). This study's setting included policy that reflects both California Breastfeeding Model Hospital Policy (California Department of Public Health [CDPH], 2005) and Baby-Friendly (2012) policy.

The hospital policy and procedures and guidelines of care include nursing standards for assessment, interventions, and documentation of breastfeeding support. The written breastfeeding policy itself satisfied the first step in becoming a Baby-Friendly institution. The remaining 9 steps for Baby-Friendly include evidence-based practices that promote breastfeeding. Of relevance to this study is Step 8 which highlights the importance of infant-led (cue-based) feedings or "on demand" and unrestricted, which has replaced a prescriptive number of times in a 24-hour period. This on-demand philosophy is strategically supported by Step 7, maintaining unhindered and

uninterrupted, maternal and infant contact. Included in this policy is the requirement that all new and existing nurses have a standardized minimum training to support exclusive breastfeeding. The training and policy contains detailed information regarding the frequency and method of nursing documentation of breastfeeding episodes, as well as practical infant feeding instructions and/or interventions if assessment reveals an inadequate breastfeeding pattern.

At the time of this investigation, the hospital policy also contained instructions on when and how to address mothers who requested formula supplementation outside of a medical indication including the nurse “exploring” questions/concerns mothers have about breastfeeding that may be underlying this request. There was also direction that required the nurse to provide the mother with information of potential health risks associated with formula and the nurse honor a mother’s choice to supplement, followed by documentation of time and reason for supplementation.

Separate supplementary feeding policy of well newborns indicated the procedure for the nurse to follow in the management of all healthy infants (≥ 37 weeks). This policy included: skin to skin contact immediately after birth (Step 4), feeding on cue [≥ 8 times in 24 hours (Step 8)]; hand expression for poor latch (Step 5); referral to a lactation consultation (Step 5); and pumping initiation if LATCH scores were “consistently” < 7 or no sustained latch [for at least 5 min (Step 5)]; While both policies indicated the nurse’s requirement to document reason for supplementation and the education to be provided to the mother, absent from the infant feeding policy and the supplementary feeding policy is guidance for the nurse in determining which interventions were appropriate to address inadequate maternal response to infant feeding readiness cues.

Further, there was no explicitly stated breastfeeding management interventions to address specific components of suboptimal (<7) LATCH scores. Provision of any particular intervention is left to the discretion of the individual nurse.

Nurses' Breastfeeding Education

As the primary promoters of breastfeeding during the hospital stay, nurses have a marked influence on a mother's initiation, duration, and exclusivity of breastfeeding which has lasting short-term and long-term maternal and child health implications. The enormity of this responsibility is echoed in the hospital's Baby-Friendly policy and the educational training required of nurses caring for infants and mothers in this particular study's setting. This policy regarding nurses' breastfeeding training represents Step 2 of the Ten Steps and includes completion of 15 breastfeeding lessons within 6 months of hire, 5 hours of lactation consultant-supervised clinical experience, and ongoing training to reinforce "basic skills". The breastfeeding education should be a minimum of 20 hours (Baby-Friendly USA, 2012). As with any clinical competency, there is likely to be some degree of drift from best practice (Kohn, Corrigan, & Donaldson, 1999). This drift may partially translate to supplementation among breastfeeding infants when it's not medically indicated-measuring this has not been investigated.

The philosophy behind the comprehensive standardized education for nurses is every mother and baby born in a Baby-Friendly facility must receive the same high quality care, regardless of infant feeding method. Whether or not the nurse's breastfeed preparation consistently equates to optimal breastfeeding outcomes is questionable, given the publically reported estimates for supplementation among breastfeeding infants.

Sample

Data from a cohort of mother/infant dyads was obtained from a sample of women who gave birth between January 1 and June 30, 2015 at a hospital for women and newborns in Southern California. Notwithstanding the volume of deliveries at this given hospital, the hospital's population was demographically representative of the surrounding community increasing generalizability of potential study findings.

Inclusion and Exclusion Criteria

Inclusion criteria: healthy, singleton, full-term (37 0/7 weeks-42 0/7 weeks gestation) infants (American College of Obstetricians and Gynecologists, 2013), born to mothers who identified intent to exclusively breastfeed at time of admission to the hospital. Participants excluded from the study cohort included mothers whose infants were admitted to the neonatal intensive care unit (NICU), were twins (or multiples), infants born with gross congenital anomalies, or infants born by surrogate mothers. The PDD and EMR provided information related to inclusion and exclusion criteria.

Rationale for these inclusion criteria was based on the literature review. Studies have shown multiparous women have different breastfeeding support needs and outcomes compared to first-time mothers. Length of stay has been shown to be associated with formula supplementation, yet contraindications to breastfeeding related to reasons for longer than normal stay has not been studied, thus, the inclusion (providing the inclusion criteria) of all infants delivered.

Sample Size, Power, and Effect

The literature review provided parameters for sample size calculation, as well as this study's primary hypotheses. It was estimated within a 6 month time frame, a

minimum of 1,200-1,250 mother-infant dyads would meet the study inclusion criteria, of whom greater than 40% would be supplemented or 440 to 470. This is a similar supplementation rate found by Gagnon and colleagues (2005). The entire 6-month cohort size was estimated to have 80% power to detect a statistical difference of 10% in the rate of risk factors between supplemented and un-supplemented infants and could easily accommodate the 12 independent variables and be included in any multivariable regression modeling.

Of the approximate 1,200 infants in a six-month time frame who were supplemented, about 70% were estimated to be supplemented for medical reasons including: delayed onset of lactation >72 hours, hyperbilirubinemia, hypoglycemia, infant weight loss with associated factors, intolerable maternal pain with breastfeeding, late preterm, mother not available, poor milk transfer, provider order, and other. Another 5% of infants were supplemented due to no intent to breastfeed. It was anticipated the remaining 25% would be supplemented for non-medical reasons. It was originally estimated the 450 supplemented infants would be the focus for the aim describing nursing factors related to breastfeeding.

Variables

There is inconsistency in the literature regarding the term *risk factor*. In this study, the risk factor was defined as follows; something that increases risk or susceptibility for formula supplementation and included 13 independent variables.

Table 1 includes variables for the cohort of infants, as well as their respective operational definitions, variable type, and source of data. **Obstetrical variables** included: *mode of delivery, time of birth, parity, gestational age, maternal age, infant gender, and*

infant weight, provided by the PDD. **Nursing characteristics** included: *first breastfeed in first hour* and *age of infant at first breastfeed*. **Nursing characteristics** included: *lactation consultation (LC) occurred*, *time of day LC occurred*, *age of infant at time of LC*, and *median LATCH score per twenty-four hours*. The outcome variable was whether or not the infant was *supplemented* in-hospital or exclusively breastfed.

LATCH Assessment

An assessment to gauge and document the level of breastfeeding effort is the LATCH. This measure assesses five key characteristics of successful breastfeeding: **L**atch of infant on the nipple, **A**udible swallowing amount, **T**ype of nipple, **C**omfort – mother’s level of comfort, and **H**old – amount of help mother needs to hold the baby to breast. Each element is scored between 0-2 with a maximum score of 10. Besides being an uniform method for assessing and documenting overall breastfeeding effort, assessment of each element can indicate to the nurse the level and kind of support a mother may need and the type of specific interventions needed to facilitate successful breastfeeding (Jenson, Wallace, & Kelsay, 1994).

In the study institution, per Baby-Friendly (2012) the policy guides, RN’s assessment and documentation of breastfeeding effort and LATCH scores. Breastfeeding is expected to be directly observed with a corresponding LATCH score documented a minimum of 3 times per 24-hour period. Additionally, nurse-initiated, appropriate interventions were to be documented, to address poor LATCH scores according to the CDPH (2005), breastfeeding guidelines and Baby-Friendly. An example of appropriate intervention is a nurse-initiated consultation by a certified lactation consultant.

The labor and delivery and postpartum nurses' documentation of LATCH scores extracted from the EMR was used to identify if there was an association between breastfeeding patterns (LATCH scores) and in-hospital formula supplementation. LATCH scores, a nursing assessment, were for the purpose of this study, assumed as a proxy of nursing care as indicated by the EMR.

The LATCH is widely used during the immediate postpartum period for the objective assessment of breastfeeding episodes as observed by the nurse. While this instrument's intended use is to identify areas of need for nursing intervention, and to aid nurses' prioritization of education, the psychometric soundness is inconclusive (Howe, Lin, Fu, Su, & Hsieh, 2008). Riordan and Koehn (1997) reported poor Spearman correlation coefficients between 3 individual nurse raters observing the same breastfeeding episodes which yielded weak correlations among the three raters .11, .46, and .48, indicating a weak correlation between rater LATCH scores or low inter-rater reliability of the measure. While this study's results may have indicated a poor LATCH score reliability, it did not investigate whether or not nurses were using the LATCH score as it was originally intended. Research findings for the validity of the LATCH has also shown to be inconsistent. Riordan, Bibb, Miller, and Rawlins (2001) assessed construct validity and found mothers' scores were significantly correlated with the evaluators' scores ($n = 132$; $r = .56$, $p = .001$). A second study found among 299 Italian infant-mother dyads, supplementation was positively associated with decreasing LATCH scores in the first 24 hours of the hospital stay with supplemented infant scoring less (6.9) than exclusively breastfed infants (7.6) at time of discharge (Tornese et al., 2012). While this study's aim was to investigate the predictive ability of LATCH score, no information was

provided regarding the standard for documentation of LATCH scores. It is unclear how many LATCH scores per infant were evaluated within the defined 24 hours post delivery and partial LATCH scores were considered as part of the analysis making it difficult to ascertain the validity of the study's results.

The inconsistent reports of predictive ability of LATCH, as well as mixed findings and no recent investigation of the reliability and validity of the instrument indicate its use as the basis of nursing intervention and education should be used with caution. Aside from Baby-Friendly guidelines indicating nurses evaluate and assess breastfeeding, no specific method for doing so is included in these recommendations. Reported LATCH scores per twenty-four hours, was the only measure of breastfeeding evaluation by nurses, reported consistently in this study's investigational site as an indicator of breastfeeding episodic success.

Table 1.

Variables and Operational Definitions for Cases

Variable Name	Variable Definition	Variable Type	Data Source
Gestational Age, <i>weeks</i>	Age of infant at time of birth	Continuous	PDD
Parity	Primiparous or multiparous mother at time of delivery	Categorical	PDD
Age, <i>years</i>	Maternal age at time of delivery	Continuous	EMR
Age of infant at first breastfeed, <i>hours, min</i>	Age of infant at first breastfeed after birth	Continuous	PDD
Time of Birth, <i>hours, min</i>	Documented time of birth	Continuous	PDD
Infant weight, <i>grams</i>	Documented birth weight	Continuous	PDD

Median LATCH scores (0-10)	Median LATCH scores per 24-hour period (q 8 hrs)	Continuous	EMR
Mode of Delivery	Vaginal vs. Cesarean	Categorical	PDD
Age of infant at first supplementation, <i>hours, min</i>	Age of infant at first supplementation following birth	Continuous	PDD
Lactation Consultation (LC)	LC occurred	Categorical	PDD
Age of Infant at LC, <i>hours, min</i>	Documented time of LC subtracted from time of birth	Continuous	PDD

Description of Independent Variables

The distribution of time of birth variable indicated an approximately normal distribution, and was subsequently categorized into four equal time periods, based on previous literature. This was done to allow for further examination, using clinically intuitive ranges of: 0-6, 6.1-12, 12.1-18, 18.1-24 hours.

Age of infant measured in hours, at first breastfeed, first supplementation, and at time of lactation consultation, was calculated as the difference between the time of birth and time of first feed, time of first supplementation, and time of lactation consultation, respectfully.

Data Analysis Procedures

Demographic characteristics and the key variables of this study were analyzed using frequencies and percentages for categorical data, such as parity and delivery mode, as well as means, standard deviations, and ranges for continuous data, i.e. gestational age and LATCH score, and medians and inter-quartile ranges for non-normally distributed variables e.g., time of supplementation.

Descriptive analysis of variables was conducted to detect possible outliers (Mertler & Vannatta, 2002). The relationships among key variables were tested using Pearson correlation coefficients. Scatter plots of residuals were examined to assess that assumptions of normality, linearity, and homogeneity of variances were met (or not). Multicollinearity diagnostics were used to check for possible high correlations among the predictor variables. The level of significance in this study will be set as .05. Statistical analysis was performed using SPSS software (Release 22 for Windows, SPSS Inc.) (IBM Corp., 2015).

Logistic regression was performed to examine relationships among the dependent and independent variables while simultaneously controlling for the effects of other variables in the model. The selection of variables as potential confounders was based upon published literature and empirical findings in the data. The goal was the identification of smallest number of variables that best predicted the outcome of interest, supplementation, and to assess the impact of these predictors on supplementation. Multivariable logistic regression modeling using backward stepwise method in SPSS which enters all variables simultaneously meeting the entrance criteria of .10 and elimination criteria of .05 was used to identify the best model and calculate adjusted odds ratios and 95% confidence intervals. Goodness-of-fit was assessed using Hosmer-Lemeshow test with the null hypothesis that the model is a good fit for the data, and a p-value greater than 0.05 indicating the model is a good fit for the data.

Since reasons for supplementation was a text field in the EMR, the plan was to capture the words in this field and categorize them into a limited number of reasons for supplementation, including medical and non-medical reasons.

Protection of Human Subjects

This study proposal was submitted for review by the University of San Diego's School of Nursing Departmental Review Board and the hospital's Institutional Review Board. This study focused on retrospectively collected prospective data with no interaction with investigated subjects, therefore consent from subjects was not necessary or indicated. Data access, analysis, storage, and reporting, was conducted according to the study protocol as outlined by the two independent review boards. This study was deemed exempt according to both IRBs as this study did not involve interaction with human subjects. Regardless, all data were protected, maintained, and stored according to the standards outlined in the hospital's Institutional Review Board's policy. With any study, subject confidentiality, in this case the identity of mother-infant dyads and individual nurses is paramount. All data were de-identified and recoded only using a study identification number. The list with patients' financial account numbers that provided the means for extracting data from the EMR were assigned study numbers and remained with the principle investigator at all the times during data collection and when not in use, was kept in a locked file. Backed-up computer copies of the assigned numbers was password protected. Any personally identifying data of subjects was and will be used in the aggregate form alone.

Chapter VI

Results

The primary objective to evaluate in-hospital formula supplementation risk associated with different breastfeeding characteristics, hospital factors, and nursing factors was achieved with a comparison of cases, those breastfeeding infants who were supplemented compared to those exclusively breastfed, born in the same time frame. Initially, the PDD was used to identify breastfeeding infants who were supplemented and those who were not. The PDD met regulatory reporting standards as an archival electronic medical record database. Accuracy of supplementation categorization was confirmed among the final sample of 1,023, where information from the EMR was accessed and used to confirm all cases and controls on supplementation status.

Data Collection Procedure

The PDD provided the majority of the data for the study during the 6-month timeframe. Medical records of the final sample of cases included in this cohort were accessed to manually validate accuracy of data reported in the PDD dataset and to collect LATCH scores and time of first supplementation. The sample was sufficient in number given the overall publically reported data for exclusive breastfeeding and the volume of births annually and the particular aims of this investigation.

A final sample size of 1,023 mother-infant dyads, for which available data on in-hospital formula supplementation use and breastfeeding practices through time of discharge was available, were included in the analyses. This cohort was believed to be similar in characteristics to the overall population who delivered in the defined 6-month time frame.

An initial data query of the perinatal download database (PDD) for singleton, term breastfeeding infants resulted in 4,684 mothers who delivered during the 6-month time period. Of these mothers, 1 of every 4 were randomly selected, reducing the sample to 1,172 mother-infant dyads. The sample was further reduced by 149 cases (13%), which failed to meet inclusion criteria including NICU observation, surrogacy, records indicating bottle-feeding as the admission feeding plan (with no documented breastfeeds during the hospital stay), or deliveries resulting in multiples. The final sample size was 1,023 maternal-infant dyads, all of which were analyzed in this study. This final sample size was adequate to meet the specific aims of this study (see Figure 2).

Figure 2. Sample Selection

Not all of the data as originally conceived were possible. Although time of discharge was requested from the PDD, it was not provided among the original PDD data. In addition, during the manual extraction process it was clear that the reason for supplementation, and education provided at time of supplementation, were either not provided, or were missing or of questionable accuracy.

LATCH score data were manually extracted, as greater than 75% was missing from the initial PDD download, yet discoverable in the EMR. Frequencies were run on all LATCH scores to detect possible entry errors made during manual data entry. Reasons for supplementation were reviewed in PDD of which multiple responses existed for any single record. Attempts were made to manually validate inconsistencies when both a medical and non-medical reason was documented. Investigation revealed documented reasons for medical and non-medical supplementation were not reliable, and when combined with the free text note entered by the lactation consultant, no primary reason could be reliably determined. Primary reason for supplementation was inconclusive for greater than 30% of cases. This finding rendered this data minimally useful in explaining reasons for supplementation among this sample. This was partly due to the allowance of multiple reasons for supplementation, no rank ordering required of the reasons, and no policy that the primary reason for supplementation be noted in the lactation note.

Specific Aims

The overall purpose of this study was to examine the association between specific factors related to obstetric history, delivery mode, breastfeeding characteristics, and nursing care and formula supplementation among healthy, breastfeeding newborns whose mothers were planning to exclusively breastfeed on admission. This study examined and

compared infants who were supplemented with those who were not, among a cohort of healthy infants born to mothers who delivered during a 6-month timeframe in 2015.

Specific Aim # 1

Examine the relationships between aspects of the hospital delivery of infants who are supplemented compared to infants exclusively breastfed among a cohort of breastfeeding infants born to mothers who delivered in a women's hospital in Southern California.

Research Question #1

Are there significant differences by maternal age, obstetric factors, infant factors, and an order for lactation consultant between those infants who are supplemented and those who are not?

Of the 1,023 mother-infant dyads, 801 (78.3%) were exclusively breastfeed while in hospital and 222 (21.7%) were supplemented at least once during the hospital stay. This supplementation rate was consistent with the hospital's reported supplementation data for healthy, full-term (37-42 weeks) infants during the timeframe in which these deliveries occurred. The median time of first supplementation was 25 hours of age with a range from half an hour to 82.7 hours after birth.

Baseline maternal, infant, and obstetric characteristics of the study sample and observations of supplementation are presented in Table 2. Mean (SD) maternal age was 29.7 (5.4) years (range 15-47) and greater than two-thirds of mothers were nulliparous prior to delivery. There was a statistically significant relationship between the parity classification and supplementation ($\chi^2 = 27.35$, $p = <.001$). Mean (SD) infant gestational age and birth weight was 39.3 (1.01) weeks and 3,375 g (13), respectively. Of the total

sample, 68.8% of infants were delivered vaginally with 31.2% born by cesarean. Results indicated a significant relationship existed between time of delivery and supplementation ($\chi^2 = 11.4, p = <.05$). The sample was evenly distributed by infant gender.

Less than half of the study sample (45%) initiated breastfeeding in the first hour after birth with a mean (SD) time to first breastfed of 1.5 hours (1.6). Even fewer, 11%, initiated breastfeeding in the first 30 minutes after birth. Of those for whom breastfeeding was not initiated within the first hour ($n = 543$), 26% were supplemented compared to the 17% (80 out of 400) for those who initiated breastfeeding within the first hour ($\chi^2 = 13.49, p = <.001$). Of the 222 infants who were supplemented, one-third (36%) initiated breastfeeding in the first hour.

During the hospital stay, the mean (SD) time to lactation consultation was 30 (14) hours after birth. Additionally, median (SD) time to first supplementation from time of first breastfeed, for infants who were supplemented, was 23.5 (range 4.4- 81.5) hours, with four infants experiencing a first supplementation before their first breastfeed and approximately one-half (52%) supplemented in the first 24 hours from the time of first documented breastfeed.

Nurse documentation of primary reason for lactation consultation, was inconsistent and unclear at times. There was a drop-down menu of choices in the EMR, allowing free text, and responses varied widely. Some reported responses included *poor LATCH*, *low maternal breastfeeding confidence*, and *baby sleepy*. Of those infants who were supplemented, 90% ($n=199$) received a lactation consultation. It is unclear whether mothers experienced breastfeeding problems before, concurrently, or following the supplementation due the documentation variation. Also noted, was a significant

relationship between lactation consultation occurring and supplementation (χ^2 26.1 DF 1, $p < .001$).

Investigation of time of day in which infants were supplemented found 33% of all initial formula supplementation occurrences happened between the 3-hour window of midnight and 0300. Supplementation times were not evenly distributed, with a positive skew. The median time of supplementation was 27 hours with an interquartile value of 24.6. This finding represented a significant difference. The time of day at which infants were born, was evenly distributed across day times and night times, but evening births were associated with higher supplementation rates.

Table 2.

Characteristics of Mother-Infant Dyads Supplemented during the Hospital Stay (born January 1, 2015-June 30, 2015)

<i>Characteristics</i>	Total Sample (N=1023)	Supplemented (n=223)	Not Supplemented (n=800)	<i>p</i>
Maternal-Infant				
Maternal age, mean, y (SD)	29.7 (5.4)	30.1 (6.2)	29.6 (5.2)	<i>Ns</i>
Gestational Age, wk (SD)	39.3 (1.01)	39.3 (0.9)	39.1(1.1)	*
Parity				**
Primiparous (%)	87.7	19.2	80.8	
Multiparous (%)	12.3	39.7	60.3	
Delivery Mode				**
Vaginal birth (%)	68.8	52.7	25.2	
Cesarean birth (%)	31.2	47.3	74.8	
Time of birth, mean, h, (SD)	12.7 (6.6)	11.6 (7.2)	13.1 (6.5)	*
Birth weight, g (SD)	3375 (416)	3379 (433)	3374 (412)	<i>Ns</i>

Infant gender				<i>Ns</i>
Female, (%)	50.0	22.3	77.7	
Male, (%)	50.0	21.1	78.9	
First breastfeed, <i>h</i> , (SD)	1.5 (1.3)	1.9 (1.7)	1.4 (1.2)	**
Lactation consult occurred (%)				**
Yes	786 (76.8)	199 (89.6)	587(73.4)	
No	237 (23.20)%	23 (10.4)	214 (26.7)	

Note: * $p \leq .05$, ** $p \leq .001$; ***based on first LATCH scores, in first 24 hours; SD=Standard Deviation; *h*=hours; *y*= years; *wk*= weeks; *g*=grams

Specific Aim #2

To identify in-hospital risk factors that increase the odds of formula supplementation among a sample of breastfeeding infants.

Research Question #2

What obstetric, breastfeeding characteristics, and hospital factors, increase the odds for formula supplementation among this cohort of breastfeeding infants?

Nine variables were analyzed in the bivariate analysis: maternal age, parity (primiparous or multiparous), mode of delivery (vaginal or cesarean), time of birth, gestational age, infant gender, birth-weight, first breastfeed within first hour of birth, lactation consultant visit. Five variables differed between supplemented and not supplemented groups and were retained for the logistic analysis: *parity status, delivery mode, time of birth, initiating breastfeeding in the first hour, and lactation consultation.* Time of birth was divided into four time periods: 0000-0600, 0601-1200; 1201-1800, and 1801-2400 because it more clearly showed the time period of risk and resulted in slightly better model statistics than using a day/night classification. The variables not retained did not improve the model statistics and did not change the odds ratios. Results of the logistic

analysis are presented in Table 2. These five variables contributed significantly to the model's reliability in predicting which mother-infant dyads would be supplemented. (-2 Log Likelihood = 953.09; χ^2 (7) = 117.16, $p = <.001$). The model fit was good with Hosmer-Lemeshow Test of χ^2 (8) = 3.31 ($p=.914$). The model correctly classified 79.6% of the infants as being supplemented, a modest improvement over the baseline model with no predictors (78.3%). The Nagelkerke's R^2 of .167 indicated a very modest association between the combined five variables and supplementation.

Table 3 contains the unadjusted and adjusted odds ratios for the retained variables. There was only a modest amount of confounding between the unadjusted and adjusted odds ratios. Multiparous women had greater than 2.5 times the odds of having their infants supplemented compared to first time mothers; similar odds were observed for women with a cesarean compared to a vaginal birth. The infants who were born during the evening hours had twice the odds of being supplemented compared to those born between 6 a.m. and noon. No other birth time periods showed a statistically significant increase. The odds of being supplemented were 1.5 times more likely for infants who reportedly initiated breastfeeding outside of the first hour after birth. Mother-infant dyads who experienced a lactation consultation were more than three times as likely to be supplemented, the highest identified factor.

Table 3

Final logistic regression for odds of being supplemented among term, healthy, singleton, breastfed infants.

Variable	Supplemented Percent (n)	No supplement Percent (n)	b(SE)	Wald	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Constant			-3.18 (.29)	120.477		
Parity						
Primipara	19.3 (173)	80.7 (724)			referent	referent
Multipara	39.7 (50)	60.3 (76)	1.10 (.22)	24.772	2.75 (1.86, 4.08)	3.01 (1.95, 4.64)
Delivery Mode						
Vaginal	15.1 (136)	84.9 (598)			referent	referent
Cesarean	36.7 (117)	63.3 (202)	.99 (.17)	35.310	2.55 (1.90, 3.42)	2.68 (1.94, 3.72)
Time of birth						
Daytime (0600-1200)	18.3 (61)	81.7 (273)			referent	referent
Afternoon (1201-1800)	19.6 (50)	80.4 (205)	.11 (.22)	.221	1.09 (.72, 1.65)	1.11 (.72, 1.72)
Evening (1801-2400)	30.0 (61)	70.0 (142)	.70 (.22)	9.906	1.92 (1.28, 2.89)	2.01 (1.30, 3.09)
Night (0001-0600)	21.6 (50)	78.4 (181)	.21 (.23)	.815	1.24 (.82, 1.89)	1.23 (.79, 1.93)
Breastfeed initiation						
1 hour or less	16.7 (80)	83.3 (400)			referent	referent
Greater 1 hr	26.2 (142)	73.6 (401)	.35 (.17)	4.221	1.78 (1.30, 2.41)	1.42 (1.02, 1.96)
Lactation Consultation						
None	9.7 (23)	90.3 (214)			referent	referent
Yes	25.3 (199)	74.7 (587)	1.12 (.25)	20.089	3.15 (1.99-4.99)	3.08 (1.88, 5.03)

Likelihood ratio test = 953.09, df =8, p<.001

Nagelkerke R^2 = .167

Homser-Leeshow Goodness of Fit = $\chi^2(3.31, df = 8, p= .914$

After adjusting for known confounders, parity and delivery mode continued to be characteristics of significant risk factors increasing the odds of infants being supplemented.

Data documentation of reason for supplementation was unclear; therefore, it was not possible to differentiate true medical reasons from maternal or nursing reasons for supplementation. In addition, there was no reliable measure of nursing assessments for the need to supplementation or of nursing interventions undertaken prior to supplementation that could be constructed to answer this question. However, proxy indicators of nursing care can be defined as initiating breastfeeding outside of the first hour of life. This factor, as previously shown, increases the odds of supplementation by 1.42 (Table 3).

Another nursing care variable available from the EMR was LATCH scores. Presence of a minimum of 3 LATCH scores were consistently reported in individual medical records and were believed to be reliably recorded given the high frequency of scores entered and low frequency of missing data. A natural cut-off for LATCH scores was not identified after initial descriptive statistics were explored, therefore the literature-based LATCH score of less than 7, was used as a suboptimal score and entered into the analysis as a predictor variable for supplementation. These scores represent a nurse-quantified measure of episodic-specific breastfeeding status. Individual LATCH scores less than 7 in the first 24 hours were not significantly related to supplementation but the mean overall LATCH score was less than 7 (6.8, SD 1.37). While in general, mean LATCH scores improved from the first to the third score, 30% of score means fell below the suboptimal 7 rating for all three data points. This is significant as nearly half (45.5%)

of all infants who were supplemented experienced their first supplementation in the first 24 hours of life, highlighting the importance of diligent nursing assessment, timely support, and preventive measures to avoid supplementation.

Chapter V

Discussion and Conclusion

All hospitals, regardless of Baby-Friendly designation status, experience exclusive breastfeeding rates below national and global goals. Systematic adoption of Baby-Friendly measures is associated with earlier breastfeeding initiation, less formula supplementation, and higher breastfeeding exclusivity compared to hospitals who partially adopt Baby-Friendly measures, and those who abstain completely. When the adoption of Baby-Friendly policies fail to achieve exclusive breastfeeding goals, determining which hospital factors represent the highest risk for supplementation, is essential to closing the gap between mothers who plan to exclusively breastfeed and those who actually do. Infants born to mothers who initiate breastfeeding during the hospital stay are at risk for supplementation and subsequent health risks associated with formula feedings. Interactions between obstetrical factors, in-hospital factors, and nursing care can increase this risk. When an infant receives any formula feeds, in lieu of a feeding of breast milk, they not only are at increased odds for early breastfeeding cessation, but are no longer considered *exclusively breastfed* by most hospital standards. Some evidence has shown early limited formula (ELF) intervention among infants who lose $\geq 5\%$ birth weight, may reduce longer-term formula use, and increase longer-term breastfeeding without supplementation (Flaherman et al., 2013). However, this practice is not supported by public health policy, and fails to directly address the reasons for supplementation and the phenomenon of supplementation for non-medical reasons and the quandary faced by so many mothers in the early morning hours, when supplementation occurs most often.

Furthermore, the exact dose-dependent health risks of *minimal/ELF* supplementation are unknown.

While research has shown in-hospital supplementation is associated with early breastfeeding cessation (Chantry et al., 2014), more relevant to this investigation is evidence of modifiable factors within the hospital, contributing to unnecessary supplementation, thereby increasing health risks for mothers and infants. This study found associations between the exposures of interest within, parity, mode of delivery, time of birth, breastfeeding initiation, and lactation consultation with formula supplementation. After statistically adjusting for known obstetrical confounders, mode of delivery and parity, all five variables continued to be significantly predictive.

Aims

This research had two aims, each addressed to better understand in-hospital factors associated with formula use among a sample of healthy, full term breastfeeding infants. These aims were to:

Aim 1: Examine the relationships between aspects of the hospital delivery of infants who are supplemented compared to infants exclusively breastfed among a cohort of breastfeeding infants born to mothers who delivered in a hospital for women and newborns in Southern California.

Aim 2: To identify in-hospital risk factors that increase the odds of formula supplementation among a sample of breastfeeding infants.

Ajzen's (1991) Theory of Planned Behavior (TPB) and Barnard's (1989) Parent-Child Interaction Model (PCI), describe the complex interactions that exist between internal and external belief systems surrounding breastfeeding one's infant and the

hospital and nurse influence on mothers who struggle to overcome the inherent difficulties of breastfeeding initiation and sustainment. As evidenced by the results of this research, aspects of care in the hospital setting have direct influence over the outcome of exclusive breastfeeding versus formula supplementation. It is reasonable to question how a mother's perceived behavioral control over breastfeeding is altered, from the time of indication of plan to exclusively breastfed, to time of formula supplementation. Evidence also supports that the construct of infant-feeding in the hospital may be drastically altered for women who experience a shift from breast to formula, and that hospital practices disrupt a women's understanding of their bodies and their role in feeding their infants (Braithwaite, & Davies, 2014). While Braithwaite and Davies (2014) argue formula supplementation may not pose an imminent threat to overall breastfeeding duration and formula might be a viable option to get more mothers to breastfeed longer, the authors failed to recognize any formula supplementation negates the science behind current breastfeeding standards. Twenty-two percent of mothers in this study were supplemented prior to hospital discharge automatically excluding them from the breastfeeding exclusivity standard.

Results indicated more infants born during the evening, between the hours of 1800-midnight, were supplemented, than those born on any other shift. This echoes the findings of Gagnon et al. (2005) and Grassley et al. (2014) which span nearly thirty years indicating little has changed with regard to the time phenomenon and supplementation during the hospital stay. This may be partially explained by length of labor which for many primiparous mothers, may have started the preceding night, resulting in overly fatigued mothers who may have been more inclined to supplement in the hours following

an evening delivery. The time trend in this study also found infants in this sample were most frequently supplemented between midnight and 0300 (33%). This discovery has not been seen in previous research and warrants further investigation.

Even though hospital policy at the time of the study incorporated the *Ten Steps to Successful Breastfeeding* (UNICEF & World Health Organization, 1989), initiating breastfeeding in the first hour of life was not the reported norm, with 55% having a first documented breastfeed outside the first hour. In related study, findings reported by Demirtis (2012), revealed infants who initiated breastfeeding within 1-2 hours postpartum were at higher odds of experiencing breastfeeding problems e.g. nipple pain and poor latch, compared to those who initiated within half an hour, though their findings were not statistically significant and were at greater risk of supplementation. These results were limited in generalizability since the sample was limited to uncomplicated vaginal births and women were discharged within 24 hours failing to capture supplementation that occurs in U.S. hospitals in the second 24 hours. However, a greater understanding of the processes in the hours immediately following birth is needed to identify promoters of breastfeeding and explanations as to why breastfeeding is not immediately initiated which is known to enhance breastfeeding success and duration. The practice of skin-to-skin immediately after birth was a standard of care at this hospital and supported in the guidelines of care, as means to facilitate early breastfeeding initiation. While skin-to-skin supersedes the previous language indicating that infants should initiate breastfeeding in the first hour, the superiority of the latter translation of Step 4 remains to be seen. A possible explanation for the increased odds for supplementation when breastfeeding was not initiated in the first hour may have been attributed whether or not

the nurses encouraged mothers to recognize infant feeding readiness behavior in the first hour, though this was not discernible from the available data. Additionally, the hospital environment adds a complex contextual element that heightens the importance and urgency of supporting mothers and infants with breastfeeding attempts in the first hour if the infant is ready. A lack of outcomes to reflect using the standard of skin-to-skin, in lieu of an emphasis on early breastfeeding initiation, represents a need for further investigation into what is occurring with nursing processes during this critical period of time.

Among infants who were supplemented ($n = 222$), the first documented supplementation occurred for the majority of infants in the first 2 days of life, within the first 48 hours (86%), which translated to 18% of the total sample ($n = 1,023$). This finding is similar to prior research, although slightly lower by comparison to publicly reported data (USDHHS, 2010) of 19% of all infants who are supplemented in the first 2 days. The 24-hour increment is important given the average length of stay for uncomplicated vaginal or cesarean deliveries which has shaped how supplementation is reported. While this study's 2-day supplementation rate is lower than the national average, this would translate to approximately 1,600 supplemented infants in the first two days alone for a hospital this size. This emphasizes the need for improvements in the assessment of breastfeeding episodes. It is reasonable to expect that to reduce the 2-day supplementation rate to the goal of 10% will require more diligence with helping all mothers initiate breastfeeding in the first hour and improving support of breastfeeding dyads in the first 24 hours after delivery.

Attempts to describe reasons for supplementation, both medical and non-medical, were thwarted by limitations in how the nurses documented their assessment. While the most frequently documented reason for supplementation was “maternal request” (88%), it is unclear for many dyads, if this was the reason for supplementation or if there was a true medical indication, given both a medical and non-medical reason was allowable. This finding supports the need for improvements in how breastfeeding episodes are documented, if goals for reducing non-medical supplementation are to be achieved. More supplementation occurred during the night, between the hours of 1900 and 0659 (59.9%), when fewer resources were available including lactation consultants. This combined with the findings of a mean age of first supplementation of 27.4 hours, compared to the mean age of infant at time of lactation consultation of 30 hours, implies many infants were supplemented prior to receiving resources, such as a lactation consultation. Paradoxically, most (78.3%) infants received a lactation consultation. During a time when hospitals are faced with increased demands to stretch already scarce resources, attention should be directed at appropriate use of the lactation resource. Additionally, hospitals striving for Baby-Friendly standards, are allocating dedicated funds towards breastfeeding education for clinical staff that is often incorporated as part of the new-hire orientation process and extends into annual/ongoing competencies. An overlooked criticism in the literature is the lack of standardization of lactation resource utilization in hospitals aiming for Baby-Friendly status. If the primary purpose of lactation services is to reduce unnecessary supplementation, these services need to be utilized in a more timely fashion. Furthermore, clinical nurses are arguably qualified to serve as frontline educators and breastfeeding supporters, yet nurses are utilizing lactation resources at alarming rates,

indicating there may be a mismatch between expected preparedness and clinical competency or perhaps competing demands, which interfere with a nurse's ability to fully support a breastfeeding mother-infant dyad.

In contrast to Biro and colleagues (2011), who found infants born to primiparous mothers had twice the odds of being supplemented compared to multiparous mothers, this study found the odds of multiparous mothers being supplemented was three times higher than primiparous mothers, (OR 3.01 CI 1.95 – 4.64). Of those supplemented, more primiparous mothers (78.5%) received lactation consultations than multiparous mothers (65.1%). Combined with the fact a higher percentage of multiparous mothers were supplemented than primiparous, it is reasonable to speculate that experienced mothers and the nurses caring for them, may have overestimated the mother's propensity for breastfeeding success and underestimated their need for breastfeeding support.

Unlike the finding of association between time of breastfeeding initiation and parity reported by Sutherland and colleagues (2012), mothers in this study initiated breastfeeding at fairly equal times regardless of parity with 47% of both primiparous and multiparous mothers with a reported first feed occurring in the first hour. Sutherland et al. (2012) reported multiparous mothers' initiation and success with breastfeeding (or failure) in their first pregnancy, influenced breastfeeding success (or failure) with subsequent pregnancies, which might explain why more multiparous mothers in this study were supplemented than the primiparous mothers. It is possible some multiparous mothers in this sample, were previously unsuccessful with breastfeeding, and fell into this category. Per Step 5 (*Ten Steps to Successful Breastfeeding*) of (Baby Friendly USA, 2010), mothers with no breastfeeding experience (primiparous mothers) and moms who

previously encountered problems with breastfeeding, should be provided extra breastfeeding support. Based on the available data in this investigation, it was not discernible as to whether or not multiparous mothers were routinely screened for previous breastfeeding experience. Conversely, it is also possible experienced mothers who *were* successful previously, had confidence in their ability and may have perhaps been more inclined to consider a single or multiple formula feeds, having the confidence to continue breastfeeding regardless. A related study, by Bai, Fong, & Tarrant (2015) revealed the need for greater support of multiparous breastfeeding mothers with no or little prior breastfeeding experience is recommended, in addition to the assertion multiparous mothers with longer breastfeeding success be supported to not only meet their previous breastfeeding duration but exceed it in an effort to reach the 6-month exclusivity goal. These findings indicate a greater need for lactation support for multiparous mothers than what's currently being provided, regardless of their past experience with breastfeeding.

Considering the theoretical framework supporting this study, mothers are influenced by the nurses caring for them, and multiparous mothers may be less perceived as needing support compared to their primiparous counterparts. Direct observation of breastfeeds may be undervalued and multiparous mother in the larger population may be referred less to lactation consultations as seen with this sample.

Reliability and usefulness of LATCH scores in understanding the role of mother-infant behaviors and interaction with supplementation is under-investigated. Similar to de Souza and colleagues (2015), this study found LATCH scores were not a reliable predictor of supplementation. This study found that all three mean LATCH scores in the first 24 hours were suboptimal at <7 (0-10). The LATCH tool was initially designed to

provide nurses with systematic means to document breastfeeding episodes and assist with identifying specific maternal or infant behaviors that could be targeted for intervention or education. Unfortunately, due to the limited charting, this study could not discern if nurses were using LATCH scores to guide their education and/or interventions. LATCH scores also purportedly standardize communication between care providers about the relative success of the breastfeeding dyad, yet variability in time at which LATCH scores were recorded make this aspect problematic. Perhaps support for more strict guidelines of care dictating how soon breastfeeding must be formally assessed would make them more useful in providing, timely attention to unsuccessful breastfeeding episodes earlier on thereby decreasing infant's likelihood for supplementation.

The LATCH score includes an evaluation of the presence of an audible swallow, known to be poorly detected in the first few postpartum days until a true milk supply is established. There currently is no indication from the documentation available as to whether or not this was accounted for. It is reasonable to suggest the LATCH be modified or alternative tools for breastfeeding assessment be considered in the first few days. Another possible explanation for this current study's finding is no well-established LATCH score cutoff reliably predicts formula supplementation during the hospital stay. Previous researchers' found the LATCH had poor inter-rater reliability (Riordan & Koehn, 1997), which is supportive of increasing the frequency of direct observation and documentation of breastfeeding and adopting other means to assess and document. Additionally, the LATCH addresses whether or not the infant is sleepy and poor latch, but it does not address infant behavior i.e. feeding readiness (Heinig et al., 2006), and mother's behavior, or response to infant feeding cues as an integral component to

effective breastfeeding (Mulder, 2006). Appropriate interpretation of normal infant behavior versus infant feeding readiness and mother's accurate interpretation and response to these feeding skills is a known antecedent to effective latch and effective breastfeeding. Absence of consistent documentation of concurrent infant and maternal behavior observed with suboptimal LATCH scores, points to a need to consider adopting more reliable ways of assessing and communicating maternal-infant behavior concurrent of breastfeeding episodes.

Lastly, with regard to suboptimal LATCH scores, it is unclear whether or not nursing interventions were tailored to address specific components of suboptimal scores. This is believed to be a result of the under-investigation of effective interventions for suboptimal LATCH scores, specifically, a poor understanding of definitive ways to address the individual components of the LATCH score. Further, the allowance of selection from the drop-down options, "*LATCH scores consistently below 7*", as a reasonable event qualifying an infant for supplementation, indicates guidance for appropriate nursing interventions, including policy is lacking. Modifying policy to better direct appropriate nursing interventions to address poor LATCH score items, may not only lessen resource utilization, i.e. lactation services, result in fewer infants being supplemented, but may also enhance the mother's experience with breastfeeding as a positive one, sparing them the negative feelings and frustration associated with not being able to fulfill their plan to exclusively breastfeed.

Mode of birth, specifically cesarean, was not a primary event of concern in this study but like other studies, cesarean delivered infants were associated with increased risk for supplementation. However, it is a potential confounder since these mothers have

a longer length of stay and therefore, their infants have a longer period of time to be exposed to a hospital environment that may increase the risk for supplementation. The 31% cesarean rate in this sample is similar to the national rate of 32% (Martin et al., 2015), well above the “medically necessary” target of 10-15% (WHO, 2015).

In summary, this study succeeded in identifying modifiable hospital factors that increase an infant’s risk for supplementation including breastfeeding initiation, whether or not infants experienced a lactation consultation, and cesarean delivery. Similar to other studies, obstetrical, non-modifiable factors, including time of birth and parity, were associated with supplementation. This knowledge reinforces the need to consider additional support as the standard for these maternal-infant dyads vulnerable to supplementation and resultant health risks of such.

Health Policy Implications

Variability within reasons for supplementation and allowances for multiple reasons documented among this sample, and lack of clarity of purported medically-supported reasons for supplementation, underscore a need for clear guidelines for any supplementation including medical reasons more in line with the, *Acceptable medical reasons for use of breast-milk substitutes*, upheld by the WHO (2009). This study also found an immediate increased need for education for both the clinical nurses and the patients they care for regarding cautious supplementation for medical indication and better defined plans of care to address the non-medical requests for formula.

Li and colleagues (2014) found enhancements to staff training and structural-organizational aspects of care delivery equated to better breastfeeding outcomes, and mitigation of supplementation use. While this hospital was on their journey to earning

Baby-friendly designation and had enacted extensive policy, education, and organizational structure to support breastfeeding mothers, there are areas in need of improvements. It is reasonable to expect with changes to clinical practice at this study site, made based on findings from this study, practice may be improved. Changes in breastfeeding policy to include enhancements to nursing process related to breastfeeding support, including higher standards of frequency of direct breastfeeding observation, assessment, documentation, intervention, and evaluation of outcomes, may directly reduce formula supplementation.

As alluded to earlier, when the majority of infants receive lactation consultation(s), this may represent a misappropriation of resources. Frontline nurses should be adequately equipped to provide breastfeeding support for mothers, including tailoring education specific to needs identified through direct observation, especially when lactation services are scarce, during night time when mothers are fatigued and infants are most vulnerable to supplementation. If nurses are not providing the support mothers need, further investigation is warranted. Future policy-focused research including exploring the impact funding of services provided, including the use of widespread lactation consultations, and the outcomes for high-risk infants, especially among those supplemented for non-medical reasons.

Limitations of the study

The use of the hospital's administrative data base as the source of data, limited the available data included in the analysis. The missing time of discharge would have permitted a more detailed analysis of time to supplementation. Limitations of EMR to capture nursing processes, specifically nursing interventions related to LATCH scores,

made the examination of targeted recommendations for education for nurses difficult and should be considered for future research. Reasons for non-medical supplementation compared to medical indications could not be fully investigated due to the reporting methods in the EMR.

Missing data in the original 6-month sample resulted in a final sample that may have been systematically different than the original sample. While this sample was similar demographically to the original sample, a degree of selection bias may have been introduced, although there is no reason to assume missing data was not missing completely at random.

Conclusion

Breastfeeding infants born to mothers who deliver in the hospital face an increased risk for supplementation, in spite of their status as healthy, full-term infants. Exclusive breastfeeding rates are lower than desired, and factors associated with in-hospital supplementation are not adequately being addressed. Failure to focus on supplementation risk factors leads to subjecting infants to unnecessary supplementation, and fails to help mothers realize their plan to exclusively breastfeed. Recognizing the dynamic influence of the hospital environment, including the nurses, have on the maternal-infant dyad, provides context and supports modifying hospital policy to enlist resources to better identify infants at risk for supplementation outside of medical necessity. The knowledge gained from this study can inform nursing practice, health policy, and future research, all of which are essential in closing the gap between those intending to breastfeed their infants and those who ultimately do breastfeed during the hospital stay. The hospital stay represents not only a critical time for the maternal-infant

dyad, but ample time for appropriate resource utilization, and due diligence to preserve something as basic as exclusive breastfeeding.

Future Research Goals

Research is needed on the nursing care of breastfeeding infants who are supplemented compared to those who are not. Considering the nurses influence on maternal-infant breastfeeding success, little is known about how nurses select interventions when supporting mothers experiencing breastfeeding problems. Further, investigating the nurses' influence on breastfeeding success may be accomplished by attempting to determine whether or not individual nurses supplement more frequently than others within the same hospital environment. Research to determine how the nurses are assessing the infant and maternal behavior concurrent with breastfeeding episodes is also necessary in gaining an understanding of those at risk for supplementation. All of these research interests may identify modifiable factors within nurses' influence.

References

- Abrahams, S. W., & Labbok, M. H. (2009). Exploring the impact of the Baby-Friendly Hospital Initiative on trends in exclusive breastfeeding. *International Breastfeed Journal*, 4(11), e1-e6.
- Ajzen, I. (1991). The theory of planned behavior. *Organizational behavior and human decision processes*, 50(2), 179-211.
- Alikaşıfođlu, M., Erginoz, E., Gur, E. T., Baltas, Z., Beker, B., & Arvas, A. (2001). Factors influencing the duration of exclusive breastfeeding in a group of Turkish women. *Journal of Human Lactation*, 17, 220-226. doi: 10.1177/089033440101700305
- American Nurses Association. (2012). The value of nursing care coordination: A white paper of the American Nurses Association.
- American Academy of Pediatrics. (2012). The AAP updates its policy on breastfeeding and reaches consensus on recommended duration of exclusive breastfeeding. *Journal of Human Lactation*, 28, 116-117. doi:10.1177/0890334412442826
- American College of Obstetricians and Gynecologists. (2013). ACOG Committee Opinion No 579: Definition of term pregnancy. *Obstetrics and Gynecology*, 122(5), 1139-1140.
- Bai, D. L., Fong, D. Y. T., & Tarrant, M. (2015). Previous breastfeeding experience and duration of any and exclusive breastfeeding among multiparous mothers. *Birth*, 42(1), 70-77.
- Baby-Friendly USA. (2010). Guidelines and evaluation criteria for facilities seeking baby-friendly designation. Sandwich, MA: Baby-Friendly USA.

- Barnard, K. E., Hammond, M. A., Booth, C. L., Bee, H. L., Mitchell, S. K., & Spieker, S. J. (1989). Measurement and meaning of parent-child interaction. *Applied developmental psychology*, 3, 39-80.
- Berry, N. J., & Gribble, K. D. (2008). Breast is no longer best: Promoting normal infant feeding. *Maternal & Child Nutrition*, 4(1), 74-79.
- Biro, M. A., Sutherland, G. A., Yelland, J. S., Hardy, P., & Brown, S. J. (2011). In-hospital formula supplementation of breastfed babies: A population-based survey. *Birth*, 38, 302-310. doi: 10.1111/j.1523-536X.2011.00485.x
- Black, R. E., Allen, L. H., Bhutta, Z. A., Caulfield, L. E., de Onis, M., Ezzati, M., & Rivera, J. (2008). Maternal and child undernutrition: Global and regional exposures and health consequences. *The Lancet*, 371, 5-22. doi:10.1016/S0140-6736(7)61690-0
- Braimoh, J., & Davies, L. (2014). When 'breast' is no longer 'best': Post-partum constructions of infant-feeding in the hospital. *Social Science & Medicine*, 123, 82-89.
- California Department of Public Health, Maternal, Child and Adolescent Health/Office of Family Planning Branch (2005, June). *Providing breastfeeding support: Model hospital policy recommendations*. Available at <https://www.cdph.ca.gov/programs/breastfeeding/Documents/MO-05ModelHospitalPolicyRecommend.pdf>
- Centers for Disease Control and Prevention (2013). *National Survey of Maternity Practices in Infant Nutrition and Care*. Available at <http://www.cdc.gov/breastfeeding/data/mpinc/index.htm>

Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report

(MMWR) (2011) *Vital signs: Hospital Practices to support breastfeeding, United States, 2007-2009*. Retrieved from

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6030a4.htm#tab1>

Centers for Disease Control and Prevention. (2014): *Breastfeeding among U.S. children born 2001–2011, CDC National Immunization Survey*. Retrieved from

http://www.cdc.gov/breastfeeding/data/NIS_data/#formula-sup-bf-children

Chantry, C. J., Dewey, K. G., Peerson, J. M., Wagner, E. A., & Nommsen-Rivers, L. A.

(2014). In-hospital formula use increases early breastfeeding cessation among first-time mothers intending to exclusively breastfeed. *Journal of Pediatrics*, 164,

1339-1345. doi: <http://dx.doi.org/10.1016/j.jpeds.2013.12.035>

Collaborative Group on Hormonal Factors in Breast Cancer. (2002). Breast cancer and breastfeeding: Collaborative reanalysis of individual data from 47

epidemiological studies in thirty countries, including 50,302 women with breast cancer and 96,973 women without the disease. *The Lancet*, 360, 187-195.

doi:10.1016/S0140-6736(02)09454-0

Debes, A. K., Kohli, A., Walker, N., Edmond, K., & Mullany, L. C. (2013). Time to initiation of breastfeeding and neonatal mortality and morbidity: A systematic review. *BMC Public Health*, 13(Suppl 3), S19-S-32.

Declercq, E. R., Sakala, C., Corry, M. P., Applebaum, S., & Herrlich, A. (2013).

Listening to Mothers III: Pregnancy and birth; Report of the third national US Survey of women's childbearing experiences. New York, NY: Childbirth Connection.

- Declercq, E., Labbok, M. H., Sakala, C., & O'Hara, M. (2009). Hospital practices and women's likelihood of fulfilling their intention to exclusively breastfeed. *American Journal of Public Health, 99*(5), 929-935.
- Declercq, E. R., Sakala, C., Corry, M. P., & Applebaum, S. (2007). Listening to mothers II: Report of the second national US survey of women's childbearing experiences. *The Journal of Perinatal Education, 16*(4), 9-14.
- Demirtas, B. (2012). Breastfeeding support received by Turkish first-time mothers. *International Nursing Review, 59*(3), 338-344.
- Dewey, K. G., Nommsen-Rivers, L. A., Heinig, M. J., & Cohen, R. J. (2003). Risk factors for suboptimal infant breastfeeding behavior, delayed onset of lactation, and excess neonatal weight loss. *Pediatrics, 112*, 607-619.
- DiGirolamo, A. M., Grummer-Strawn, L. M., & Fein, S. B. (2008). Effect of maternity-care practices on breastfeeding. *Pediatrics, 122*(Supplement 2), S43-S49.
- Fishbein, M., & Ajzen, I. (1977). Belief, attitude, intention, and behavior: An introduction to theory and research.
- Flaherman, V. J., Aby, J., Burgos, A. E., Lee, K. A., Cabana, M. D., & Newman, T. B. (2013). Effect of early limited formula on duration and exclusivity of breastfeeding in at-risk infants: An RCT. *Pediatrics, 131*(6), 1059-1065
doi:10.1542/peds.2012-2809
- Gagnon, A. J., Leduc, G., Waghorn, K., Yang, H., & Platt, R. W. (2005). In-hospital formula supplementation of healthy breastfeeding newborns. *Journal of Human Lactation, 21*, 397-405. doi: 10.1177/0890334405280835

- Grassley, J. S., Schleiss, J., Bennett, Chapman, S. & Lind, B. (2014). Reasons for initial formula supplementation of healthy breastfeeding newborns. *Nursing for Women's Health*, 18 (3), 196-203. doi:10.1111/1751-486X.12120
- Hamilton, B.E., Martin, J.A., Osterman, M.J.K., & Curtin, S.C. (2015). Births: Final data for 2014. National Vital Statistics Reports. Retrieved from http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_06.pdf
- Heinig, M. J., Follett, J. R., Ishii, K. D., Kavanagh-Prochaska, K., Cohen, R., & Panchula, J. (2006). Barriers to compliance with infant-feeding recommendations among low-income women. *Journal of Human Lactation*, 22(1), 27-38.
- Horta, B. L., Bahl, R., Martines, J. C., & Victora, C. G. (2007). Evidence on the long-term effects of breastfeeding. *Systematic Reviews and Meta-Analyses*, 978(92), 1-52.
- Howe, T. H., Lin, K. C., Fu, C. P., Su, C. T., & Hsieh, C. L. (2008). A review of psychometric properties of feeding assessment tools used in neonates. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 37(3), 338-349.
- IBM Corp. (2015). IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.
- Jensen, D., Wallace, S., & Kelsay, P. (1994). LATCH: a breastfeeding charting system and documentation tool. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 23(1), 27-32. doi:10.1111/j.1552-6909.1994.tb01847.x
- Kohn, K.T., Corrigan, J.M., & Donaldson, M.S. (1999). *To err is human: Building a safer health system*. Washington, DC: National Academy Press.

- Kumar, S., Mooney, R., Wieser, L., & Havstad, S. (2006). The LATCH scoring system and prediction of breastfeeding duration. *Journal of Human Lactation*, 22(4), 391-397.
- Kreuter, M. W., Lukwago, S. N., Bucholtz, D. C., Clark, E. M., & Sanders-Thompson, V. (2003). Achieving cultural appropriateness in health promotion programs: targeted and tailored approaches. *Health Education & Behavior*, 30(2), 133-146.
- Li, C. M., Li, R., Ashley, C. G., Smiley, J. M., Cohen, J. H., & Dee, D. L. (2014). Associations of hospital staff training and policies with early breastfeeding practices. *Journal of Human Lactation*, 30(1), 88-96.
- Lutsiv, O., Pullenayegum, E., Foster, G., Vera, C., Giglia, L., Chapman, B., . . . & McDonald, S. D. (2013). Women's intentions to breastfeed: A population-based cohort study. *BJOG: An International Journal of Obstetrics & Gynaecology*, 120, 1490-1499. doi:10.1111/1471-0528.12376
- Martin, J.A., Hamilton, B.E., Osterman, J.K., Curtin, S.C. & Matthew, T.J. (2015) Births: final data for 2013. *National Vital Statistics Report*, 64(1), 1-67.
- Moore, E. R., Anderson, G. C., Bergman, N., & Dowswell, T. (2012). Early skin-to-skin contact for mothers and their healthy newborn infants. *Cochrane Database Syst Rev*, 5(3).
- Mertler, C. A., & Vannatta, R. A. (2002). *Advanced and multivariate statistical methods*. Los Angeles, CA: Pyrczak.
- Mulder, P. J. (2006). A concept analysis of effective breastfeeding. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 35(3), 332-339.

- Parry, J. E., Ip, D. K., Chau, P. Y., Wu, K. M., & Tarrant, M. (2013). Predictors and consequences of in-hospital formula supplementation for healthy breastfeeding newborns. *Journal of Human Lactation*, 29, 527-536. doi: 10.1177/0890334412474719
- Pereira de Souza, R. M., Alves, V. H., Rodrigues, D. P., Lutterbach Riker Branco, M. B., de Oliveira Lopes, F., & de Souza Barbosa M. R. (2015). Nursing strategies in the clinical management of breastfeeding: a descriptive and exploratory study. *Online Brazilian Journal of Nursing*, 14(1), 51-61.
- Riordan, J., Bibb, D., Miller, M., & Rawlins, T. (2001). Predicting breastfeeding duration using the LATCH breastfeeding assessment tool. *Journal of Human Lactation*, 17(1), 20-23.
- Riordan, J. M., & Koehn, M. (1997). Reliability and validity testing of three breastfeeding assessment tools. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, 26(2), 181-187.
- Semenic, S., Loiselle, C., & Gottlieb, L. (2008). Predictors of the duration of exclusive breastfeeding among first-time mothers. *Research in Nursing & Health*, 31, 428-441. doi: 10.1002/nur.20275
- Simpson, K. R. (2013) *AWHONN's perinatal nursing*. Philadelphia, PA: Lippincott Williams & Wilkins.
- Sutherland, T., Pierce, C. B., Blomquist, J. L., & Handa, V. L. (2012). Breastfeeding practices among first-time mothers and across multiple pregnancies. *Maternal and child health journal*, 16(8), 1665-1671.

Tarrant, M., Wu, K. M., Fong, D. Y., Lee, I. L., Wong, E. M., Sham, A., . . . & Dodgson, J. E. (2011). Impact of baby-friendly hospital practices on breastfeeding in Hong Kong. *Birth*, 38, 238-245. doi: 10.1111/j.1523-536X.2011.00483.x

The Joint Commission: *Specifications Manual for National Hospital Inpatient Quality Measures* (applicable for 10/1/2015 - 6/30/2016) Retrieved from http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx

Tornese, G., Ronfani, L., Pavan, C., Demarini, S., Monasta, L., & Davanzo, R. (2012). Does the LATCH score assessed in the first 24 hours after delivery predict non-exclusive breastfeeding at hospital discharge? *Breastfeeding Medicine*, 7(6), 423-430.

United Nations International Children's Emergency Fund (2015). Baby Friendly Hospital Initiative. Retrieved from <http://www.unicef.org/programme/breastfeeding/baby.htm>

UNICEF, WHO (1992). The Global Criteria for the WHO/UNICEF Baby Friendly Hospital Initiative. *Geneva: WHO/UNICEF*.

United Nations International Children's Emergency Fund & World Health Organization. (1989). Protecting, promoting and supporting breast-feeding: the special role of maternity services.

United States Breastfeeding Committee, & Implementing the Joint Commission. (2010). Perinatal Care core measure on exclusive breast milk feeding. *Washington, DC: United States Breastfeeding Committee*.

U. S. Department of Health and Human Services. (2010). *Healthy People 2020*

objectives: Maternal, infant, and child health. Retrieved from

<http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health>

Weddig, J., Baker, S. S., & Auld, G. (2011). Perspectives of hospital-based nurses on breastfeeding initiation best practices. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 40(2), 166-178. doi:10.1111/j.1552-6909.2011.01232.x

Widström, A. M., Lilja, G., Aaltomaa-Michalias, P., Dahllöf, A., Lintula, M., & Nissen, E. (2011). Newborn behaviour to locate the breast when skin-to-skin: a possible method for enabling early self-regulation. *Acta paediatrica*, 100(1), 79-85.

World Health Organization. (2009). Acceptable medical reasons for use of breast-milk substitutes.

World Health Organization. (2014). Nutrition: The World Health Organization's infant feeding recommendation. Retrieved from http://www.who.int/nutrition/topics/infantfeeding_recommendation/en/

World Health Organization. (2015). WHO Statement on caesarean section rates. Retrieved from http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/cs-statement/en/

Appendix A – IRB Exemption

Institutional Review Board Project Action Summary

Action Date: March 4, 2016

Note: Approval expires one year after this date.

Type: ☐ New Full Review ☐ New Expedited Review ☐ Continuation Review ☒ Exempt Review
☐ Modification

Action: ☒ Approved ☐ Approved Pending Modification ☐ Not Approved

Project Number: 2016-03-134

Researcher(s): Jodi O'Brien Fac SON
Mary Barger and Cynthia Connelly Fac SON
Deborah Poettler

Project Title: In-Hospital Factors associated with Formula Supplementation of Healthy breastfeed Infants

Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.

Modifications Required or Reasons for Non-Approval

None

The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited review at any time.

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