

DELIVERING PRENATAL BREASTFEEDING EDUCATION  
TO A VULNERABLE POPULATION  
IN RURAL MONTANA

by

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of

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## ABSTRACT

The educational project aimed to document the efficacy of delivering prenatal breastfeeding education on exclusive breastfeeding (EBF) rates of mothers identified as vulnerable in a rural western Montana community. A convenience sample was utilized to implement the pilot project that included three educational sessions, taught by certified lactation counselors scheduled to coincide with routine prenatal appointment. A control group (CG) was established from a two-month sample of mothers delivering at the implementation site one year before implementation. The education was expected to enhance breastfeeding intentions as evidenced by the scores on the Infant Feeding Intentions (IFI) Scale, thus leading to higher rates of EBF in the participant group (PG) versus a control group.

The PG mothers had slightly higher rates of EBF at both hospital discharge (PG 62% vs. CG 59%) and 7-10 days after birth (PG 57% vs. CG 53%), which failed to show statistically significant differences. One statistically significant difference was noted in the higher rates of EBF at 7-10 after birth for PG first-time mothers versus CG first-time mothers (73% vs. 0%,  $p < .001$ , 95% CL), indicating prenatal breastfeeding education may have made a more significant impact with first-time mothers. However, the efficacy of delivering prenatal breastfeeding education to impact EBF rates in this vulnerable population can neither be supported nor refuted based on the project results.

A review of medical records showed that over 90% of the participant mothers attempted to breastfeed in the hospital (control 76%) and 75% of participant mothers who were not EBF while in the hospital were still giving their infant their breast milk versus 33% of the CG mothers. Seventy-five percent of the PG and CG mothers who were not EBF at 7-10 days were offering breast milk with formula supplementation.

Due to acknowledged limitations in design, measurement and data collection, it is not possible to credit the statistically significant results mentioned above to the educational project. This project did provide useful information to guide future project modifications in implementation design and significant suggestions for further study.

## CHAPTER ONE

## INTRODUCTION

Mothers are provided many recommendations during the course of prenatal care regarding healthy choices for their pregnancy, the birth process, and the care of their infant. One of these choices is to breastfeed their new baby, which contributes to optimal health outcomes for both baby and mother. Not only is human breast milk the ideal balanced source of nutrition for well infants and most preterm infants, it is also associated with lower incidence of diarrhea, urinary tract infection, respiratory tract infection, otitis media, childhood overweight and obesity, bacteremia, necrotizing enterocolitis, type 1 and type 2 diabetes, and some childhood cancers (Eidelman & Schanler, 2012; Bibbins-Domingo et al., 2016). The health benefits of breastfeeding extend to mothers also, as longer breastfeeding duration is associated with lower incidence of breast and premenopausal ovarian cancers, diabetes, hypertension, and myocardial infarctions; in addition *exclusive breastfeeding* (EBF) is associated with decreased postpartum bleeding, lactation induced amenorrhea, and earlier return to pre-pregnancy weight (Bartick et al., 2016; Eidelman & Schanler, 2012).

The World Health Organization [WHO] (2018) evidence-based breastfeeding recommendations should be reinforced with all mothers on multiple occasions during the antenatal period, which will impact her ability to establish and sustain EBF through six months of age. The recommendations include: initiating breastfeeding within the first hour of birth, feeding infant on-demand based on feeding cues presented by infant, practicing EBF through six months of age (no other solids or fluids including water), and

no use of pacifiers, artificial teats, or bottles (WHO, 2018). Exclusive breastfeeding is encouraged up to the second year or longer if mutually desired by mother and infant, with high-quality complementary foods offered to the infant beginning at six months of age (WHO, 2018). This recommendation is reinforced in multiple ways, such as through visits with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), prenatal visits, prenatal education classes, pregnancy books, journals, and breastfeeding websites. Based on this strong evidence, many mothers eagerly commit to breastfeeding their baby according to the recommended guidelines.

### Problem Summary

The United States Department of Health and Human Services launched Healthy People (HP2020) National Objectives to increase the initiation and duration of breastfeeding. Since then, the healthcare community has engaged in continuous efforts and made steady progress toward reaching these goals. Healthcare facilities are providing staff education and changing policies and procedures to create a more supportive environment to help mothers establish a solid foundation with breastfeeding. The efficacy of these changes is reflected in the early infant feeding practices in Montana. According to the Centers for Disease Control and Prevention (CDC) breastfeeding report card (2018), Montana has a state breastfeeding initiation rate of 83.9% surpassing the HP2020 goal of 81.9%. However, the U.S. Surgeon General's *Call to Action to Support Breastfeeding* (2011), reports that unacceptable disparities in breastfeeding persist among certain maternal populations categorized by race/ethnicity, socioeconomic characteristics, and geographical locations. The American Indian/Alaskan Native (AI/AN) populations

have lower breastfeeding initiation rates (73.8%) as well as duration rates (43% at 6 months, 22.4% at 12 months) compared to all other ethnic groups except Non-Hispanic African American mothers (Call to Action, 2011). This document further states that income level and educational attainment, two factors that are correlated with one another, are also both closely associated breastfeeding outcomes. Mothers participating in the WIC program and those with less than a high school education are less likely to breastfeed than mothers from middle to upper-income families or those with some college education. The Call to Action (2011) report further points out that mothers living in rural areas as opposed to urban areas are less likely to breastfeed.

The site for this project is a 22-bed critical access hospital with an attached outpatient medical clinic that also offers prenatal care and birth services. The facility is located in a rural northwestern Montana town on the southern end of Flathead Lake with a population of less than 4,700. This community is also within the Flathead Indian Reservation. The facility serves the local population, as well as people from other remote rural towns in the county and neighboring counties. The county (population 29,311) has been designated a Health Professional Shortage Area (HPSA) due to the low income and Native American populations and its rural location (Health Resources & Services Administration [HRSA], 2019). According to the 2016 U.S. census, the county reports an annual average household income of slightly less than \$40,000, and approximately 21.4% of county residents have incomes below the federal poverty level (FPL). More importantly, residents of childbearing age (18-24 years and 25-34 years) are more likely to be living below the FPL (55% and 44.9% respectively) (U.S. Census Bureau, 2016).

The Census Bureau Data (2016) reports Native Americans make up just over 25.3% of the total county population; residents who identify their race as white represent 68.1% of the population, 5% are of mixed race, and less the 0.5% identify as *other racial minorities*. The county's unemployment rate is 5.0% and almost 90.6% of the residents have a high school education or higher. Seventy-two percent of the mothers giving birth at the intervention site in the past year were covered under Medicaid according to R. Vinsant, Accounting Supervisor (Personal communication, October 22, 2018).

### Background

Rural communities are commonly associated with breastfeeding disparities so much so that the CDC recognizes rural mothers as one of the priority groups for which breastfeeding promotion programs should be targeted. Rural mothers experience reduced availability of services and providers, hospital practices that offer fewer resources than those in urban centers can, and physical isolation in more remote areas (Aschbrenner & Cornish, 2016). Characteristics commonly associated with poor breastfeeding outcomes are more prevalent among mothers in rural communities. Rural communities have a greater percentage of younger women (less than 20 years old) giving birth. Aschbrenner and Cornish (2016) cite a study stating 52.9% of births in rural hospitals are to women under twenty-five years as opposed to 37.5 percent in urban hospitals. Lower-income and higher poverty rates are negatively associated with breastfeeding, and rural women are much more likely to be in a lower socioeconomic status than urban mothers (Aschbrenner & Cornish, 2016). A study by Hildebrand et al. (2014) found an initiation rate of 67% for infants living in households with incomes below the FPL. In addition to most rural

counties in Montana being designated as *medically underserved*, these vulnerable subgroups with known health disparities unequally populate rural communities in Montana (Montana Department of Health and Human Services [MDHHS], 2013).

Some mothers intentionally plan to wean their infants before the recommended duration of one year for various personal reasons. The length of time a mother decides to breastfeed or whether she breastfeeds at all is a personal choice and all healthcare professionals involved in the mother's or her baby's care should support her informed decision. More often, a mother discontinues breastfeeding prior to when she had originally intended due to multiple factors. Common factors found to influence breastfeeding outcomes include age, knowledge/preparation, family/social support, previous experience, cultural values/influence, social pressures, or need to return to work/school (Jones, Power, Queenan, & Schulkin, 2015). Several of these factors influence a woman's ability or motivation to navigate breastfeeding challenges that commonly present in the first days to weeks following delivery. Without adequate support, a mother may decide to terminate breastfeeding prematurely or to supplement her breast milk with infant formula, which frequently leads to early termination as well. Robert, Coppieters, Swennen, & Dramaix (2014) for example, report the primary reason mothers quit breastfeeding before three months is breastfeeding difficulties, the most prevalent being *perceived milk insufficiency* (PMI). This is a common concern for many breastfeeding mothers across cultural, ethnic, and socioeconomic boundaries, which is easily minimized by teaching a mother how to recognize her baby is getting enough milk.

Providing mothers with education, resources, and tools that empower them to achieve their breastfeeding goals is a fundamental part of holistic patient-centered care.

A woman's intention to achieve her breastfeeding goals is an additional factor affecting breastfeeding outcomes. Breastfeeding intentions are the extent to which a mother has planned to breastfeed her infant after birth. Breastfeeding intentions are formed by attitudes toward and knowledge about breastfeeding, the perceptions of whether breastfeeding is a behavior accepted or expected by others, and a mother's belief that she is capable to breastfeed (Bartle & Harvey, 2017). Linares, Rayens, Gomez, Gokun, and Dignan (2015) state breastfeeding intention is a modifiable and strong predictor of breastfeeding behavior and has been shown to be significantly associated with EBF rates. Raissian and Su (2018) point to evidence suggesting that prenatal intentions to breastfeed are a stronger factor than demographic characteristics in predicting actual breastfeeding behaviors. Women identified as having stronger breastfeeding intentions in the prenatal period, have a higher likelihood of EBF and doing so for longer duration. In developing efforts to improve breastfeeding outcomes, the design of interventions that aim to enhance a woman's breastfeeding intentions will likely lead to increasing EBF among vulnerable populations (Linares et al., 2015). Meedya, Fahy, and Kable (2010) also suggest that these interventions ought to target a woman's partner and broader social networks as well.

#### PICOT Statement

Does improving the breastfeeding knowledge and strengthening the breastfeeding intentions of mothers from vulnerable rural populations by providing a prenatal

breastfeeding education (PBE) curriculum delivered synchronously with third-trimester prenatal care visits, demonstrate improved initiation, and EBF rates at hospital discharge and 7-10 days postpartum?

### Statement of the Problem

The question becomes, *what* educational interventions can healthcare professionals provide mothers from vulnerable rural populations, that will improve the likelihood of them developing intent to EBF and impact their skill and confidence to achieve their personal breastfeeding goals.

Evidence suggests that effective breastfeeding education should be part of a mother's routine prenatal care in addition to breastfeeding support after birth (Rosen-Carole, Hartman, & The Academy of Breastfeeding Medicine (ABM), 2015). An informal survey of perinatal nurses at the intervention site reveal that many mothers (especially mothers breastfeeding for the first time) demonstrate lack of basic knowledge about initiating and maintaining breast milk supply, typical infant feeding cues and behaviors, how to navigate common challenges and barriers in early breastfeeding, and how to assess for a proper latch and milk transfer. Prenatal breastfeeding education addresses all these topics and more and can increase a mother's knowledge and confidence in her ability to breastfeed, even if she had a history of previous breastfeeding difficulties or has never attempted to breastfeed (Manjula, Suresh, Kannaiah, & Nirmala, 2016).

Barriers exist in providing uniform prenatal breastfeeding education and preparation for all mothers who intend to breastfeed. Participation in childbirth education

classes has become less common than in the past. Only 11% of women consider prenatal education a routine part of prenatal care according to Morton and Hsu (2007). Women from vulnerable and disadvantaged socioeconomic populations are generally underrepresented in childbirth classes (Morton & Hsu, 2007). Last year, less than 12% of the women who delivered at the intervention site were noted to have attended the free childbirth class offered four times/year. Women who attended the childbirth classes also attended the breastfeeding education classes (although these classes are offered separately). Jones, Power, Queenan, and Schulkin (2015) found that mothers were 75% more likely to initiate breastfeeding when they attend childbirth classes than mothers who did not attend. However, the demographic description of a woman attending perinatal education is white, 25+ years, has a husband or stable partner, above average-income, some post-high school education, is under an obstetrician's care, and covered by private insurance (Morton & Hsu, 2007).

While most maternal child providers are supportive of breastfeeding mothers and inform their patients of the current recommendations to EBF, few include breastfeeding education in their clinic visits, observe a feeding, assess an infant's latch, or assist a mother with breastfeeding challenges. This may be due to time constraints in the clinic practice, and/or lack of current and up-to-date knowledge about breastfeeding (Jones et al., 2015).

Breastfeeding mothers' lack of knowledge and preparation is reflected in the early breastfeeding initiation and EBF rates of the local population. The *Perinatal Care-Exclusive Breast Milk* quality matrix is a record of the percentage of newborn infants who

initiated breastfeeding at birth and who continued to receive only breast milk feedings through hospital discharge. This quality matrix is required by the Joint Commission on Accreditation of Healthcare Organizations (JCOH) and is reported on a quarterly basis. The average percentage of newborns receiving exclusively breast milk through hospital discharge at the intervention site during a one-year time frame from August 2017 to 2018 was 62.9% (Personal communication with Quality Specialist, J. Pinsonneault, January 12, 2019). The county WIC Program serves many members of the vulnerable perinatal population delivering at the intervention site and according to their data records, only 27.0% of infants are exclusively breastfed and an additional 14.4% are partially breastfed (U.S. Department of Agriculture [USDA], 2018). These statistics are intensified by the overall health disparities of lower-income and rural populations in Montana (Montana Department of Public Health and Human Services [MDHHS], 2016).

Breastfeeding is presumed to be instinctive, however, it does require some preparation on the part of the mother and time to become efficient at it. This requires a new mother to understand what behaviors and challenges are expected in the learning period, how to recognize when she is having trouble with breastfeeding, and how to access help for her to feel confident in her capability to successfully breastfeed. Lack of breastfeeding knowledge contributes to suboptimal breastfeeding outcomes. Prenatal childbirth education addresses these topics, but women in vulnerable populations have multiple barriers to attending separate education classes outside of their routine prenatal visits. These barriers include financial challenges (e.g. travel expenses, childcare, cost of classes), reduced social and cultural support, and scarce access to reliable educational

resources. This population is shown to have lower breastfeeding confidence; consequently, these mothers have suboptimal breastfeeding outcomes (Manjula et al., 2016; Pitts, Faucher, & Spencer, 2015).

Three-month EBF rates are reflective of the successful establishment of early breastfeeding practice. When these rates are low, it may be indicative of a mother not receiving adequate support to acquire these skills during a critical time in the prenatal and early postpartum period. Prenatal breastfeeding education proactively addresses knowledge gaps and common challenges associated with early breastfeeding and can increase a woman's knowledge and confidence in her ability to breastfeed and provide her with the skills to achieve her breastfeeding goals. Evidence reveals that prenatal education and positive encouragement can significantly increase initiation, duration, and exclusivity of breastfeeding (De Jager et al., 2015). Providing access for breastfeeding mothers to professional support extending from the prenatal period through the duration of breastfeeding is associated with a 3-fold increase in EBF rates at 3 months and increased the duration of any breastfeeding; Herold, Bonuck, Marinelli and Gill (2016) suggest this would have an even greater impact for mothers in vulnerable population groups. This recommendation is supported by the Office of the US Surgeon General, the United States Preventive Services Task Force (USPSTF), the Center for Medicare and Medicaid Services (CMS) (Herold et al., 2016). Additionally, Herold et al. (2016) state that the Affordable Care Act (ACA) requires private insurers and newly expanded Medicaid programs to cover these support services.

Current evidence suggests that implementing an evidence-based education program that is conveniently coordinated with prenatal appointments and taught by a trained lactation specialist could improve prenatal maternal knowledge, preparation and skill regarding breastfeeding. A quality program offered to all mothers and their birth/parenting partner may foster the mother's belief in her ability to breastfeed, help her partner identify ways in which to support breastfeeding, and help both mother and partner to identify resources available to assist her should she encounter difficulties, thus improving her breastfeeding intentions. The expected outcome of this educational program would be improved prenatal breastfeeding intention leading to increased initiation rates and increased EBF rates at hospital discharge and 7-10 days postpartum. A secondary expected outcome in the long-term is an increased EBF rate at three and six months postpartum (not measured in this project). Realizing these outcomes would have an even greater impact in the high-risk population served at the intervention site.

#### Purpose Statement

This clinical project aims to assure the delivery of evidence-based prenatal breastfeeding education to every mother at the project implementation site. It is anticipated that increasing prenatal knowledge and preparation regarding breastfeeding and providing supportive encouragement from a trained lactation specialist will increase initiation rates and exclusivity during the first 7-10 days following delivery. The expectation for this educational intervention is to build knowledge and skill to manage common challenges that typically lead to early supplementation or termination of breastfeeding, to enable women to establish *high-quality breastfeeding practices* early in

the lactation process, as well as to support and help foster their intent to breastfeed. This will be accomplished by providing an evidence-based Prenatal Breastfeeding Education (PBE) Curriculum delivered to all mothers and their support person(s) by a trained lactation specialist in three separate 20-min sessions in coordination with routine prenatal clinic visits.

### Project Objectives

1. To increase support, knowledge, and preparation for managing initiation and continuance of early breastfeeding by assuring all mothers intending to breastfeed or undecided on their feeding choice receive three 20-min sessions of the PBE Curriculum.
2. To foster and strengthen the breastfeeding intentions of mothers in the late prenatal period prior to birth.
3. Following implementation of the PBE Curriculum, to increase breastfeeding initiation rates at intervention site.
4. Following implementation of the PBE Curriculum, to increase breastfeeding exclusivity at hospital discharge, and at 7-10 days after birth at intervention site.

### Conceptual Theory

The Healthy People initiative was developed to identify and set measurable objectives for national health priorities, based on determinants of health. Health determinants impact and influence health outcomes and they fall under five broad categories: policymaking, social factors, health services, individual behaviors, and

biology and genetics (Office of Disease Prevention and Health Promotion [ODPHP], 2016). Over a century ago, Florence Nightingale recognized intuitively that certain factors such as environmental conditions and lifestyle behaviors could be altered to positively or negatively impact health and disease. Effective interventions that focus on *multiple* health determinants have the highest likelihood to yield improved health outcomes. Improving breastfeeding outcomes is one of the many Healthy People 2020 target objectives, but to significantly impact breastfeeding outcomes, we must look at the individual mother-child dyad, within the context of their environment that has a direct influence on these outcomes (ODPHP, 2016). Every mother-child dyad is part of a more extensive social system, so it is essential to recognize that the improvement of breastfeeding outcomes has a broader influence and affects the overall health of families and communities.

When breastfeeding is the *normal and expected* method of feeding infants in a mothers' social culture, educational instruction is almost not necessary. From the time children are small, they see their siblings, cousins, and other babies in their social community being breastfed; they hear women talking about feeding problems, and friends or family members giving advice, support, and encouragement (Cadwell & Turner-Maffei, 2009). This is not the case in our current culture in the United States, particularly among women of vulnerable populations. Many young mothers have never actually seen an infant being fed at the breast in their community, or they may have witnessed a young mother being ridiculed or shamed for breastfeeding her baby in public. If a friend or family member has attempted to breastfeed unsuccessfully, they may have

only heard of the negative outcome. It is not uncommon for a perinatal nurse to be told by her patient that they hope to breastfeed their infant *if they can*, adding that their mother or sister (cousin, friend...) *tried to breastfeed but never got any milk, or the baby wasn't getting enough*. Thus the responsibility falls upon the healthcare community to educate expectant families on the benefits and management of breastfeeding as well as offset the misinformation women may have received from current cultural media, family, friends, and even uninformed healthcare providers (Cadwell & Turner-Maffei, 2009).

Healthcare professionals have the opportunity to provide multiple interventions to influence the breastfeeding outcomes of their patients. But which interventions will influence the development of a mother's informed prenatal intent to EBF and give her the skill and confidence to develop high quality early breastfeeding practices that support breastfeeding success and help her achieve her intended breastfeeding goals? Again, effective interventions consider health determinants from a multifactorial perspective. The Theory of Planned Behavior (TPB) provided the framework to answer this question as well as guide and organize the clinical project intervention.

In 1985, Icek Ajzen developed the TPB as an extension of an earlier theory he co-developed with Martine Fishbein, the Theory of Reasoned Action (Montano & Kasprzyk, 2008). The goal of the TPB according to Ajzen (1991), is to explain human behavior rather than predict it. Critical beliefs, which Ajzen labels *salient beliefs*, regarding a particular behavior will influence three key *constructs*: behavioral attitude, subjective norm, and perceived behavioral control. These three constructs interplay to influence the level of intent one has towards a specific behavior, which will, in turn, affect the adoption

of that behavior in a given circumstance (Armitage & Connor, 2001). “It is these salient beliefs that are considered to be the prevailing determinants of a person’s intentions and actions” (Ajzen, 1991, p. 189). The likelihood of a person choosing to perform a behavior is dependent on how favorable or unfavorable each construct is, based on their underlying beliefs about the behavior. Ajzen (1991) further delineates these beliefs as *behavioral beliefs* that influence one’s attitudes toward a behavior, *normative beliefs* that formulate perceptions of subjective norms, and *control beliefs* that are the foundation of individuals’ perceived behavioral control. Regarding the three constructs Ajzen states, “each reveals a different aspect of the behavior, and each can serve as a point of attack in attempts to change it.” (Ajzen, 1991, p. 206).

The *behavioral attitude construct* is how a person thinks and feels about the behavior. Ajzen (1991) explains that the attitude one has toward a behavior develops out of prominent beliefs they hold regarding a behavior. The belief about the behavior has a positive or negative value associated with it, which will automatically become associated with the behavior. A person may question, *will performing the behavior be enjoyable or unenjoyable, or produce a beneficial or harmful outcome* (Ajzen, 1991)? A provider seeking to alter a patient’s attitude toward a behavior must first explore and address their prominent beliefs underlying the attitude.

In the project design, the behavioral attitude construct was addressed through individualizing every session for each mother and her partner. The *certified lactation counselor* (CLC), the lactation specialists for the intervention site, began the first session by discussing with each mother personal beliefs about breastfeeding. The survey queried

each mother's previous breastfeeding experiences and satisfaction with those experiences. Through conversation about these experiences, the CLC could help a mother reframe a negative experience differently, for instance, helping the mother to recognize that her previous breastfeeding experience could have been different if she had received assistance and support earlier in the process of breastfeeding. Particular concerns that a mother expressed were written in her notes so it could be addressed at each session from a positive perspective. Another aspect of the program that addressed the behavioral attitude construct was the conversation of the multiple benefits that breastfeeding offers infants and mothers.

The likelihood that significant members of a person's social/peer group, family, or support system would encourage or disapprove of them performing a particular behavior describes the beliefs influencing the *subjective norms construct*. When a person believes important people in their life will be supportive of their endeavor to perform the behavior, they are more likely to develop intention to adopt the behavior. Likewise, if a family member or close friend is or has participated in the same behavior with positive outcomes, then a person is more likely to identify this behavior as positive and develop intention to adopt the behavior (Ajzen, 1991). Research has shown that father or partner support is pivotal for mothers in achieving their breastfeeding goals (Abbass-Dick & Dennis, 2017). With the subjective norms construct in mind, birth partners and spouses were strongly encouraged to participate in the educational sessions along with the mother. Each session was individualized to address the mother's current needs as well as reinforce the knowledge and experiences the mother or her partner had. The significance

of the supportive role that a birth partner plays in early breastfeeding was explained to parents. Partners were offered practical suggestions of how they could help the mother and reminded them that they might need to defend the decision to EBF their infant to family or friends. Many mothers from vulnerable populations lack support in their social community for their decision to breastfeed. The subjective norm construct was also addressed by providing information about trusted breastfeeding resources, availability of one-to-one breastfeeding assistance in the lactation clinic, and a personal invitation for parents to attend the hospital weekly support group. Mothers were also encouraged to utilize the excellent resources for breastfeeding assistance in the WIC program if they were involved in it. A final TPB construct, *perceived behavioral control*, pertains to whether an individual feels they are confident and capable of performing the behavior. This construct develops from the beliefs one has about the ability and skill they possess in performing the behavior. The belief is heavily weighted on their identification of facilitators and barriers (control factors) that will impact their behavioral performance. The individual also assesses the magnitude of the perceived impact each control factor has to facilitate or inhibit the behavior (Montano & Kasprzyk, 2008). This belief may be based on personal experience, second-hand information, and the experiences of personal associates or friends, according to Ajzen (1991). However, when one can identify trustworthy resources and opportunities, they generally anticipate fewer barriers and experience greater perceived control over behavior performance. The perceived behavioral control construct was addressed through conversations about breastfeeding positions, how to achieve a deep latch, use of skin-to-skin contact, recognition of infant

feeding cues, and how to assess for adequate milk transfer. The use of role-playing, modeling, photos, and videos to practice these skills was intended to reinforce the mothers' feelings of being confident and capable that she will be able to breastfeed. Mothers were reminded that breastfeeding a new baby is a learning process for both mother and baby, and confidence comes with time and practice. It was also important to discuss common challenges in breastfeeding, solutions for these challenges, and how to access help to resolve breastfeeding problems. This demonstrates to a mother that breastfeeding difficulties are not uncommon, and she will have the tools to deal with them if they present. Another influence on this construct is the mothers' recognition of trusted and knowledgeable resources that can help her overcome barriers. The relationships that developed naturally in one-to-one sessions between the CLC and the parents formed the beginning of a trusting relationship with the lactation staff that would be assisting them with breastfeeding after birth.

The TPB provided a clear framework to support the interventions implemented in this clinical improvement project. The education was individualized for every participating mother and her support partner(s) in consideration of how their community, environment, and cultural background may have influenced the mother's attitude and beliefs regarding breastfeeding. The educational project was designed to foster the understanding of the health benefits associated with breastfeeding, reinforce parents' knowledge and skills regarding breastfeeding, and help them identify availability of trusted resources, all of which was intended to contribute to their confidence in the ability to successfully achieve their intended breastfeeding goals.

## CHAPTER TWO

## REVIEW OF LITERATURE

Numerous research studies and systematic reviews have established the accepted conclusion that human breast milk is held as the *gold standard* for infant nutrition. Additionally, all other forms of nutrition should be compared to breast milk (Eidelman & Schanler, 2012). The recommendation supported by multiple health organizations (American Academy of Pediatrics (AAP), American College of Obstetricians and Gynecologist (ACOG), American Academy of Family Physicians (AAFP), United Nations Children's Emergency Fund (UNICEF), WHO) is for infants to be EBF until about six months of age, followed by EBF, along with offering high-quality complementary foods until twelve months of age or longer as mutually desired (Bibbins-Domingo et al., 2016). All mothers and infants stand to benefit from adhering to these recommended guidelines for breastfeeding; however, the benefits have a significantly higher impact on vulnerable women. This population of women and their infants are disproportionately affected by adverse health outcomes, which would likely improve with optimal breastfeeding practices (Jones et al., 2015).

Much of the breastfeeding research concerning vulnerable maternal populations focuses on racial and ethnic minorities, primarily African American (AA) and Hispanic women. While the project intervention site does not have a large proportion of these minority population groups, similar factors affecting breastfeeding outcomes exist across vulnerable populations. Common factors associated with lower initiation, duration and exclusivity of breastfeeding are mothers with a less than a high school education,

maternal age less than 20, women involved in WIC, single or unmarried mothers, overweight/obese weight status before pregnancy, women having limited access to quality information about breastfeeding (due to geographical location, language barriers, or lack of insurance), alcohol and drug use, and having an unintended pregnancy (Bibbins-Domingo et al., 2016; Danawi, Estrada, Hasbini, & Wilson, 2016; Jones, et al., 2015). Jones et al. (2015) conducted a literature review involving various diverse racial/ethnic groups and the differences between them regarding breastfeeding practices. Their research found AA mothers to have the lowest initiation rate (60%) and the lowest six and twelve-month breastfeeding rates 28% and 13%, respectively. These results are consistent with the most current research. Although the literature is scarce on American Indians and Alaskan Natives (AI/AN), Jones et al. (2015) found this subgroup to have the second-lowest initiation rate (73%) and six and twelve-month duration rates (42.4% and 20.7%, respectively). “Apart from African American women, breastfeeding duration and exclusivity rates decline faster among AI/AN women than among other racial/ethnic groups,” and of the AI/AN mothers who initiate breastfeeding after birth, over 50% will terminate breastfeeding prior to four months after birth (Jones et al., 2015, p.189). An interesting fact revealed in the literature is that AI/AN mothers who continued breastfeeding their infant until six months showed a higher rate of continuance through 12 months of age, similar to the general population (Jones et al., 2015; Sparks, 2011).

In addition to considering breastfeeding disparity and outcomes, we must also take into account the overall societal burden of suboptimal breastfeeding practices, which costs the US economy billions of dollars annually (Sparks, 2011; McKinney et al., 2016).

Bartick et al. (2016) considered multiple maternal and child diseases in which longer breastfeeding duration resulted in decreasing the incidence of diseases. The researchers chose seven diseases due to the strong scientific evidence of the disease incidence being influenced by breastfeeding outcomes. To determine the maternal and child costs of suboptimal breastfeeding, the researchers estimated the long-term mortality/morbidity risk of the chosen diseases. The simulation study showed significantly fewer deaths and a significant decrease in both medical and non-medically related costs associated with optimal breastfeeding practices. According to Bartick et al. (2016), suboptimal breastfeeding in this country is associated with more than 3,340 deaths (78% are maternal deaths) and generates over 18 billion dollars in medical, non-medical, and premature death costs. Most importantly, McKinney et al. (2016) state “the social, health, and economic burdens of low breastfeeding rates are not shared equally across racial and ethnic groups” (p. 2).

The Surgeon General’s *Call to Action to Support Breastfeeding* (2011) identifies the numerous barriers to overcome in achieving breastfeeding outcome improvement among vulnerable populations: lack of knowledge, social norms, inadequate family and social support, embarrassment, lactation problems, employment, childcare issues, and barriers related to health services. Some of these barriers must be addressed through public policy, some through healthcare policy, and some through direct education and support provided to an expectant mother and her support system. Several of the barriers recognized in the Call to Action (2011) have been prevalent in most breastfeeding

research in the past 10-15 years, and yet continue to be hindrances to optimal breastfeeding outcomes currently.

It is common for pregnant women to have heard that breast milk is the ideal source of nutrition for a newborn baby, but few understand what the specific benefits are or, more importantly, the risks associated with not breastfeeding. Due to a lack of exposure to breastfeeding in their culture or lack of healthcare access, many women have never received breastfeeding education. Additionally, vulnerable ethnic populations (AI/AN, AA, Hispanic) more commonly have delayed access to prenatal care and will not experience the repetitive exposure to breastfeeding education they could receive from their maternity provider over time (Danawi et al., 2016). Because the physiological changes allowing for milk production is a naturally occurring process during the pregnancy, many women expect breastfeeding to be easy. Few women understand that breastfeeding is a learning process for both baby and mother and experiencing difficulty and challenging times is quite common. Experiencing these early difficulties coupled with unrealistic expectations is identified as a common reason mothers stop breastfeeding within the first two weeks postpartum (Rozga, Kerver, & Olson, 2015b). Lack of understanding about lactation maintenance also interferes with the duration a woman nurses her infant. Multiple studies of women participating in the WIC program revealed the top two reasons for terminating breastfeeding was mother preference (reasons not cited) and perceived insufficient milk (PIM) supply (Tenfelde, Zielinski, & Heidarisaifa, 2013; Rozga et al., 2015b). These reasons were more likely to be reported by mothers who were single, less than 20 years old, a racial minority (Hispanic/AA), or have less

than a high school education according to Rozga et al. (2015b). These maternal characteristics are also associated with adverse maternal health outcomes. Early breastfeeding termination due to PIM supply usually occurs in the first 2-8 weeks (Rozga et al., 2015b).

Another common barrier to breastfeeding is the lack of social familiarity and acceptance of breastfeeding in many communities, especially in more vulnerable populations. As the efficacy of infant formula used as an alternative nutrition source became better supported by research, aggressive marketing of human milk substitutes in the mid-1920s led to a global decline in breastfeeding (Stevens, Patrick, & Pickler, 2009). Amid protests from health advocates and medical professionals, the aggressive marketing techniques continued in the form of free formula samples provided to new mothers to bring home from the hospital and a barrage of coupons for discounted formula (Stevens et al., 2009). The American public accepted formula feeding as the *modern* and *appropriate* way to feed an infant and breastfeeding was associated with less developed countries that lacked any other options (Danawi et al., 2016). Lower-income mothers who qualified financially were able to continue to receive infant formula through the WIC program. To this day, the evidence shows women participating in WIC have breastfeeding initiation rates similar to those seen with AA mothers (67.5%) according to Jones et al. (2015) despite a racially/ethnically diverse WIC population. Tenfelde et al. (2013) report breastfeeding mothers participating in the WIC program breastfed an average of 6.7 months, whereas mothers eligible but not participating in WIC breastfed 8.2 months (women not participating and not eligible for WIC- 9.3 months). In recent

years, the WIC program has made heroic strides in offering breastfeeding education, breastfeeding peer support programs, and visiting nurse programs after birth for breastfeeding support. However, the FY 2017 WIC Breastfeeding Data Local Agency Report shows only modest increases in the past five years of infants reported as being fully or partially breastfed (27.0% & 14.4%, respectively); still considerably below the HP2020 goals (USDA, 2018). Heinig et al. (2006) offer that infant formula is still recognized as being an equivalent substitute for human breast milk by lower-income and racial/ethnic minority populations.

The beliefs and values found in a woman's culture or social community have a strong influence on a mother's feeding choices and breastfeeding behaviors. Despite the evidence, many ethnic/racial groups continue to believe that *big babies are healthy babies*. Since a mother can not see or measure the amount of breast milk her infant is getting, she may supplement her breast milk with formula or introduce solid food prematurely for fear her baby is not getting enough (Surgeon General's Call, 2011). Heinig et al. (2006) used focus groups to understand why less than ideal feeding choices were so prevalent among a group of culturally diverse mothers participating in WIC regardless of the counseling and comprehensive education provided. The population in this study was predominantly Spanish speaking Hispanic and English speaking AA mothers. Most participants reported that they planned to both breastfeed and formula feed but within the first few weeks, 60% of the mothers were feeding formula only. Mothers reported concerns about milk supply or delayed milk production, postpartum medications, latch problems, infant intolerance to breast milk, planning to return to work

or school, and a belief that offering formula to their infant was their only choice as the reasons why they altered their feeding intentions (Heinig et al., 2006). Few mothers in this qualitative study reported knowing the best time to start an infant on solid food. Mothers typically commented they introduced solid foods when the infant *seemed* like she was at the right age or when he gave cues that *he was ready* for food. The average age to introduce solid foods in this population was four months, but 22% of infants received first foods at two to four months. Other reasons for using supplemental infant formula or early introduction of solid foods revealed by the research were infant fussiness, belief that waking in the night indicated infant hunger and solid foods would help infant sleep through the night, and feeling uncertain of whether the infant was getting enough milk. Assuring a baby was *full enough* and seeing plenty of *baby fat* seemed to be a shared goal for the study participants' families, partners, and friends as well (Heinig et al., 2006). A "family history of breastfeeding, especially from the mother's side, bolsters breastfeeding outcomes, and this intergenerational factor mediates racial/ethnic breastfeeding disparities" (McKinney et al., 2016, p.8-9). First-generation mothers from most Hispanic populations have similar breastfeeding rate as the non-Hispanic white population, despite sharing the multiple health disparities associated with suboptimal breastfeeding outcomes. McKinney et al. (2016) attribute this to the social and family influence on breastfeeding from their country of origin.

Along similar lines as cultural beliefs and values, the support a mother receives from her social network (partner, family, and peers) is a crucial factor in her breastfeeding intentions and outcomes. If a woman's friends or family members have

breastfed successfully, she is more likely to intend to breastfeed and more likely to succeed in reaching her intended breastfeeding goals. The converse is true also, when a mother has family or friends that report negatively about their breastfeeding experience, she is less likely to initiate or continue to breastfeed. A qualitative study utilizing focus groups of First Nation women in Canada was conducted by Eni, Phillips-Beck, and Mehta (2014), in which they report less than half of this population initiated breastfeeding. Similar to Native American women, this Canadian population had multiple known health and social disparities. Of extreme importance to this group of women was emotional support and acceptance of breastfeeding by their partners (baby fathers). Mothers who did not feel supported by their partners were less likely to breastfeed and had a higher incidence of postpartum depression. Cultural acceptance or approval of elders was also influential in breastfeeding decisions, especially that of the paternal grandmother (Eni et al., 2014). Abbass-Dick and Dennis (2017) found implementation of interventions designed to develop and improve fathers' support of breastfeeding mothers could increase initiation, duration, and exclusivity of breastfeeding. This vital support element should be included in breastfeeding education as research suggests many fathers indicate they want to be more involved in supporting breastfeeding, but often do not know anything about breastfeeding or how to help (Abbass-Dick & Dennis, 2017).

Women also find healthcare professionals (providers, office staff, lactation specialists, doulas) a significant resource for support. The *Ten Steps to Successful Breastfeeding* addresses the importance of adequately trained staff in the perinatal environment to support breastfeeding, the importance of continuous discussion and

education throughout the prenatal and postnatal period regarding breastfeeding, and creation of an environment that actively supports breastfeeding and complies with the International Code of Marketing of Breast-milk substitutes (WHO, 1998). Rosen-Carole, Hartman, and the Academy of Breastfeeding Medicine (2015) provided a clinical protocol to guide perinatal health professionals in the care and support of breastfeeding mothers and infants. This protocol references the importance of having a breastfeeding-friendly office space (pro-breastfeeding posters and artwork, area for staff and clients to feed or pump), written policies that facilitate support, adequately trained staff to answer questions and support breastfeeding, culturally sensitive written materials provided for mothers, and a current listing of community breastfeeding resources available for clients. Most importantly, this statement recommends there is discussion about breastfeeding at each prenatal visit (Rosen-Carole et al., 2015). According to a recent study reported by Bibbins-Domingo et al. (2016), many women do not receive any breastfeeding advice or they received advice that was inconsistent with the AAP recommendations. Inconsistent information can come from their health provider or staff. Jones et al. (2015) report on a study finding that physicians and their patients engage in conversations about breastfeeding in about 29% of their visits, and those conversations are typically less than 40 seconds long. Providers report a *lack of time* in preventative visits and *personal lack of education* regarding breastfeeding education as the most common barriers to providing breastfeeding information during office appointments (Bibbins-Domingo et al., 2016).

The most prevalent reason for early termination of breastfeeding in the first two to four weeks following birth is lactation difficulties (Rozga, Kerver, & Olson, 2015a;

Bibbins-Domingo et al., 2016; Odom, Li, Scanlon, Perrine, & Grummer-Strawn, 2013). Common lactation difficulties include difficulty obtaining an adequate latch, breast or nipple pain, a fussy infant, engorgement, maternal choice, and insufficient milk supply (perceived or actual). Most of these issues can be resolved with education and assistance from professional and lay lactation support personnel or an experienced family member. With a lack of adequate breastfeeding support, mothers may believe they have no other option but to turn to formula feeding when they experience breastfeeding problems (Rozga et al., 2015a). An insufficient milk supply can result from an improper latch, infrequent feeding, or supplemental formula feedings. However, more often than not, the maternal assessment of PIM is simply a lack of understanding normal lactation physiology, lack of confidence in breastfeeding ability, or lack of information regarding signs of satiety, assessment of milk transfer, and evidence of adequate feeding (Surgeon General's Call, 2011).

Strategies intended to counter the multiple barriers to EBF must be designed from a multidisciplinary framework. Changes must be able to influence the mother, her social network, her community, her healthcare setting, and even further reaching to influence federal and state policymakers or insurance providers. Stuebe and Bonuck (2011) state that prenatal intentions to breastfeed are the strongest predictors of duration and exclusivity, so when considering a small-scale intervention, efforts to provide information and education to allow mothers to make a well-informed decision for infant feeding seems like an optimal place to start. However, evidence shows that if excellent prenatal education and preparation is not reinforced with postnatal follow-up and support,

EBF or any breastfeeding, are less likely to be sustained for the recommended six months (Debevec & Evanson, 2016).

In a systematic review of 17 studies to expose effective elements of breastfeeding interventions, over half of the studies resulted in significant improvements in EBF (Skouteris et al., 2014). Most of the successful interventions reported by Skouteris et al. (2014) occurred in the postnatal period and extended through five weeks to six months after birth. Haroon, Das, Salam, Imdad, and Bhutta (2013) performed a systematic review to examine interventions designed to promote EBF. The variety of interventions included one-to-one counseling/education with follow-up telephone support, group counseling with no follow-up, community-based interventions with in-home visits, and hospital or clinic-based education. Group and individual counseling/education were found to be most effective in improving EBF from one day up to five months but it was not statistically significant. There was however, a significant reduction in the number of women who chose to formula feed only after birth (Haroon et al., 2013). In a randomized control trial, Su et al. (2007) compared two intervention groups to a control group that received usual care (optional patient-initiated education/support). The first intervention group participated in an antenatal class with video and discussion about breastfeeding, and the second intervention group received two postnatal support sessions within three days of discharge and during the first office visit at 1-2 weeks after discharge. Both intervention groups, compared to the control group, were significantly more likely ( $p > 0.05$ ) to be EBF at two weeks, six weeks, and six months (Su et al., 2007).

Bonuck et al. (2014) conducted two randomized control trials in urban medical centers associated with prenatal clinics serving low to middle-income participants. Both studies randomized some women to a control group, which received usual care. Neither healthcare setting had initiated intentional breastfeeding support or promotion at the time of the study, but both settings had one professional lactation specialist on staff. The mothers assigned to intervention groups received one of three interventions. The first intervention included electronically prompted (EP) anticipatory guidance from their obstetric care provider that included open-ended questions asked at five separate prenatal visits. A second intervention involved care received by a lactation consultant (LC) that included two face-to-face prenatal visits, one visit in the hospital, and phone calls or home visits after birth up to three months. The final group received both the EP and LC intervention. The researchers hypothesized that the interventions would increase breastfeeding exclusivity and intensity (frequency) at one, three, and six months, as compared with the control group (Bonuck et al., 2014). The results of the first trial setting in this study showed significantly more mothers in all intervention groups practiced EBF or any breastfeeding at one and three months ( $p=0.01$  to  $p<0.001$ ) in one trial setting. In the other trial setting, in which the participants were less educated, mostly unmarried, had a higher percentage of WIC participation, and fewer mothers who planned to EBF, only the three-month EBF rate was significantly higher ( $p=0.02$ ) (Bonuck et al., 2014). The LC only and the EP+LC interventions were found to be the most effective for trial participants.

The importance of maternal support in breastfeeding cannot be underestimated, particularly the support from the mother's partner. This encouragement has a considerable impact on the mother's likelihood of reaching her intended breastfeeding goals (Abbass-Dick & Dennis, 2017). Previous studies have clarified the fact that fathers want to be involved in breastfeeding support and want information about how they could be most helpful. Breastfeeding education is often geared towards the *mother only*, according to Abbass-Dick and Dennis (2018), leaving the father feeling frustrated, left out, not included in parenting, and uncertain about where to find quality information or practical ideas about how to support their partner. Abbass-Dick and Dennis (2018) introduced an evidence-based education program into a randomized control trial (RTC) to evaluate the satisfaction of mothers and their support person with a *co-parenting breastfeeding support* intervention. The effort was to include fathers (or support persons) in a *team approach* to joint decision-making regarding baby care and breastfeeding. The program, which used multiple modes of education delivery and information, was directed to both parents or individually to support persons. Discussion was centered on ways fathers could support the new mother with breastfeeding and foster achieving the breastfeeding goals set by both parents. The data obtained via questionnaires at six and 12 weeks postpartum showed that significantly more fathers in the intervention group indicated that the breastfeeding education received specifically targeted their needs in addition to the mothers' needs ( $p < 0.01$ ). Additionally, in the intervention group, significantly more mothers ( $p < 0.04$ ) stated they felt satisfied with the involvement of their support person compared to the control group mothers. Finally, the intervention

group fathers showed a significant improvement in the paternal breastfeeding self-efficacy scores ( $p < 0.03$ ) over the control group (Abbass-Dick & Dennis, 2018).

A Danish cluster-randomized study by Nilsson, Strandberg-Larsen, Knight, Hansen, and Kronborg (2017) designed a postnatal intervention intended to enhance maternal breastfeeding self-efficacy, increase duration in breastfeeding, and decrease the number of infant readmissions due to nutritional problems. Ten medium-sized hospitals participated in the study, with the typical cluster size at each facility being 291-540. The intervention included 11 hours of training for the healthcare professionals who contributed to the breastfeeding knowledge and support for new mothers (mainly nurses and midwives) at each facility. These healthcare professionals provided education in the immediate postnatal period to mothers and support persons at the intervention sites ( $n=2065$ ) based on four core program components: providing skin-to-skin contact as much as possible in the first three days of life; providing increased frequency of feedings (minimum of eight/day) based on identification of infant cues and recognition of infant satiety; teaching on proper positioning and changing positions to minimize maternal pain; and acknowledgment of the mother and father both being equal parents with different roles that support breastfeeding. The facilities randomized as the control hospitals ( $n=1476$ ) delivered *usual care*, which varied considerably. However, all mothers received basic education from healthcare professionals based on national evidence-based recommendations provided in a Danish governmental resource on breastfeeding. The breastfeeding self-efficacy score and EBF rates up to one month were not notably different between the intervention and control setting participants. There were however

significantly higher odds of EBF at six months postpartum at the intervention sites ( $p < 0.04$ ). There were also significantly lower odds ( $p < 0.01$ ) of infant readmission due to nutritional problems in the first week of life (Nilsson et al., 2017). Additional analysis showed that infants from the intervention groups were given more hours of skin-to-skin contact by both parents, were breastfed more frequently, and were less likely to be tested for hyperbilirubinemia (Nilsson et al., 2017). The mothers in the intervention setting did report the most breastfeeding problems, which the researchers noted were primarily due to breastfeeding frequency and length, but the mothers at the control settings were more likely to experience pain with nursing and rate their pain more severely (Nilsson et al., 2017).

The primary aim of a randomized control trial by Khan et al. (2017) in a rural setting of Bangladesh was to determine whether the timely introduction of combined foods and micronutrient supplementation would further increase EBF duration in the participant mothers with a high incidence of maternal malnutrition. Additionally, breastfeeding counseling was provided in a total of eight sessions (lasting 20-40 min.) with two sessions during the third trimester, a session within one week after delivery, and the remaining sessions monthly until the infant was six months. The peer counselors delivering the counseling sessions received 40 hours of *WHO/UNICEF* breastfeeding counseling training (Khan et al., 2017). Mothers who received the one-to-one counseling, as opposed to the usual health message (which provided recommendations for EBF and positive messages about EBF) practiced EBF two months longer regardless of supplementation or micronutrients given. The researchers' results supported the multiple

studies they reviewed that showed interventions offering support and counseling by trained individuals over a variety of peripartum periods are associated with a more considerable positive influence on breastfeeding outcomes (Khan et al., 2017).

An older study reported by Pugin, Valdes, Labbok, Perez, and Aravena (1996) focused on assessing the effectiveness of a comprehensive intervention with five components designed to improve breastfeeding intensity and duration. A sixth component was added to the intervention after the study commenced, creating a second outcome expectation that the additional component, a prenatal breastfeeding skills group education (PBSGE), would further improve the breastfeeding outcomes. Pugin et al. (1996) designed the quasi-experimental study with the objectives to improve breastfeeding practices and have a protocol that could easily be adapted to other settings. The first five components of the comprehensive intervention included training of maternal health professionals, prenatal and inpatient activities for participants related to breastfeeding, creating an outpatient lactation clinic, and education on Lactation Amenorrhea Method (LAM) for family planning. The additional breastfeeding education component was evaluated separately on a sub-group of the participants. The results of this intervention were impressive. The intervention group showed a marked increase over the control group in *fully breastfeeding* (defined as having no greater than two supplemental feedings/week) at six months ( $p < 0.0001$ ) regardless of parity (Pugin et al., 1996). The impact of the breastfeeding education component on the participants exposed to this additional intervention exhibited significantly higher breastfeeding rates at six months compared to participants who did not receive this part of the intervention ( $p < 0.0026$ )

(Pugin et al., 1996). The breastfeeding education component of the intervention exhibited a more significant impact on primiparas according to Pugin et al. (1996), however, the significant increase in EBF was seen in multiparous mothers as well. See Appendix F for literature search methods and terms.

### Definition of Terms

For the purpose of this project, the following definitions were used:

- *Minority Women/Mothers*- Women from certain ethnic groups with known health disparity (Native Alaskan/American Indian (American Indian also referred to as Native American in the literature), African American, Hispanic).
- *Vulnerable Populations*- Population groups at risk for greater health disparities due to multiple contributing factors (less than a HS education, low income, less than 20 years of age, 1<sup>st</sup> time BF, Primiparous, minority ethnicity, WIC participant). For this paper, this term is referring primarily to women of childbearing years.
- *Health Disparities*- Differences or gaps in health outcomes between different groups of the population.
- *Health Determinants*- These are social, environmental, and cultural factors that are influential in the development of health outcomes and are closely related to health disparities.
- *Health Outcomes*- Maternal and infant health outcomes, or population health outcomes, refer to the state of health that results from multiple factors of influence

including healthy choices and behaviors. Not all influencing factors are modifiable (race), but many are (diet, blood pressure control, breastfeeding). Optimal, suboptimal, and adverse health outcomes are included under this definition.

- *Breastfeeding Outcomes*- Like health outcomes, breastfeeding outcomes are the breastfeeding behaviors that are adopted and practiced by the mother-child dyad. Literature shows that in most cases, the gold standard for infant feeding behavior is EBF as described in the first paragraph of the introduction portion of this paper. So, *suboptimal breastfeeding outcomes* would infer not practicing EBF the recommended length of time, and *optimal breastfeeding outcomes* would be EBF the recommended length of time.
- *Exclusive Breastfeeding (EBF)*- Feeding infant only breast milk (directly from breast, bottle, spoon, cup, or supplemental nursing system [SNS] including screened donor milk) and offering no formula, human milk substitute, juices, or water to the recommended age of six months followed by continuing EBF while introducing high-quality complementary foods to 12 months or longer as mutually desired by mother and baby.
- *Breastfeeding Intention*- The extent to which a woman plans to breastfeed her infant prior to birth. This is influenced by multiple factors including sociodemographic background, environment, culture, attitude, beliefs, social norms and knowledge or experience.

- *Demand Feeding*- This implies feeding an infant based on demonstrated feeding cues. These cues may be subtle, and parents can learn to recognize them.
- *Breastfeeding Initiation and Duration*- Initiation refers to the first infant breast milk feeding, which evidence suggests should occur preferably within one hour of birth of a stable infant. Duration of breastfeeding is the length of time an infant is fed breast milk (e.g. two days, four weeks, or eight months).
- *Medically Underserved Areas*- Geographic locations that have a shortage of primary health providers or health services to meet the local health needs. This designation is based on a threshold ratio for population to providers established by the Health Resources and Service Administration, but also may be based solely on the population the facility serves.
- *Perceived Milk Insufficiency (PMI)*- This refers to a mother's perception that the breast milk she is producing is inadequate to meet her infant's nutritional needs. This may be based on her interpretation of infant needs.
- *Breastfeeding Education*- Any quality evidence-based breastfeeding education a mother receives occurring both prenatally and after delivery. For the purpose of this paper, prenatal breastfeeding education is the primary focus.

The definitions formulated in this section were generated from the review of the literature and the following sources (CDC, 2019; ODPHP, 2019; Raissian & Su, 2018; HRSA, 2019).

## CHAPTER THREE

## METHODS

Breastfeeding support and education for every mother and her support system is associated with increased duration and exclusivity of breastfeeding and should be provided throughout the prenatal, peripartum, and postpartum period (Bibbins-Domingo et al., 2016). The CDC (2013) has set goals for breastfeeding education, which are to improve mothers' knowledge and skills, help them frame breastfeeding as normal and achievable, as well as helping mothers form positive breastfeeding attitudes.

The education curriculum in this project is expected to increase knowledge: regarding the benefits of breastfeeding for both mother and infant; that increases awareness of breast milk production and maintenance; that helps a mother and her partner recognize common breastfeeding challenges and plan how to navigate them; and that helps a mother and her partner connect with helpful resources available to them and prepare to build a social support network. By affecting these areas of influence, it is hypothesized that *breastfeeding intention* will increase, resulting in increased initiation rates and exclusivity of breastfeeding. This quality improvement project involving prenatal education was designed to complement the peripartum and postpartum support already in place at the project implementation site by improving the delivery of basic breastfeeding information and preparation for *every* mother.

Design

I have been a perinatal nurse for over 20 years and a *Certified Lactation Counselor (CLC)* for over six years. Throughout my nursing career, I have always been a strong advocate of breastfeeding and feel that every woman deserves the opportunity to experience breastfeeding unencumbered by myths and terror stories of what breastfeeding is like. In my experience, women who have received an undesirable depiction from family or friends inevitably will struggle and often leap quickly into supplementing with formula. It is common to hear these mothers make self-defeating comments such as *I don't think I am making enough milk for my baby* or *my baby doesn't like my milk*. I have also seen mothers who came from a social environment that considered breast milk as the only option for an infant. These mothers still had to learn how to breastfeed, still struggled with fussy infants, nipple pain, and difficulty obtaining a deep latch, but never asked for formula, because from their cultural perspective, it was not a reasonable option. It is an inequitable disadvantage when women start with less social support, hearing fewer success stories, and not having witness effective breastfeeding in their social circle. Providing education and encouragement in the prenatal period will help present an alternative perspective to these women of what to expect with breastfeeding. This may only make a small contribution, but it is worth the effort to bridge this cultural disadvantage.

The primary project manager conducted a literature review that guided the selection of the PBE curriculum based on best evidence. The CLCs, as well as the perinatal RN staff, were given an informal survey to identify breastfeeding knowledge

gaps particular to the population at the intervention site (see appendix E). The one and a half page survey explained the intent of the DNP student's project, a description of how the program would be implemented, some important topics to include that had already been identified by the project team, followed by request to offer their written ideas regarding educational content. The perinatal nurses and CLCs were asked to think of mothers they had recently assisted with breastfeeding and consider the following two questions: *What information could have helped this mother be better prepared for this situation*, and *If this mother understood \_\_\_\_\_ about breastfeeding, it would make it easier for me to help her*. The staff was given ten days to return the survey and six staff (60%) members responded. Areas of educational needs were also used to guide the selection of the best PBE curriculum. Common needs identified by this survey were:

1. Basic education on breast milk production and maintenance;
2. Benefits of EBF for the first six months of life and abstaining from offering solid foods before six months;
3. Discussing the process of hand expression of breast milk;
4. Reinforcing the fact that it takes time for a newborn and their mother to learn how to breastfeed;
5. Importance and benefits of skin-to-skin contact not only right after birth but continuing while the newborn baby is learning to breastfeed;
6. Information on positioning baby to achieve a good latch and signs of adequate milk transfer;
7. Information on how partners can support the breastfeeding mother;
8. Informing mothers about breastfeeding resources available to them and encouraging new mothers to ask for help.

The PBE curriculum addressed all of the above topics and included multiple modes of information delivery including but not limited to discussions, videos and photographs, hands-on practice, role-playing, a reference list for evidence-based online education sites, local resources, and a printed parent booklet to take home.

The curriculum chosen for the PBE project was *Ready, Set, Baby* (RSB). The RSB prenatal breastfeeding education curriculum was initially developed from 2012-2015 by the Carolina Global Breastfeeding Institute (CGBI) and North Carolina Women's Hospital (Parry, Tully, Hopper, Schildkamp, & Lobbok, 2018). This evidence-based education program is based on the requirements of step three of the WHO (1998) *Ten Steps to Successful Breastfeeding*. The recommendation suggests that all expectant mothers are provided necessary education regarding the benefits and management of breastfeeding. The North Carolina Women's Hospital and researchers from the University of North Carolina contributed additional collaborative efforts in the development of the RSB curriculum; the curriculum was pilot tested in seven separated locations in the U.S. and Puerto Rico with multiethnic populations (n=416).

The RSB breastfeeding curriculum offers high-quality materials easily downloaded in a PDF file from the CGBI website at no cost. No permission was required for the use of the materials. The project manager signed a copyright agreement indicating that the materials will not be modified without permission from the curriculum developers. The curriculum had been updated as recently as 2018.

The RSB curriculum is divided into three units. All three units were reviewed in the education, one unit in each session. The educational included the following content:

1. Preparation for hospital stay (including rooming-in, skin to skin contact, demand feeding by infant cues, and pacifier use).
2. Breastfeeding tips and information (including early initiation, EBF, benefits of breastfeeding, positioning and latch, assessing adequacy of feeding, establishment and maintenance of milk supply).
3. Preparing for the first week at home (mothers adjustment to parenting and new baby, how can partners can support the breastfeeding mother, hand expression of breast milk, management of engorgement, overcoming common breastfeeding challenges, and where to go for help).

The intervention facility employs seven staff members who are CLCs. The CLCs assigned to staff the lactation clinic were part of the PBE team (along with the project manager) delivering the project educational sessions. Three staff CLC's that provide coverage for the lactation clinic were asked to review the two educator training tutorials offered by CGBI online before implementation. The team met several times for discussion regarding education delivery prior to program commencement.

The project commenced on April 15<sup>th</sup>, 2019. Eligible mothers between 24-32 weeks gestation were informed of the project by telephone. Participants who agreed to participate were pre-scheduled for three PBE sessions to coincide with three of their prenatal visits between 28-36 weeks. The PBE intervention was delivered for most mothers directly following their prenatal visit. At the time of the first session, participants signed a consent form (See Appendix A), completed a breastfeeding information and demographic survey (See Appendix C), and filled out an initial IFI scale. These forms were kept in a locked clinic cabinet for the duration of the project.

### Setting and Sample

The project was implemented in a rural community located in northwestern Montana. This 22-bed critical access hospital facility has approximately 120-140 births annually, and two board-certified OB/GYN physicians provide prenatal and peripartum care. The education was delivered primarily in the lactation clinic, located adjacent to the waiting area for the OB/GYN clinic. The intervention facility employed the three staff CLCs who were part of the PBE team, and there was no other compensation for the educational session they taught. The facility has one off-site clinic located approximately 20 miles south of the facility where perinatal services are provided one day a week. The PBE education was to mothers at this off-site location. The project manager taught all the educational sessions at this location. The implementation facility supports a vulnerable perinatal population. The town in which the intervention facility is located has a population of less than 4,700, and this hospital is one of two similar critical access hospitals that provide perinatal care to a county population of 29,311. The county has been designated an HPSA, with an annual average household income of slightly less than \$40,000. Additionally, regarding women of childbearing age, 55% of the 18-24 year olds and 44.9% of the 25-34 years olds reportedly live below the FPL. The Native American population, in which there are known health disparities, comprises just over 25% of the population. Just over 68% of the population identifies their race as white, 5% are of mixed race and less than 0.5% identify as other racial minorities (HRSA, 2019; U.S. Census Bureau, 2016). The breastfeeding rates reported by this facility are well below those reported for the state.

This facility, like many others, has already taken steps to support breastfeeding mothers by implementing a breastfeeding-friendly practice; increasing the number of CLCs on staff to provide education and assistance for breastfeeding mothers; creating and modifying hospital policy to accommodate best practice for breastfeeding mothers; establishing a peer support group facilitated by trained staff; and establishing a lactation clinic that is available for lactation assistance five days a week.

A convenience sample was utilized for the project. Eligible women included all mothers receiving prenatal care at the intervention site. Attempts were made to reach eligible perinatal patients by telephone when they were between 24-34 weeks gestation during the period between April 15<sup>th</sup>, 2019 and July 19<sup>th</sup>, 2019. Expectant mothers were informed of the PBE program and asked if they would like to participate. An incentive was offered for attending all three sessions of a \$5 gift card for a local yogurt/coffee shop as well as the opportunity to be entered into a drawing for two Wal-Mart Gift cards (1<sup>st</sup> draw- \$60, 2<sup>nd</sup> draw- \$30) at the end of the study. Mothers who agreed to participate were scheduled for their first PBE session to coincide with their next prenatal visit. After being seen by their provider, they were instructed to visit the lactation clinic to talk with one of three CLC instructors (two staff members from the facility and the project manager-DNP student). The CLC explained the program, obtained consent, and administered a *pregnancy information and background survey* as well as the IFI scale. Mothers were excluded from the reported outcome data if they had infants: born at less than 37 weeks gestation; who required transfer to a higher level of care; who were on neonatal abstinence scoring protocol; or who were readmitted to the hospital within one week of

birth for primary reasons other than feeding/nutrition related difficulties; these mothers were still able to participate in the PBE sessions. The educational project was implemented over a period of approximately four months. Participants were recruited through July 19<sup>th</sup>, 2019 and the last patient delivered and attended her 7-10 day lactation follow-up visit in the final week of August. The project yielded a total of 23 participants.

#### Institutional Review Board (IRB) Approval

Montana State University's Institutional Review Board approved the implementation of this project under the *Exempt* category. Project approval was also procured from the participating healthcare institution's Health Service Joint Investigational Review Board and the Tribal Health Administrator (See Appendix G).

#### Data Collection and Tools

The primary project manager performed an electronic records review to establish data on a two-month sample (women delivering at a similar time of year as the participant group, except one year earlier) of the perinatal population and their breastfeeding outcomes. The data from this sample of mothers served as the control population. The data intended to be collected on this two month sample was the following: age, educational and income level, ethnicity, gravity/parity, previous breastfeeding experience, prenatal infant feeding intentions, and type of delivery, what percentage of mothers received antepartum breastfeeding education, what percentage of mothers attempted to breastfed within the first two hours of birth, what percentage of mothers were EBF at hospital discharge, and what percentage of mothers were EBF at 7-

10 days postpartum (based on notes from a lactation clinic visit or the first infant well visit) as was available in the electronic medical record (EMR). Assessment of EBF in the hospital included the review of neonatal flow sheets that have an exclusive line for breastfeeding (labeled as *occurrences*) and a separate line for Oral Intake (formula measured in *ml*). The next measurable outcome was EBF at 7-10 days after birth. This outcome was a little harder to measure but was obtained from review of the lactation notes, or the newborn provider notes for incidental or well-baby visit.

The same data mentioned above were collected on the PBE participants. The participants' data were collected primarily by direct inquiry via survey at the mother's first PBE sessions. Further information regarding maternal characteristics and birth information was also retrieved from the EMR.

The clinical project aimed to deliver evidence-based prenatal breastfeeding education to every mother. Increasing prenatal knowledge and preparation regarding breastfeeding and providing supportive encouragement from a trained lactation specialist will foster and cultivate a woman's *intent to breastfeed*. Breastfeeding intention was measured by administering the Infant Feeding Intention (IFI) scale to the participants before and after the program was delivered (See Appendix B). The IFI scale was designed to provide a quantitative metric to evaluate a mother's feeding intentions and is significantly associated with planned and actual EBF (Nommsen-Rivers, Cohen, Chantry, & Dewey, 2010). Across multiple ethnic groups, evidence indicates that women with stronger breastfeeding intentions are significantly more likely to EBF and for a longer duration (Linares et al., 2015). Nommsen-Rivers and Dewey (2009) utilized the IFI scale

in a multiethnic group of low-income first-time mothers and found the tool to demonstrate both content and construct validity, and internal consistency reliability (a Cronbach's alpha value of 0.90). It is important to note that this tool has not been tested specifically with Native American women, which is the largest ethnic minority in the population of the intervention site. In the studies regarding this tool, there is data included regarding ethnic groups that are labeled *other* or *mixed* ethnicity. There may have been Native American women in these groups, but this is not identified in the literature; this demonstrates a gap in the literature as well as identifies a need for studies directed at assisting this particular ethnic group represented in the literature and local demographics as "vulnerable." Attempt was made to contact the lead author and co-developer of the IFI scale, Laurie A. Nommsen-Rivers, by email on three occasions to acquire permission to use the IFI tool, which was unsuccessful.

All private health information, such as that pulled from EMR, the Breastfeeding Information and Demographic survey, and the IFI scale forms were coded by the primary project manager only and entered into a private password-protected computer.

### Data Analysis

The difference in breastfeeding outcomes between the *control* group (two-month sample of women who received prenatal care and delivered at the intervention facility approximately a year before program implementation) and the PBE participant group was analyzed. The comparison revealed data regarding the association between participation in the PBE program and overall breastfeeding outcomes. The IFI scale score of each participant before participating in the PBE program was compared to the score after

attending all three sessions, which was obtained at the first lactation visit or newborn well visit. A higher score suggests a greater likelihood the mother will engage in EBF along with sustained breastfeeding for a longer duration. The time constraints of this project prohibited the ability to evaluate EBF outcomes further out than ten days after birth. The researcher recommended to the CLC staff involved in this education program to continue to monitor the EBF rates of participants up to 6 months after birth. This data should be used to evaluate if the sample population exposed to the educational intervention had significant EBF outcomes at three and six months after birth

The result of differences between the participation group and control group were analyzed with the Survey Monkey AB testing calculator for statistical significance generating in a  $p$  value for each proportion reported in the results section (SurveyMonkey Inc., 2019).

## CHAPTER FOUR

## RESULTS

Outcomes of EBF

There were very slight differences in the overall EBF outcomes between the control group and the participation group, both at hospital discharge (control group 59% and participation group 62%) and at 7-10 days after birth (control group 53% and participation group 57%). Neither of the differences were statistically significant; EBF at discharge ( $p = .40$ , 95% CL) and at 7-10 days after birth ( $p = .42$ , 95% CL). Initiation rates, or those mothers who attempted to breastfeed after birth, varied minimally with the control mothers' rate (76%) slightly lower than the participation mothers' rate (90%). This was not a significant difference ( $p = .12$ , 95% CL). Two of the participation group mothers who were not able to EBF while in the hospital due to neonatal complications were EBF by 7-10 days after birth, and 44% of the mothers who did not EBF at 7-10 days after birth were still breastfeeding at that time but offering formula supplementation. These two observations may indicate that there was an increased awareness of the importance of offering breast milk to an infant, even if the baby is not EBF. It is essential to recognize even subtle variations when attempting to implement health behavior changes in high-risk populations.

When looking only at first-time mothers in both groups (5 control group first-time mothers and 11 participation group first-time mothers), a similar increase in initiation and EBF was noted including one statistically significant difference between the two groups.

In first-time mothers in the control group initiated breastfeeding at the rate of 60% versus the participation group with initiation rates of 100% ( $p = .03$ , 95% CL). At hospital discharge, 40% of the control first-time mothers were EBF versus 73% of the participant first-time mothers ( $p = .10$ , 95% CL). Neither of these differences was statistically significant. Exclusivity of breastfeeding amongst first-time mothers was statistically significant at 7-10 days after birth with 73% of the participant mothers EBF and none of the control mothers EBF ( $p < .001$ , 95% CL). Please see the results in figures 1 & 2 below.

Figure 1. Exclusive Breastfeeding Rates, entire sample & 1<sup>st</sup> time mothers only.

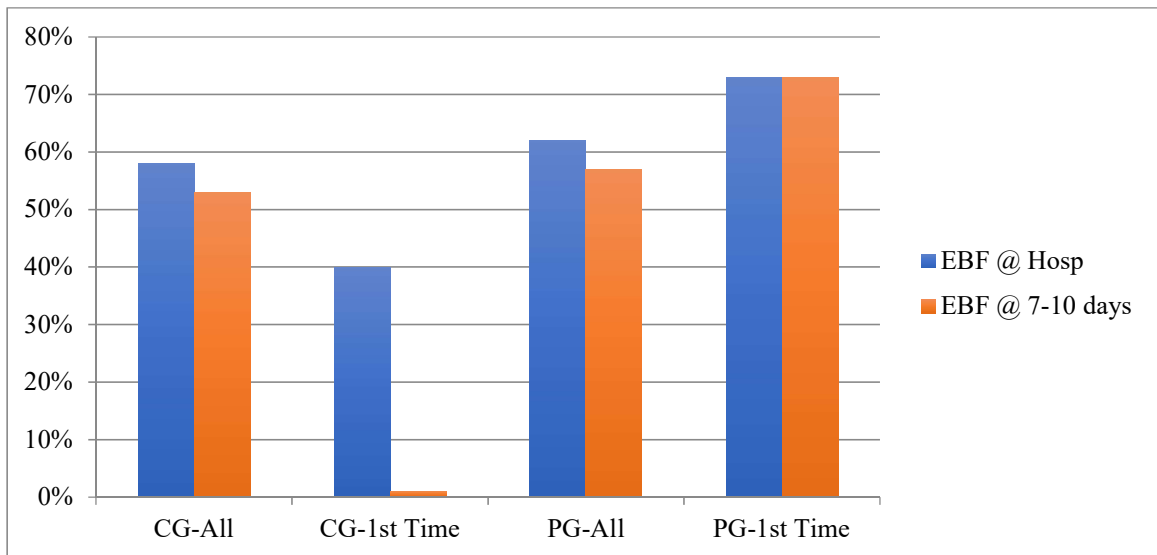
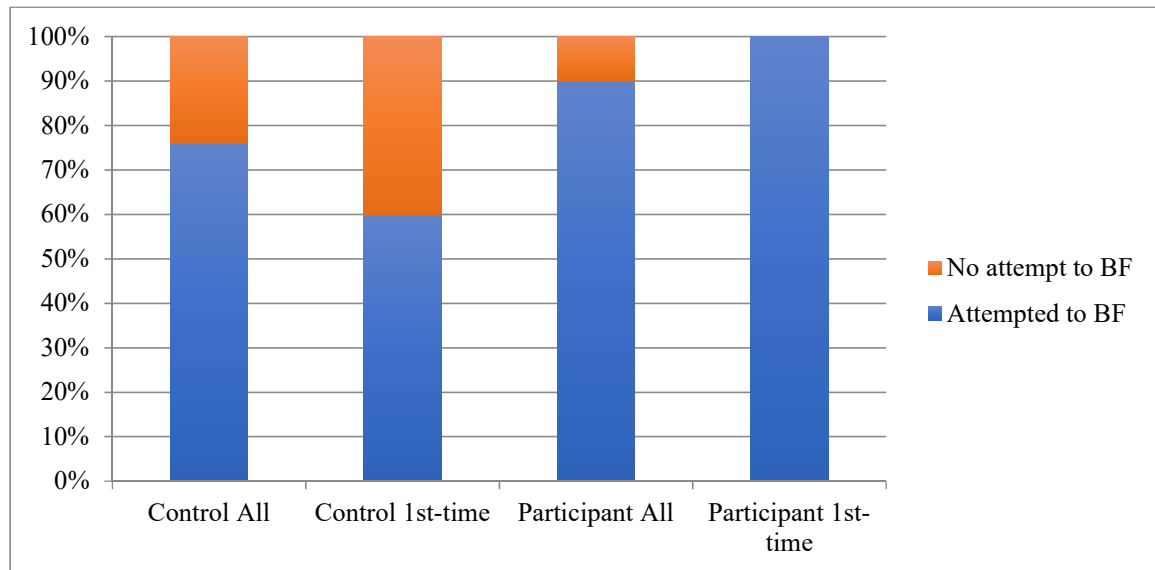


Figure 2. Breastfeeding Initiation Rates, % of mothers who attempted to breastfeed



### Feeding Intent Outcomes and IFI Scale

The prenatal feeding choice/intent of the participation group was 90% breastfeeding, and none of these mothers intended to exclusively formula feed. The participant mothers may have placed a higher value on breastfeeding, thus, leading them to participate in the PBE because they saw it as beneficial. The scores on the initial prenatal IFI scale varied from 6-16 with the mean score being 13.4, a median of 14, and a mode of 16. Scores closer to 16 indicate very strong intentions to breastfeed exclusively for up to six months. Mothers whose initial IFI scores were 12-16 were EBF at a rate of 75% while at the hospital and 75% at 7-10 days after birth. Only twenty percent of the mothers who had a score on the initial IFI scale ranging between 6-11 were EBF at the hospital, and 7-10 days after birth none of those mothers were still EBF. In the postpartum survey, eight mothers' IFI scores dropped, two scores increased, ten stayed the same, and one mother did not attend a lactation visit after birth but she continued to

EBF her infant. These results reflect the evidence in current literature that prenatal breastfeeding intent is a strong predictor of breastfeeding behaviors and outcomes. The second IFI score obtained will be discussed at length in the limitation section.

The information about feeding intent was difficult to ascertain in the control group through EMR review. Maternal feeding intent was rarely mentioned in the prenatal provider records as anticipated. The decision was made that if the intended infant feeding choice was not documented in the provider record, and the infant was breastfed immediately after birth according to the EMR, then it was assumed that the mother had intended to breastfeed her infant. Using this assumption as a guideline, 65% of the control group mothers intended to breastfeed, 18% intended to formula feed, and the rest planned to use a combination (both formula and breast milk) to feed their infants. Please see the results in figures 3 & 4 below.

Figure 3. Prenatal Infant Feeding Choice

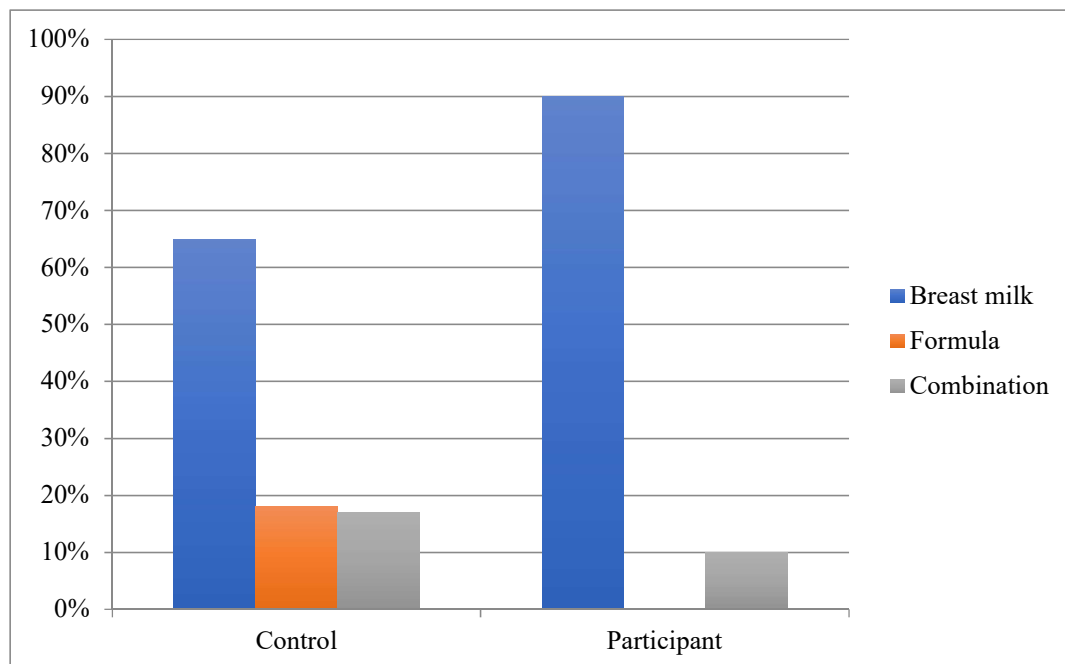
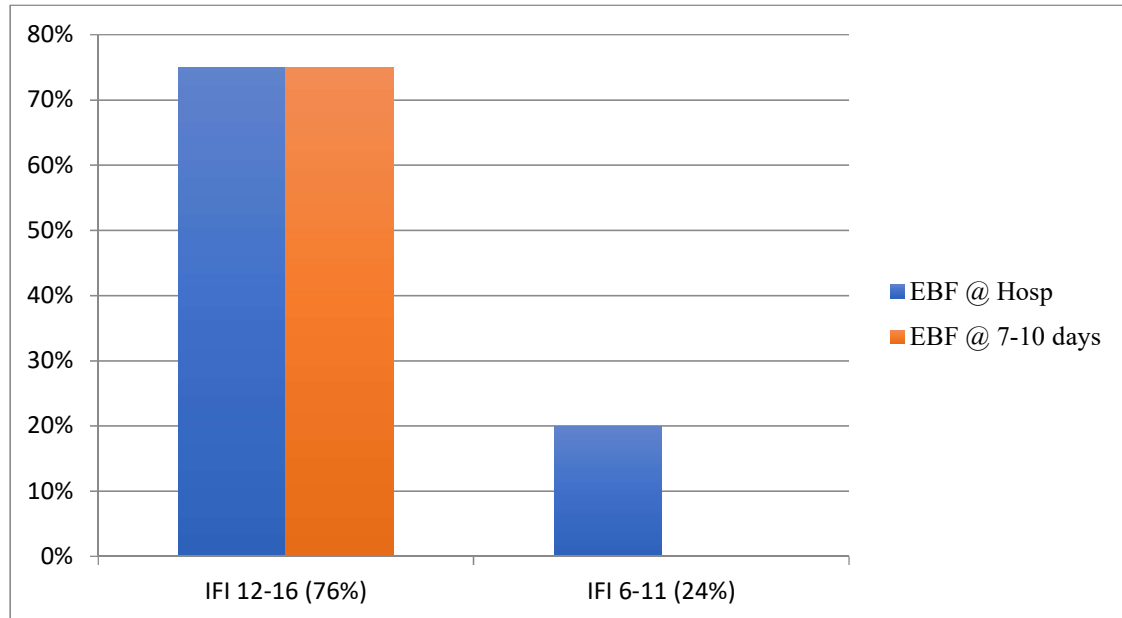


Figure 4. % EBF Based on Initial IFI Scores



### Participant and Stakeholder Feedback Outcomes

The mothers who agreed to participate in the educational project delivered positive feedback to the CLCs who provided the instruction. General comments heard repetitively were that expectant mothers stated *they wished they had been given this information before attempting to breastfeed previous children* or that *they really appreciated the information and found it very helpful*. It is also encouraging that the Perinatal Education Coordinator at the project site, who was also a CLC and an essential PBE team member, has verified that this project will continue at the facility. There is much benefit in continuing to implement this education as it helps mothers become more knowledgeable and have more realistic expectations of what to expect in the first week of breastfeeding a new baby.

The perinatal nurses and CLCs who predominantly work in the labor and delivery unit were also supportive of the program, feeling that it may make their efforts in helping mothers breastfeed a little smoother. Following implementation, both of the head nurses of the perinatal unit commented on the difference in the level of confidence of mothers who participated in the program and their knowledge level of what to expect in the early learning period of breastfeeding. They report that participant mothers seem more comfortable with practicing skin-to-skin, breastfeeding positioning, and less anxious when their baby doesn't latch perfectly the first few times.

The perinatal physicians both commented that they have had positive feedback from mothers who attended the PBE sessions expressing that *they found the information very helpful*. J. Straub, D.O stated, "I have some moms that did not breastfeed their older children but did this new baby" (Personal communication, September 22, 2019).

Often mothers do not anticipate that they and their infant will have to *learn* how to breastfeed. They may not be aware of common breastfeeding challenges that can usually be resolved with lactation support staff. They also may not be aware of behaviors that can either enhance breastfeeding outcomes or hinder breastfeeding success. Discussing the importance of breastfeeding and how to initiate and manage breastfeeding with women and their support persons in the antenatal period is part of the WHO/UNICEF Ten Steps To Successful Breastfeeding recommendations (WHO, 1998). The efficacy of the *ten steps* policies and procedures in promoting and supporting improved breastfeeding outcomes is endorsed by the AAP, AAFP, and ACOG (Eidelman & Schanler 2012; Hauk, 2015; ACOG, 2018). Based on the positive feedback from

participating mothers, and the recognized value of the education by the lactation specialist staff, there is no doubt that this is a useful and worthwhile project. Prenatal breastfeeding education is anticipatory guidance, similar to guidelines offered to women in order to help them to achieve a healthy pregnancy or guidelines given to new parents to help them to understand appropriate developmental stages as their child grows.

#### Comparison Outcomes Between the Control and Participant Groups

After analyzing the data, it would appear that breastfeeding education had minimal influence on breastfeeding outcomes in the initial intervention. The two sample groups were fairly well matched in age and type of delivery. The groups also had similar pregnancy, delivery, and postpartum events as well as neonatal complications that could have influenced breastfeeding outcomes. The control group was composed of a higher percentage of ethnic minority groups' known to have breastfeeding disparity (53% versus 38%,  $p = .82$ , 95% CL), and a slightly higher percentage of mothers who received their healthcare through Medicaid reimbursements (65% versus 52%,  $p = .78$ , 95% CL). Medicaid funded patients have also been shown to have lower breastfeeding rates than their privately insured counterparts (Mercier, Burcher, Horowitz, & Wolf, 2018). Neither of these differences significantly impacted the breastfeeding outcomes. The percentage of first-time mothers was higher in the participation group than the control group (52% versus 29%,  $p = .07$ , 95% CL). This observation may suggest that the first-time mothers in the participation group had a higher eagerness to learn or attempt breastfeeding that may have influenced their willingness to participate in the educational offering. However,

previous experience can also affect breastfeeding continuance positively if the previous experience was successful or even if it was unsuccessful and the mother is determined to have a better breastfeeding experience with successive children. Additionally, skin-to-skin contact with a newborn infant immediately after birth is a practice associated with improved breastfeeding outcomes according to Hughes (2015), which was documented more frequently with the participation group (90%) than in the control group (71%) ( $p = .06$ , 95% CL). Please see the results in figure 5a-f below.

Figure 5:a-f. Control Group versus Participation Group Comparison Graphs

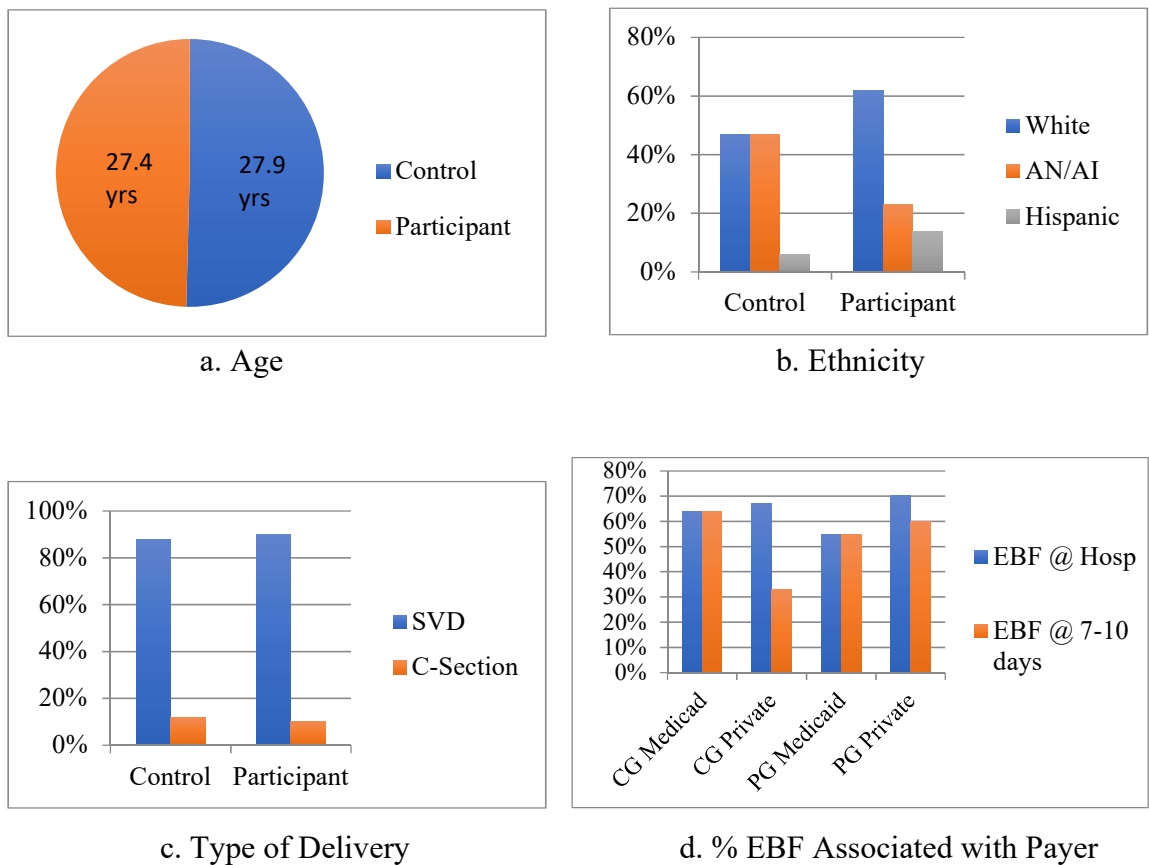
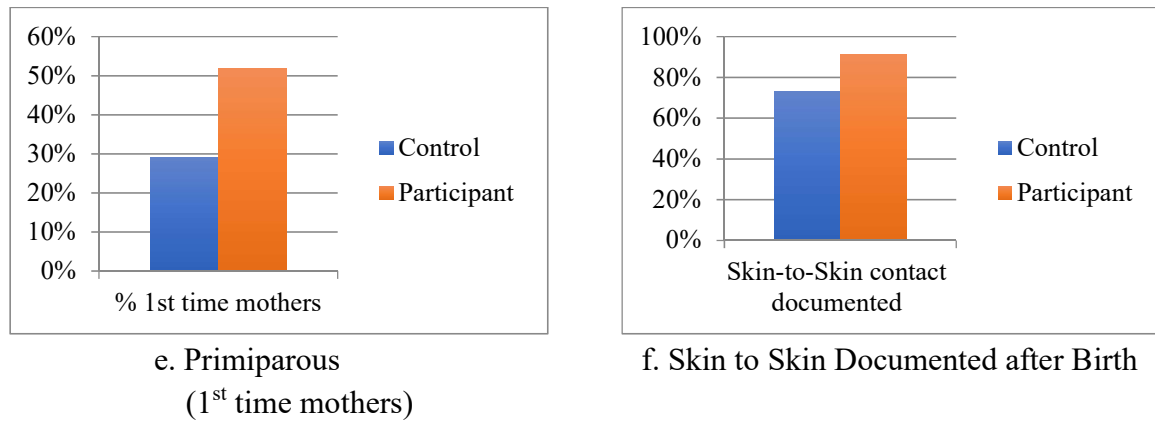


Figure 5:a-f. Control Group versus Participation Group Comparison Graphs, continued



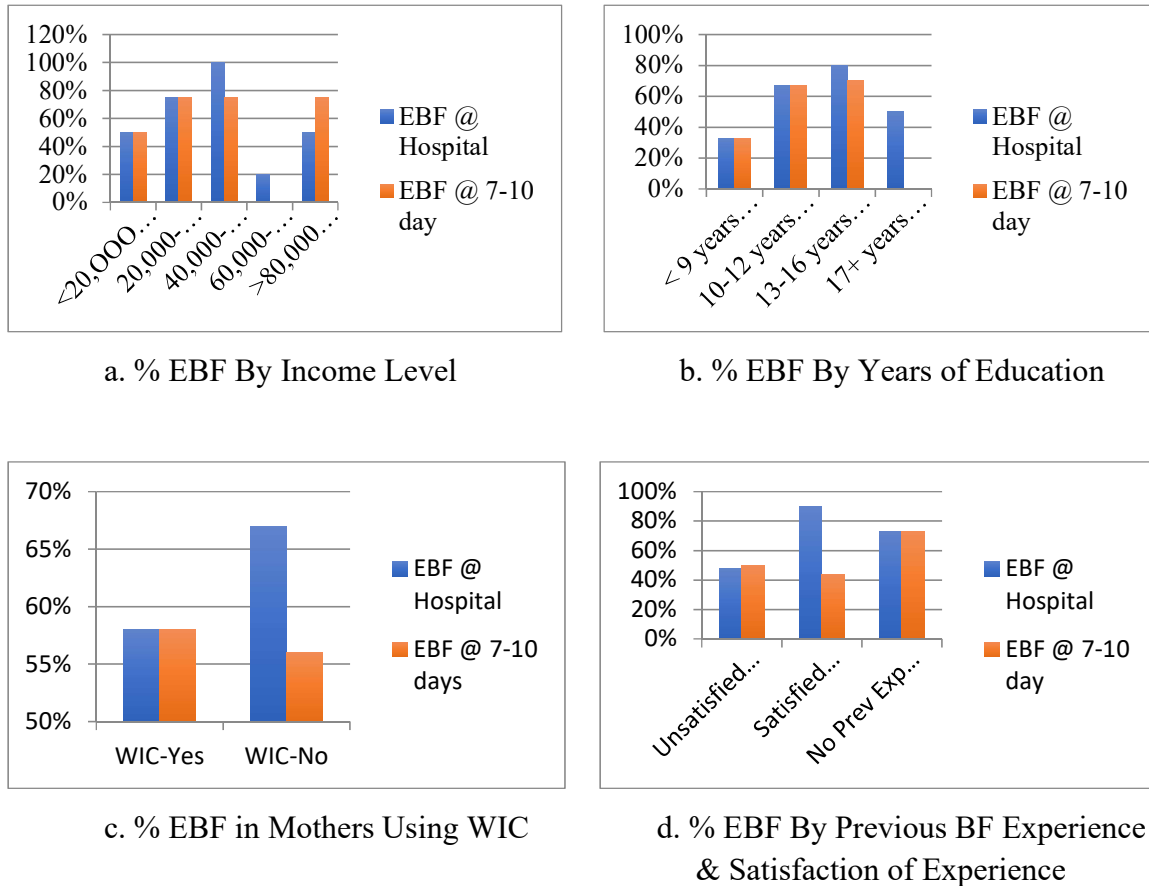
#### EBF Outcomes Associated with Participant Group Variables

Further data gathered on the participation group through the breastfeeding information and demographic survey revealed the following associations with EBF. The largest income level group was mothers having an annual income of less than 20K (38%). Seventy-six percent of the women had income levels less than 60K annually. Mothers with an annual income over 60K accounted for 24% of the participant mothers and these mothers surprisingly had lower overall EBF rates than those reporting a lower income. In comparison with women in lower income brackets, higher income levels are usually associated with higher breastfeeding rates (McDowell, Wang, & Kennedy-Stephenson, 2008). A total of twelve mothers indicated they were participating in WIC. Expectant mothers are automatically eligible for WIC benefits if they are on the Supplemental Nutrition Assistance Program (SNAP), the Food Distribution Program on Indian Reservations (FDPIR) or are receiving their perinatal care through Medicaid reimbursement according to G. Lozar with the County WIC department (Personal

communication, October 1, 2019). Ms. Lozar further stated that qualification for these supplemental food programs is more stringent than qualification for WIC and all mothers are encouraged to apply even if not currently eligible for a food and nutrition supplementation program. Mothers who reported being involved in the WIC program had a slightly lower rate (58%) of EBF in the hospital compared to mothers not using WIC (67%). At 7-10 days after birth, the EBF rates were similar regardless of whether WIC services were being used. The mean years of education completed among the participant mothers was 13 (HS+ some college, tech, or trade school). Exclusivity of breastfeeding was the highest in mothers with 13-16 years of education (80%), and lowest among mothers who had completed nine years or less of education (33%), which is consistent with current literature. Therefore, in our sample, income was a less reliable indicator of EBF outcomes. The EBF outcome results in the participant sample in association with educational level and participation in WIC was consistent with the literature.

Mothers were also asked if they had previous breastfeeding experience and if so, how satisfactory that experience was (see survey in Appendix C). Ten mothers stated they had previous experience with breastfeeding and nine of those mothers reported being unsatisfied with that experience. Approximately 50% of the mothers with previous unsatisfying breastfeeding experiences did EBF after birth. Mothers with no previous experience were EBF at 73%. Given that the mothers with previous breastfeeding experience EBF at a similar rate to the control group, it is difficult to conclude whether or not exposure to the PBE influenced their breastfeeding practices after birth. Please see the results in figure 6a-d below.

Figure 6:a-d. Participation Group Variables Related to EBF Outcomes



Summary of Results

Although minimal increases in EBF were recognized in the mothers who participated in the educational project, with one exception, most of these differences failed to show statistical significance. Therefore, the efficacy of delivering prenatal breastfeeding education to impact EBF rates in this vulnerable population can neither be supported nor refuted based on the project results.

In retrospect, it would have been ideal to survey mothers who participated in the program to query the following information: was the PBE helpful; what information was

most/least useful; was the information delivered at an appropriate time in the prenatal period; did the information discussed in the PBE help you to make decisions about infant feeding choices; what else would have been helpful to know about breastfeeding prior to delivery? A survey of this nature would have enlightened the projected manager and implementation team as to how the intended audience felt about the education, what should be added or left out, and whether the mother's educational needs were being met. It also would have been most appropriate to administer the IFI scale after all three education sessions had been attended but before the mother's expected date of delivery and hospital stay, to ascertain if IFI scores increased after the education was delivered. This idea will be further explored in the discussion section.

## CHAPTER FIVE

## DISCUSSION

Successes and Difficulties

By far the most important success of the project was the feedback the team received from the mothers who participated. Changing the mindset of a community takes time and is achieved by attempting several small steps forward and occasionally a few steps backward. If the information provided was instrumental in assisting even one mother to continue EBF through a difficult period, then the implementation was deemed to be a success. She will be one mother who will be a breastfeeding resource and a positive influence for other mothers in her social circle, thereby extending the ripple of positive influence and creating a bridge to a cultural mindset that supports EBF for all infants and mothers within the community.

Another strength of the project previously mentioned was the broad support and enthusiasm received by all of the stakeholders. The OB physicians, clinic staff, inpatient perinatal staff, and hospital administration at the project site were very supportive of the project and recognized its value. The opportunity to participate in the PBE was offered to all mothers receiving care at the project site and many (51%) patients were willing to participate.

It became evident from the beginning of the project that scheduling and implementing the project required much coordination and resulted in the staff CLC team members extending themselves above and beyond their normal routines and

responsibilities to include the project educational sessions. Unfortunately, there were time conflicts and staffing shortages that influenced the team's ability to implement the three educational sessions to every consenting participant without flaw.

One difficulty was that the education was delivered in a separate room (the lactation clinic) just outside the OB clinic. While this seems convenient, if the clinic staff or the patient check-in staff did not remind the patients of their PBE appointment, sometimes they would leave without attending their PBE visit. This improved with implementation practice and as all staff became more familiar with the program.

It was also impossible to schedule every mother in the time frame when the lactation clinic was open and exclusively staffed. For this reason, the CLC staff that taught the PBE session had to leave other positions they held in the hospital to teach the session. This placed an extra burden on the CLC's to complete the work they left when they were teaching.

A pediatric clinic nurse/CLC was assigned to staff the lactation clinic on Fridays. Due to a staffing shortage during the time of implementation, this nurse was required to work extra hours in the clinic and had minimal availability to staff the lactation clinic or participate as a CLC instructor as originally planned. This placed further scheduling restrictions during the implementation of the program.

Lastly, as indicated previously, the facility includes one off-site clinic location where perinatal visits occur approximately 20 miles south of the facility. The project manager was able to cover these PBE sessions, however, the staff CLC's would not have

been able to leave the hospital to teach these sessions, which affects the sustainability of the project at this off-site location.

#### Issues of Financial Costs

The RSB prenatal breastfeeding curriculum that was chosen for this project included quality materials that were easily downloaded in a PDF file from the CGBI website and printed on the hospital laser printer at the cost of approximately \$0.06-0.08 per page. The costs associated with the patient booklet were less than \$1.25 each. Each of the three CLC instructors was provided a personal teaching flipchart so that they could customize the teaching materials to include their own notes. The PDF file for the flip chart pages was also downloaded at no cost from the CGBI website, downloaded pages were placed in plastic sheet protectors in a ring binder easel for each instructor. This instructor tool cost less than \$16.00 to produce and will continue to be used in the clinic with current and future patients. The curriculum is evidence-based requiring very little preparatory instructor training. The ease and low cost of implementing this curriculum are two strengths of the project. This fact also makes it easier to implement in multiple rural settings similar to the project site. Interestingly, in a recent meeting of the local *Breastfeeding Coalition* chapter, a representative from the Lake County WIC department brought up this breastfeeding curriculum stating they would like to start using it. The PBE team members who attend the coalition meetings were able to share with the WIC representative that it is already being used at the project site and they were able to share their personal experience with the curriculum.

### Outcomes Contrasting Those Found in the Literature

The researcher found it challenging to be able to compare and contrast the outcomes of this project with those found in the literature. This was due in large part to imbedded time constraints built into the project timeline along with EBF outcomes that were assessed only at hospital discharge and at 7-10 days after birth. If time were not a factor, it would have been preferential to assess EBF outcomes at one, three, and six months after delivery. Additionally, assessing the rate of breastfeeding continuance through one year should be considered. The research reviewed for this paper varied in terms of the length of time for the evaluation of breastfeeding outcomes. Haroon et al. (2013) assessed outcomes from one day to five months after birth, but most studies followed breastfeeding outcomes from one to three months and up to six to twelve months after birth.

Many breastfeeding studies reviewed in the literature considered all breastfeeding outcomes rather than only EBF (Haroon et al., 2013). Some studies also evaluated individual characteristics associated with improved breastfeeding (using skin to skin, recognizing feeding cues, achieving deep latch (Nilsson et al., 2017; Parry et al., 2018; Skouteris et al., 2014). Further, Abbass-Dick and Dennis (2018) and Evans, Dick, Lewallen, and Jeffrey (2004) reported qualitative data regarding maternal satisfaction, achieving breastfeeding goals, or breastfeeding self-efficacy. In this project, the decision was made to measure only EBF but had more subtle aspects of improved breastfeeding experience been measured like those mentioned, improvement in breastfeeding practices possibly may have been recognized.

Another limiting factor in contrasting this project to others reported in the literature is the population sample size. A few of the systematic reviews included studies of 40-60 participants, however, individual studies reviewed for this paper had sample sizes ranging in the lower hundreds to over twelve thousand. Time was a major limiting factor, as the number of participants would have grown had the project been implemented for several months or longer, although delivery rates for this particular rural facility remain steady at between 120-140 births annually. As it was, there were only twenty-three participants of which two had to be eliminated due to meeting the exclusion criteria.

#### Differences in Observed Versus Expected Outcomes

The focus of this project would not have been selected had there not been an *expectation* or *hope* for improved rates of EBF in the early postpartum period recognized in the sample data. Subsequently, the observed breastfeeding outcomes were not what the team had hoped for or expected, as the EBF rates of the participation group (with the exception of first-time mothers 7-10 days after birth) were similar to the control group. There was anticipation that the project outcomes would provide evidence to justify continuance of the program at the project site and justify a fulltime staff position for the lactation clinic. However, due to the sample size, and several limitations in the project design, there is not data to support this expectation.

The retrieval of desired data on the control group was another unexpected difficulty. The variables of educational level, income level, previous breastfeeding experience, and pre-delivery intentions for breastfeeding, were simply not available in the

EMR. These are important variables that affect or are associated with breastfeeding. Having this data would have enabled the control group and the participation group to be compared more completely and accurately. The 7-10 day breastfeeding data gathered on the control group was extracted mostly from the newborn provider records. There may be inconsistencies when a provider states an infant is breastfed in their note, which will be discussed in the next section. The data that was reported was recorded on the assumption that when a provider stated that a baby was breastfeeding, and there was no mention of formula or supplementation in the note, then the infant was considered to have been EBF, but this may not be fully accurate.

## CHAPTER SIX

## LIMITATIONS

Polit and Beck (2017) observe that there is a delicate balance between internal and external validity in the process of designing and implementing evidence-based clinical interventions. That being said, several threats to both internal and external validity presented in evaluating this program.

Threats to Internal Validity

The small sample size utilized for both the control group and the participation group presented a limiting factor in establishing causality. With samples of this size, it is difficult to establish if the sample was truly representative of the perinatal population of interest. This, in turn, limits the ability to recognize a true association between the intervention and the outcomes.

Compensating for sample size is often an issue when working with small rural populations. Randomization is an option and would have improved the statistical power as would control for confounding variables in the control and participation group. The project manager didn't feel randomization was plausible given the population size and time limits of the project. Attempts to identify confounding variables were made but many were unattainable on the control group.

A convenience sample was used for the implementation of this project. A convenience sample was certainly the most logical way to implement this program, however, it was not without limitations to internal validity due to sampling bias. It is

likely the women who agreed to participate felt that they may benefit from the education, felt they had time to participate, and possibly they had already planned to breastfeed or at least wanted to get more information because they were still considering breastfeeding. The women that either did not want any information about breastfeeding, those that felt that they didn't need any further breastfeeding guidance, or those that felt that they simply didn't have time to participate would have been less likely to agree to participate. The participants viewed the PBE as positive, whereas those who chose not to participate viewed it as negative or unnecessary.

Randomization is one way to avoid sample bias but this was not done as previously mentioned due to limitations in the available population size and project delivery time. The project facility has approximately 120-140 births annually, if half of the expectant women were randomized to received the breastfeeding education (intervention group), the project would have needed to be carried out over close to two years to obtain a valuable sample size, yet the project could have utilized this design in spite of the small sample size.

An additional issue is a lack of adherence to the program or an attrition threat to internal validity. Participant expectations that every mother would attend three PBE 20-minute sessions and fill out the paperwork at the first visit were explained at the time of consent. In spite of incentives offered, four mothers missed at least one PBE session, three of them by choice, and one mother due to scheduling issues. These mothers were included in the data as long as they had attended at least one session.

A significant flaw in the project design was also identified in the area of measurement causing a maturation threat to internal validity. The intent of measuring the IFI score a second time was to assess if the PBE resulted in increasing the overall IFI scores, thus indicating an increased likelihood the mother would EBF and for a longer duration after receiving the education. Since the post-PBE IFI score was assessed at the first lactation visit or newborn visit, and the mother had already experienced the challenges of early breastfeeding, the post-PBE IFI scores were not reflective of the PBE, but rather more likely reflective of the mothers initial experiences with breastfeeding. In identifying this error, it is surprising that the mean post-PBE IFI score was 11.1, only slightly lower than the mean pre-PBE IFI score of 13.4. The pilot testing done on the RSB curriculum also used this tool and revealed a significant improvement in Pre to Post education IFI scores, 14.0 and 15.5, respectably (Parry et al., 2018). The second IFI scores measured after birth were ineffective in measuring what they intended too. Since there were not IFI scores from the control group, this data has minimal usefulness. As stated earlier, attempts were made to contact (three times by email) Laurie A. Nommsen-Rivers, lead author and co-developer of the IFI scale to acquire permission to use the tool, but no response was received. For this reason, any attempt to publish this paper will be delayed until proper permission can be obtained from the developer of the tool, which presents an additional limitation in the project.

As any project implementation continues over time and problems that present initially are resolved, this often allows the project to be implemented more efficiently and effectively. As improvements are made to delivery, reductions to the threats to internal

validity from maturation and attrition are achieved. Had this project been continued for another 3-4 months, it is highly possible that the education may have been able to invoke a greater impact on the participants, possibly resulting in improved breastfeeding outcomes.

Some of the confounding variables that would create bias and influence the effect that the PBE had on breastfeeding outcomes have more to do with variables that affect breastfeeding in general. For instance, it is shown in the literature that age, education, income level, participation in WIC, primiparous women, prenatal feeding intentions, previous education or experience (first hand or with close family/friend) with breastfeeding, and satisfaction with previous personal experience, all have an effect on breastfeeding outcomes (Bibbins-Domingo et al., 2016; Raissian & Su, 2018; Danawi et al., 2016; Jones, et al., 2015). The team was able to collect most of these individual maternal characteristics on the participation group in our breastfeeding information and demographic survey, but the OB clinic and inpatient records of the control group offered less consistent data regarding these variables. For this reason, it was difficult to control for confounding variables. Did the participation group have slightly better outcomes due to the PBE education, or could it have been because they had more women who represented a higher income level, more experience with breastfeeding, higher educational attainment, or any of a number of other factors?

There are numerous factors involving pregnancy and delivery complications that can influence breastfeeding, for instance, gestational diabetes, perinatal substance abuse, preeclampsia, preterm delivery, perinatal hemorrhage, prolonged labor, or emergency

cesarean section. There are also postpartum and neonatal complications that can have an influence on breastfeeding such as postpartum hemorrhage, preeclampsia, neonatal abstinence syndrome (NAS), hypoglycemia, and hyperbilirubinemia.

The data collection plan for the project was to retrieve this data from the obstetrical records and the nursing labor and delivery intake records. The project manager either did not have access to EMR records where the information was available, or the data simply was not in the EMR records. The following variables regarding maternal characteristics were available for both the control and the participation group: age, ethnicity (if answered on face sheet), third party payer (loosely related to income level), gravity/parity, type of delivery, and rarely feeding intention as stated in the OB records. A few of the obstetrical, labor and delivery, and neonatal complication variables, but not all, were considered as explained in the exclusion criteria. As the project manager reviewed the EMR, notes were recorded if there was a pregnancy, delivery, postpartum, or neonatal complication, but these factors didn't seem to influence the overall EBF outcomes with exception to parity at 7-10 days after birth.

### Reliability

An additional limitation in the data collection design was discovered in retrieving accurate outcome data regarding EBF at 7-10 days after birth, particularly with regards to the control group, presenting an intra-rater reliability threat. Seventy-six percent of the participation group mothers were seen in a lactation visit follow-up after birth, including several who were no longer meeting the definition of EBF. The feeding data gathered by the CLC would be considered accurate, as a CLC will ask and enter in their notes if the

mother is offering formula to the baby. Only 53% of the control group mothers attended a lactation visit (over half of these visits occurred at less than 4 days after discharge), therefore the information regarding infant feeding at 7-10 days after birth was retrieved from the neonatal provider records rather than the CLC notes. As commented earlier, there may be inconsistencies in this information; most providers record if a baby was breastfeeding but not that the baby was EBF. *Breastfeeding* could mean the baby is getting breast milk only, or that they are getting mostly breast milk and some supplementation with formula. This potential inconsistency could make the measured outcomes less reliable.

One clever way to compensate utilizing the modern capabilities of the EMR is to attach an electronic pop up (alert) note to the infant chart that appears at 7-10 days of age, this would prompt the staff member, whether it was the medical assistant rooming the mother and baby, or the CLC doing the lactation visit to ask the mother if the baby has been receiving any supplementation.

### External Validity

Using a standard curriculum, the content of each session clearly defined in the instructor flip chart, aided in controlling interventional fidelity so all participants received similar education from three different instructors. Each instructor had the same lactation certification background accredited by the American National Standards Institute, which is certified by the Academy of Lactation Policy and Practice. Several face-to-face curriculum meetings, an online tutorial, and a review of materials by the CLC instructors assured that all were delivering the content as designed in the curriculum. The fact that

there was no post-PBE follow-up survey administered to the mothers to determine if the PBE was received, as intended, was an unfortunate oversight.

The hope in delivering the PBE project was that if improved breastfeeding outcomes were observed following implementation, this curriculum could be considered for implementation in other rural settings, namely at a similar hospital facility less than 20 miles from the project site with a similar patient population. It is important to analyze factors affecting the generalizability of the program results if this data is used to frame a similar implementation at another site.

For this project, efforts were made to make sure the education was delivered efficiently and conveniently for the patient population. Location, scheduling, and shorter class times were all centered around making sure the participant did not have to wait or make a special visit to the facility to participate in the educational offering, in the hope of encouraging participation and minimizing attrition from the program. By taking these actions, education delivery was designed to meet the needs of the target population. The design of the program and the content is certainly appropriate for delivery to other similar rural populations, which are located all over the rural Rocky Mountain region. As significant improvement outcomes were not recognized in the participation group and certain variables were not controlled for in the initial project, the ability to generalize the project results is limited. Additionally, the project site also had an excellent breastfeeding support structure in place as eluded to earlier in this paper, which is essential to the success of breastfeeding. This is not necessarily common in rural settings so this fact also threatens ability generalized in the project results.

The project manager mined all data from the inpatient EMR and outpatient EMR of the newborn and mother. The data regarding hospital EBF was very straightforward and considered valid and reliable. The 7-10 day EBF data lacks validity and reliability due to the variance in how each provider might define breastfeeding.

## CHAPTER SEVEN

## CONCLUSION

This project involved making evidence-based breastfeeding education available to mothers during the last several weeks of their pregnancies to assist the mothers to make informed decisions regarding infant feeding choices and to help the mothers to prepare for early breastfeeding. The evidence shows that best practice is demonstrated by providing anticipatory guidance regarding EBF during the last trimester of pregnancy. Every mother should be fully informed about the benefits breastfeeding offers for women and the benefits breast milk offers for infants, for mothers to be able to make an informed decision regarding infant feeding choices. Mothers should also be given basic knowledge about how to maintain an adequate milk supply as well as where to find support to help them achieve their breastfeeding goals should they choose to breastfeed their infant.

Overall Project Application and Usefulness

The PBE program developed for this project site was designed to utilize the expertise already available at the facility, limit the time commitment required by the staff and participants, and provide current evidence-based breastfeeding education. By design, this project did not produce overwhelming evidence of improvements in breastfeeding outcomes in the participation group versus the control group. The EBF of participation group first-time mothers were associated with significantly higher rates at 7-10 days after birth than the control group first-time mothers. However, the feedback received from the participants and offered by the Labor and Delivery and CLC staff suggests there may be

positive results from this program that were not revealed due to the limitations of the project design, data collection, time constraints, and analysis. Regardless of the project results, this intervention with design and implementation amendments should be continued. The EBF training and education delivers best practice for this rural, vulnerable perinatal population. If the PBE program were to continue over a longer-term, it is quite possible it may have revealed associations with improved breastfeeding outcomes.

#### Implications for Future Studies or Project Implementation

Several modifications to the program design are recommended for future implementation of similar projects.

First, using a randomized sample of the population would have improved the statistical power of the results regardless of having small sample sizes. This could be accomplished by delivering education to all perinatal patients while they are waiting to be seen by their provider in the exam rooms. Every patient could be randomized into either the education group or the usual care group.

Next, gathering the same maternal characteristics data on all maternity patients, those who choose to participate, and those who decline to participate would enable the team to statistically control for confounding variables and improve internal validity regarding sample bias. A meeting with an IT/EPIC specialist to discuss data mining would be useful in this pursuit.

The decision was made to look at EBF (infants who were given only breast milk) results only as this is the gold standard for infant feeding. In looking at outcome results in

a population that already has a lower rate of EBF as well as any breastfeeding, it may have been more helpful to measure and identify breastfeeding outcomes in both infants receiving only breast milk (even if that was delivered via a spoon, cup, bottle or SNS) as well as those who continued to receive breast milk via pumped milk or at breast in addition to formula supplementation (i.e. as in the instance of excessive neonatal weight loss). Locating an appropriate tool to measure maternal behaviors associated with improved breastfeeding (using skin to skin, recognizing feeding cues, achieving deep latch) and measuring maternal qualitative data (maternal satisfaction, achievement of breastfeeding goals, or breastfeeding self-efficacy) would be beneficial in evaluating the efficacy of the program.

Additionally, it is also important to follow breastfeeding outcomes longer, for example to three or six months after birth, even if the mother is offering supplemental formula occasionally. This is more consistent with the literature and may even reveal positive breastfeeding outcomes in mothers who continue breastfeeding until six months of age or up to one year of age.

As previously mentioned the project manager hoped to implement this program at another hospital in the same county, with a similar patient population. This facility has traditionally had poorer breastfeeding outcomes, as there are fewer CLC staff, a lack of breastfeeding support, and less breastfeeding training for staff. Implementation of the program at that facility or other similar sites should include a commitment from the implementation team to offer training courses in lactation support for the facility staff (RN, MA, LPN, LCSW) unless the community happens to have a good network of

breastfeeding support. In consideration of convenience and accessibility for mothers, the educational intervention should be incorporated into the workflow of prenatal care already being delivered.

### Closing Statement

As scientific evidence builds in the area of breastfeeding, and marketing of artificial milk substitutes is regulated, breastfeeding should become more and more the standard infant feeding choice. In vulnerable communities, this will have a major impact on infant and maternal health, as well as the long-term health of the community.

Changing the standard will likely happen over time, with small incremental changes.

Those who support breastfeeding should refrain from becoming discouraged and continue to focus on the long-term goal that every infant, with few exceptions, will receive the benefits of breast milk to optimize growth and development during their infancy.

APPENDICES

APPENDIX A

SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN  
RESEARCH AT MONTANA STATE UNIVERSITY (MSU)  
& AUTHORIZATION TO SHARE PERSONAL  
HEALTH INFORMATION IN RESEARCH

SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN RESEARCH AT  
MONTANA STATE UNIVERSITY (MSU)

Delivering Prenatal Breastfeeding Education: A Vulnerable Population in Rural Montana

You are invited to participate in a quality improvement project here at Providence Saint Joseph Hospital (PSJH) involving delivery of prenatal breastfeeding education (PBE) in coordination with scheduled prenatal visits. You are being asked to participate because you expressed an interest or have potential interest in breastfeeding the baby you will soon deliver.

Description

Breastfeeding your baby provides him or her with a foundational health benefits that cannot be found in any other source. Many mothers who intend to breastfeed their baby discontinue breastfeeding earlier than planned because they encounter unexpected challenges. Breastfeeding is a learning process for both mother and baby, and most of these challenges can be overcome with preparation and utilization of resources for help. The PBE program will be taught individually for every mother and her support person because all parents are unique in their learning needs. The education is intended for all new mothers; whether they are undecided about their infant feeding choice, are intending to breastfeed, have previous experience with breastfeeding an infant, or no experience at all. Evaluating the results of this project will help us better understand if prenatal breastfeeding education and skill building will help a mother gain more confidence in her decision to breastfeed, and help her persist through challenging times that commonly occur when first initiating breastfeeding.

Requirement of Participants, Information Collected, Project Funding and Cost

If you agree to participate, we ask you to fill out *two short surveys*. The first survey has questions about your current pregnancy and breastfeeding experience (either personally or with friends and family), as well as statistical data similar to that asked on a US Census form. The second survey is a 5-question evaluation of your personal feeding plans for your new baby (called the Infant Feeding Intention Scale). In addition to the two initial surveys, we will collect data from you and/or your baby's hospital records. The data collected will be information about delivery, and your infant feeding records while in the hospital, and up to ten days after birth. Lastly, we ask that you participate in three 20-min PBE sessions with one of our breastfeeding specialists.

The PBE sessions will cover the basics about benefits and the management of breastfeeding (how to get started, how do you know baby is getting enough, recognizing when to feed baby, tips to avoid or how to work through problems, and resources for help). These sessions will be provided immediately after or before your scheduled prenatal visit so will not require extra trips to the OB clinic. There is no outside funding source for this project or cost to you as a participant.

Risk

The only foreseeable risk to participating in the PBE is that a participant might feel an *obligation* to breastfeed longer than she wants too. We want to assure you that this is not intended and the maternity health providers here at Saint Joseph Hospital want to support your personal feeding decisions no matter what they are. You may refuse to attend the PBE sessions at any point. You also may continue to attend all three sessions, but refuse to participate in the PBE program evaluation. Refusal to participate will not influence the high-quality prenatal care or the breastfeeding education you receive. However, by continuing to participate, you will help us gather important information about whether to continue, modify, or discontinue the PBE program.

### Confidentiality

Your questions or concerns regarding participation in this project are encouraged. Please direct questions to *project manager*; Cindy Young, (406) 249-9392[cindy.young@student.montana.edu]. If you have additional questions about the rights of human subjects you may contact the Chair of the Institutional Review Board for MSU, Mark Quinn, (406) 994-4707 [mquinn@montana.edu].

Protecting your personal information is of the utmost importance to us. No personal information will be shared. The project manager will be the only person receiving *protected health information* (PHI) from your medical records. This information will be assigned a separate identification code having no connection to your name, date of birth, or medical record number associated with the hospital. The primary project manager will be the only person who has the coding information, which will be held in a file on a password-protected computer, and destroyed when the project is over. Only group information pertaining to the results of the project will be shared with the MSU faculty committee for this project (Julie Ruff, Helen Melland, Maria Wines, & Laura Larsson), graduate school faculty and doctoral nursing students who attend the presentation of the project next fall, and the obstetrical and pediatric healthcare staff at the hospital (doctors, nurses, and breastfeeding specialist).

### Compensation

In appreciation of your participation in this project, every participant who attends all three PBE sessions and participates in the program through its duration will each receive a \$5 gift certificate to Sweet Bliss in Polson or Dairy Queen in Ronan and will be included in a drawing for two Wal-Mart gift cards: first draw-\$60, second draw-\$30. Participants who withdraw from the education program or who choose not to finish all three sessions will not be included in the drawing.

**AUTHORIZATION:** I have read the above and understand the discomforts, inconvenience and risk of this study. I, \_\_\_\_\_ (*name of subject*), agree to participate in this research. I also agree that my health information can be collected and used by the researchers and staff for the research study described in this consent form (See Authorization to Share Personal Health Information in Research). I understand that I may later refuse to participate and that I may withdraw from the study at any time. I have received a copy of this consent form for my own records.

Signed: \_\_\_\_\_ Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

### **Statement of Consent**

I have read the above information, and have received answers to any questions I asked. I consent to take part in the project.

Your Signature \_\_\_\_\_ Date \_\_\_\_\_

Your Name (printed) \_\_\_\_\_

Signature of person obtaining consent \_\_\_\_\_ Date \_\_\_\_\_

Printed name of person obtaining consent \_\_\_\_\_

This consent form will be kept by the researcher for five years beyond the end of the study.

Authorization to Share Personal Health Information in Research

We are asking you to take part in the breastfeeding education quality improvement project described in the *attached consent form*. To do this research, we need to collect health information that identifies you. The information collected will be the two surveys mentioned in the attached consent form (3<sup>rd</sup> paragraph), delivery information and infant feeding information from you and/or your baby's hospital medical records (also described in the attached consent form in 3<sup>rd</sup> paragraph). We will only collect information that is needed for the research. For you to participate in this research, we need your permission to collect and share this information.

We will not share your personal health information with people at the hospital or outside the hospital. We will share group data with all who help with the research (with no personal identifiers attached). The data collected will be presented as group data, and individual results will not be utilized or reported. For example, the data may look like this; *mothers between the age of 18-22 year were most likely to be exclusively breastfeeding at discharge from hospital; or mothers who had unplanned cesarean sections were more likely to breastfeed for the first time after 2 hours of birth.*

This collective group information may be shared with healthcare providers and staff at Saint Joseph Hospital, with people involved in implementation of the project, with project committee members associated in the Montana State University Department of Nursing. It may also be shared with representatives of MSU who are in charge of the research project of MSU students, as these people make sure we do the research properly. The "confidentiality" section of the consent form says who these people are.

If you sign this form, we will collect only the health information mentioned until the end of the research project (Dec 13, 2019). We will protect the information and keep it confidential.

If you sign this form, you are giving us permission to collect, use and share your health information under the guidelines provided above. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher (project manager) listed on the attached consent form. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

**AUTHORIZATION:** I have read the above and understand the discomforts, inconvenience and risk of this study. I, \_\_\_\_\_ (*name of subject*), agree to participate in this research. I also agree that my health information can be collected and used by the researchers and staff for the research study described in this consent form. I understand that I may later refuse to participate and that I may withdraw from the study at any time. I have received a copy of this consent form for my own records.

Signed: \_\_\_\_\_ Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

APPENDIX B

INFANT FEEDING INTENTIONS (IFI) SCALE

Instructions read to subject:

*I am going to read to you some statements about feeding your baby. Please choose the answer that most closely matches your opinion, considering both your feeding plans and the likelihood that you will carry out those plans*

		Very much agree	Some what agree	Unsure	Some what disagree	Very much disagree
1.	I am planning to only formula feed my baby (I will not breastfeed at all)	0	1	2	3	4
2.	I am planning to at least give breastfeeding a try	4	3	2	1	0
3.	When my baby is 1 month old, I will be breastfeeding without using any formula or other milk	4	3	2	1	0
4.	When my baby is 3 months old, I will be breastfeeding without using any formula or other milk	4	3	2	1	0
5.	When my baby is 6 months old, I will be breastfeeding without using any formula or other milk	4	3	2	1	0

(Nommsen-Rivers & Dewey, 2009)

Numbers within grid represent the point value for each response. Total score = (mean of items 1 + 2) + (sum of items 3, 4, 5). Thus, total score ranges from 0 (very strong intention to not breastfeed at all) to 16 (very strong intention to breastfeed exclusively throughout the first 6 months)

#### Reference

Nommsen-Rivers, L.A. & Dewey, K.G. (2009). Development and validation of the Infant Feeding Intentions Scale. *Maternal Child Health Journal* 13(3), pp. 334–342. doi: 10.1007/s10995-008-0356-y.

APPENDIX C

BREASTFEEDING INFORMATION  
AND BACKGROUND SURVEY

Breastfeeding Information and Background Survey

Thank you for participating in our Prenatal Breastfeeding Education Program. This information is optional, please answer only the questions you feel comfortable answering. By answering these questions, you will help us continue to improve the education in order to best meet the needs of our birth parents

Pregnancy Information

1. Have you attended a breastfeeding class in the last 5 years? 

Yes	No
-----	----

2. Have you ever breastfed (any length of time) any previous children? 

Yes	No
-----	----

3. If so, were you satisfied with your breastfeeding experience? 

Yes	not completely	Not at all
-----	----------------	------------

(Please circle one answer)

4. Are you participating in or do you plan to sign up for WIC? 

Yes	No
-----	----

  
(Federal Special Supplemental Nutrition Program for Women, Infants, and Children)

Demographic Information (please circle best answer)

5. What is your age (of the pregnant mother)? \_\_\_\_\_

6. Please identify your ethnic background by placing an X by the ethnicity(s) that best describes you.

African American \_\_\_ Alaskan Native \_\_\_ American Indian \_\_\_ Asian \_\_\_ Hispanic \_\_\_  
Native Hawaiian/Pacific Islander \_\_\_ White \_\_\_ Other or Mixed \_\_\_\_\_ (write-in)

7. Circle the number of years in education you have completed.

Circle Type of Education	High School GED/ HiSET				Some College Tech/Cert Program Assoc/Bach Degree				Post Grad
# of Educational Years	9	10	11	12	13	14	15	16	17+

8. What best describe your total annual household earning before taxes?  
< \$20,000 \_\_\_ \$20,000-\$39,999 \_\_\_ \$40,000-\$59,999 \_\_\_ \$60,000-\$79,999 \_\_\_ >80,000 \_\_\_

APPENDIX D

SAMPLE DATA AND CHARACTERISTICS

The following sample data was extracted from a EMR review, the Breastfeeding information and Background survey, and two separately administered Infant Feeding Intentions Scales.

<b>CONTROL GROUP</b> deliveries from 5/15/18-7/15/18 (2 months) 24 deliveries, 17 included in data, 7 eliminated, (1 preterm, 6 infants on NAS scoring after birth)			
Age	Range 17-42	Mean 27.9	Median 27
Ethnicity	Cauc/Wht(8)- 47%	AI/AN(8)- 47%	Hispanic(1)- 6%
Payer	Medicaid- 65%	Private- 35%	Self- 0%
Infant Feeding choice	Breast- 65%	Combined- 17%	Formula- 18%
Primagravida	29%		
EBF @ hospital Discharge	59%	Primagravida 40%	
EBF @ 7-10 days after birth	53%	Primagravida 0%	

<b>PARTICIPATION GROUP</b> consented from 4/15-6/15 deliveries covered a span of 4/27 to 8/18, 2019 23 deliveries, 21 included in data, 2 eliminated, (1 PROM, 1 d/t transferred care)			
Age	Range 15-42	Mean 27.4	Median 27
Ethnicity	Cauc/Wht(13)- 62%	AI/AN(5)- 23%	Hispanic(3)- 14%
Payer	Medicaid- 48%	Private- 52%	Self- 0%
Infant Feeding choice	Breast- 90%	Combined- 10%	Formula- 0%
Primagravida	52%		
EBF @ hospital Discharge	62%	Primagravida 73%	
EBF @ 7-10 days after birth	57%	Primagravida 73%	
<b>**Extra data pulled from <i>Breastfeeding Info and Background Survey</i> for participation group**</b>			
Education level (years of school)	range 9-17+	mean 12.9	
Annual Income level	<20K-38%	20-39,999K-19%	40-59,999K-19%
	60-79,999K-5%	>80K-19%	
Involved in WIC	57.1%		
Previous BF experience (90% of those with previous experience report being unsatisfied with that experience)	46.6%		

<b>Infant Feeding Intention (IFI) Scale Scoring (2 scores increased, 8 scores decreased)</b>	
IFI @ time of consent	IFI @ lactation follow up
range 6-16	range 0-16
mean 13.4	mean 11.1
median 14	median 13
mode 16	mode 16

APPENDIX E

BREASTFEEDING NEEDS ASSESSMENT

LACTATION STAFF SURVEY

Dear CLC Staff;

I am working with Jessica Larson on a breastfeeding education improvement project for our mothers at Providence Saint Joseph's Hospital (PSJH) and to fulfill the requirements to earn my Doctorate of Nursing Practice through Montana State University.

Research on the most successful breastfeeding interventions points to a blend of education occurring in the prenatal, peripartum, and postnatal periods.<sup>5</sup> The goal of this project is to *improve breastfeeding outcomes* and *enhance quality of care* through implementing an evidence-based practice change for an identified healthcare need.

In the past year, the Lake county WIC office has documented an average 6 month exclusive breast feeding (EBF) rate of 8.3%, far below the Healthy People 2020 target of 22.3%.<sup>1,3</sup> This breastfeeding (BF) education project aims is to support improvement of BF initiation and duration of *any* BF, as well as encouraging EBF for the first six months of life.

Lack of BF knowledge regarding the health benefits of BF, establishing a milk supply, high quality feeding practices, as well as unrealistic expectations and lack of skills to maneuver through challenges contributes to suboptimal breastfeeding outcomes.<sup>2</sup> Antenatal education addresses these and related issues, however less than 12% of our antenatal clients seek out the BF education offered in free evening classes. Evidence reveals that prenatal BF education and positive encouragement can increase a woman's confidence in her abilities to BF, and can significantly increase rates of BF initiation and EBF.<sup>4</sup> Hence, the project we propose to implement is **integrating breastfeeding education into routine prenatal visits**, to assure that all mothers who plan to breastfeed receive basic information to improve their breastfeeding knowledge and confidence in the earliest postpartum period (first week after birth).

Breastfeeding requires some preparation on the part of the mother and her family, although it is presumed to be an instinctive and natural process.<sup>2</sup> Experiencing early difficulties, which we know frequently occurs, can lead mothers with even the best intentions to consider early formula supplementation. Since the L&D nurses and CLC staff is providing the frontline assistance for mothers in the first week of breastfeeding, I am seeking your input in identifying common knowledge gaps that could be addressed that might be influential in establishing a healthy start to BF in the first week after birth. Think of the mothers you provide BF assistance for initially after birth or within the first week postpartum and answer the following questions or considerations;

*What information could have helped this mother be better prepared for this situation?*

OR

*If this mother understood \_\_\_\_\_ about breastfeeding, it would make it easier to help her.*

On the next page is a little information about the plan for the breastfeeding education classes and the primary topic areas. These classes are only 20 min each, so we want to focus on the most essential information that is pertinent to BF initiation. The asterisk (\*) identifies the topics that Jessica and I have recognized as being common knowledge gaps we believe are instrumental in establishing a healthy start in the early postpartum period.

I truly value and desire your expert input on this project, *thank you* in advance for taking a few moments to thoughtfully express your professional observations. When finished, please place your comments on the yellow clipboard marked- Cindy's Breastfeeding Projects located by the front computer; and thank you so much for your help!

Below is a brief overview of the breastfeeding education intervention we wish to implement with your support:

The prenatal appt. @ 29-35wk will be co-scheduled with 3 separate breastfeeding education sessions (20min)

@29-30 wks Gest

- ✓ benefits for mom/baby
- ✓ \*estab. & maint of milk supply

@30-32 wks Gest

- ✓ \*skin-2-skin, demand feed, room-in
- ✓ latch, position, pacifiers
- ✓ \*hunger & satiety cues

@32-35 wks Gest

- ✓ \*assessing milk transfer
- ✓ \*managing challenges
- ✓ resources
- ✓ \*partner/social support

The evidence-based breastfeeding education sessions will be developed by myself in coordination with input from the CLC staff to account for the needs of our local population. Jessica Larson will be the primary instructor for the educational sessions, however in her absence, an outline will guide any CLC who is staffing the lactation clinic.

- An outline of the basic information will be utilized to guide education sessions, but the education will be individualized for each mother and her support person.
- To measure the outcome of the intervention, The CLC and the Nesting place staff will fill out a survey prior to and after implementation of the project. The survey will focus on the staff perception of the participating mother's knowledge of breastfeeding and preparation in the initial postpartum period.
- The survey will be filled out at each participant's lactation clinic visit as well.

**Please offer your comments and suggestions in the space provided below and use the back of this page if needed.**

References:

1. Centers for Disease Control and Prevention [CDC]. (2006.) Racial and socioeconomic disparities in breastfeeding--United States, 2004. *Morbidity and Mortality Weekly Report*, 55(12), pp.335-9. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5512a3.htm>.
2. Manjula, M.R., Suresh, N.S., Kannaiah, B., & Nirmala, C. (2016). Impact of antenatal counselling on knowledge, attitude and practice regarding breastfeeding. *Journal of Evolution of Medical and Dental Sciences* 5(43), pp. 27022704. doi: 10.14260/jemds/2016/631.
3. Montana Department of Health and Human Services[MDHHS] (2018). Weekly WIC newsletter reports (Breastfeeding Peer Counselor Report), March 5<sup>th</sup>, 2018. Retrieved from <http://dphhs.mt.gov/Portals/85/publichealth/documents/WIC/Newsletters/Jan-Feb-Mar/3-5-18/3-5-18.pdf>.
4. Pitts, A., Faucher, M.A., & Spencer, R. (2015). Incorporating breastfeeding education into prenatal care. *Breastfeeding Medicine*, 10(2), pp.118-123. doi.org/10.1089/bfm.2014.0034.
5. U. S. Preventative Services Task Force [USPSTF], (2016). Primary care interventions to support breastfeeding, US Preventative Services Task Force recommendation statement. *Journal of the American Medical Association* 316(16), pp.1688-1693. Retrieved from <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breastfeeding-primary-care-interventions>.

APPENDIX F

SEARCH METHODS AND TERMS

1. Review of Literature (Current Best Evidence)- (BF= Breastfeeding)
2. Data Bases Searched- Google, Google Scholar, Medline, PubMed, CINAHL
3. Terms: BF, Breast milk, lactation, nursing+BF, BF+self-efficacy(confidence), exclusive breast feeding (EBF), prenatal(antenatal)(perinatal)+BF+education, BF education (intervention), BF disparity(ethnic/racial disparity), suboptimal BF, low-income (disadvantaged) (vulnerable)(underserved)(high-risk)+women+BF, BF+Barriers(challenges) (obstacles), BF+outcome (intervention) (initiation)(duration) (longevity)(termination\*), supplementation+formula+early, (neonatal)infant+feeding(nutrition), BF=Native American\*, earlier searches included BF+peer (counselor\*)(educators)(support)(lactation support)
4. Journals searched- with above terms- (J=Journal of) J Human Lactation, J Breastfeeding Medicine, Breastfeeding Review, International breastfeeding Journal, Pediatrics, AJOG, J Perinatal and Neonatal nursing
5. Gray Literature- MtDpHHS(WIC), USDpHHS/CMS, CDC, WHO/UNICEF, AAP, US Census Bureau.

APPENDIX G

MONTANA STATE UNIVERSITY IRB APPROVAL AND  
ST. PATRICK HOSPITAL AND HEALTH SCIENCE  
CENTER JOINT INVESTIGATIONAL  
REVIEW BOARD APPROVAL



**INSTITUTIONAL REVIEW BOARD**  
**For the Protection of Human Subjects**  
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**MEMORANDUM**

**TO:** Cindy Young and Julie Ruff  
**FROM:** Mark Quinn *Mark Quinn CJ*  
Chair, Institutional Review Board for the Protection of Human Subjects  
**DATE:** February 28, 2019  
**RE:** "Delivering Prenatal Breastfeeding Education: A Vulnerable Population in Rural Montana" [CY022619-EX]

The above research, described in your submission of February 28, 2019, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

- (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation; and (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by section 16.111(a)(7).
- (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.
- (b) (5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (b) (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.



ST. PATRICK HOSPITAL AND HEALTH SCIENCES CENTER  
COMMUNITY MEDICAL CENTER INC.

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**JOINT INVESTIGATIONAL REVIEW BOARD**

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500 W. Broadway • Missoula, MT 59802 • 406/329-5669 • Fax: 406/549-2757

Dear Cindy Young

Date 3/18/19

**PROJECT TITLE: Delivering Prenatal Breastfeeding Education: A Vulnerable Population in Rural Montana**

This is to advise you that the above referenced project has been reviewed by a SPH/CMC Joint IRB member/staff and the following determination has been made with explanation provided:

(1) X The project DOES NOT meet the definition of research. Project activities are limited to Quality Improvement or Evidence Based Practice and does not require IRB oversight under 45 CFR 46; and 21 CFR 56, under the following criteria:

- The project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge.
- X The project does not seek to test issues that are beyond current science and experience, such as new treatments or untested clinical interventions, or establish scientific evidence.

(2) \_\_\_\_\_ The project meets the definition of research but is exempt from IRB oversight under (45 CFR 46.101(b) specifically:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Please note that this determination is based upon the information submitted only. Any revisions to this project must be submitted to the IRB before they are implemented for further IRB consideration to determine whether or not the revisions affect this determination. This determination does not exempt you from following hospital policies and procedures as they relate to conduct of this project. It is your responsibility to ensure compliance with those policies.

Signature of IRB Member/Staff

REFERENCES

- Abbass-Dick, J. & Dennis, C. (2017). Breast-feeding coparenting framework: A new framework to improve breast-feeding duration and exclusivity. *Family and Community Health, 40*(1), 28–31. doi:10.1097/FCH.0000000000000137
- Abbass-Dick, & Dennis. (2018). Maternal and paternal experiences and satisfaction with a co-parenting breastfeeding support intervention in Canada. *Midwifery, 56*, 135–141. doi:10.1016/j.midw.2017.10.005
- Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes, 50*(2), 179–211. doi:10.1016/0749-5978(91)90020-T
- American College of Obstetricians and Gynecologists [ACOG]. (2018). Committee Opinion No. 756: Optimizing support for breastfeeding as part of obstetric practice. *Obstetrics & Gynecology, 132*(4), e187–e196. doi:10.1097/AOG.0000000000002890
- Armitage, C.J. & Connor, M. (2001). Efficacy of the theory of planned behaviour: A meta-analytic review. *British Journal of Social Psychology, 40*(4), 471–499. doi:10.1348/014466601164939
- Aschbrenner, K. & Cornish, D.L. (2016). Barriers to breastfeeding among rural women in the United States. *The University of Northern Iowa Journal of Research, Scholarship, and Creative Activity, 12*. Retrieved from <https://universitas.uni.edu/volume-12-2016-2017/barriers-breastfeeding-among-rural-women-united-states>
- Bartick, M.C., Schwartz, E.B., Green, B. D., Jegler, B.J., Reinhold, A.G., Colaizy, T.T., . . . Stuebe, A.M. (2016). Suboptimal breastfeeding in the United States: Maternal and pediatric health outcomes and costs. *Maternal & Child Nutrition, 13*(1), 1–13. doi:10.1111/mcn.12366
- Bartle, N., & Harvey, K. (2017). Explaining infant feeding: The role of previous personal and vicarious experience on attitudes, subjective norms, self-efficacy, and breastfeeding outcomes. *British Journal of Health Psychology, 22*(4), 763–785. doi:10.1111/bjhp.12254
- Bibbins-Domingo, K., Grossman, D., Curry, S., Davidson, K., Epling, J., García, F., . . . Pignone, M. (2016). Primary care interventions to support breastfeeding: US Preventive Services Task Force recommendation statement. *JAMA, 316*(16), 1688–1693. doi:10.1001/jama.2016.14697
- Bonuck, K., Stuebe, A., Barnett, J., Labbok, M., Fletcher, J., & Bernstein, P. (2014). Effect of primary care intervention on breastfeeding duration and intensity.

*American Journal of Public Health*, 104(1), S119–S127.  
doi:10.2105/AJPH.2013.301360

- Cadwell, K. & Turner-Maffei, C. (2009). *Continuity of care in breastfeeding*. Sudbury, MA: Jones and Bartlet.
- Centers for Disease Control and Prevention [CDC]. (2006.) Racial and socioeconomic disparities in breastfeeding--United States, 2004. *Morbidity and Mortality Weekly Report*, 55(12), 335–339. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5512a3.htm>
- Centers for Disease Control and Prevention [CDC]. (2013). *Strategies to prevent obesity and other chronic diseases: The CDC guide to strategies to support breastfeeding mothers and babies*. Retrieved from <https://www.cdc.gov/breastfeeding/pdf/bf-guide-508.pdf>
- Center for Disease Control and Prevention [CDC]. (2018). *Breastfeeding report card*. Retrieved from <https://www.cdc.gov/breastfeeding/pdf/2018breastfeedingreportcard.pdf>
- Centers for Disease Control and Prevention [CDC]. (2019). *CDC health disparities & inequalities report*. Retrieved from <https://www.cdc.gov/disparitiesanalytics/>
- Danawi, H., Estrada, L., Hasbini, T., & Wilson, D.R. (2016). Health inequalities and breastfeeding in the United States of America. *International Journal of Childbirth Education*, 31(1), 35–39. Retrieved from <https://search-proquest-com.proxybz.lib.montana.edu:3443/docview/1789782707?accountid=28148>
- De Jager, E., Broadbent, J., Fuller-Tyszkiewicz, M., Nagle, C., McPhie, S., & Skouteris, H. (2015). A longitudinal study of the effect of psychosocial factors on exclusive breastfeeding duration. *Midwifery*, 31(1), 103–111. doi:10.1016/j.midw.2014.06.009
- Debevec, A.D. & Evanson, T.A. (2016). Improving breastfeeding support by understanding women's perspectives and emotional experiences of breastfeeding. *Nursing for Women's Health*, 20(5), 464–474. doi:10.1016/j.nwh.2016.08.008
- Eidelman, A.L. & Schanler, R.J. (2012). Policy statement: Breastfeeding and the use of human milk. *Pediatrics*, 129(3), e827–e842. doi:10.1542/peds.2011-3552
- Eni, R., Phillips-Beck, W. & Mehta, P. (2014). At the edges of embodiment: Determinants of breastfeeding for First Nations women. *Breastfeeding Medicine*, 9(4), 203–214. doi:10.1089/bfm.2013.0129

- Evans, M.L., Dick, M.J., Lewallen, L.P., & Jeffrey, C. (2004). Modified breastfeeding attrition prediction tool: Prenatal and postpartum tests. *The Journal of Perinatal Education, 13*(1), 1–8. doi:10.1624/105812404X109348
- Haroon, S., Das, J.K., Salam, R.A., Imdad, A., & Bhutta, Z.A. (2013). Breastfeeding promotion interventions and breastfeeding practices: A systematic review. *BMC Public Health, 13*(3), 1–18. doi:10.1186/1471-2458-13-S3-S20
- Hauk, L. (2015). AAFP releases position paper on breastfeeding. *American Family Physician, 91*(1), 56–57. Retrieved from <http://search.ebscohost.com.proxybz.lib.montana.edu/login.aspx?direct=true&db=c cm&AN=109693702&login.asp&site=ehost-live>
- Health Resources & Services Administration [HRSA], (2019). Map gallery: Health professional shortage areas. Retrieved from <https://data.hrsa.gov/maps/map-gallery>
- Heinig, M.J., Follett, J.R., Ishii, K.D., Kavanagh-Prechaska, 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. doi:10.1177/0890334405284333
- Herold, R., Bonuck, K., Marinelli, K., & Gill, S. (2016). Medicaid IBCLC service coverage following the Affordable Care Act and the Center for Medicare and Medicaid Services update. *Journal of Human Lactation, 32*(1), 89–94. doi:10.1177/0890334415599164
- Hildebrand, D.A., Mccarthy, P., Tipton, D., Merriman, C., Schrank, M. & Newport, M. (2014). Innovative use of influential prenatal counseling may improve breastfeeding initiation rates among WIC participants. *Journal of Nutrition Education and Behavior, 46*(6), 458–466. doi:10.1016/j.jneb.2014.05.005
- Hughes, K.N. (2015). Using skin-to-skin contact to increase exclusive breastfeeding at a military medical center. *Nursing for Women's Health, 19*(6), 478-489. doi:10.1111/1751-486X.12244
- Jones, K.M., Power, M.L., Queenan, J.T., & Schulkin J. (2015). Racial and ethnic disparities in breastfeeding. *Breastfeeding Medicine, 10*(4), 186–196. doi:10.1089/bfm.2014.0152
- Khan, A., Kabir, I., Eneroth, H., El Arifeen, S., Ekström, E., Frongillo, E., & Persson, L. (2017). Effect of a randomised exclusive breastfeeding counselling intervention nested into the MINIMat prenatal nutrition trial in Bangladesh. *Acta Paediatrica, 106*(1), 49–54. doi:10.1111/apa.13601

- Linares, A. M., Rayens, M. K., Gomez, M. L., Gokun, Y., & Dignan, M. B. (2015). Intention to breastfeed as a predictor of initiation of exclusive breastfeeding in Hispanic women. *Journal of Immigrant and Minority Health, 17*(4), 1192–1198. doi:10.1007/s10903-014-0049-0
- Manjula, M.R., Suresh, N.S., Kannaiah, B., & Nirmala, C. (2016). Impact of antenatal counselling on knowledge, attitude and practice regarding breastfeeding. *Journal of Evolution of Medical and Dental Sciences, 5*(43), 2702–2704. doi:10.14260/jemds/2016/631
- McDowell, M.M., Wang, C., & Kennedy-Stephenson, J. (2008). Breastfeeding in the United States: Findings from the National Health and Nutrition Examination Surveys, 1999-2006. (NCHS data briefs, no 5). Hyattsville, MD: National Center for Health Statistics.
- McKinney, C.O., Hahn-Holbrook, J., Chase-Lansdale, P.L., Ramey, S.L., Krohn, J., Reed-Vance, M., ...Shalowitz, M.U. (2016). Racial and ethnic differences in breastfeeding. *Pediatrics, 138*(2), 1-11. doi:10.1542/peds.2015–2388
- Meedya, S., Fahy, K., & Kable, A. (2010). Factors that positively influence breastfeeding duration to 6 months: A literature review. *Women and Birth, 23*(4), 135–145. doi:10. 1016/j.wombi.2010.02.002
- Mercier, R.J., Burcher, T.A., Horowitz, R., & Wolf, A. (2018). Differences in breastfeeding among medicaid and commercially insured patients: A retrospective cohort study. *Breastfeeding Medicine, 13*(4), 286-291. doi:10.1089/bfm.2017.0228
- Montana Department of Health and Human Services [MDHHS], (2013, June). *The state of the state's health: A report on the health of Montanans*. (Report, Version 1.0). Retrieved from <https://dphhs.mt.gov/Portals/85/publichealth/documents/Epidemiology/StateOfTheStatesHealth.pdf>
- Montana Department of Health and Human Services [MDHHS], (2016, February). *WIC Participation Had Positive Impact On Breastfeeding At Hospital Discharge for Montana Residents in 2014*. (Maternal and Child Health Epidemiology surveillance report). Retrieved from <http://dphhs.mt.gov/publichealth/mchepe.aspx#148473223-surveillance-reports>
- Montana Department of Health and Human Services [MDHHS] (2018). Weekly WIC newsletter reports (Breastfeeding Peer Counselor Report), March 5<sup>th</sup>, 2018. Retrieved from <http://dphhs.mt.gov/Portals/85/publichealth/documents/WIC/Newsletters/Jan-Feb-Mar/3-5-18/3-5-18.pdf>

- Montano, D.E. & Kasprzyk, D. (2008). Theory of reasoned action, theory of planned behavior, and the integrated behavior model. In: K. Glanz, B.K. Rimer, K. Viswanath, (Eds.), *Health behavior and health education: Theory, research, and practice* (pp. 95–124). Retrieved from [https://www.researchgate.net/publication/288927435\\_Health\\_Behavior\\_and\\_Health\\_Education\\_Theory\\_Research\\_and\\_Practice](https://www.researchgate.net/publication/288927435_Health_Behavior_and_Health_Education_Theory_Research_and_Practice)
- Morton, C. H., & Hsu, C. (2007). Contemporary dilemmas in American childbirth education: Findings from a comparative ethnographic study. *The Journal of Perinatal Education*, 16(4), 25–37. doi:10.1624/105812407X245614
- Nilsson, I.M.S., Strandberg-Larsen, K., Knight, C.H., Hansen, A.V., & Kronborg, H. (2017). Focused breastfeeding counselling improves short- and long-term success in an early-discharge setting: A cluster-randomized study. *Maternal Child Nutrition*, 13(4), 1–10. doi:10.1111/mcn.12432
- Nommsen-Rivers, L.A., Cohen, R.J., Chantry, C.J. & Dewey, K.G. (2010). The Infant Feeding Intentions scale demonstrates construct validity and comparability in quantifying maternal breastfeeding intentions across multiple ethnic groups. *Maternal & Child Nutrition*, 6(3), 220–227. doi:10.1111/j.1740-8709.2009.00213.x.mcn\_213\_220
- Nommsen-Rivers, L.A. & Dewey, K.G. (2009). Development and validation of the Infant Feeding Intentions Scale. *Maternal Child Health Journal*, 13(3), 334–342. doi:10.1007/s10995-008-0356-y
- Odom, E.C., Li, R., Scanlon, K.S., Perrine, C.G., & Grummer-Strawn, L. (2013). Reasons for earlier than desired cessation of breastfeeding. *Pediatrics*, 131(3), 726–732. doi:10.1542/peds.2012-1295
- Office of Disease Prevention and Health Promotion [ODPHP] (2016). Determinants of health. In *Healthy People 2020*. Retrieved from <https://www.healthypeople.gov/2020/about/foundation-health-measures/Determinants-of-Health>
- Office of Disease Prevention and Health Promotion [ODPHP] (2019). *Healthy People 2020*. Retrieved from <https://www.healthypeople.gov/>
- Parry, K.C., Tully, K.P., Hopper, L.N., Schildkamp, P.E., & Labbok, M.H. (2018). Evaluation of Ready, Set, BABY: A prenatal breastfeeding education and counseling approach. *Birth*, 46(1), 113–120. doi:10.1111/birt.12393

- Pitts, A., Faucher, M.A., & Spencer, R. (2015). Incorporating breastfeeding education into prenatal care. *Breastfeeding Medicine*, *10*(2), 118–123. doi:10.1089/bfm.2014.0034
- Polit, D.F. & Beck, C.T. (2017). *Nursing research: Generating and assessing evidence for nursing practice* (10<sup>th</sup> ed.). Philadelphia, PA: Wolters Kluwer.
- Pugin E., Valdes, V., Labbock, M.H., Perez, A., & Aravena, R. (1996). Does prenatal breastfeeding skills group education increase the effectiveness of a comprehensive breastfeeding promotion program? *Journal of Human Lactation*, *12*(1), 15–19. Retrieved from <http://journals.sagepub.com.proxybz.lib.montana.edu/doi/pdf/10.1177/089033449601200105>
- Raissian, K.M. & Su, J.H. (2018). The best of intentions: Prenatal breastfeeding intentions and infant health. *SSM - Population Health*, *5*, 86–100. doi: 10.1016/j.ssmph.2018.05.002
- Robert, E., Coppieters, Y., Swennen, B., & Dramaix, M. (2014). Breastfeeding duration: A survival analysis-data from a regional immunization survey. [Article ID 529790]. *BioMed Research International*, 1–8. doi:10.1155/2014/529790
- Rosen-Carole, C., Hartman, S, and the Academy of Breastfeeding Medicine [ABM] (2015). ABM Clinical Protocol #19: Breastfeeding Promotion in the Prenatal Setting, Revision 2015. *Breastfeeding Medicine*, *10*(10), 451–457. doi:10.1089/bfm.2015.29016.ros
- Rozga, M.R., Kerver, J.M., & Olson, B.H.P. (2015a) Prioritization of resources for participants in a peer counseling breastfeeding support program. *Journal of Human Lactation*, *31*(1), 111–119. doi:10.1177/0890334414554420
- Rozga, M.R., Kerver, J.M., & Olson, B.H.P. (2015b). Self-reported reasons for breastfeeding cessation among low-income women enrolled in a peer counseling breastfeeding support program. *Journal of Human Lactation*, *31*(1), 129–137. doi:10.1177/0890334414548070
- Skouteris, H., Nagle, C., Fowler, M., Kent, B., Sahota, P., & Morris, H. (2014). Interventions designed to promote exclusive breastfeeding in high-income countries: A systematic review. *Breastfeed Medicine*, *9*(3), 113–127. doi:10.1089/bfm.2013.0081
- Sparks, P.J. (2011). Racial/ethnic differences in breastfeeding duration among WIC-eligible families. *Women's Health Issues*, *21*(5), 374–382. doi:10.1016/j.whi.2011.03.002

- Stevens, E.E., Patrick, T.E., & Pickler, R. (2009). A history of infant feeding. *The Journal of Perinatal Education*, 18(2), 32–29. doi:10.1624/105812409X426314
- Stuebe, A.M. & Bonuck, K. (2011). What predicts intent to breastfeed exclusively? Breastfeeding knowledge, attitudes, and beliefs in a diverse urban population. *Breastfeeding Medicine*, 6(6), 413–420. doi:10.1089/bfm.2010.0088
- Su, L-L., Chong, Y-S., Chan, Y-H., Chan, Y-S., Fok, D., Tun, K-T., ...Rauff, M. (2007). Antenatal education and postnatal support strategies for improving rates of exclusive breastfeeding: Randomised controlled trial. *British Medical Journal*, 335(7620), 1–7. doi:10.1136/bmj.39279.656343.55
- SurveyMonkey Inc. (2019). AB testing calculator: For statistical significance [Online calculation software]. Unpublished instrument. Retrieved from <https://www.surveymonkey.com/mp/ab-testing-significance-calculator/>
- Tenfelde, S., Zielinski, R., & Heidarisaifa, R.L. (2013). Why WIC women stop breastfeeding? Analysis of maternal characteristics and time to cessation. *Journal of Human Lactation*, 32(1), 103–111. doi:10.1177/1941406413492820
- World Health Organization [WHO], (1998). Evidence for the ten steps to successful breastfeeding. WHO, Division of Child Health and Development Manual. Retrieved from [https://www.who.int/nutrition/publications/evidence\\_ten\\_step\\_eng.pdf](https://www.who.int/nutrition/publications/evidence_ten_step_eng.pdf)
- World Health Organization [WHO], (2018). Nutrition: Breastfeeding. Retrieved from [http://www.who.int/nutrition/topics/exclusive\\_breastfeeding/en/](http://www.who.int/nutrition/topics/exclusive_breastfeeding/en/)
- U.S. Census Bureau (2016). American fact finder: Montana, Lake County. Retrieved from <https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk>
- U.S. Department of Agriculture [USDA] (2018). FY 2017 WIC breastfeeding data local agency report. USDA Food and Nutrition Service. Retrieved from <https://fns-prod.azureedge.net/sites/default/files/wic/FY%202017%20BFDLA%20Report.pdf>
- U.S. Department of Health and Human Services [DHHS]. (2011). *The Surgeon General's call to action to support breastfeeding*. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/21452448>

U. S. Preventative Services Task Force [USPSTF]. (2016). Primary care interventions to support breastfeeding, US Preventative Services Task Force recommendation statement. *Journal of the American Medical Association*, 316(16), 1688-1693. Retrieved from <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breastfeeding-primary-care-interventions>