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Effectiveness of a Postpartum Breastfeeding Protocol for Avoiding Pregnancy and Descriptive Analysis of the Physiology of the Postpartum Transition

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EFFECTIVENESS OF A POSTPARTUM BREASTFEEDING PROTOCOL FOR AVOIDING PREGNANCY AND

DESCRIPTIVE ANALYSIS OF THE PHYSIOLOGY OF THE POSTPARTUM TRANSITION

by

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ABSTRACT

EFFECTIVENESS OF A POSTPARTUM BREASTFEEDING PROTOCOL FOR AVOIDING PREGNANCY AND
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Mary M. Schneider BSN, MSN, APRN, FNP-BC

Marquette University, 2021

Traditionally, postpartum breastfeeding women used Natural Family Planning (NFP) methods that required observation of cervical mucus and basal body temperature as indicators of return to fertility. These indicators resulted in high unintended pregnancy rates (i.e., 14-32 over 12 months of use). High pregnancy rates were due to the inaccuracy and subjectivity of those fertility indicators which required extended periods of abstinence. Ineffectiveness of NFP methods is also related to changing patterns of fertility during lactation amenorrhea (LA) and the first six menstrual cycles postpartum.

Studies of a NFP protocol where women used objective urine hormone biomarkers were 92-98% effective for avoiding unintended pregnancy while in LA. The protocol has women test urine pre-ovulatory estrogen (E3G) and luteinizing hormone with an electronic home fertility monitor. In 2013 a revised protocol was published. The revised protocol increased daily testing to twice a day and added instructions for the initial menstrual cycles.

The purposes of this study were to describe the physiological breastfeeding transition to fertility from LA through the first six cycles postpartum and to evaluate the correct and typical use effectiveness pregnancy rates of the revised protocol at 12 months and 12 cycles of use.

This repeated measures quasi-experimental (n = 216) and descriptive study (n= 64) used an established data set from an archived NFP website. Kaplan-Meier survival rate analysis showed four unintended pregnancies per 100 women at 12 months and 6 per 100 women at 12 cycles of use. A descriptive analysis of LA's length and the following 6 cycles found LA and cycle one positively skewed. Cycles two through six were normally distributed. On average, 89% of the women experienced an estimated day of ovulation (EDO). The EDO occurred around 8 months and first menses around 9 months. In cycle one, the EDO occurred around day 28, and in cycles two through six, the EDO occurred between days 19-22. Comparison between the original and revised protocols found menstrual cycle parameters and characteristics of the first menses were near identical. Findings from this study were used to develop new algorithms to improve accessibility of the protocol.

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Finally, this and future work is dedicated to Our Lady of La Leche who nursed Our Lord and Savior Jesus Christ! May she always watch over the work done by the Marquette University College of Nursing Institute for Natural Family Planning.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

APPENDICES

Chapter 1: Introduction

Over the last 50 years, women who used natural family planning (NFP) methods during lactation amenorrhea (LA) and the following 6 cycles relied on the subjective determination fertility signs of cervical mucus (CM) and basal body temperature (BBT) (Bouchard et al., 2018; Brown, 2011; Hatherley, 1985; Kennedy et al., 1995). With these NFP methods, 14 - 32 women out of 100 could expect to get pregnant within the first year postpartum. Fear of an unintended pregnancy negatively affected postpartum breastfeeding women's desire to use an NFP method during LA. High unintended pregnancy rates also decreased healthcare providers' trust and desire to promote NFP methods. However, with the introduction of home fertility monitoring devices integrated into an NFP method called the Marquette Method (MM) of NFP, 2 - 8 women out of 100 were expected to get pregnant the first year. The monitor identified the primary pre-ovulatory urine hormones estrogen (E3G) and luteinizing hormone (LH). The addition of urine hormones to the MM of NFP created a renewed interest in the use of NFP during postpartum breastfeeding. However, the addition of the monitor and test sticks increased cost. Therefore, it was important to identify the method's effectiveness and find new ways to lower cost and improve the method.

This chapter summarizes current knowledge about NFP during LA and the following 6 cycles. The chapter provides a historical overview of NFP methods developed over the last 50 years and the effectiveness of the different biomarkers these methods used. A physiologic endocrine discussion shows the connection between reproductive hormonal events and menstrual cycle parameters during postpartum amenorrhea and regular cycles. Terminology unique to the physiologic process of breastfeeding, NFP and fertility are described.   The chapter ends with a discussion of the studies significance, assumptions, limitations, and delimitations.

Finally, a brief discussion shows how results from this study contributed to the future of nursing practice and NFP.

Background of the Problem

Postpartum breastfeeding women prefer Natural Family Planning (NFP) as a safe and healthy method of spacing children (Severy & Robinson, 2004). Breastfeeding has been a natural method of spacing children since biblical times (Wolf, 2001). However, variability in the first postpartum menstrual cycles with prolonged time to ovulation and variability in the identification of ovulation by traditional biomarkers during breastfeeding transition make it difficult for women to avoid an unintended pregnancy (Bouchard et al., 2018; Brown, 2011; Hatherley, 1985; Hatherley, 1985; Kennedy et al., 1995).

The term NFP describes a cadre of different methods that rely on women's ability to identify their biological signs of fertility. Methods of NFP are divided into traditional and conventional. Traditional methods use the biomarkers of cervical mucus (CM) changes, shifts in basal body temperature (BBT), and calendar-based algorithms. Conventional NFP methods may or may not combine traditional biomarkers with home urine testing. The ability for women to test their urine for key pre-ovulatory hormones and chart the results into an NFP fertility charting system have significantly improved women's ability to avoid an unintended pregnancy during the postpartum breastfeeding transition (Bouchard et al., 2013; Fehring et al., 2017; Mu et al., 2020). However, daily testing with a home urine device and daily charting of these results into an NFP chart during the postpartum transition can be expensive and arduous, limiting the accessibility of the method.

Breastfeeding, Fertility, and NFP

The physiologic, endocrine control mechanisms between breastfeeding and ovulation have been studied since the 20th century (Brown, 2011; McNeilly, 2001a; McNeilly 2001b). The resumption of women's fertility postpartum is called the return to fertility. This time begins with the infant's birth and ends once menses or ovulation have occurred. The time from the birth of the infant to first menses is called lactation amenorrhea (LA). First menses is used as the clinical sign to determine that fertility has returned, and ovulation is the physiological sign that fertility has returned (Lawrence & Lawrence, 2016). Up to 70% of women who fully breastfeed are in LA for 6 months, and 37% are in LA for 12 months (McNeilly, 2001; Labbok, 2015). Therefore, even if women fully breastfeed, at least one-fourth are expected to return to fertility before six months postpartum (Barbieri, 2014). Knowing which fully breastfeeding women will return to fertility before 6 months is unpredictable which makes avoiding an unintended pregnancy difficult (Labbok, 2015; Lawrence & Lawrence, 2016). Therefore, understanding signs of fertility that can help couples who use NFP methods anticipate their return to fertility and avoid pregnancy during the postpartum breastfeeding transition is essential.

A Brief Overview of NFP

NFP methods can be categorized as either traditional or conventional. Traditional NFP methods, developed in the 20th century, have women track cervical mucus (CM), basal body temperature (BBT) and use calendar formulas. Typically, these methods are between 68-84% effective in preventing pregnancy postpartum (Brown et al., 1985; Hatherley, 1985b; Howard & Stanford, 1999; Klaus et al., 1979). Conventional NFP methods, developed in the 21st century, have women track urine hormones and use protocols determined by the phase of the menstrual cycle. These protocols help women know what days are fertile or infertile based on the phase of the cycle they are in. Menstrual cycle phases are determined by the day of ovulation. That is

the first phase is from the first day of menses to the day of ovulation. The second phase is the few days around ovulation also called the fertile window (FW). The third phase is the day after ovulation up to the next day of menses. NFP methods that use urine biomarker protocols to identify menstrual cycle phases are 92-98% effective during the postpartum breastfeeding transition (Bouchard et al., 2013; Fehring et al., 2017; Mu et al., 2020).

Studies in the 20th century by Brown (2011) from women who provided daily urine and CM observations discovered that return to fertility patterns in breastfeeding and non-breastfeeding women were different. Time to ovulation was identified using daily urine testing for the pre-ovulatory hormone estrogen and the post-ovulatory hormone progesterone. Elevated progesterone levels above a set threshold confirmed ovulation and return to fertility. Women who fully breastfed returned to fertility later than those who did not breastfeed (Brown, 2011). A comparison between CM and urine hormones in the study showed that CM significantly over-extended the fertile time. A more recent study by Bouchard, et al. (2018) also reported CM over-extended the fertile time compared to urine hormones. Both Brown (2011) and Bouchard et al. (2018) concluded that CM signs increased the estimated number of fertile days during the transition; thus, increasing the chance of unintended pregnancy.

For more than 50 years women who used traditional NFP methods, that relied on changes in CM, BBT and full breastfeeding to space children, had higher rates of pregnancy in the first 6-12 months than conventional methods (Bouchard et al., 2013; Brown, 2011; Fehring et al., 2017; Hatherley, 1985; Kennedy et al., 1995; Klaus et al.,1979; Mu et al., 2020). Conventional NFP methods, that integrated objective urine hormone signs into fertility charting are new to the 21st century and not well known. Even today, most women use traditional methods of NFP and are not aware of conventional NFP methods that are more effective.

Women choose NFP methods for personal, religious, or health reasons (Severy & Robinson 2004).

Breastfeeding Menstrual Cycle Parameter Terminology

This section defines terms and concepts that support this study. A distinction between the physiologic menstrual cycle parameters and endocrine activity that occur during regular cycles and postpartum breastfeeding are discussed.

The Postpartum Breastfeeding Transition

The postpartum breastfeeding transition begins with the birth of a baby and ends when women return to regular menstrual cycles (Arevalo & Sinai, 2005). The postpartum menstrual cycle transition includes 1) the anovulatory amenorrhoeic phase 2) ovarian activity and ovulation, 3) the post-ovulatory phase 4) first menses and 5) return of the first few cycles, which can be irregular in length (Bouchard et al., 2018; Brown, 2011). The end of the transition usually occurs by the third menstrual cycle when women return to regular length cycles (Brown, 2011). The length of the amenorrhoeic phase depends on if women breastfeed or not. Non-breastfeeding women have shorter amenorrhoeic phases and can ovulate as early as 45 days (Campbell, et al., 1993; Gray et al., 1990). However, breastfeeding women can remain in amenorrhea and not ovulate for several months to a year or more (Campino et al., 1994; McNeilly, 2001). The length of postpartum amenorrhea and phases of the menstrual cycle during this time depends on breastfeeding patterns. In this paper breastfeeding patterns are defined as frequency of breastfeeding.

Physiologic Events of the Postpartum Menstrual Cycle

Variability and return to fertility during the postpartum amenorrhea phase of the

menstrual cycle depends on if women breastfeed or not (Brown, 2011; McNeilly, 2001). The

phase begins with the infant's birth (parturition) and ends just before the first menses. For

breastfeeding or lactating women, this phase is lactation amenorrhea (LA). LA is a time that can

be infertile for months and years and is affected by breastfeeding patterns (Berens & Labbok,

2015; Lawrence & Lawrence, 2016c). When breastfeeding frequency is every few hours this

suppresses ovulation and decreases fertility. As the infant ages and breastfeeding frequency

decreases ovulation and menses will return. Although breastfeeding suppresses ovulation

during LA two-thirds of women will ovulate before their first menses (Eslami et al., 1990; Gray et

al., 1990). Thus, identification of ovulation during LA is vital for preventing an unintended

pregnancy postpartum. Tracking changes of urine hormones during the transition is useful for

determining patterns that identify impending ovulation.

The physiologic and endocrine processes that interconnect LA, breastfeeding, and

fertility are complex and not fully understood (McNeilly, 1979, 1993, 2001). However, the

actions of reproductive hormone markers like prolactin (PRL), gonadotropin releasing hormone

(GnRH), follicle stimulating hormone (FSH), luteinizing hormone (LH), estrogen and progesterone

provide a model for understanding the connection.

Reproductive Hormones

Hormones are chemical messengers released by glands into the bloodstream to regulate

physiologic organ/s and organ systems (Heffner & Schust, 2014). As chemical messengers,

hormones act as feedback mechanisms to help the body adapt to internal and external stimuli.

External stimuli initiate internal physiologic processes and hormonal systems for the body to

adapt to new stimuli. The body's innate response to hormonal activity is an essential protective

mechanism for regulating and maintaining physiologic balance. With growth and maturation,

human adaptation to external and internal stimuli is dynamic and requires continuous

physiologic changes for survival (Roy et al., 2011; Roy, 2009).

For postpartum women, breastfeeding is an external stimulus that causes changes in

reproductive hormones responsible for ovulation and the ability to get pregnant. Reproductive

hormones are the chemical messengers that continuously communicate to the brain and ovaries

throughout women's menstrual cycle events. The process is known as the neuroendocrine

feedback system. For postpartum women who breastfeed, stimulus on the breast from the

infant's suckling suppresses the reproductive neuroendocrine feedback system and ovulation.

However, as the infant grows or breastfeeding lessens, the system becomes active again, and

ovulation is possible (Heffner & Schust, 2014; Johnson, 2013; McNeilly, 2001). Menstrual cycle

events that indicate ovulation did occur are used to identify different menstrual cycle

parameters critical to understanding events indicating return to fertility.

Menstrual cycle events

The menstrual cycle begins and ends with a menstrual bleed. The fertile phase of the

menstrual cycle begins with the development of an egg protected and nourished by a follicle in

the ovary. As the egg within the follicle grows, the follicle releases the hormone estrogen.

Elevated estrogen levels thicken the uterine lining or endometrium, preparing it for possible

implantation of the egg. Rising estrogen levels also communicate to the brain when the egg is

mature and ready to be released. A sustained estrogen rise triggers the hormone LH. The LH

surges just prior to ovulation. After the egg is released, the follicle collapses in the ovary. The

collapsed follicle produces progesterone that continues to thicken the endometrium and heat

the body 2-4 tenths of a degree Fahrenheit (Heffner et al., 2014). If conception did not occur,

hormone levels drop, and the endometrial lining sheds; this is the source of the menstrual

bleed. The entire process usually occurs every 29 days (range 22-36 days) in women who are not pregnant or not breastfeeding (Fehring et al., 2006).

A menstrual cycle usually starts with heavy vaginal bleeding that tapers off to light bleeding and spotting. At the beginning of menstruation bleeding is heavy or moderate and lasts about five to eight consecutive days (Fehring & Rodriguez, 2016; Fehring & Schneider, 2008; Fraser et al., 2011). The days before ovulation, from the first day of menses to just before ovulation, make up the follicular phase. The days following ovulation, just before the next menstrual bleed, are the luteal phase. Ovulation occurs one day in each cycle. However, it is possible to have more than one ovulation within 24 hours. Parameters necessary for understanding menstrual cycle and reproductive health are the days that make up the pre-ovulatory follicular phase, ovulation, and the post-ovulatory luteal phase. The three phases of the menstrual cycle are managed physiologically by the hormone GnRH.

GnRH is a hormone released by the brain in pulses and is considered the gatekeeper of women's reproductive neuroendocrine systems (Heffner & Schust, 2014). The primary glands and organs of the reproductive neuroendocrine system are the hypothalamus, anterior pituitary gland, and ovaries. When the hypothalamus releases the hormone GnRH, it stimulates the anterior pituitary gland. In response, the anterior pituitary gland releases two primary hormones; FSH and LH (Heffner & Schust, 2014).

The menstrual cycle begins with the activity of FSH, a pre-ovulatory hormone that stimulates the follicle's growth in the ovary. As the follicle grows, it releases estrogen. Once the estrogen levels reach a threshold, this stimulates the hypothalamus, and GnRH is released. GnRH stimulates the anterior pituitary gland to release LH. When LH levels reach a threshold, ovulation occurs 24-36 hours later. The two critical pre-ovulatory hormones are estrogen and LH, and the primary post-ovulatory hormone is progesterone (Heffner & Schust, 2014). The

cyclic patterns of the hormones acting on the brain and ovaries each menstrual cycle is necessary for understanding menstrual cycle parameters.

Lactation Amenorrhea

Phases of the menstrual cycle follow the same neuroendocrine pattern regardless of whether women are in regular cycles or waiting for ovulation as in LA. The difference between the pre and post ovulatory phases, however, are the length of the follicular or pre-ovulatory phase. In women who are postpartum breastfeeding, the follicular phase is quite variable and can last from a few months to over a year (Brown, 2011; Labbok 2015; McNeilly, 2001). The hormone prolactin (PRL) is released during breastfeeding and prolongs the follicular phase (Brown, 2011).   Prolactin is a vital lactation hormone released from the anterior pituitary gland. When a woman is pregnant PRL increases by 200% (Buckley, 2015). Upon birth and for the first 40 days, if women breastfeed, PRL levels will stay elevated for months. In the early months postpartum PRL remain elevated from the infants suckling at the breasts (McNeilly, 2001b). Elevated PRL levels slow down GnRH pulsation inhibiting the release of FSH. FSH is necessary for maturation and growth of the egg within the follicle. Thus, breastfeeding prolongs the follicular phase of the menstrual cycle and can be used by women either formally or informally as an NFP method for child spacing (Berens & Labbok, 2015; Brown, 2011; Labbok, 2015; Tommaselli et al., 2000; Van der Wijden et al., 2008; Van der Wijden & Manion, 2015).

Traditional Methods of NFP

Traditional methods of NFP that used CM, BBT, and calendar-based algorithms to identify the fertile and infertile times during the postpartum breastfeeding transition were difficult to use, resulting in high pregnancy rates. CM is a non-specific sign of fertility. BBT requires a rigorous routine that is often difficult for postpartum breastfeeding women to use, and algorithm terminology may be vague. In this section, a description of the difficulties in using these methods is discussed.

Lactational Amenorrhea Method

The frequency and efficiency of the infants suckling at the breast indirectly controls the length of LA (McNeilly, 2001). Exclusive or full breastfeeding is when the infant suckles frequently and on-demand every three to four hours during the day and then six hours at night. Researchers determined this pattern of breastfeeding was essential to extending LA to 6 months or more (Berens & Labbok, 2015). This breastfeeding pattern was also determined to be essential for prolonging ovulation (Brown, 2011; McNeilly, 2001). It was found that when amenorrhoeic women exclusively or fully breastfed and were less than six months postpartum 1-2 women out of 100 would get pregnant (Berens & Labbok, 2015). In 1988 these findings were formalized into the lactational amenorrhea method (LAM) (Labbok, 2012). A historical overview of the development and effectiveness of the LAM is discussed in chapter 2.

The effectiveness of the LAM reflects the conceptual theory that breastfeeding suppresses ovulation for at least 6 months. The American Academy of Pediatrics (AAP) recommends that all infant nutrition comes from the breast for the first 6 months and the infant should be breastfed up to 12 months or more (American Academy of Pediatrics, 2012). The nutritional recommendation for exclusive breastfeeding through 6 months was based on the theoretical supposition that GnRH activity is suppressed during this time, thus reducing the

probability of pregnancy (Arévalo et al., 2002; Marcos Arevalo et al., 2004). After 6 months, the chance of pregnancy increases, and the resumption of ovulation is expected. However, when ovulation will occur is not predictable. Therefore, when women no longer are within the LAM protocol criteria, they are instructed to begin another method of family planning. For women who used NFP methods the time between no longer eligible for the LAM protocol and regular cycles can be a difficult time to avoid pregnancy.

The LAM was developed by the researchers from Georgetown University Institute for Reproductive Health (IRH). These researchers understood that for women who used NFP methods during postpartum breastfeeding transition and no longer met the LAM criteria there could be several months where the couple would not be covered by an effective NFP method. Therefore, the IRH developed a fertility awareness-based method (FABM) called the Bridge Method (Sinai & Cachan, 2012b). The purpose of the Bridge Method was to help women manage the postpartum breastfeeding transition cycles once they were outside the LAM protocol. Both NFP and FABM are natural methods of family planning.

Fertility Awareness Based Methods

FABM and NFP methods are terms that have been used interchangeably in the literature since the early 1900's (Arévalo et al., 2002). The fundamental difference between the two methods is that the FABM encouraged the use of barriers during the fertile time, whereas NFP methods recommended abstinence. A fundamental difference that could artificially improve pregnancy rates when barriers are used. Thus, there is a philosophic and operational difference between the two methods, and this makes the methods non comparable. For this reason, a brief review of the development and pregnancy effectiveness research on the Bridge Method is presented below and not in the literature review in Chapter 2.

Effectiveness of FABM: Development of the Bridge Method. The Standard Days Method (SDM)

and Two Days Method (TDM) developed at the Institute for Reproductive Health at Georgetown

University were two FABM used to create the Bridge Method (Arevalo et al., 2004). The SDM is

a fixed day method that does not require observation of CM or BBT (Arévalo et al., 2002;

Arévalo et al., 2004).   Women with cycle lengths that are 26-32 days long can use the SDM.

Days of fertility are 8-19. Women whose cycles are outside of the 26-32 days should use

another method of family planning.   The TDM was a method that asked women if there were

vaginal secretions today or yesterday (Sinai & Cachan, 2012a, 2012b). If the answer was no to

both days, the second day was considered infertile. Cumulative pregnancy effectiveness rates

for one year of use are 88-95% for women in regular cycles (Arévalo et al., 2002; Arévalo et al.,

2004).

The TDM and SDM were not designed for women in the breastfeeding transition.

However, developers of the methods applied the TDM and SDM protocols to a data set of 73

postpartum breastfeeding women. In this investigation, data from a previous study where

women provided urine hormones, CM, and BBT changes from three sites during 1986-1990

were used (Arevalo & Sinai, 2005; Sinai & Cachan, 2012a). The researchers analyzed CM and

urine hormones signs from postpartum breastfeeding women. The study was a secondary

analysis of data that assumed pregnancy would be less than 2% in the first 6 months since

women were covered by the LAM criteria (Sinai & Cachan, 2012a). Therefore, the TDM protocol

was applied to the data starting at 6 months postpartum. Application of both the TDM and SDM

protocols to previous postpartum breastfeeding data were the beginning of the theoretical

development of the Bridge Method.

Using the established data sets from postpartum breastfeeding women when the IRH

researchers applied the TDM protocol women had vaginal secretions/CM more than 80% of the

time during LA. Thus, about 80% of LA cycles were fertile using the TDM rules. Next, using the

same data set the researchers found the SDM rules showed that ovulation occurred outside of

the days of fertility (Sinai & Cachan, 2012a, 2012b). The authors pointed out that ovulation

occurred on average on day 22.4 (SD = 7.74) in cycle 1, day 19.1 (SD = 3.23) in cycle 2, day 18.4

(SD = 3.58) in cycle 3 and day 17.8 (SD = 2.12) in cycle 4. In the SDM instructions, fertility ends

on day 19. Thus, the authors concluded that postpartum women could not be eligible to use the

SDM until cycle 4. Thus, since 80% of LA was considered fertile using the TDM and the SDM

could not be used until the fourth cycle postpartum a gap still existed. The gap was after 6

months postpartum or when women were covered by the LAM until they had three full cycles

postpartum. From this analysis, researchers at the IRH concluded that another FABM was

needed to bridge the gap (Sinai & Cachan, 2012b).

Subsequently, the Bridge Method, a FABM for postpartum/breastfeeding women was

developed. The method covered the time when women were outside the LAM protocol to the

fourth cycle when regular length menstrual cycles returned.   With the Bridge method, the first

10 days after the first menses were considered infertile. In the next two cycles, women were

considered fertile days 8-24. By the fourth cycle, when breastfeeding women cycles returned to

26-32 days (i.e., regular length cycles), the SDM could be used. The Bridge Method required

several weeks to months of abstinence after 6 months but before the beginning of the fourth

cycle (Sinai & Cachan, 2012a). The theoretical efficacy of the Bridge Method was determined to

be reasonable based on the effectiveness rates of the SDM (i.e., 95%) and the TDM (i.e., 96%)

and the daily probability of pregnancy (Brown et al., 1985; Hatherley, 1985a; Zinaman &

Stevenson, 1991). However, the theoretical effectiveness needed to be tested.

To test the effectiveness of the Bridge method, the IRH researchers, Sinai and Cachan

(2012b) studied 153 breastfeeding women from Guatemala and Peru. A paper chart was

developed and used by the women to track the days between LA and the first three cycles.   The

chart showed the fertile window for cycle four, the first cycle when the SDM could be used.

Results showed 8 Guatemalan and 9 Peruvian women experienced unintended pregnancies.

One pregnancy occurred in cycle one, and the others occurred in the following three cycles. This

study found that the time between LA and the end of the third postpartum cycle could be as

long as several months requiring extended periods of abstinence until women were eligible for

the SDM. The authors concluded that because the Bridge method required long periods of

abstinence, it increased couples' anxiety and tension, which probably decreased the

effectiveness of the method (Sinai & Cachan, 2012b).

CM and BBT Method of NFP

Traditional NFP methods that combine CM and BBT called Symptothermal Methods rely

on changes in CM throughout the cycle and a shift in body temperature (Knight, 2017). The shift

in temperature can be a few degrees rise from the woman's baseline. This occurs after

ovulation and is due to the presence of progesterone from the Corpus Luteum. When the two

biological signs of fertility are combined changes in CM from fertile to infertile and the shift in

BBT are used to identify ovulation.   When the BBT rises 0.2° F. above baseline for at least 3 days

this is an indication ovulation occurred. Progesterone is present, and the woman is in the luteal

phase of the cycle. The rise in temperature is usually minimal and is susceptible to changes in

activity (Barron & Fehring, 2005). That is women must take their temperature at the same time

every day. If they wake an hour or two later one morning the temperature could be up 0.1°-

0.2°F (Knight, 2017).   This increase could cause confusion, since women could interpret this to

be a post-ovulatory sign. For the postpartum breastfeeding women who are up at different

hours of the night BBT may be difficult to interpret. A few studies have looked at the

effectiveness of CM and BBT during LA and the postpartum breastfeeding transition.

Few studies evaluated the effectiveness of Symptothermal Methods of NFP. One study of 55 Australian women who provided daily urine samples, CM and BBT signs, found 40% of the time CM extended the fertile time, because there was no change in BBT. When compared to urine hormones during LA, fertile CM was present when urine hormones were low, indicating no ovarian activity (Brown et al., 1985). Twenty-two pregnancies occurred in this study. The authors concluded that confusing CM signs might have increased pregnancy rates. A second study compared CM and BBT to serum reproductive hormones and found 34 (n =208) experienced an unplanned pregnancy. The author of this study concluded that high pregnancy rates were due to confusing CM and no shift in BBT and stated that these indicators resulted in "frustration and misapplication of the rules" (Hatherley, 1985a; Hatherley, 1985b). A prospective study of 73 women who charted CM, BBT, and urine hormones found that the CM over identified the fertile time when compared to urine hormones. The study determined CM was not sensitive to the fertile window and overextended the fertile days in LA by more than half (Kennedy et al., 1995). Thus, past studies have shown that when women in LA and the breastfeeding transition used CM it overextended the fertile time significantly and adding BBT was not helpful since a shift may not be identifiable until the third cycle postpartum (Brown et al., 1985; Tommaselli et al., 2000).

CM Methods of NFP

Single biomarker CM methods of NFP are known as ovulation methods (OM). These traditional NFP methods rely on the presence and changes in CM. Cervical mucus patterns in regular length cycles have a consistent pattern (Knight, 2017). Early in the pre-ovulatory phase of the cycle, infertile CM is white, thick, cloudy with minimal stretch. As estrogen levels increase from the growing follicle, fertile CM becomes profuse, transparent, slippery, and stretches an inch or more. After ovulation, infertile CM is present for a few more days. After a few days of

the infertile CM, there can be several days of no vaginal discharge (i.e., dry days) until the next menses. Physiologically the presence of CM is a sign of follicular growth and maturation of the egg. Changes in CM are a sign ovulation occurred and the follicle collapsed (i.e., now known as the Corpus Luteum). The Corpus Luteum produced progesterone which heated up the body a few tenths of a degree and this hormonal activity changed the consistency of the CM from fertile to infertile (Knight, 2017).

Women and couples who used CM methods during the transition feared an unintended pregnancy because CM was challenging to interpret due to patches of fertile and infertile CM that could last for several days and weeks at a time. Confusing CM patterns for several months could frustrate women. To return to a discernable regular CM pattern woman would often be told to discontinue breastfeeding prematurely or earlier than planned (Odom et al., 2013). When women discontinue breastfeeding, GnRH levels drop, FSH levels increase, and follicular development begins. This cascade of hormone events triggered ovulation followed by menses. When women returned to menses and regular cycles, CM signs occurred consistently and were more reliable than during the postpartum breastfeeding transition.

Although intermittent days, weeks and months of fertile and infertile CM was difficult for women to interpret during LA some women had a pattern of continuous fertile type of CM. This pattern of continuous fertile CM could be more challenging. It occurs when the ovarian follicle is immature but active for several months before ovulation occurs (Bouchard et al., 2018; Brown, 2011). An active immature follicle can stimulate fertile looking CM for months during LA. A study by Kennedy et al. (1995) found CM to be sensitive, but not specific, for identifying the fertile time during LA. The authors compared CM signs to urine hormones in breastfeeding women and found that greater than three-fourths of the cycle was fertile with CM, while less than half of the same cycle was fertile according to urine hormones. Kennedy et al. (1995)

concluded that CM significantly extended the days of fertility during LA. However, other vaginal fluids can also appear fertile.

Other non-cervical fluids that look like fertile CM are arousal and seminal fluid (Knight, 2017). Arousal fluid originates in the Bartholin glands located at either side of the vaginal opening. These glands produce lubricative fluid that can look like fertile CM. Seminal fluid occurs after intercourse can last for a few days and looks like fertile CM. For women who want to use traditional NFP methods during LA intermittent fertile and infertile CM, continuous CM, arousal fluid, and seminal fluid can create months of confusion and anxiety. Vaginal fluids and CM are subjective biomarkers of fertility that rely on women's ability to manage these signs and discern if they are fertile or not. When women have difficulty discerning cervical fluids, they may turn to an NFP teacher versed in helping couples manage this time. Teachers often find these couples come confused and frustrated (Fehring, 2002; Knight, 2017). Adding objective biomarkers to confirm ovulation can reduce the confusion and anxiety.

Dissociation Between CM and Urine Hormones

A recent study by Bouchard et al. (2018) re-analyzed 26 breastfeeding women cases. The purpose of the study was to compare CM signs to urine hormone biomarkers and identify patterns of return to fertility. A comparison between the urinary hormones (total estrogen [TE] and progesterone [PDG]) to CM found that 65% of the time, there was no correlation between the two. The lack of correlation was explained by three different hormonal transition patterns observed during LA. The first hormonal pattern showed 11 women who had no ovarian activity until they began supplementing the infant. The second hormonal pattern showed that 4 women had signs of follicular growth with elevated estrogen levels for months before ovulation occurred. The third pattern showed 11 women had early ovulation despite the fact; they were fully breastfeeding. The average time to first menses and ovulation was similar among the three

different return to fertility transition patterns. The range of first menses for the three patterns

was 6.5-7.5 months and to first ovulation was 7.9-9 months. No significant clinical differences

were found in the length of LA or time to first ovulation (Bouchard et al., 2018). Thus, the

different ovulation patterns during the breastfeeding transition did not correlate with CM and

explained why CM was not a useful biomarker of fertility.

Conventional Method of NFP

In the year 2000 a home hormone fertility monitoring device called the ClearPlan Easy[TM]

Fertility Monitor (CPFM) entered the market for women and couples to use to achieve a

pregnancy . The CPFM required women test their first morning urine (FMU) with a test strip for

10 or 20 days each cycle. The monitor was designed to detect estrogen (E3G) and LH in urine.

The monitor had a built-in algorithm which informed women when they should begin testing

each cycle (Unipath, 2001). In 2015 a new Touchscreen ClearBlue Fertility Monitor (CBFM) with

the same built-in algorithm was introduced (Procter & Gamble, 2021). These devices have been

included in the MM of NFP since 2005. The MM is the only researched conventional NFP

method available at this time.

The Marquette Method of NFP

The MM of NFP is a high-tech hormonal and calendar based NFP method (Fehring,

2005). Women who used the MM learned to observe and record CM, urine hormones, vaginal

bleeding, and intercourse events in a standardized fertility charting system. The MM NFP

system has women test urine hormones using the CBFM (henceforth the "monitor"). The

monitor was used with the MM NFP fertility charting system to test for the pre-ovulatory urine

hormones, estrogen, and LH (as seen in Figure 1). It is marketed for women in regular length

cycles, 21-42 days long who want to achieve a pregnancy (Procter & Gamble, 2021).

The MM NFP system has women use the monitor to identify the day when ovulation is most likely to occur. This day is also referred to as the peak day (PD). A statistical algorithm is used in the MM NFP system that depends on accurate identification of the PD. Using the PD indicated by the CBFM, women can identify the fertile time or the fertile window. The fertile window includes the day of ovulation and the 5 days before (Wilcox et al., 2000). For women in regular cycles using the MM online charting system, the "fertile window" was bracketed to clearly show the fertile time. The algorithm used for the fertile window was dependent on the PD. However, because knowing exactly when ovulation occurred was impossible without viewing the ovary through trans-vaginal ultrasound, the peak day is considered the estimated day of ovulation (EDO) (Scarpa et al., 2007). Women in regular cycles who used the MM of NFP learned that the EDO or the peak day is a point of reference for establishing the fertile window. The effectiveness of the MM NFP fertility algorithm depends on the accuracy of the biological sign of fertility used to identify the peak day.

Figure 1

Marquette Method NFP Chart
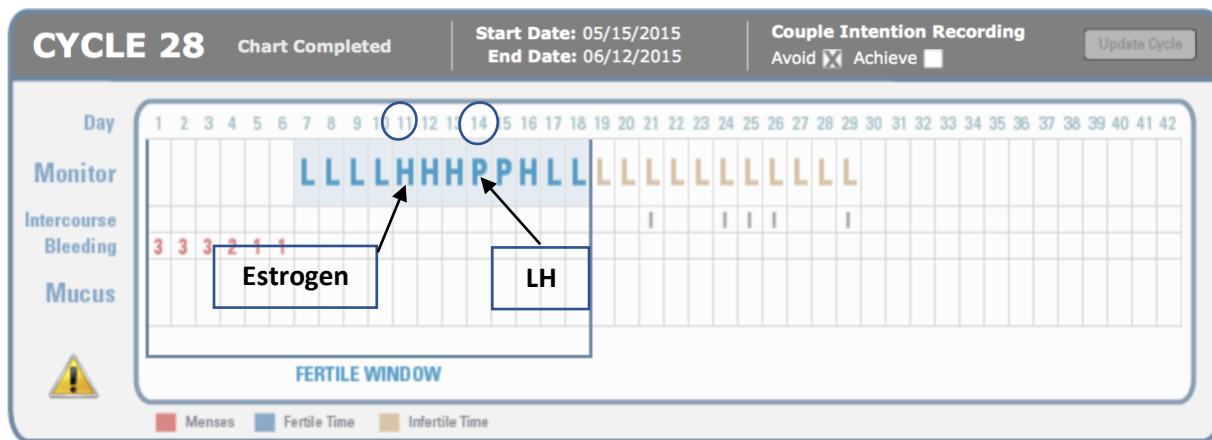
Note. This figure is a sample of the Marquette Method of NFP fertility chart found in the archived website. The figure shows a woman with a 29-day menstrual cycle. The first high or day estrogen levels are detected by the CBFM is cycle day 11 and the day the CBFM detected the LH is cycle day 14.

The Marquette Method Breastfeeding Protocols

Fehring (2005) and others developed a postpartum breastfeeding protocol for women using the CBFM and CM during lactation amenorrhea (LA). In the first study Fehring (2005) compared CM and urine hormones from 10 women in LA who charted their fertility. In the charts CM more than doubled the fertile time during LA when compared to urine hormone signs (Fehring et al., 2005). Use of the urine hormone biomarkers significantly reduced the fertile time during LA when compared to CM. Since the 2005 study was published, hundreds of women have used the protocol providing months, years, and many cycles of data.

A second study on the breastfeeding protocol looked at the effectiveness of the method for avoiding pregnancy in postpartum women (Bouchard et al., 2013). In this study 183 postpartum breastfeeding and 15 postpartum non-breastfeeding women's charts found

effectiveness rates for avoiding a pregnancy was 92-98% effective at 12 months of use. In the

study two correct use pregnancies occurred, one during LA and the second was in the third

menstrual cycle. A review of the pregnancies resulted in a change in the protocol. That change

had women test daily and reset the monitor every 10 day, extended the number of pre-infertile

days for the first five cycles postpartum and added an optional evening LH test (Bouchard et al.,

2013). (In Appendix A, a description of the original and revised protocol is available.) A third

study of women using the original and revised breastfeeding protocol by Fehring et al. (2017),

found a typical use pregnancy rate of 6 (*SE* = 0.02) and 16 (*SE* = 0.03) women (*n* = 380) at 6 and

12 cycles of use. Finally, a study by Mu et al. (2020) reported a pregnancy rate of 92% (n = 741).

Over the years, analysis of the protocol has looked at its effectiveness. However, these

analyses were not able to isolate the women who used the optional LH evening test. Pregnancy

rates were reported at 6 months (Fehring et al., 2011) 12 months (Bouchard et al., 2013; Mu et

al., 2020) and 6 and 12 cycles of use (Fehring et al., 2017). Reporting pregnancy rates by cycles

of use considers the possibility that women could be in LA for a year or more and more

accurately reflects typical use of the method (Fehring et al., 2017). Although analysis of the

effectiveness of a method is important, knowing the menstrual cycle parameter patterns can

help to simplify the method.

Menstrual Cycle Parameters and the Pilot Study. Descriptive analysis of the menstrual cycle parameters and first menses are necessary to understand the breastfeeding transition. Previous studies have used CM, urine hormones and transvaginal ultrasound to describe menstrual cycle parameters and characteristics over the last 50 years (Arevalo & Sinai, 2005; Bouchard, 2018; Brown, 2011; Campbell & Gray, 1993; Fehring et al., 2005; Kennedy et al., 1988; McNeilly, 2001; Short et al., 1991; Velasquez et al., 2006; Wei et al., 2007). A look at these studies showed three different hormonal fertility patterns with short luteal phases ($\leq$ 12 days) occurred (Brown, 2011; Bouchard et al., 2018; Hatherley, 1985c). Once first menses occurred the next ovulation was late in the cycle and again the luteal phase was short (Arevalo & Sinai, 2005; Bouchard, 2018; Brown, 2011; McNeilly, 2001).   As cycles progressed the time to ovulation became shorter and the luteal phase lengthened. Whereby the third cycle the women had returned to their pre-pregnancy parameters.

The previous studies had small sample sizes and tested women's urine samples in a lab. The urine was tested for total estrogen (TE) and progesterone (PDG) levels. Replacing the lab test, the CBFM was instituted to detect estrogen (E3G) and LH. Therefore, a pilot study from women who used the MM postpartum breastfeeding protocol was completed to test the monitors accuracy. In that unpublished descriptive study parameters of the breastfeeding menstrual cycle transition showed similar variability in the menstrual cycle parameters. A complete discussion of this pilot study is in Chapter 2.

Statement of the Problem

Women have been using the revised MM breastfeeding protocol found in Bouchard et al. (2013) for nearly 10 years. Since the Bouchard et al. (2013) study, two more effectiveness studies were published (Fehring & Schneider, 2017; Mu et al., 2020). However, these two

studies included all women using both the original and the revised MM breastfeeding protocol. That is, the studies included women who registered as postpartum breastfeeding to learn the protocol from the website. The website posted both protocols. Thus, to understand if the revised protocol is effective, it is necessary to evaluate charts from women who used it.

Finally, the revised protocol included an optional LH test in the evening and added instructions for the 6 cycles following the first menses. These instructions increased the complexity of the protocol and added cost.

Purposes of the Study

The purposes of this study were to describe the physiological breastfeeding transition to fertility from lactation amenorrhea (LA) through the first six cycles postpartum and to evaluate the correct and typical use effectiveness pregnancy rates of the revised protocol at 12 months and 12 cycles of use.

Aims and Research Questions

This study aimed to understand the effectiveness of avoiding pregnancy in women who used the revised breastfeeding protocol during LA (referred to as cycle zero) through the first 11 menstrual cycles after the return of fertility. The second aim was to describe the physiologic postpartum breastfeeding transition to fertility through the first 6 menstrual cycles from women who used the revised MM postpartum breastfeeding protocol.

Aim 1 - Research Questions

1. What are the mean and median times to the first high and peak day, EDO, and menses in cycle zero and the following 6 cycles?

2. What are the mean and median time from the first high to the EDO and menses in cycle

zero and the following 6 cycles?

3. What are the characteristics of first menses?

Aim 2 – Research Questions

1. What is the correct use unintended pregnancy rate at 12 months and 12 cycles of use among women who used the revised MM breastfeeding protocol?

2. What is the typical use unintended pregnancy rate at 12 months and 12 cycles of use among women who used the revised MM breastfeeding protocol?

Significance of the Study

Analysis of the typical use of the revised MM breastfeeding protocol was necessary to understanding it effectiveness and feasibility of use. The revised protocol is more complex than the original. By adding by a second LH test in the evening and changing every other day testing for 20 days to daily testing for 10 days during LA, the method significantly increased cost. Couples have indicated they prefer family planning methods that are simple, effective and natural (Severey & Robinson, 2004). Although the revised protocol is effective and natural it is becoming burdensome for the couple and this presents barriers to the methods use. Therefore, understanding the effectiveness of the revised protocol and urine hormone patterns during the postpartum breastfeeding transition are vital to simplifying the method, decreasing cost and increasing accessibility.

Assumptions of the Study

This study included the following assumptions: 1) women who registered as postpartum breastfeeding between July 1, 2015 and May 1, 2019 correctly used the revised MM protocol; 2) women who used the revised protocol used the optional evening LH test; 3) the data collected accurately represented the effectiveness of the method and, the characteristics of the

menstrual cycles charted; 4) interpretation of the data using descriptive analysis accurately

reflected the menstrual cycle parameters and characteristics, and ; 5) The web-based tools used

to collect, process and analyze the data will accurately represent the original data.

Limitations of the Study

The study has the following limitations:

1. The archived data analyzed for this study is owned and managed by the Marquette Institute

for NFP.

2. Women whose data was analyzed were self-taught since both protocols were posted on the

website for their use.

3. All of these women had access to a MM nurse expert to ask questions, however the amount

of support the user received from the MM nurse is not known.

4. Many variables outside the control of the researchers could impact women's accurate use of

the revised protocol. Some of these variables are the women's access to the monitor and sticks,

spouses support for the method, access to a computer and other technology important for using

the method.

5. There are inherent design problems with retrospective analysis and recall of data.

Delimitations of the Study

A delimitation in this study was only postpartum breastfeeding women who registered in the archived MM NFP site were evaluated. There are over 70 active MM teachers in the U.S. and Canada teaching women the revised protocol (www.marquettemethod.com). An email to these teachers could have yielded a much larger data set and increased the studies generalizability. However, focusing on women who self-taught the revised protocol and were supported by the same two MM nurses throughout the time the website was available eliminates inherent variability of instruction.

Significance to Nursing

Nurse researchers at Marquette University have used the MM system of NFP as an objective fertility tool to help women naturally plan their families and understand their fertility health for more than 20 years (Bouchard et al., 2013; Fehring et al., 2013, 2017; Fehring & Schneider, 2017; Fehring & Mu, 2014; Fehring et al., 2007, 2008; Mu et al., 2020). During this time six effectiveness studies and a randomized controlled trial study demonstrated adding the CBFM to the MM NFP system improved NFP effectiveness rates. The MM NFP system has also been an important women's health tool. The MM fertility chart helped women understand when they were fertile and when to see a healthcare provider. MM nurses and women users worked together to identify normal and abnormal menstrual cycle health issues. Through charting urine hormones, over time, symptoms such as abnormal uterine bleeding seen in the chart helped to identify conditions such as uterine fibroids, cervical cancer, and other serious reproductive health disorders (Fehring et al., 2006; Fehring & Rodriguez, 2016; Fehring & Schneider, 2008).

Nurses with advanced training in the MM and fertility health interpreted NFP charting and empowered women to understand and appreciate their fertility, not fear it. The MM nurse understood the sacredness of the sexual and reproductive health (SRH) relationship. These nurses worked with a wide range of SRH issues and learned how to communicate with women and couples about sensitive SRH concerns that involve the physical, spiritual, and moral nature of this specialty.

The American College of Obstetrics and Gynecologists (Cycle & Sign, 2015) and the American Academy of Pediatrics (Sanfilippo, 2014) have declared the menstrual cycle an important vital sign. MM nurses trained to understand menstrual cycle events recognized the uniqueness of every fertility chart, these nurses learned to identify serious health conditions revealed by the charts. Working with the women/couple the MM nurse empowered women and couples to understand normal and abnormal menstrual cycle charting and use it to manage their health.   With advanced training and an understanding of their scope of practice the MM nurse 1) integrates knowledge of normal menstrual cycle events into their practice 2) helps couples manage their fertility with more confidence 3) empowers women and couples to advocate for healthier family planning choices and 4) understands when changes in menstrual cycle events indicate the need to refer women to other healthcare providers.

Conclusion

 Low effectiveness rates for CM methods in postpartum breastfeeding women over the last 50 years are related to the dissociation found between CM and urine hormones biomarkers (Bouchard et al., 2018; Kennedy et al.,1995). BBT signs were not discernable during LA and required a rigorous daily routine (Barron & Fehring, 2005; Hatherley, 1985). The LAM did not require the same rigorous daily routine; however, inconsistent translation of protocol criteria

created confusion for the user and healthcare provider. This made it difficult for women to use it correctly (Fabic & Choi, 2013; Van der Wijden et al., 2008; Van der Wijden & Manion, 2015).

The LAM is very effective for the first six months, however after this time the postpartum women who wanted to continue using an NFP method and breastfeed had few options. The options were, 1) to use a less effective method of NFP, 2) abstain until regular cycles returned, or 3) use the effective but expensive revised protocol. Therefore, an important first step to improve these options was to do a descriptive analysis of the menstrual cycle parameters. Having a better understanding of these parameters will improve understanding of the breastfeeding transition's physiology to simplify the method.

A discussion about the physiologic underpinnings of breastfeeding and fertility in this chapter provided a beginning framework for understanding key factors for defining the menstrual cycle parameters.   Physiologic patterns of the menstrual cycle events are ordered and consistent; however, the patterns are less predictable during breastfeeding (Brown, 2011; Bouchard et al., 2018; McNeilly, 2001). Documentation of the urine biomarker LH as a PD in the MM charts can help identify patterns in menstrual cycle parameter variability. With more than two-thirds of postpartum breastfeeding women ovulating before their first menses urine hormone biomarkers documented in the MM fertility charting system can be used to identify return to fertility patterns (Arevalo & Sinai, 2005; Campbell & Gray, 1993). These patterns are important for helping MM teachers confidently guide couples through the postpartum breastfeeding transition successfully. Although descriptive analysis is a basic form of research, the lack of research in this area warrants a first-level descriptive analysis of the menstrual cycle parameters during LA and the following 6 cycles.

Chapter 2 provides a comprehensive review of related literature, including results from a descriptive analysis of data used in a pilot study. In chapter 2 a discussion of the conceptual,

theoretical, empirical framework, and philosophical underpinnings that supported this study

and its methodology are provided.

Chapter 2: Review of the Literature

This chapter includes a chronologic comprehensive literature review on the relationship between breastfeeding and fertility. A historical and physiologic description of this topic gives a foundation for the natural connection between breastfeeding, fertility and birth spacing. A critical analysis of modern technology research used to understand the physiologic fertility biomarkers in breastfeeding women going through the postpartum transition is presented.

Scientists have understood that breastfeeding spaces childbirth naturally and have studied the effect of breastfeeding on fertility using biomarkers since the early 20th century. The progression of modern science, natural family planning (NFP) methods, and technology related to postpartum/breastfeeding women and the transition to fertility are described using a chronological framework. Data was collected using *the Cumulative Index to Nursing and Allied Health Literature* (CINAHL), PubMed, MEDLINE, Web of Science, and the Cochrane Library. MeSH terms used were lactation, lactat*, amenorrhea, postpartum, fertility, breastfeeding, natural family planning, and hormones. Subheadings used were: estrone-3-glucuronide, pregnanediol, and luteinizing hormone. Reference lists from articles that met the inclusion criteria provided added resources.

Inclusion criteria for the review were studies of postpartum women in lactation amenorrhea (LA) that were followed through to their return to fertility, biomarkers of fertility used to find the estimated day of ovulation (EDO), the use and effectiveness of those biomarkers for avoiding pregnancy and the effect of breastfeeding on fertility and pregnancy. A summary of the literature review is in Appendix B. This review used studies in English from the time of 1900-2020. Table 1 lists studies that met the review criteria. The fertility awareness-based method (FABM) studies in Table 1.; will not be discussed in chapter 2 since the studies were described in detail in chapter 1.

Table 1

Breastfeeding and NFP effectiveness/transition studies – Literature review

Authors	Title	Year	Design	Sample Size (N)	Biomarker	Results
Brown, Harrison and Smith	A study of returning fertility after childbirth and during lactation by measurement of urinary oestrogen and pregnanediol excretion and cervical mucus production	1985	Prospective cohort study, convenience samples of breastfeeding women were charting STM 7.8 months charting/woman	55	Urinary – Estrogen (TE) and pregnandiol (PdG) Cervical mucus BBT and vaginal bleeding	CM – correlated with hormones 60% of the time. 22:55 pregnancies 14:55 unintended.
Hatherley(a)	Late infertile days in early postpartum cycles	1985	Prospective six-year study to identify the use effectiveness of CM and	N = 259 n = 195 BF n = 43 not BF	Urinary – TE and PdG (assays done with Brown, J.) BBT, CM	BF woman 6 with >16-day luteal phase; 2 with pos. UCG (women didn't know

BBT in the first three cycles postpartum.	n = 21 post-abortion	Sample chart has no acts of I recorded. First 24hr urine done (and continued weekly): BF – 6 weeks Not BF – 4 weeks Post-abortion – 1wk.	they were pregnant and were not included in final count. Total pregnancies: Cycle 1 = 2:190 Cycle 2 = 11:154 Cycle 3 5:103 BBT pregnancies = 12 EDO identified using BBT shift or peak day (CM). 74%, 78% and 75% of cycles had a biphasic shift at 1,2 and 3 cycles. Peak type CM present in luteal phase, BF woman: Cycle 1 – 26:190 (13.68%) Cycle 2 – 18:154 (11.68%) Cycle 3 – 5:103 (4.85%)

Hatherley(b)	Lactation and postpartum infertility: the use-effectiveness of natural family planning (NFP) after term pregnancy	1985	Prospective six-year cohort study of breastfeeding women through 12 months postpartum to identify use effectiveness of CM and BBT.	N = 251 n = 208 BF n = 43 not BF	BBT, CM and vaginal bleeding Serum – Prolactin LH and FSH	34 of 208 Unplanned pregnancy Pregnancies occurred at 9 and 12 months. First ovulation in Full BF = 43 days
Hatherley(c)	Natural family planning for women with previously irregular menstrual cycles.	1985	Prospective six-year study to assess menstrual cycle parameters in BF women with a history of irregular cycles. Irregular cycles – validated through their NFP charts.	N = 226 BF n = 205 BF. n = 21 not BF.	Urinary – TE and PdG (assays done with Brown, J.) BBT, CM	EDO defined as a shift in BBT or peak day of CM. 7:8 pregnancies from BF Patterns of oestrogen PPA: 1. Low level – steady (69%) 2. Erratic levels (31%) BF only (28%) Pregnanediol – stable Women with history of long cycles were more likely to have

						erratic oestrogen patterns PPA.
Labbok, Stallings, Shah, Perez, Klaus, Jacobson & Muruthi	Ovulation method use during breastfeeding: Is there increased risk of unplanned pregnancy?	1991	A retrospective analysis of two prospective studies: 1. Nyahururu, Kenya 2. Santiago, Chile Looked specifically at the BF transition period through 12 mo. Life table analysis.	N = 521 (Kenya) N=110 (Chile)	CM and vaginal bleeding	Pregnancies Nyahururu, 22:100 Santiago,13:110 Women adhered OM rules more than to LAM.
Zinaman and Stevenson	Efficacy of the symptothermal method of natural family planning in lactating women after the return of menses	1991	Prospective pilot study that looked at the first three cycles post-menses. Length 9-17 months, average 13 months. (No mention of when women entered study or what data showed during LA.)	25	CM, BBT and vaginal bleeding Urinary – E3G, LH and PdG	BBT rose P+5 in first cycle 23:25 cases. Luteal phases are short <10 days before 6 months pp and >10 6 plus months pp.

Sottong, U., Bremme, M & Fruendl, G.	Lactational amenorrhea and lactational anovulation in 109 breastfeeding women (abstract)	1992	Prospective longitudinal observation study.	109	CM, BBT and vaginal bleeding. Ovulation defined as the last day before the first high temperature correlated with CM	12 women ovulated while fully breastfeeding. 3:12 has a normal luteal phase. 35 (32.1%) had a menses by 6 months PP. 31 (28.4%) had ovulated by 6 months PP. 51.4% women ovulated before the first menses.
Kennedy, Gross, Parenteau-Carreau, Flynn, Brown and Visness	Breastfeeding and the symptothermal method	1995	Prospective cohort study to detect the fertile time using the STM during breastfeeding range 39-42 weeks. LAM principles were applied. Survival analysis, t-test and Chi-square (detailed peak mucus description)	73	CM, BBT, vaginal bleeding. Daily urinary estrogen and pregnandiol. PdG > 9umoles/24 hours=ovulation.	3 site – Montreal Birmingham Sydney 2 preg./site = 6 preg. All in first 3 cycles after first menses. High no. fertile days - STM not specific but sensitive to identifying ovulation.

			Entered into study – 42 days postpartum.			Women in study 36-42 weeks postpartum.
Tommaselli, Guida, Palomba, Barbato, Nappi	Using complete breastfeeding and Spacing Methods	2000	Prospective cohort study N=40 breastfeeding women	40	CM, BBT, salivary ferning, Transvaginal US Vaginal bleeding	20% had menses before weaning. 20% BBT shift was inadequate. Salivary ferning -60% no evidence of ovulation.
Howard & Stanford	Pregnancy probabilities during use of the Creighton Model Fertility Care System	2010	Prospective cohort study to assess the effectiveness of the CrM, BF women were a subgroup (total and partial bf) n=701.	Cumulative months of use =821.5	CM	23:100 8:100 Pregnancies (net) 821.5 months of use.
Bouchard, Fehring & Schneider	Efficacy of a new postpartum transition protocol for avoiding pregnancy	2013	Prospective 12 months cohort study. N = 198 women whose charts could be evaluated	198	Urinary estrogen and LH (CBFM)	At 12 months 0:100 correct use. Method related 2:100 1 PPA at 9mos. 1 – 3rd cycle PP.
Fehring Schneider & Bouchard	Effectiveness of an online natural family	2017	Prospective longitudinal cohort study that looked at 12 cycles of use.	N =816 EHFM =380	Urinary estrogen and LH (CBFM) and MM breastfeeding protocol's	Correct use pregnancies = 7 Total pregnancy = 62

| | planning program for breastfeeding women | | Cycle 0 (LA) = counted as one cycle. Can be few to several months long. | EHFM & CM =391 CM = 45 | (Cycle 0 and first 6 cycles) | 36 in the first cycle. 13 intended pregnancies. 6 during PPA. 3:100 correct use at 12 cycles in both groups. Typical use: 6 and 12 cycles of use: EHFM 6 and 16 CM 23 and 81 EHFM and CM 6 and 12 |

FABM

Authors	Title	Year	Design		Biomarker	Results
Arevalo, Jennings & Sinai	Application of simple fertility awareness-based method of family planning to breastfeeding women	2003	Retrospective review of FHI data set from 1986-1990.To determine theoretical effectiveness of the SDM and TDM in cycle 0 and the first few cycles.	73	CM, urinary estrogen and progesterone.	In cycles of BF women >6 months PP 80% of the time has CM and is fertile. TDM is not effective during cycle 0. SDM can be applied after the 3-4th cycle

					postpartum. When cycles become regular.
Sinai & Cachan	A bridge for postpartum women in Standard Days Method I. Developing the bridge	2012	Applied the same data set that Arevalo et al. (2003) used to develop a bridge method to the SDM for BF women in cycles. N = 73	73	CM, urinary estrogen and progesterone	After LAM if woman is still BF, she is considered fertile until CD1 - CD10 of the first cycle and again fertile CD11 to next menses.
Sinai & Cachan	A bridge for postpartum women in Standard Days Method II. Developing the bridge	2012	Prospective non-randomized multi-center efficacy study to test the bridge to SDM N = 157 in cycle 1 N=134 in cycle 2 441 cycles analyzed, women from Guatemala and Peru.	73	The bridge protocol was applied. After woman not eligible for LAM she is fertile until cycle 1; CD1-CD10 are in fertile, CD11 to end of cycle is fertile. Then CD8-24 are fertile until 3 cycles are 26-32 days long than SDM could be applied.	Typical use: 11.2 for 6 months. 17 pregnancies: Cycle1 =7 pregnant. Cycle 2 =10 pregnant

Note. Natural Family Planning (NFP) and Fertility Awareness Based Methods (FABM) are not the same. FABM instructions provide the user with information about when barriers can be used during the fertile time, NFP method instructions discourage use of barrier methods or other types of contraception that interfere with the procreative act.

Breastfeeding and Fertility: A Lost Art

Historically, women have been using breastfeeding to space their children since biblical times. In the passage II Maccabees 7:27. a Jewish mother tells her youngest son before his execution that she carried him for 9 months and nursed him for 3 years. This passage described a cultural pattern of breastfeeding (Ellison, 2001). In 1492 Leonardo Da Vinci's drawing titled "I display to men the origin of the second – first or perhaps the second cause of their existence." Da Vinci showed an understanding of what has been called the "milk vein"(Ellison, 2001). The milk vein represented the passage of menstrual blood (i.e., it was considered a vital fluid for life) redirected to the breasts in the form of breast milk. Breastmilk was revered as the life-sustaining fluid for the infant (O'Neill et al., 1983). The vein was drawn from the uterus to the breasts to show the connection between breastfeeding and fertility (Ellison, 2001).

In the 1930s, German folklore and medical textbooks affirmed that women could not get pregnant while breastfeeding (Friedman, 1982). The French demographer Louis Henry considered breastfeeding a way to space children and called this "natural fertility" (Friedman, 1982). Henry used the term natural to show that breastfeeding was a physiologic and socially determined method of family planning (Henry, 1961). Nevertheless, by the late 1900s, breastfeeding was replaced by the bottle and hand-feeding the infant. With advances in modernity, bottles gave women the freedom to leave the infant and work; bottles also allowed other family members to feed the infant (Wolf, 2001, 2018). For women in the industrial nations, by the 1950s, breastfeeding used to naturally space children was being replaced by artificial milk and hormonal contraception (Short et al., 1991; Wolf, 2001).

By the 20th century women expected to receive anesthesia and opioids to relieve the discomfort of labor and birth, formula to replace breastmilk and hormonal contraception to prevent pregnancy (Leavitt, 1983; Short, 1984; Wolf, 2001). Thus, medical professionals, did not know what to do with breastfeeding women (Short et al., 1984). For women who breastfed, once the baby was born there

was no need to continue with the obstetrician because the breast was not considered part of the

reproductive system. Pediatricians were involved only when the infant was sick and family practice

doctors did not trust breastfeeding to space children. The only group of physicians that dealt with breast

physiology were the surgeons who treated women with breast cancer. Therefore, very few women in

the US and industrial nations breastfed. Those who did clung to folklore and traditions of cultural

breastfeeding.

Medicines Renewed Interest in Breastfeeding and Fertility

In 1988 a group of international breastfeeding scientists gathered in Bellagio, Italy, to review

studies on the effect breastfeeding had on birth spacing as a means of natural birth control (Kennedy et

al., 1988; Labbok, 2012). The meeting known as the Bellagio Consensus was a gathering of physicians

and researchers from England, the United States, Australia, Scotland, Thailand, Canada, Egypt, Italy, and

Chile. At the meeting, a review of 13 prospective population studies resulted in the lactational

amenorrhea method (LAM). Development of the LAM came from 3 prospective studies that considered

the probability of pregnancy and 10 that considered the probability of ovulation. Researchers at the

meeting determined that if a woman was amenorrhoeic, fully breastfeeding, and less than six months

postpartum, the chance of pregnancy was 2% or less. These scientists agreed the method would require

field testing to confirm their hypotheses (Gross, 1999; Kennedy et al., 1988; Labbok, 2012).

In 1995 scientists reconvened for the second Bellagio Conference. At the 1995 meeting studies

from 1988-1995 were reviewed (Finger, 1996). The review included clinical and population-based

studies from family planning clinics worldwide. Large population studies applied the three criteria of the

LAM to data from breastfeeding women, while other studies provided extensive support for women

using the method to be successful. These studies were analyzed and discussed by the researchers at this

meeting (Finger, 1996).   After reviewing the new studies on the clinical effectiveness of the LAM,

researchers concluded that it was indeed a highly effective temporary NFP method. The final report

from this meeting concluded the theoretical effectiveness of the LAM translated to a highly effective clinical method that was "scientifically validated by 24 experts" and "should receive program and policy support necessary to become available worldwide" (Finger, 1996, p.5).   The LAM was developed over time first as a theoretical model and second as an applied field-tested model. The LAM's application studies included observing return to fertility patterns in large populations of breastfeeding women worldwide.

Theoretical Effectiveness of the LAM

The first meeting in Bellagio, Italy, was reported in a document commonly referred to as the "Consensus Statement." This document reviewed the results of 13 studies and provided background and rationale describing the development of the LAM (Kennedy et al., 1988). Three of the 13 studies reported were published a few years after the meeting. A table in the report divided women into two groups labeled "any" and "fully" breastfeeding. The first group included three studies that assessed the probability of pregnancy, the second group of ten studies assessed the probability of ovulation. In the first group, the number of women observed was not reported in two studies, in the third study 101 fully breastfeeding women were observed.   The cumulative probability of pregnancy for the three studies was less than 2%.

The second group of 10 studies in the Consensus Statement report considered the probability of pregnancy during LA (Kennedy et al., 1988). In that group five of the ten studies did not report the number of fully breastfeeding women. In the five studies where the sample sizes were reported there was a mean total of 49.6 (*SD* = 37.5; range 26 -113) fully breastfeeding women in the samples. Sample sizes for three studies were: 26, 26 and 28. Conclusion from the review of the second group of studies was that the probability of pregnancy ranged from 0-2.9%. To determine the probability of pregnancy scientists considered the pregnancy rates for non-lactating women on the most fertile day of the cycle to be 25%. Therefore, since the probability was lower among non-ovulatory postpartum breastfeeding

women the researchers reduced the probability by half on the most fertile day.   When the two groups

of studies that considered the probability of ovulation and probability of pregnancy were combined the

mean number of fully breastfeeding women per study were 58.16 (*SD* = 39.57, range 26-113, n=6)

(Kennedy et al., 1988).

At the first Bellagio meeting in 1988, scientists determined the relationship between

breastfeeding, length of LA, ovulation, and length of the luteal phase were consistent themes across all

studies evaluated.   A consensus among these scientists concluded the characteristics of full

breastfeeding, LA, and the period of 6 months postpartum could be a safe, natural, and effective NFP

method. These three characteristics were developed into the algorithm known as the LAM (Finger,

1996). The LAM's theoretical effectiveness, however, came from studies with small sample sizes as

previously shown (Kennedy et al., 1988). Population based studies with large samples did not directly

study the LAM but applied the protocol's principles to the results (Von Hertzen et al., 1999; World

Health Organization Task Force on Adolescent Reproductive Health, 1986; World Health Organization

Task Force on Method for the Natural Regulation of Fertility, 1999; World Health Organization Task

Force on Method for the Natural Regulation of Fertility & World Health Organization, 1998).

Use Effectiveness of the LAM

In 1996 the United Nations Population Information Network (POPIN), supported by the United

Nations Population Fund (UNFPA), released a report that stated the effectiveness and generalizability of

the LAM had been validated by large population studies (Finger, 1996). This report, sometimes referred

to as the "Finger" report, noted that prospective studies on the LAM confirmed the method was 98%

effective for avoiding pregnancy if women were within the method's criteria. Clinical studies from three

different unrelated research organizations conducted effectiveness studies on the LAM: The World

Health Organization (WHO), Family Health International (FHI) and the Georgetown University Institute

for Reproductive Health (IRH) (Finger, 1996).

The first research institution, the WHO, reported observations of 4118 breastfeeding women. These women attended family planning clinics in China, Mexico, India, Africa, South America, Australia, and Europe. The purpose of the study was not to look at the effectiveness of the LAM, but rather to observe women's breastfeeding and return to fertility (i.e., length of LA and first menses) patterns over six months postpartum (see Appendix C). From this single study, four articles were published (Von Hertzen et al., 1999; World Health Organization Task Force on Adolescent Reproductive Health, 1986; World Health Organization Task Force on Method for the Natural Regulation of Fertility, 1999; World Health Organization Task Force on Method for the Natural Regulation of Fertility & World Health Organization, 1998). In the abstract of the third publication, the authors stated that " These results support the Bellagio Consensus on the use of lactational amenorrhea for family planning and confirm that the lactational amenorrhea method is a viable approach to postpartum contraception." (World Health Organization Task Force on Method for the Natural Regulation of Fertility, 1999, p.431). This statement is an example of how the WHO study indirectly promoted LAM.

The second research organization in the summary report, (FHI) conducted studies in Pakistan and Manila (Kazi et al., 1995; Ramos et al., 1996). The purpose of these studies was to determine pregnancy rates from women using the LAM. The sample sizes for these studies were: 399 (Pakistan) and 485 (Philippines). In both studies, women were taught the LAM and received monthly home visits from the midwife or healthcare providers who discussed the method with the women. Correct use pregnancy rates at 6 months, where 0.6% and 0.9% respectively. Months without recorded acts of intercourse were not included in the results. The studies did not provide information about how the LAM criteria were taught nor how the three criteria were interpreted by the women in the study or the researchers collecting the data (Kazi et al., 1995; Ramos et al., 1996).

The third research organization in the summary report, the IRH, studied middle-class women (n=409) in Santiago, Chile (Perez et al., 1992). This study aimed to look at the effectiveness of the LAM

as an intervention in a breastfeeding support program. Women learned the method using the three

criteria for LAM in the first visit. They then were visited monthly and reminded of the three criteria for

up to 6 months. A total pregnancy rate over the 6 months was reported at 0.45% or one out of 409

women. One woman did get pregnant using the LAM algorithm, she was reported to be fully

breastfeeding, and in LA (Perez et al., 1992).

In conclusion, the two IRH and FHI studies discussed in the POPIN report provided monthly

support to LAM users. The two IRH and FHI studies also relied on the women in family planning clinics

to recall the dates when the first menses occurred, and when a change in breastfeeding happened. The

large WHO study did not assess the effectiveness of LAM; however, the three LAM criteria were

retrospectively applied to the results (World Health Organization Task Force on Method for the Natural

Regulation of Fertility, 1999). Therefore, since studies in the summary report (Finger, 1996) stated

women received monthly support for the LAM, the method's effectiveness cannot be applied beyond

family planning clinics.

Therefore, it is not reasonable to apply the LAM's effectiveness to all women as a reliable method of

family planning. The POPIN report stated, the LAM should be promoted in family planning clinics where

women received support from LAM educators. Pregnancy rates reported in the studies found in the

Finger (1996) were reported as effectiveness rates. However, when a study is designed to assess a

family planning method, like the LAM, pregnancy rates should be reported as efficacy rates to reflect the

women agreed to be part of the study (Trussell, 2011).

The terms effective and efficacy are often used interchangeably when pregnancy rates are

reported (Trussell, 2011). Pregnancy rates reported as effective reflect everyday use of a family

planning method, while pregnancy rates reported in a study are efficacy rates. Efficacy rates can be

biased within a study. Understanding the difference between effectiveness and efficacy rates is a good

guide for knowing how to interpret and apply family planning results (Trussell, 2011).

Few structured clinical trials have evaluated the efficacy of an NFP method during postpartum breastfeeding. NFP efficacy studies, according to Lamprecht & Trussell (1997) lack rigor due to how pregnancy rates were calculated and reported. Trussell (2011) suggested to improve reporting of pregnancy rates NFP studies should be broken down into four categories. These 4 categories will help couples and healthcare providers appreciate how pregnancy rates were determined. These categories are "typical use, perfect use, imperfect use, and percent of perfect use" (Trussell, 2011). Typical use is also use effectiveness of the method and is important to understand how hard it is for the couple to use. Perfect use can be considered the theoretical effectiveness of the method and shows how effective it is when the couple used it perfectly, and there were no errors in how it was taught or applied. Imperfect use is a term to identify when a method is not used correctly. Percent of perfect use shows how hard the method is to use and is reported over six or twelve months of use. It is the difference between the theoretical use of the method and the actual use of the method. The term "effectiveness" identifies how many pregnancies occurred in normal living conditions. The difference between perfect or correct use and imperfect or typical use provides an index for understanding how difficult a family planning method was for a couple to use. Typical use effectiveness rates for women who used the LAM are 26% (Fabic and Choi, 2013). That is, 26 out of 100 women use it correctly and out of those 26 women two will get pregnant.

In a secondary analysis of demographic health survey (DHS) results used to assess the effectiveness of the LAM, Fabic and Choi (2013) determined that use effectiveness of the method was low because key terminology used in the algorithm was inconsistent and subjective. The assessment of LAM users in the study were broken down into three different groups. The authors stated it was not possible to describe breastfeeding patterns because of this. However, since all surveys described when supplemental foods were added this could be used to assess use effectiveness of the LAM. The terminology used in the DHS that described breastfeeding patterns in the review were inconsistent or

nonexistent. This discovery was important to understanding if the women who used the LAM differed

within and among various groups of women. The purpose of the retrospective review of the DHS were

to begin looking at how the LAM could be promoted into international family planning clinics. The

findings of inconsistent terminology limited this project (Fabic & Choi, 2013).

  The inconsistency in how breastfeeding patterns were defined in each survey made it impossible

for the researchers to categorize breastfeeding frequency. As a result, the authors stated a compromise

was made by categorizing breastfeeding frequency by when nutritional supplements were introduced.

The United States Agency for International Development (USAID) conducted these surveys from 1998

through 2011 in 45 countries to assess the expansion of the program (Fabic & Choi, 2013). The purpose

of the secondary analysis of the survey data was to determine the feasibility of increasing LAM services

within family planning clinics worldwide. However, the authors of the secondary analysis concluded

expansion of the LAM in family planning services was not recommended. Due to inconsistent definitions

of breastfeeding frequency used to determine LAM effectiveness. They stated inconsistency in how the

surveys were conducted across sites resulted in "false beliefs" of the methods use effectiveness, and this

affected the validity of the conflated results (Fabic & Choi, 2013). Conflation of DHS results and

heterogeneity of key variables were not just common to this review, both problems were also found in a

systematic review of effectiveness studies on the LAM (Van der Wijden et al., 2008; Van der Wijden &

Manion, 2015).

  Authors of two systematic reviews on the effectiveness of the LAM in the Cochrane Database

system found heterogeneity of terminology in LAM studies significantly affected the ability to do a meta-

analysis. Criteria for the review included prospective controlled studies with endpoints of menses and

pregnancy.   The reviews found no difference in effectiveness to avoid a pregnancy between women

who used the LAM and those who were fully breastfeeding.   (Van der Wijden et al., 2008; Van der

Wijden & Manion, 2015). Claims that the LAM is highly effective has caused millions of women to

wonder why they are an anomaly, because the method did not work for them. Review of the LAM

studies showed a continuing need for robust and objective NFP methods for breastfeeding women.

Modern NFP Methods a Call to Scientists

Modern technology and fertility apps have created a renewed interest in NFP among young

women today (Duane et al., 2016; Starling et al., 2018). In an online pilot study, 1000 women recruited

through Facebook completed a survey that asked what features were important to them in a fertility

app? Over half of the women stated features most important to them in choosing a fertility app were,

the app should have scientific validity, be research-based and maintain privacy (Starling et al., 2018).

In a systematic review, Duane et al. (2016) found over 100 fertility apps available on the web,

Android, and iPhone. The study aimed to identify and rank the apps according to the ability to

accurately identify the most fertile days. The systematic review of fertility apps found that women

commonly tracked their fertility using CM, BBT, and calendar rhythm methods. In the review Duane et

al. (2016) found 1 app that recorded urine hormones and 6 apps that accurately identified the fertile

window. The authors concluded that most fertility apps were not designed to avoid pregnancy and

were not supported by research. A proliferation of fertility apps over the years has resulted in an

increase interest of NFP methods. The increase in young women's interest of NFP prompted a meeting

with NFP scientists in Washington, D.C. The meeting discussed the state of the science of NFP methods

(Manhart & Fehring, 2018).

The purpose of the state of the science meeting was to identify gaps in evidence based NFP

research and prioritize the gaps for future studies. Topics of primary interest included quality of past

studies, use of new technology, and special populations of women that have not been well represented

in the studies over the last 50 years. Before the meeting it was determined that there were minimal

NFP studies in the literature on the postpartum breastfeeding transition, perimenopause, post hormonal

and endocrine disorders like polycystic ovarian syndrome (PCOS), endometriosis and frequent

miscarriages. Researchers with a special interest in each of these areas presented. The group concluded

five areas for future research were: 1) well-designed effectiveness studies 2) validation of studies that

can be used to identify and manage women's reproductive health issues 3) ongoing evaluation of

fertility tracking apps 4) ongoing research of technologies used to identify the fertile window and 5)

development of a data set portal for collecting and evaluating NFP data (Manhart & Fehring, 2018).

In a comprehensive systematic review of prospective NFP effectiveness studies Peragallo Urrutia

et al. (2018), showed that most studies were of poor quality and lacked rigor. The authors of this review

confirmed that NFP studies did not meet rigorous research standards and were biased. Interestingly,

the authors also stated that CM studies might have artificially inflated effectiveness rates because of the

self-selection of pregnancy effectiveness data. The authors also found that most NFP studies were from

women in regular length menstrual cycles (one perimenopause). Studies in this review were rated as low

or moderate quality; no study received a high rating (Peragallo Urrutia et al., 2018). Thus, with the

results from the meeting in Washington D.C. to examine the state of the science, the systematic reviews

of NFP effectiveness studies, and the increase interest in fertility tracking apps the state of the science of

NFP research showed there is a need to improve the quality of NFP research and effectiveness studies.

Traditional NFP Methods and Breastfeeding

Endometrial biopsy, changes in breastmilk properties, basal body temperature (BBT), cervical

mucus (CM) and 24-hour urine collections have all been used to identify ovulation; however, in the past,

these methods were found to be unreliable, tedious and even dangerous to women. Endometrial

biopsy, used in the mid-1900s to identify ovulation had occurred, was a risky procedure that could cause

an early pregnancy loss (Perez et al., 1972). In the 1970's changes in the composition of breastmilk were

found when women ovulated (Hartmann & Prosser, 1982). In this study, Hartman and Prosser (1982)

found that human breast milk had an increase in sodium and chloride and a decrease in lactose and

potassium after ovulation. The authors concluded that mammary gland permeability might have been

affected by the follicle's maturation process.

Basal body temperature (BBT) and CM are not reliable nor practical during the breastfeeding

transition. Compared to urine hormones, CM can unnecessarily extend abstinence during LA and the

first few cycles postpartum (Brown et al., 1985; Fehring, 2005; Hatherley, 1985a, 1985b; Kennedy et al.,

1995). Urine metabolites from the hormone's estrogen, LH, and progesterone have been used in NFP

research since the mid-20th century (Brown, 2011). Brown (2011) provided a lifetime of work to show

the benefits of adding urine hormone to NFP methods.   Many comparison studies between CM and

urine hormone from postpartum breastfeeding women in the transition done in the 1900's sent

specimens to Brown's lab (Hatherley, 1985a, 1985b; Kennedy et al., 1991, 1995). Because NFP urine

hormone studies relied on Brown's lab this slowed progress of NFP research until the 21st century when

the Clear Blue Fertility Monitor (CBFM) hit the market. The CBFM is an electronic device that used test

strips and is for home use. This type of testing is called point of care (POC) testing. The CBFM is

marketed for women in regular length cycles (Procter & Gamble, 2021).

For women in regular length cycles, urine hormones are more reliable and objective then CM

and BBT. But these signs do not correlate during postpartum/breastfeeding. The following review of

NFP studies that compared BBT, CM and urine hormones provides an in-depth look at problems with

each biological marker. Analysis of the gaps in previous NFP research has been used to support this

studies design.

BBT a Post-ovulatory Sign of Ovulation

The BBT method of NFP requires that women take their temperature the same way and at the

same time daily (i.e., usually immediately after waking). Variances in the route or routine can affect the

results. Routes recommended for checking BBT are oral, rectal, and vaginal. The oral route is preferred;

however, if the BBT is too variable, it can be stabilized through the vaginal or rectal route (Barron &

Fehring, 2005). The use of the vaginal or rectal route could put women at risk for vaginal infections if the thermometer were not cleaned. Therefore, the oral route is preferred.

The shift in BBT is a post-ovulatory sign of fertility and is called the biphasic shift (Barron & Fehring, 2005; Knight, 2017). A shift in temperature at least 0.1-0.2 degrees Centigrade or Fahrenheit above the previous 6 temperatures for three or more days indicates that ovulation occurred (Heffner & Schust, 2014). A rise in temperature after ovulation is due to progesterone. When BBT is above the woman's baseline for ten or more days this is an indication that if pregnancy occurred, it would be maintained by sufficient levels of progesterone (Brown, 2011; Heffner & Schust, 2014). If a pregnancy did not take place than progesterone levels drop, and menses occurs. BBT is used to confirm ovulation and is used as a clinical post-ovulatory sign (Heffner & Schust, 2014).

For postpartum breastfeeding women in LA who want to avoid pregnancy, BBT NFP methods are not practical since ovulation may not happen for several months to years (Brown et al., 1985; McNeilly, 2001). Since breastfeeding prolongs ovulation, women who use BBT as an NFP method can expect long periods of abstinence until a biphasic shift occurs and changes in sleep-wake patterns that can cause the BBT to fluctuate almost daily, making interpretation difficult (Knight, 2017). A review by Barron and Fehring (2005) that looked at the biphasic shift's accuracy as a sign of ovulation found BBT shifts were not good indicators of ovulation. However, since there are studies where postpartum breastfeeding women used BBT NFP methods a guide for critiquing these studies was necessary for this literature review.

In a literature review on the effectiveness of BBT as a sign of ovulation, Barron, and Fehring (2005) provided an overview which addressed problems inherent in the use of the biphasic BBT shift as an accurate sign of ovulation when compared to transvaginal ultrasound and LH urine testing. The purpose of the article was to be a guide for Advanced Practice Nurses (APN's) who recommend BBT to patients for identifying ovulation. Factors identified as important for interpreting BBT were the 1) route

used and was it consistent, 2) the routine and, the 3) rule used to determine the BBT shift. These three

factors (i.e., route, routine, and rule) were used to guide the review of past NFP studies in postpartum

breastfeeding women that used BBT to identify ovulation. Table 2 provides a list of the 6 postpartum

breastfeeding transition studies reviewed.

When women learn about BBT instructions they are told success requires a commitment to daily

rigorous routine (Knight, 2017). The routine includes taking their temperature at the same time every

day, having a consistent sleep wake pattern and being aware that other lifestyle decisions such as having

a glass of wine the night before can change waking temperatures. They learn different rules for

interpreting these aberrations but often these rules increase confusion. To avoid confusion best

practices are BBT should be taken at the same time daily, before getting out of bed, eating, or drinking

(Knight, 2017). In research studies these same practices should be applied and are considered in this

literature review.

In a review of 6 articles that assessed the effectiveness of BBT in postpartum breastfeeding

women 2 of 6 studies provided this information. In Table 2, Hatherley et al. (1985a) reported that

women took their BBT before getting out of bed, taking any fluid or foods. Tommaselli et al. (2000)

requested that women take their temperature after sleeping a minimum of two hours. The other four

studies did not discuss routine.

Zinaman and Stevenson (1991) studied breastfeeding women (*n* = 25) who used urine LH and

BBT signs in the first three cycles, postpartum. The study's purpose was to compare efficacy between

women who used the Symptothermal method of NFP and urine hormones. The Symptothermal method

has women check CM and BBT signs daily. The study did not describe how the BBT shift was determined

or what rule the women used. However, the authors reported that the shift occurred on average about

five days from the LH surge in the first cycle (i.e., LA) postpartum (Zinaman & Stevenson, 1991). The

authors stated the difference between the number of days from the LH surge and the BBT shift

decreased by a day with each passing cycle whereby the third cycle, there was only a day difference

between the two biomarkers (Zinaman & Stevenson, 1991).

Other BBT studies that used a rule called "3 over 6" were completed by Brown et al. (1985),

Hatherley (1985a) and Kennedy et al. (1995). In these studies, women users and scientists drew a

coverline 0.05 to 0.2 degrees above the highest of the six temperatures once three consecutive

temperatures remained elevated. The shift in BBT was determined retrospectively by the scientists.

Hatherley (1985a) had women collect urine samples on the last day of peak CM and again 3 or 4 days

after the BBT shift. If there was no biphasic shift urine was collected 4-5 days after the last peak CM

day. The horizontal cover line was drawn 0.1-degree Centigrade over the highest of the previous six

days before the shift. In the Brown et al. (1985) study 29 women provided 92 cycles with BBT, CM and

urine hormone. The rule for determining the infertile time was the "day when the temperature

increased above that of the previous six" (Brown, et al., 1985, pg. 7). In 9 cycles, no ovulation was seen

with urine hormones but eight of the cycles showed a biphasic shift in BBT. In 70 cycles where ovulation

was determined by urine hormones the BBT shift occurred a mean of 4 days after. In the Kennedy et al.

(1995) study, women used a coverline of 0.05 degrees Centigrade. Although all the previous 3 studies

used the same BBT rule of 3 over 6, each study used different coverline instructions. Therefore,

inconsistent definitions of the coverline makes it difficult to compare results.

Problems with inconsistent coverline rules effect effectiveness rates of the method. That is,

where the coverline was drawn affected the number of fertile days and the effectiveness of the method.

For example, a coverline drawn 0.2 degree above the highest of the previous six will be more

conservative than the coverline drawn 0.05 degrees above the highest of the previous six days. In the

three studies evaluated in this literature review two of the studies had different cover line rules, and

one did not provide the rule used.

The BBT shift rule is also important to identify the length of a luteal phase. The luteal phase is the day after the estimated day of ovulation (EDO) to just before menses (Fehring et al., 2006). The length of a luteal phase is important for knowing if a pregnancy occurred. Women in regular cycles have a luteal phase 9-16 days (Fehring et al., 2006). A luteal phase longer than 16 days can be a sign of pregnancy (Heffner & Schust, 2014). For, Hatherley (1985b) pregnancy occurred in six women with luteal phases longer than 16 days. Two of the six women who recorded BBT shifts tested positive for pregnancy. However, the women menstruated on days 17 and 19. These two women did not consider themselves pregnant. Thus, these pregnancies were not included in the final use effectiveness rates because the length of the luteal phase was within normal limits defined in that study (Hatherley, 1985b).

The discrepancies in how ovulation was defined and the under-reporting of pregnancies due to the possibility of early pregnancy loss affected the results of these older studies. Inconsistent rules used to define the fertile time and the length of the luteal phase affected pregnancy effectiveness rates. When BBT was compared to urinary LH during LA there was a four-day difference between the shift and ovulation (Zinaman & Stevenson, 1991). By the third cycle however, only a single day difference was found between the shift in BBT and urine LH. Therefore, in combination with urine biomarkers of fertility, BBT was determined to be a good marker for determining the EDO and post-ovulatory phase by the fourth cycle postpartum.

Table 2

NFP Studies That Used BBT Signs Indicating Ovulation During Breastfeeding

Author	Date	N	Route	Routine	Rule to determine ovulation	Cycles Studied
Brown, Harrisson Smith	1985	55	Unknown	Unknown	Highest three temps over the previous six days.	Unknown
Hatherley	1985a	197	Women were instructed to use the same route (most used vaginal)	Women were instructed to take BBT at same time in am.	Highest three temps over the previous six days and a cover line of .1 degree Centigrade	Cycles 0 through the first three.
Zinaman & Stevenson	1991	25	Unknown	Unknown	LH compared to the shift.	Cycles 1-3
Sottong, Bremme & Fruendl*	1992	109	Unknown	Unknown	The last day prior to the shift that lasted >/= 10 days.	Cycle 0

| Kennedy. Gross, Parenteau-Carreau, Brown & Visness | 1995 | 73 | Unknown | Unknown | Cover line was drawn .05 degree above the highest of the previous six days. | Cycle 0 |
| Tommaselli Guida, Palomba, Barbato & Nappi | 2000 | 40 | Oral (sublingual) | Women were instructed temp was to be taken with at least two hours of sleep. | Shift of .2 degrees Centigrade that was >/= 8 days. Anovulation = < 8 days | Cycle 0 through cycle 1 |

Note. *Indicates a poster presentation, other studies were published in professional journals.

Cervical Mucus a Specific Not Sensitive Indicator of the Fertile Time

Since the 1970s, CM has been used as a sign of fertility because it is inexpensive, and women can easily observe it. Compared to urine hormone signs, CM was found to be a highly specific and reliable biomarker of fertility; however, it was not a sensitive sign of the fertile time (Kennedy et al., 1995). Characteristics thought to be important for documenting CM are its consistency, amount present, and how far it stretches between the thumb and index finger.

An indirect characteristic of CM as a sign of fertility is the sensation a woman has at the vulva while wiping the perineal area. When tissue drags (i.e., it is dry) over the perineal area, it is considered a sign of infertility, if the tissue slides (i.e., it is slippery), it is considered fertile. CM that is slippery, abundant, and clear like egg white, is considered fertile, and the last day of this slippery mucus is called the peak day (PD). The PD is the day closest to ovulation, also referred to as the EDO for peak CM

(Fehring, 2002; Scarpa et al., 2007). The EDO can occur within 3 to 4 days from the PD. Most NFP methods using CM to find the PD will characterize fertility continuing for 3 days after the PD. Thus, infertility begins the fourth-day post-peak (Fehring, 2002). Couples who use CM may have trouble identifying the PD if they cannot discern the difference between fertile and infertile mucus.

CM is produced in the cervical crypts located at the base of the uterus. In the pre-ovulatory phase, when estrogen-stimulated CM is present, sperm are nourished and survive up to five days in the cervical crypts. When the egg is released from the follicle (i.e., ovulation), it travels down the fallopian tubes. Sperm will travel through the cervix, uterus and into the fallopian tube to unite with the egg when good quality fertile CM is present. The egg lives up to 24 hours and is fertilized by the sperm in the fallopian tube. When the egg and sperm unite, this is the beginning of new human life. If sperm were not present when ovulation occurred, the body absorbs the egg, estrogen, and progesterone levels drop, and menses occurs. For sperm to pass through the cervix and fertilize the egg good quality CM must be present (Fehring, 2002; Knight, 2017). NFP methods that have women observe and chart CM rely on the fertile and infertile characteristics of CM present at the vulva or opening of the vagina.

Methods of NFP that teach changes in CM and sensation at the vulva are called ovulation methods (OM). There are several different OM's, and each one has different rules for describing CM and vulvar sensations. Ovulation Methods also interpret the fertile and infertile phase, and PD slightly different (Fehring, 2002). Different descriptions and rules of CM used to interpret the fertile time result in different PD's and lengths of the fertile window. Thus, understanding which CM characteristics correlate best with the EDO is important for narrowing the fertile window and improving the identification of the PD.

The most reliable characteristic of CM for detecting the EDO is the PD. The PD of CM is the last day of clear, stretchy, and slippery mucus. In a study of 53 women in regular cycles, Fehring (2002) evaluated 108 cycles and compared CM observations to the presence of urinary LH (i.e., EDO). The EDO

was defined as the day after the LH occurred. Ninety-eight percent of the time the PD of CM occurred a mean of four days before or after the EDO. Women recorded both the PD of CM and LH in 93 (i.e., 86%) of the 108 cycles. The PD was defined as the last day CM was clear, stretched more than an inch or was slippery at the vulva. Of the 93 cycles, approximately 36% of the time the PD occurred on the EDO. Thus, 64% of the time the PD of CM varied within eight days of the EDO (Fehring, 2002). The PD of CM was found to be a specific indicator for the EDO but not a sensitive one. Since the PD could vary within 8 days of the EDO.

Although, the PD can be a reliable biomarker of the EDO (Fehring, 2002), rules for CM observation and how the PD is determined should be factored into use effectiveness rates of the OM (Lamprecht & Trussell, 1997). That is OM rules for identifying the PD of CM and managing the fertile time impact the length of abstinence (Lamprecht & Trussell, 1997). An example of how OM rules effect the length of the fertile time and abstinence is the "fake Fertility Fehring formula" (Fehring, 2005). In this formula, infertile days are the first and last days of the cycle, and the PD occurs sometime during this window. Couples who follow this method have less than a 1% chance of pregnancy; however, they are abstaining most of the cycle. Therefore, even if an OM is an effective method, it will not be a practical method because of extended abstinence. How CM observations were defined (i.e., infertile, or fertile) and the rules used to identify the PD and fertile time were important for understanding OM effectiveness studies in this literature review.

Brown et al. (1985) and Hatherley (1985) found high unintended pregnancy rates from postpartum breastfeeding women during LA and the first few cycles. Both studies attributed the pregnancies to women's confusion with the interpretation of CM observations. Brown, et al. (1985) reviewed 55 postpartum breastfeeding women's cycles. In the study women were asked to record their CM on a chart and give it a score of negative one (infertile) through nine (fertile). Infertile observations ranged from dry sensations and no mucus to mucus that was white and clumpy with a little stretch.

Fertile observations ranged from a slight stretch in the mucus to mucus that stretched more than an inch, was slippery and clear. The women also provided weekly 24-hour urine samples tested for total estrogen (TE) and pregnanediol (PDG). A control group of 40 women in regular cycles were used for comparison. In the control group, TE levels of 40 micrograms or higher, followed by a sustained level of PDG above 2.0 mg per 24 hours, were used to identify ovulation had occurred. The researchers used TE because the levels peaked about 1-2 days before the EDO in the control group. The EDO was confirmed when PDG levels were 2.0 mg per 24 hours, or higher and menses occurred eleven or more days after the highest TE level. In the LA group, CM correlated with TE and PDG levels 57% (19/33) of the time.

Brown et al., 1985 found from the group of women who continued to breastfeed in the first cycle, 58% of the time, CM and urine signs correlated and, with each completed cycle, there was a slight increase in the levels of TE and PDG. The group also found as women cycles progressed, the CM peak to urine TE and PDG peak level correlation improved. In the seventh cycle, 81% of the time, CM signs correlated with TE and PDG urine hormones. Seven of the 55 women did get pregnant during LA. The authors of this study concluded that women were at a higher risk for pregnancy because almost half the time, CM signs did not reflect the urine EDO and the fertile time (Brown et al., 1985).

Following the methodology of Brown et al. (1985), two other studies (Hatherley, 1985a; Kennedy et al., 1995) tested postpartum breastfeeding women's urine. The purpose of these studies was to assess the use of the effectiveness of CM and BBT in postpartum breastfeeding women. Both studies compared TE and PDG levels to CM and BBT signs in breastfeeding women. The authors of these studies found there were long periods of fertility, which likely resulted in high pregnancy rates.

Hatherley (1985a, b, c) followed 259 women, 208 were breastfeeding. Of interest in this study, post-ovulatory TE was higher than post-ovulatory PDG in the first three cycles, about 40% of the time. Total Estrogen levels remained elevated post-ovulatory and throughout the luteal phase. Hatherley (1985a) postulated that elevated TE was the reason for the presence of fertile CM during the luteal

phase. Furthermore, he concluded the presence of fertile type CM during the luteal phase made it difficult for women to be confident in understanding their CM signs, which was the reason for the high pregnancy rate. He confirmed 34 (i.e., 16%) women experienced an unintended pregnancy using urinary chorionic gonadotropin (Hatherley, 1985a).

From the same use effectiveness study Hatherley (1985a) evaluated serum prolactin, FSH, and LH levels comparing the levels to CM, BBT, and breastfeeding frequency. Controls for the serum hormone levels came from the World Health Organization (1980; as cited in Hatherley, 1985c). Women recorded CM signs and BBT signs during LA and the first few cycles. Serum hormones were drawn when the urine TE/PDG levels indicated ovulation. Prolactin levels correlated with breastfeeding intensity; however, there was no correlation between CM signs. In the second paper by Hatherley (1985b) from the same study, a subgroup of breastfeeding women with a previous history of irregular length cycles also showed erratic CM signs and TE levels. In this subgroup eight (*n* = 32) unplanned pregnancies occurred (Hatherley, 1985b).

Kennedy et al. (1995) assessed CM in 73 women from three sites where the OM with BBT was taught. The OM rules for avoiding pregnancy were slightly different in each site; however, standardization of rules were applied to all data for analysis. Women were asked to record CM using four categories (i.e., sensation, stretchiness, amount, and appearance). The percent of fertile days using CM signs and the OM rules, where abstinence was necessary to avoid pregnancy during LA, ranged from 48-71%. Fertile CM predicted the EDO 21% of the time. The EDO was identified through urine hormones and a shift in BBT. The study showed how the proportion of days where CM correctly identified the fertile time was low. These authors concluded that fertile CM was a reliable biomarker with low positive predictive value. That is CM, carried a low sensitivity for identifying the true fertile time or the EDO during LA and the first few cycles after (Kennedy et al., 1995).

Other studies from postpartum breastfeeding women that used CM also found fertile type

mucus did not correlate with the other biomarkers (Sottong et al., 1992; Tommaselli et al., 2000;

Zinaman & Stevenson, 1991). Tommaselli et al. (2000) studied healthy Italian breastfeeding women ages

23-40 years old (n=40). Women with a full term, singleton delivery were given a card to record their

CM, BBT, bleeding, breastfeeding, and saliva patterns.

Saliva was tested by the women and in the lab. Women who learned to read salivary signs

correctly 80% of the time were included in the study. Tommaselli et al. (2000) found that 45% of the

first cycles had twenty or more days of fertile CM.   This study showed that in the first cycle, once

menses returned, CM was always present in 30% of cycles (12/40 cases). Also, CM was present for more

than 20 days in 15% of the cases (6/40 cases). Salivary ferning, a measurement of pre-ovulatory fertility,

and the BBT shift did indicate fertility and the EDO.   However, CM patterns were inconsistent in

identifying the fertile time (Tommaselli et al., 2000).   Zinaman and Stevenson (1991) piloted the use of

three biomarkers: urinary estrone-3-glucuronide (E3G), LH, and PDG, with CM and BBT shift in 25

women. The authors did not report results with CM symptoms but concluded that urine biomarkers

were used to help understand the correlation. Finally, an abstract reporting the results of 109 German

breastfeeding women who recorded BBT, and CM looked at the effect breastfeeding patterns had on

luteal phase length (Sottong et al., 1992). The EDO was determined by the shift in BBT and confirmed by

CM. The EDO occurred between 94-758 days during LA, and about 52% of first ovulations preceded the

first menses. There was no discussion of how CM, BBT, and breastfeeding patterns related.

Finally, three prospective studies compared CM observations to breastfeeding frequency

patterns (Howard & Stanford, 1999; Labbok et al., 1991). In Kenya, 521 women were observed from 42

family planning clinic sites. The purpose of the study was to test the use of OM protocols during LA. The

use effectiveness pregnancy rates were 22% at 12 months. From these unintended pregnancies, 19%

occurred when women were in the first six months of LA. The authors concluded, high pregnancy rates

for women using CM, were related to the ovulation method (OM) rules despite women's attempt at

rigorously following them (Labbok, 1991). In the same article a prospective study of 110 breastfeeding

Chilean women recorded CM and acts of intercourse. The percent of days where the OM rules required

abstinence ranged from 22 to 720 days postpartum during LA. In the first three months postpartum,

about 20% of the days were considered fertile. Between 3 to 6 months 33% of the days were

considered fertile. At 6 and 9-months about 41-47% of the days were fertile. The highest number of

pregnancies occurred post-menses, and after six months, 67% were user-related, and 25% were method

related. Low typical use-effectiveness rates and long periods of abstinence confirmed the ambiguous

nature of CM.

In another effectiveness study of women who used an OM called the Creighton Method (CrM)

24 pregnancies occurred (Stanford & Howard, 1999). A retrospective chart review by Stanford and

Howard (1999) reported pregnancies occurred in 821.5 cycles contributed by the breastfeeding women

in this study. The number of breastfeeding women who contributed to the study were not reported. The

authors concluded that the low-effectiveness rates were due to the women taking chances. The authors

stated that women who followed the rules of the method and had intercourse during the fertile time

chose to take chances. The Creighton OM (CrM) refers to this as risk-taking behavior and records these

pregnancies as "achieving related behavior". No other NFP method used this category to define

pregnancy.   Therefore, this makes it difficult to compare effectiveness rates from the CrM with other

NFP methods. (Howard & Stanford, 1999).

The problem with the CrM is its subclassification of use effectiveness pregnancy rates that are

not consistent with Trussell's definition of how to report effectiveness of a family planning method

(Peragallo Urrutia et al., 2018). In a systematic review of NFP method effectiveness Peragallo Urrutia et

al. (2018) rated the CrM pregnancy classification in the (Howard & Stanford, 1999) as low quality. The

systematic review used a 13-item ranking system that looked at the quality of NFP effectiveness studies.

The studies were ranked as "high", "moderate" or "low" quality. The tool was developed using modified guidelines from the U.S. Preventive Services Task Force and Cochrane guidelines. Peragallo Urrutia et al. (2018) review created clear guidelines for future review and development of NFP effectiveness studies. The guidelines provide a framework for understanding the quality of past and future effectiveness studies.

The Perragalo Urrutia et al (2018) systematic review provided a rigorous review of past NFP studies. Application of these guidelines align with current family planning studies and holds NFP research to a higher standard. This is important since findings in this literature review of CM and BBT methods used by women during postpartum/breastfeeding transition have found variability in methodology. This variability impacts both internal and external validity. Finally, variability across OM effectiveness studies in the descriptions of CM signs, identification of the PD and the different rules for identifying fertile and infertile days are some of the reasons OM effectiveness studies have been rated low quality.

This literature review found differences in NFP study designs from postpartum breastfeeding women who used BBT, CM, and urine hormones. These differences impacted the quality of the study and reporting of pregnancy rates. In their systematic review of NFP effectiveness/efficacy studies, Peragallo et al., 2018 found these types of NFP studies lacked consistent reporting techniques. They developed a guide important for increasing rigor in future NFP studies.   This literature review was guided by hallmark articles specifically designed to critique NFP studies that examined the use of CM (Fehring, 2005), BBT (Barron & Fehring, 2005), and the LAM protocol (Fabic & Choi, 2013; van der Wijden et al., 2008; van der Wijden & Manion, 2015) effectiveness studies. Review of these studies along with the guide developed by Peragallo et al., 2018 were considered in this studies design.

Conventional NFP Methods

Conventional methods or symptom-hormonal methods of NFP have been used since the 1970's (Brown, 2011). These methods used objective urine hormones that were collected by women in their home. The women froze the samples and sent them to a lab for analysis usually after one month of collection. In the early 21st century an electronic monitor was developed. The monitor allowed women to test their urine at home it provided results within 5 minutes (Swiss Precision Diagnostic, 2015).

Urine Hormones: An Objective Sign of Fertility

Dr. James B. Brown's work with reproductive urine hormones as a secondary marker of fertility advanced scientific understanding of the accuracy CM and BBT signs had as indicators of the EDO during the postpartum/breastfeeding transition (Brown, 2011; Brown et al., 1985). In his final work, known as the "Continuum," Brown showed that breastfeeding women have three different hormone patterns during the postpartum transition. He presented three model cases showing why CM was difficult for breastfeeding women and couples to use (Brown, 2011). In the Continuum, Brown stated his conclusions about CM compared to urine hormones. He provided sample cycles of women in the postpartum/breastfeeding transition. The sample, was noted to be representative of the population and followed a consistent pattern of long cycles during LA. Once ovulation was confirmed by the urine hormones (i.e., TE and PDG), a short luteal phase followed. If LA was anovulatory, then delayed ovulation occurred in the first few cycles after menses. Gradually, as cycles continued, ovulation occurred earlier each cycle. By the fourth cycle ovulation resumed a pre-pregnancy state (Brown, 2011). Other researchers who used Brown's urinary hormone test method also found similar results. These studies confirmed CM observations did not correlate with urine hormone signs (Brown et al., 1985; Hatherley, 1985a, 1985b; Hatherley, 1985; Kennedy et al., 1995). Twenty years later Bouchard et al. (2018) confirmed these findings.

CM and Urine Hormones: A new Analysis

A reanalysis of Brown's data that compared CM to urine hormones found CM over-estimated the fertile

time (Bouchard et al.,2018). Reanalysis of the data came from postpartum/breastfeeding women who

participated in the Kennedy et al. (1995) study. Although, the Kennedy et al. (1995) study included 71

women the demographic data was only available for 26. Data from these 26 women were used in the

Bouchard et al. (2018) study. Data from the Kennedy et al. (1995) study reanalyzed by Bouchard et al.

(2018) included the women's demographics, records of CM, BBT, cervical position, acts of intercourse,

and daily breastfeeding events. The shift in BBT and cervical position were not included in the Bouchard

et al. (2018) study. In the reanalysis of the data, the authors collapsed mucus readings into three

categories of green, yellow, and blue (Bouchard et al., 2018). Dry days with no mucus were coded as

"green."   When mucus was present but infertile (i.e., moist, damp, sticky) these days were coded

"yellow,". Days with peak-type quality mucus (i.e., clear, wet, slippery, stretchy) were coded as "blue."

TE levels from 0-10μg/24 hours indicated no follicular activity, 10-20 μg/24 hours indicated follicular

development, and greater than 20 μg/24 hours indicated ovulation was imminent. CM days coded as

green, yellow or blue were compared to the TE levels of each day.

When TE levels were 10-20 μg/24 hours or greater than 20 μg/24 hours on days coded as green

or yellow these days were recorded as underestimating the fertility for that day. When CM coded as

yellow or blue had a TE of < 10 μg/24hrs., these days were coded as CM days that overestimated

fertility. Blue coded CM on days where the TE level was between 10 to 20 μg/24 was scored as a day

where the CM overestimated the fertility for that day.

From this review, 53.6% of the time, CM over-estimated the fertile time, 7.3% of the time CM

underestimated the fertile time, and 39.1% of the time, CM correctly reflected the urine hormones. TE

levels in the first cycle postpartum were used to determine ovulation. In the first cycle 58% (45/78) did

not follow a typical CM pattern (i.e., dry to infertile to peak-type CM). The authors concluded that the

reanalysis of this data set confirmed previous study results. That was, CM and urine hormone levels of TE and PDG did not correlate to the EDO and fertile window. The authors concluded as a single indicator when CM was used during the postpartum/breastfeeding transition s not an effective biomarker of fertility (Bouchard et al., 2018).

Bouchard et al. (2018) was the first study of its kind designed to assess the disassociation between CM and urine hormones during the postpartum/breastfeeding transition. However, the data came from breastfeeding women who charted in the 1970'and 1980s, and the sample size was small. At the time of the study, women used Brown's method for testing urine hormones. The method was inconvenient as women collected urine in the home, diluted it and then transferred it to a small tube that contained a substrate to preserve results. Once the urine was collected in the tube it was frozen. When a month of tubes were collected, the frozen tubes were sent to Brown's lab in Melbourne for analysis. Charts with CM readings and the frozen tubes were labeled with the participants number, center number, date, hours of urine collection, and volume voided each day. The process was tedious for women and required Brown's lab for analysis. Today the CBFM has allowed point of care (POC) testing this device required less work for women and researchers.

Point of Care Testing and the MM Breastfeeding Protocol

Since the early 21st century, women have monitored their first-morning urine (FMU) hormones in the comfort of their own home using the CBFM. With POC testing women were able to see results within 5 minutes after testing. The ability to do POC urine testing with the CBFM revolutionized NFP methods by providing objective results which significantly reduced the number of fertile days during LA for postpartum/breastfeeding women who used a special protocol that integrated the monitor into a NFP method. The protocol had women test their FMU daily and became known as the Marquette Method of NFP (MM) breastfeeding protocol.

The first pilot study of the MM breastfeeding protocol analyzed fertility chart data from 10 breastfeeding women (Fehring, et al., 2005). The women charted CM and urine hormones. The study compared CM and the urine reproductive hormones estrogen and LH. Women who used the protocol began testing around 6-8 weeks postpartum. The protocol required women to set the CBFM to day one and then roll the screen forward to day five. The next day (i.e., day 6) the monitor requested a test. Women would continue testing for 20 days. On the 20th day of testing, they would reset the monitor again. This programming allowed women to begin tracking artificial cycles daily during LA. After each artificial resetting of the monitor one day would be missed. Thus, this required one day of abstinence since a test could not be taken. The protocol had women test every other day if no estrogen (high) was detected by the monitor. Once the monitor detected estrogen (i.e., a high day), testing was done daily until the LH surge (peak) was detected. If the monitor did not detect a peak after 20 days of testing it needed to be reset and the protocol was started again. With this process women created artificial cycles in the monitor. Analysis of charts from postpartum breastfeeding women using this protocol showed 50% of the cycle was fertile with CM and 17% of the cycle was fertile with the CBFM (Fehring et al., 2005). Cervical mucus more than doubled the fertile time during LA.

In April 2008, the Marquette Institute for NFP began providing women in regular cycles NFP instructions. Women charted their fertility signs and received clinical support for the MM in the comfort of their own home through the website (https://nfp.marquette.edu). The purpose of the site was to give women and couples easy access to the MM of NFP, provide professional nurse support and be a place where data from menstrual cycle charts could be collected and analyzed. Internal Review Board approval from Marquette University was obtained (HR-1597). Protocols for using the MM in regular, long, irregular and postpartum/breastfeeding cycles were published on the website. Publication of the breastfeeding protocols increased the number of postpartum/breastfeeding women using the method to avoid pregnancy. By 2011 hundreds of women and couples had registered and were using the

website to learn the breastfeeding protocol. Nurse researchers at the Marquette Institute of NFP began

collecting and analyzing data contributed by the women they served. The first analysis of the online

postpartum/breastfeeding protocol taught by professional MM nurses was completed in 2011 the

results were published in 2013 (Bouchard et al., 2013).

From April 2008 through November 2011 data from breastfeeding women were analyzed for the

effectiveness of the protocol and acceptability of use of the online method (Bouchard et al., 2013). In

this study, women (N = 337) learned to chart the "original protocol" first published in the pilot study of

10 postpartum breastfeeding women (Fehring et al., 2005). The study was an analysis of prospectively

collected chart data and pregnancies from women who charted on the website. Women used the

website to learn and chart fertility signs daily. The fertility charts on the website indicated when a

pregnancy occurred by an automatic notice built into the systems algorithm. The automatic notice was

triggered by women that indicated pregnancy occurred or when charts indicated the luteal phase was

longer than 16 days. When the algorithm was triggered, an email was sent to the Nurse researchers who

managed the study.

Inclusion criteria in the Bouchard et al. (2013) study were women registered as postpartum and

they had to have at least one complete chart. Once minimal criterion was met, the women were

emailed additional questions. The study included 183 women who registered as breastfeeding and 15

postpartum not breastfeeding women. The women were a mean of 30 years old, white (70%), Catholic

(79%), married, and averaged 3 children. Two unintended correct use pregnancies were reported

(Bouchard et al., 2013). Of the correct use pregnancies, one occurred in the ninth month during

amenorrhea, and the other occurred in the third cycle.

The Bouchard et al. (2013) study also included an analysis of the women's acceptability of the

website. Acceptability was assessed from 10 questions designed to be answered on a Likert scale. The

scale used a score of one to seven. The possible range of scores was 10 – 70. Ten was low acceptability

of the website experience and 70 highest acceptability. The mean range for the surveys at 1,3, and 6 months was 55 – 58. Acceptability slightly increased over-time.

The most important limitation of the Bouchard et al. (2013) study was the high attrition rate of 57%. These couples may have dropped out because they did not have a positive experience or just signed up to see information and electronic charts in the site.   Thus, the acceptability scores of the online charting system may not reflect the true experience. Other limitations of the study were the lack of generalizability of the results due to the population's homogeneity and the lack of a control group. Although the study did have limitations, the author's suggestion of how the protocol could be improved was important for reducing pregnancy rates. Revisions of the protocol (see Appendix A) included the optional use of a second urine check using inexpensive LH test strips in the evening, testing the FMU for 10 days with the CBFM and a tapering of the beginning of the fertile window in the first 5 cycles.

In a follow-up study to assess the effectiveness of the revised postpartum/breastfeeding protocol, Fehring, Schneider and Bouchard (2017) analyzed the effectiveness rate of 816 women who charted their fertility in the MM online system. In this study, three comparison groups were used, and cycles of use were reported. Reporting the effectiveness of the method by cycles of use was important to avoid artificial inflation in the effectiveness rates. The three groups were women who used CM only, CBFM only, and CM with the CBFM. A total of 36-62 pregnancies over 6 and 12 menstrual cycles were found. Survival analysis using the Kaplan-Meier life-table analysis showed an unintended pregnancy rate of 14 per 100 users (SE = 0.019). Six pregnancies occurred during amenorrhea. Typical use pregnancy rates were similar for the women who used the CBFM with and without CM. There was, however, a significant difference in unintended pregnancies ($Chi\text{-}square$ = 9.17, p = .002) between the CM only group and the former groups. Women who used CM only were four times more likely to get pregnant at 6 and 12 cycles of use compared to women who used the CBFM alone or with CM.

Authors of the Fehring et al. (2017) study stated that a limitation in the web-based fertility chart used by women in this study was the automatic fertile window calculations (i.e., represented as fertile window brackets). The online charts were designed for women in regular cycle lengths; thus, the FW bracket may have confused postpartum/breastfeeding women who charted the protocol on these charts. In the protocol, postpartum/breastfeeding women were instructed to create artificial cycles with the CBFM.   They then recorded the results into the online charting system. The nurse researchers instructed them to ignore the calculated fertile window bracket on the chart and follow the protocol instructions. Another limitation of this study was that the infant's date of birth was not available. Without the infant's date of birth, it was impossible to know when women began charting and LA's length. Therefore, women could have started the study at any time. Despite the protocol recommendations that they start at 8 weeks postpartum. If women did start at this time, they could be in amenorrhea for several months. Women in amenorrhea are naturally infertile.   Finally, the generalizability of the protocol to all postpartum/breastfeeding women was not possible since most of the women were primarily white (67.5%), Catholic (83.2%), and had one or more college degrees (37.0%).

The Pilot Study

A pilot study of postpartum/breastfeeding women used the original protocol in a descriptive analysis of the transition. The study collected additional data not found in the online registration form completed by the women. Additional data included the infant's date of birth when the infant received supplements and if a pregnancy occurred. The purpose of the pilot study was to evaluate the reliability of the CBFM and the MM fertility charting system. The aim of the study was to identify menstrual cycle parameters in postpartum/breastfeeding women during LA through the first 6 cycles. This prospective descriptive study analyzed the menstrual cycle parameters length of LA, the length of the first 6 cycles, the length of the follicular and luteal phases in each cycle, and the characteristics of the first menses.

Chart data came from postpartum/breastfeeding women who registered on the MM NFP website between April 2008 through January 2014. Inclusion criteria for the study were women (1) registered in the online MM NFP system as either total or partial breastfeeding, (2) provided at least one complete online cycle, (3) provided the infant's date of birth (4) provided the date when nutritional supplements started for the infant she was breastfeeding when she registered. Internal Review Board approval from Marquette University was obtained as an addendum to the larger study (HR-1597). Pregnancy effectiveness rates were not part of this review.

Eighty (27%) of 295 women completed the emailed survey and provided 591 cycles of data. Emails were coded using the user's MM NFP identification number to maintain privacy. Descriptive statistics were checked for normality of distribution; an extreme outlier found in the luteal phase during LA was removed. Dates of menstrual cycle events were recorded into SPSS using *dd-mmm-yyyy*, and a digital transformation to days completed was done through the date difference function. The length of LA, the first sign of the return to fertility (i.e., first high on the monitor), and EDO were determined using the baby's birth date and the first day of menses for each cycle. Women entered the study and began charting at different stages postpartum. Management of missing data can be found in Appendix D. Of the 80 breastfeeding women, 63% were totally breastfeeding, 37% were partially breastfeeding. The average age was 31.0 years (*SD* = 5.2), the majority were Catholic (94%, *n* = 67), and married (99%, *n* = 78), with three living children (*M* = 3.2, *SD* = 1.8), and the majority had a college or university-based education (78.5%, *n* = 62). Women began charting and using the MM breastfeeding protocol in the fifth month postpartum (*M* = 156 days, *SD* = 112.0) about a month before initiating nutritional supplements (*M* = 184.18 days, *SD* = 65.10).

The start of fertility during LA was the first estrogen high. This was calculated using the infants date of birth and first high recorded on the chart. On average, the first sign of fertility (i.e., estrogen rise) in LA occurred a mean of 172.7 days or 5.8 months postpartum (*SD* = 107.7, *n* = 53 women) with a

broad range of 46 (1.5 months) to 456 days (15 months) the median for the first high was 160 days (5 months). Once the first menses occurred, the first estrogen rise in cycle one occurred a mean of 17.2 days (*SD* = 7.8, range 7 – 41, *n* = 59) later. In the following five cycles, the time from the first day of menses to the first recorded high day was a mean of 13 days. See Table 5 for more details.

An objective menses scoring system of at least three consecutive days of bleeding with a score of ≥ 5 was used (Bouchard et al., 2013). During LA 55% (*n* = 44) of the women experienced a peak on the CBFM (i.e., EDO) prior to their first menses which occurred between nine and ten months postpartum 295.5 (*SD* = 114.3, *n* = 43). Women in LA also had a mean and median of one set of peaks with a range of 2 to 10 sets of peak days. The luteal phase prior to the first menses was a mean of 9.0 days (*SD* = 5.9, *n* = 43).

First and subsequent menses were identified using the objective system mentioned previously. Menstrual cycle characteristics showed time to the first menstrual cycle was a mean of 287.8 days or 9.6 months (SD = 133.1, n = 75, 95% CI [255.7,316.6]). After the first menstrual bleed the time to the next menstrual bleed was a mean of 39.1 days (*SD* = 17.7, *n* = 68) and a median of 33.0 days, 95% CI [33.6, 41.6]. The length of subsequent cycles tapered down by one to two days and by cycle six were a mean of 29 days. Time from the first menstrual bleed to the EDO was a mean of 26.3 days (*SD* = 10.6, *n* = 50) and the luteal phase was a mean of 8.9 days (*SD* = 2.95, *n* = 52). As cycles progressed the follicular phases shortened, and the luteal phases lengthened. By the sixth cycle the follicular and luteal phases had returned to regular cycle parameters. A summary of the menstrual cycle characteristics is found in Table 6. Findings for the pilot study showed 88% (n =70) of women recorded first menses and had a mean bleeding score of 11 (*SD* = 3.2, range 5-19). Two women had a score of five (see Figure 2 for distribution of the bleeding score).

Figure 2

First Menses Bleeding Score
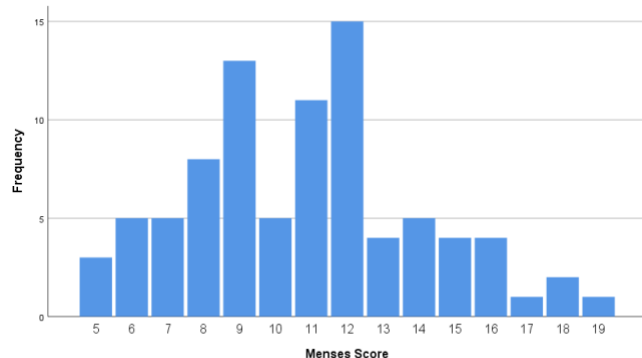
Note: This graph represents the sum bleeding score for women (*n* = 70) in the pilot study.

Results from the pilot study showed integration of the CBFM into the MM breastfeeding

protocol compared to earlier research (Brown, 2011). However, like previous NFP studies, significant

limitations in this study included a high attrition rate of 73%. Other limitations were inconsistent

charting resulting in large gaps of missing data, variability in when women-initiated charting, and the

need to contact women through email. Despite these limitations, the pilot study provided valuable

information about hormone patterns for return to fertility and the menstrual cycle parameters during

the breastfeeding transition. The CBFM, along with the MM NFP system, was a reliable tool for

understanding breastfeeding women's transition to fertility.

Conceptual Model

Roy's Adaptation Model (RAM) was used as the conceptual model and provided systematic

guidance for the methodology used in this study. Roy's use of a systems approach of input, process, and

output was used to simplify the complexities of physiologic neuroendocrine adaptation in postpartum

breastfeeding women's fertility return.

Sr. Callista Roy developed the RAM during her graduate work at Mount St. Mary's College in Los

Angeles (Blazer & Prata, 2016; Roy, 2009, 2014). Since then, the model has been used as the framework

for hundreds of nursing studies and nursing education programs around the world (Roy et al., 2011). A brief discussion of the background and overview of the RAM as a grand theory, its concepts, propositions, and scientific assumptions specific to quantitative physiologic analysis that supported this study follows.

Breastfeeding and its influence on the return to fertility and menstrual cycle parameters were explored under the guidance of the RAM concepts and principles. The underlying precepts for examining the connection between breastfeeding, ovarian function, and fertility are explained using the RAM conceptual framework for the physiologic domain. The physiologic theoretical premises of the RAM align with the theoretical physiologic endocrine model, the "suckling induced reflex theory"(Johnson, 2013). The suckling induced reflex theory supported the empirical measurement of specific reproductive urine biomarker hormones. The terminology used to describe the RAM are presented in italics throughout this chapter, and vocabulary applied specifically to this study were underlined. A summative discussion of the components used in this study is described through the Conceptual Theoretical and Empirical (CTE) framework. Finally, a discussion of the philosophic underpinnings of natural design and realism showed that Roy's understanding of human adaptation was implicit to this study's methodology.

RAM: Concepts, Propositions, and Scientific Assumptions

Roy (2009) defined health broadly "as a state of being or becoming an integrated whole" (p.27). The process of becoming fully *integrated* individuals depends on the recognition that *stimuli and adaptive levels* are related and complement the other to meet human needs (Roy, 2009). Stimuli are actions that provoke a response. Nurses intervene at the level of stimuli to promote *integrated adaptation* and optimal individual health. *Adaptation* is both a stimulus and the result of a stimulus. It contributes to changes in life processes and decisions an individual make. An individual's active decision directly reflects behavior that the nurse can use to measure the individual's level of health (Roy, 2009). The goal for the individual is *integrated adaptation*. The level of *adaptation* is dependent on

multiple internal and external environmental components; it is dynamic and important to the growth,

development, and life of an individual. A brief description of all RAM components, concepts, and

principles necessary to provide context for this study's specifics follows. Along with a description of the

RAM within the context of breastfeeding's physiologic response to show the links between the

conceptual and theoretical components of this study.

RAM: General Concepts

In the RAM, a *stimulus* is defined as an event that initiated a response of the human system. Roy

(2009) stated there are three types of *stimuli: focal, contextual, and residual*. *Focal stimuli* initiate the

change, are closest to the *human adaptive system*, and are the reason individuals reacted. *Contextual*

and residual stimuli affect how a *focal stimulus* was processed and managed. *Contextual stimuli* were

considered part of the individual's history, education, and knowledge while *residual stimuli* were

internal/external stimuli with an unknown effect on adaptation. C*ontextual stimuli* are

identifiable, *residual stimuli* may or may not be known. An example of *residual stimuli* is an underlying

chronic health condition that is unknown but affects the processing of stimuli. All three *stimuli* are

processed through the *cognator* and *regulator subsystems*, which affect adaptive responses (Roy, 2009,

2017). In the RAM, *focal stimuli* initiate and a response that is visible through human adaptive

behavior. Since behaviors are observable, they can be measured and then classified into one of the four

adaptive modes (Roy, 2009).

In the RAM, adaptive modes are applied to both the individual and group. This study applied

RAM principles to the individual. The four adaptive modes related to an individual are *self-concept, role*

function, interdependence, and *physiologic* domains. The *self-concept mode* focused on how the person

interprets "meaning" in their life. *Role function mode* looked at the type of relationship between the

individual and others, and the *interdependence mode* looked at relationships to others. The *physiologic*

mode considers how humans physically respond to their environment through neural, chemical, and cellular pathways that are innate.

All four adaptive domains of the individual receive process and adjust to new stimuli simultaneously (Roy, 2009, 2017). This study focused on the *integrated physiologic adaptive* domain specific to breastfeeding women's reproductive fertility. That is, understanding how women in LA transitioning to fertility process and adapt neuroendocrine changes that reflect if she is fertile or not. In this study the focal stimuli of breastfeeding frequency have a direct and known effect on measurable reproductive hormones estrogen and LH present in the of urine. Contextual stimuli could be women's knowledge of the protocols or women returning to work resulting in the reduction in breastfeeding frequency and the need to adapt to fertility returning. Finally, an example of residual stimuli would be the physiologic effect an endocrine disorder such as Polycystic Ovarian Syndrome (PCOS). PCOS is an insulin resistance disorder that can negatively affect breastmilk production and length of LA (Harrison et al., 2016).

Although Roy (2009) recognized three types of stimuli (i.e., focal, contextual, and residual) that affect adaptation, she also acknowledged how basic physiologic adaptive needs are also stimuli. Basic needs necessary to the *physiologic mode* are driven by the essential human desire for oxygenation, nutrition, elimination, activity, rest, protection, and reproduction (Roy, 2009). The *physiologic processes* important for contextual *adaptation* to meet these needs use the individuals: senses, fluid and electrolyte balance, neurologic and endocrine function. Understanding the context of events was important in defining health. Nurses understand how an individual views his/her state of health by observing patterns common to that cohort (Roy, 2009). Patterns or propositions specific to the *physiologic mode* common to the postpartum breastfeeding cohort of women, observed in this study were:

1. *Regulator subsystem* processes innate and acquired ways of *adapting*.

2. The characteristics of *internal and external stimuli* influence *adaptive responses*.

3. The adequacy of the *regulator subsystem* processes will affect *adaptive responses*.

4. The pooled effect of *stimuli* determines the *level of adaptation.*

5. *Adaptation* is influenced by the integration of the person within their environment.

6. The variable of time influences the process of *adaptation*.

Scientific RAM Assumptions relevant to physiologic inquiry and this study are:

1. Humans are *adaptive systems* capable of processing *stimuli* both innately and cognitively.

2. Humans participate in activity in a non-linear fashion.

3. Human systems are multifaceted and complex.

4. Human *adaptive systems* involve complex processes of interaction.

5. Integration of human and environment results in *adaptation*.

   (Frederickson, 2000)

The RAM propositions and assumptions listed provided a useful conceptual framework for this descriptive quantitative study. The propositions provide physiologic context for the innate adaptive response to breastfeeding patterns and fertility, within the context of the reproductive endocrine response to breastfeeding stimuli. The scientific assumptions support the propositions. A closer look at the RAM concepts: propositions, *stimulus, regulator subsystem and adaptation*, applied to the theoretical premise that supported the links between breastfeeding and fertility specific to this study follow.

Physiologic Adaptation of Breastfeeding to Fertility

In Figure 3, the connection between the RAM concepts and propositions specific to this study were presented. In this model, breastfeeding was the *focal stimuli*, and women's support network and knowledge of breastfeeding's ability to suppress fertility were the *contextual stimuli.* The dotted box around the *focal stimuli* represented the dynamic, ongoing relationship between the *focal* and *contextual stimuli*. *Contextual stimuli* were represented with the oval around the focal stimuli to show how breastfeeding patterns are influenced by women's knowledge of breastfeeding and support networks. Levels of breastfeeding are represented as either full or partial, which act on the reproductive neuroendocrine pathways processed by the *regulator subsystem*. Neuroendocrine events that occurred within the Regulator or fertility domain are processed, and the result is the *physiologic adaptation* of either infertility or fertility.

Figure 3

Roy Adaptation Method and Breastfeeding Physiology Model
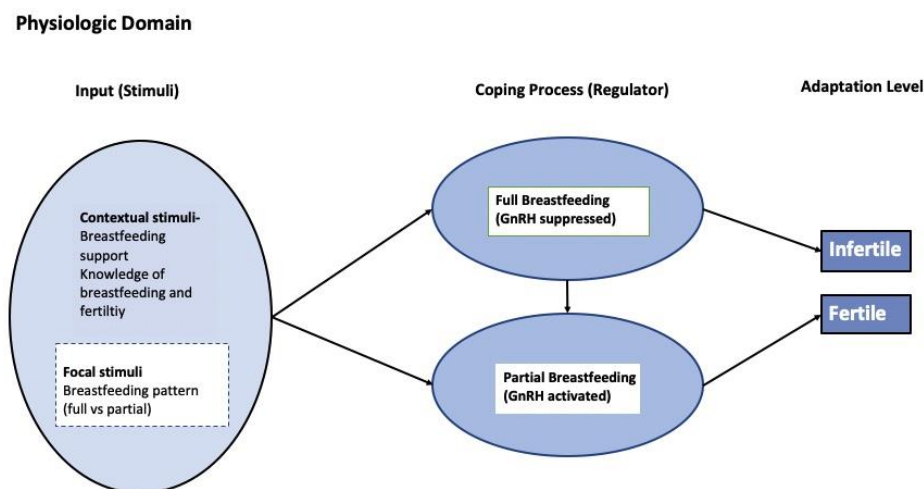
Note: RAM structure showing the physiologic adaptation of breastfeeding and fertility.

RAM, Applied to Breastfeeding and Fertility

This study focused on the *physiologic mode* of adaptation, how the stimulus, <u>breastfeeding,</u> was processed, and how the reproductive neuroendocrine system adapted ovarian activity to different breastfeeding frequency over time. Adaptation of the reproductive neuroendocrine systems occurred naturally through "neural, chemical, and endocrine" pathways (Roy, 2009, p. 27). These systems involved a natural coping process that took place within the body and was influenced by either *internal* or *external stimuli*. *External stimuli*, such as <u>breastfeeding frequency</u>, were stimuli from outside of the body, *internal stimuli*, such as the <u>neuroendocrine</u> events, were stimuli from within the body. Both *external* and *internal stimuli* were part of the human environment and adaptation.

The human environment is both external and internal. Roy (2009) considered the *external environment* as "all conditions, circumstances, and influences that surround and affect the development and behavior of humans as adaptive systems, with particular consideration of human and earth resources" (p. 26). Examples of the *external environment* for breastfeeding women is the physical relationship with the infant, spouse, and the knowledge of breastfeeding. An example of the *internal environment* was the automated activity of the reproductive neuroendocrine systems that produced breastmilk to nourish the infant and indirectly affected ovarian function. The RAM provided a conceptual framework for examining adaptive processes triggered by *physiologic stimuli* that acted on both the internal and external environments of <u>breastfeeding</u> women. External and *internal environments* were interrelated, and *breastfeeding stimuli* were processed in the *regulator subsystem*. The goal of *adaptation* was to promote growth and flourishing of oneself within one's environment (Roy, 2009). The model supported the breastfeeding physiology theory of fertility. A theory that the suckling *stimuli* affected <u>ovarian</u> function processes (i.e., *regulator subsystem*) made visible through the presence of <u>reproductive urine hormones</u>.

RAM: Breastfeeding Transition from Infertility to Fertility is a State of Wellness

This study recognized breastfeeding women's natural transition from infertility to fertility as a state of wellness. In this transition, women anticipated ovulation when breastfeeding status changed from full to partial. The transition occurred over time and was a function of human survival designed to naturally space pregnancies. However, the rate at which the transition occurs depends on women's breastfeeding patterns. For example, in countries where the culture supports full breastfeeding ovulation and pregnancies occurred several months to years apart (Cooney et al., 1996; Konner, 1978; Konner & Worthman, 1980). However, in the countries where breastfeeding was not supported culturally, the length of full breastfeeding and subsequent pregnancies were reduced to weeks and months apart (Campbell & Gray, 1993; Gray et al., 1990; Labbok, 2012).

Women have used breastfeeding to naturally space children for centuries. Thus, breastfeeding is recognized as a state of wellness that is influenced by the external environment (i.e., the culture), in which the mother-infant dyad exists. This study considered the dyadic relationship to be dependent on the proposition of time influenced by cultural practices and the internal and external environment in which the dyad live (Roy, 2009).

Roy (2009) theorized that persons were resourceful and adapted to their environment through continuous stimuli. The pattern of integrated stimuli and the environment is continuously processed by the individual and influences the outcome of adaptation. Individual responses are either adaptive or ineffective and depend upon the individual's resources to process the stimuli. Adaptability is a continuous process that comes from ongoing internal and external stimuli meant to precipitate adaptive change. Thus, Roy compared the interrelationship between stimuli, environment, and adaptation to a "kaleidoscope" (Roy, 2009, p.34). In the RAM, the analogy of the kaleidoscope represents a continuum of adaptation within the human person's four domains. Whereby a stimulus is ever-changing, and each domain is interrelated with the other.   The speed at which the kaleidoscope turned depended upon the

number and type of stimuli, the resources available to process the stimuli, and the perception of the individual's level of adaptation (Roy, 2009). Thus, if an individual was provided appropriate support processing of stimuli would lead to a state of wellness. Individuals without support to process the stimuli would eventually succumb to illness. Finally, how the individual adapted was manifested through behavior knowable to the nurse.

For the breastfeeding women in LA, the *adaptation* of infertility to fertility is a continuum of health and wellness. Nurses who understand this continuum can use this knowledge to help women manage their fertility with confidence. When nurses understand the different patterns of return to fertility or *contextual stimuli*, this helps them provide anticipatory guidance for the women to plan their next pregnancy. Women and couples who understand the physiology of the postpartum breastfeeding transition will gain confidence in managing their fertility. They can learn to appreciate and read the body's normal healthy physiologic responses during the transition.

Roy's model provided a physiologic framework to understand the transition initiated by changes in breastfeeding (*focal stimuli*) from full to partial. These changes can be measured by fertility biomarkers (i.e., urine hormones) processed through the reproductive neuroendocrine system (i.e., within the *regulator subsystem*). The effects of the changes in fertility hormones during the transition reflect fertility status and can be measured through urine. Women track these hormones through the CBFM and document the results daily in an electronic fertility chart. During the breastfeeding transition women who follow changes in urine hormones can track these changes in the MM NFP charting system. The system has developed a unique breastfeeding protocol that has been taught by over 100 professional nurse MM teachers and used by thousands of women throughout the world. This study used fertility chart data from postpartum/breastfeeding women who documented changes of urine hormones over time. Understanding the fertile signs in these charts helped to understand when women

were transitioning from an infertile to a fertile state, which is important for identifying return to fertility patterns and helping women learn how to interpret the changes to manage their fertility.

The RAM concepts discussed above show the links to variables important to understanding breastfeeding physiology during the postpartum breastfeeding transition. This broad conceptual theory provided a structural framework for this study and supported its methodology and purpose. The following section provides the linking concepts and language between RAM and the theory that breastfeeding stimuli act on ovarian function and return to fertility. Regulation of the process occurs within the physiologic domain of the neuroendocrine reproductive system. The effects on the physiologic and neuroendocrine domain due to changes in breastfeeding stimuli were measurable over time through fertility charts from women who used urine biomarkers within the guidelines of the revised MM breastfeeding protocol.

Conceptual-Theoretical-Empirical Framework

Nursing research aims to develop practice-based theory by a conceptual model that guides a testable theory (Fawcett, 2013). A well-accepted way for nurse researchers to accomplish this is the CTE framework. This study used the CTE model to guide its inquiry. The CTE diagram (Figure 4) shows the links between the RAM concepts pertinent to this study, the theoretical concept supporting the physiology of breastfeeding related to the state of women's fertility, and the empirical measurement of key reproductive hormones important for understanding menstrual cycle parameters during the transition.

Figure 4

Conceptual Theoretical Empirical Framework

Physiologic Adaptation

Conceptual (RAM)	Focal stimuli	Contextual stimuli	Regulator subsystem	Adaptive Level
↓	↓	↓	↓	↓
Theoretical (Physiology of Breastfeeding)	Breastfeeding	Knowledge and support	Biological signs fertility	Adaptation
↓	↓	↓	↓	↓
Empirical - (Biological and clinical signs of fertility)	Full vs. Partial breastfeeding.	Knowledge of breastfeeding r/t fertility. Positive support (partner and health care) provider.	Measurement of urine biomarkers (estrogen, LH and progesterone)	Fertile vs. Infertile

Note. Conceptual Theoretical Empirical Framework supports the physiologic domain for the Roy Adaptation Method that supports the Suckling Induced Reflex Theory.

As presented in Figure 4, the conceptual components of the RAM important to this study were the *focal* and *contextual stimuli*, *the regulator subsystem*, and the *adaptive mode* within the *physiologic domain* of fertility. The theory that breastfeeding suppressed ovulation and naturally spaced children provided the underlying principles for this study's methodology. In the following section, a brief overview of the physiologic reproductive neuroendocrine pathways provides empirical evidence for the use of the biomarkers of fertility used to measure the postpartum breastfeeding women's hormones estrogen, LH and progesterone. The *physiologic adaptive process is* known as the transition from infertility to fertility.

Theoretical Framework

The theoretical framework for this study used the underlying physiologic precepts of the "suckling induced reflex theory" (Johnson, 2013). The suckling induced reflex theory provided a reproductive neuroendocrine guide for understanding the physiologic effects breastfeeding had on the reproductive pathways and ovulation (Johnson, 2013). This physiologic neuroendocrine model described human growth and development that showed the mother's natural inclination to breastfeed was imprinted in her as early as her embryonic stage of life. A discussion of the RAM principles described the action of reproductive neuroendocrine processes in the breasts and ovaries to support the RAM's scientific assumptions specific to this study. The RAM's adaptive concepts: *stimuli, regulator subsystem, and adaptation* were used to show the scientific propositions that linked the neuroendocrine processes that *regulated internal and external stimuli* important to *adaptation*, maturation of human growth, and flourishing (Roy, 2009).

The next section is an overview of breast and ovarian development and the reproductive neuroendocrine function that supported the suckling induced reflex's theoretical principles. Breast development occurs in four stages: mammogenesis, lactogenesis I and II (secretory) III (galactopoesis) and involution (Barbieri, 2014; Lawrence & Lawrence, 2016a; Wambach & Watson, 2016). A description of each stage of breast development is provided to show the relationship between the anatomy and physiology of the breast and ovaries. A description of breast and ovarian development begins with the embryonic stage moves through the stages of adolescents and concludes with the perinatal and postpartum stages.

Hormonal Influence: From the Embryo to Puberty

Development of the breast or mammary gland begins at the embryonic stage but does not reach full maturity until pregnancy and lactation occur (Barbieri, 2014; Lawrence & Lawrence, 2016a). Mammogenesis or growth and development of the mammary gland occurs in stages separated by

periods of inactivity. The first two stages occur during the embryonic stage and then again at the pre-pubescent stage. "The human mammary gland is the only organ that is not fully developed at birth"(Lawrence & Lawrence, 2016a). Breast maturation stops during childhood and then starts again just before puberty. Final breast maturation happens with pregnancy and lactation.

As early as the fourth week of gestation, a "milk streak" or "mammary band" appears (Lawrence & Lawrence, 2016, pp. 34 & 58). This mammary band is a thickening of epithelial cells that will differentiate around the 12th-16th week of gestation. Differentiation is important to the development of lobular and alveolar structures of the breast, as each structure has a specific function during lactation (Wambach & Watson, 2016). In a mature adult, the mammary band runs from the axilla to the groin. This line of extra nipples can appear as "supernumerary nipples" in adults (Lawrence & Lawrence, 2016a, 2016b).

From the fourth to the twenty-eighth week of gestation, breast development will continue as layers of cells fold and replicate without hormonal direction. By the 28th week of gestation, sex hormones (i.e., estrogen and progesterone), from the placenta, begin to act on the pre-formed breast tissue. Placental sex hormones will cause continuous folding and outgrowth of the tissue, which will eventually become the ducts and branches within the breasts that are important to milk production and release. After 32 week's gestation, milk ducts, and epithelial bundles from the branches are present and appear swollen from placental sex hormone activity (Lawrence & Lawrence, 2016a). At birth, the infant's breasts consist primarily of ducts and epithelial bundles. The breasts may be swollen and have the pre-milk substance, colostrum, also known as "witches milk," common to both sexes (Lawrence & Lawrence, 2016, p. 36). Witches milk occurs as the breasts are stimulated through placenta hormones and eventually dissipate by the 3rd to 4th week of life, at which time breast growth and development remain dormant until just before puberty.

At some point, just before puberty, the young women's brain signals the ovaries (i.e., hypothalamus-pituitary and ovarian axis [HPOA]) to begin producing estrogen and progesterone. This complex hormone process occurs through the synergistic action between the central nervous system (CNS) and the ovarian system.   CNS hormones responsible for stimulating ovarian development are the growth hormone (GH), insulin growth factors (IGF), and thyroxine. The sex hormones from the HPOA system that work with CNS hormones are GnRH, estrogen, progesterone, LH, and FSH (Heffner & Schust, 2014). The orchestration of hormone activity from the brain to the ovaries is dictated by the GnRH pulse generator (Lawrence & Lawrence, 2016c). The GnRH pulse generator's role is to control HPOA activity, initiate breast and ovarian growth and development before and after puberty. Thus, before puberty, HPOA and CNS hormonal activity prepare the ovaries for future reproduction and the breasts for future lactation (Lawrence & Lawrence, 2016b,c).

The HPOA system begins to stimulate the ovaries approximately 1-2 years before puberty, a time when breast growth and development are reinitiated. Mammogenesis stage I also begins, under the influence of estrogen and progesterone. Mammogenesis, or breast development, continues throughout adulthood until pregnancy occurs. Extension of the ductal system and complex branching of the glands, important to supporting future breastfeeding, is under the influence of the HPOA system and the GnRH regulator system. These neuroendocrine systems also act on the ovaries resulting in menstrual cycling (Lawrence & Lawrence, 2016c). A new menstrual cycle starts when estrogen and progesterone levels drop, allowing for sloughing of the endometrial lining and the start of a new menstrual cycle.

Hormonal Influence: From Puberty through Adulthood

The end of puberty is marked by the first menses or "menarche", under the control of the HPOA system and indicates that ovarian activity and menstrual cycling are beginning. For the first few years after menarche begins, it is not unusual for menstrual cycles to be irregular in length, indicating the

HPOA is not fully developed (Heffner & Schust, 2014). By the time young women experience regular

menstrual cycles, the HPOA is fully developed and capable of supporting the second stage of breast

growth and development (Barbieri, 2014; Heffner & Schust, 2014).

The second stage of mammogenesis depends on hormonal changes during the menstrual cycle,

through the HPOA and GnRH activity. Early in the menstrual cycle before ovulation, estrogen stimulates

the growth of the milk ducts. Once ovulation occurs, progesterone stimulates the milk glands (Barbieri,

2014; Feldman Witchel & Plant, 2014; Lawrence & Lawrence, 2016a).

Each menstrual cycle, growth, and development of the breast ducts and glands begins and then

stops with menstruation. This pattern of growth and development of breast tissue is called remodeling.

With each cycle, when remodeling of the breast occurs, the development of breast tissue advances and

continues until women are in their late 20's to 30's. The final stage of breast development or

mammogenesis III does not occur until pregnancy (Barbieri, 2014; Lawrence & Lawrence, 2016a).

Hormonal Influence: Pregnancy, Parturition and Lactation

Both breast and ovarian growth occur through complex hormone activity and neurological

impulses from the GnRH pulse generator within the HPOA system from puberty through adulthood.

However, when women are pregnant, the hypothalamic GnRH generator is suppressed as fetal placental

GnRH takes over, controlling sex hormone activity within the fetus and mother (Feldman Witchel &

Plant, 2014; Lawrence & Lawrence, 2016b).   Placental GnRH stimulates estrogen and progesterone to

reinitiate maternal breast ductal and lobular growth early in the first trimester of pregnancy. Pregnancy

marks the third and final stage of mammogenesis (Lawrence & Lawrence, 2016b; Wambach & Watson,

2016). Early in the first few weeks of pregnancy, suppression of the maternal HPOA is the result of

elevated progesterone from the embryo.

During this time, pregnancy causes maternal GnRH pulsatility to slow down significantly.   The

slowing of maternal GnRH allows progesterone from the corpus luteum to support and nourish the

embryo during the journey through the fallopian tubes to the endometrium. Implantation of the embryo

takes place in the endometrium. Soon after implantation placental GnRH, suppresses maternal sex

hormones while placental lactogen (PL) and prolactin take over (Feldman Witchel & Plant, 2014;

Lawrence & Lawrence, 2016b). Prolactin and PL are responsible for lobular and ductal development in

the maternal breast throughout gestation (Lawrence & Lawrence, 2016b, 2016c).

About 12 weeks before birth Lactogenesis stage I (i.e., initiation of breastmilk development)

begins and will end a few days after birth. With the delivery of the placenta, lactogen levels decrease,

and maternal prolactin levels elevate. Elevated prolactin levels continue through birth and after.

Placental GnRH: stimulates progesterone to maintain the pregnancy, controls estrogen levels, stimulates

the uterus' growth, and prevents premature contractions. At the breast's level, placental GnRH controls

estrogen and progesterone hormones important to finalizing breast tissue development during

pregnancy (Barbieri, 2014; Heffner & Schust, 2014; Lawrence & Lawrence, 2016b).

Lactogenesis stage I, occurs during mammogenesis stage III, the last stage of breast

development in the third trimester of pregnancy.   Elevated PL and prolactin initiate lactogenesis stage I

(Barbieri, 2014; Lawrence & Lawrence, 2016b). Prolactin is known as the "lactogenic hormone" and is

responsible for the "stimulation of milk-protein genes" during lactogenesis stage I (Lawrence &

Lawrence, 2016b, p. 63).

The milk-protein genes turn on to produce breastmilk unique to the infant's needs throughout

all stages of Lactogenesis. The end of the Lactogenesis stage I and the start of stage II are marked by a

significant drop in estrogen and progesterone and a rise in prolactin. The drop-in estrogen and

progesterone occur just before birth and is important for the final stages of breast structure

development and milk production. During lactogenesis stage I increases in PL and prolactin prepare the

breast to store and produce milk once the baby is born. (Barbieri, 2014; Lawrence & Lawrence, 2016b).

Lactogenesis stage II ends clinically with stage III. Stage III starts when women experience a "letdown"

of milk, signaling that mature milk is present. Stage III starts several days after birth if the infant does

not breastfeed, Lactogenesis ends at stage II (Lawrence & Lawrence, 2016b).

Lactogenesis Stage II can last for a few weeks as the immature milk (colostrum) matures.

Lactogenesis Stage III is identified when women experience copious amounts of mature breast milk

under the control of prolactin (Wambach & Watson, 2016). In Lactogenesis III, elevated prolactin levels

occur with the infant's stimulation of the nipple and removal of breastmilk. Maintenance of elevated

prolactin levels happens each time the infant breastfeeds (Lawrence & Lawrence, 2016b). If the infant is

not breastfed, prolactin levels will drop within a few days postpartum, and the maternal GnRH

generator will resume its function on the HPOA system and stimulate ovarian activity.

When the HPOA system stimulates the ovaries, ovulation can occur as early as one month

postpartum in non-breastfeeding women (Campbell & Gray, 1993). However, breastfeeding women

may not ovulate for months to years (Brown, 2011; McNeilly, 2001). Prolactin levels remain elevated for

about four months when women fully breastfeed (McNeilly, 2001).

Prolactin levels remain high during full breastfeeding for the first four months and then drop.

During pregnancy prolactin levels are elevated up to 200% (Buckley, 2015). Thus, prolactin levels drop

sometime around the fourth month postpartum during LA. Despite the drop-in prolactin levels

breastfeeding women can remain in LA for several months (McNeilly, 2001). While the prolactin levels

remain high, the women's GnRH pulse amplitude will be very low, suppressing ovarian function. Figure

5 shows the natural cycling of GnRH, prolactin, and reproductive hormone levels as they are affected by

full and partial breastfeeding on the GnRH pulse generator. The model was adapted from a diagram

describing how calories affect reproduction (Schneider, 2004). In the model for this study prolactin is

affected by the suckling induced reflex and acts directly on the GnRH pulse generator.

Figure 5

Suckling Induced Reproductive Endocrine Reflex Model
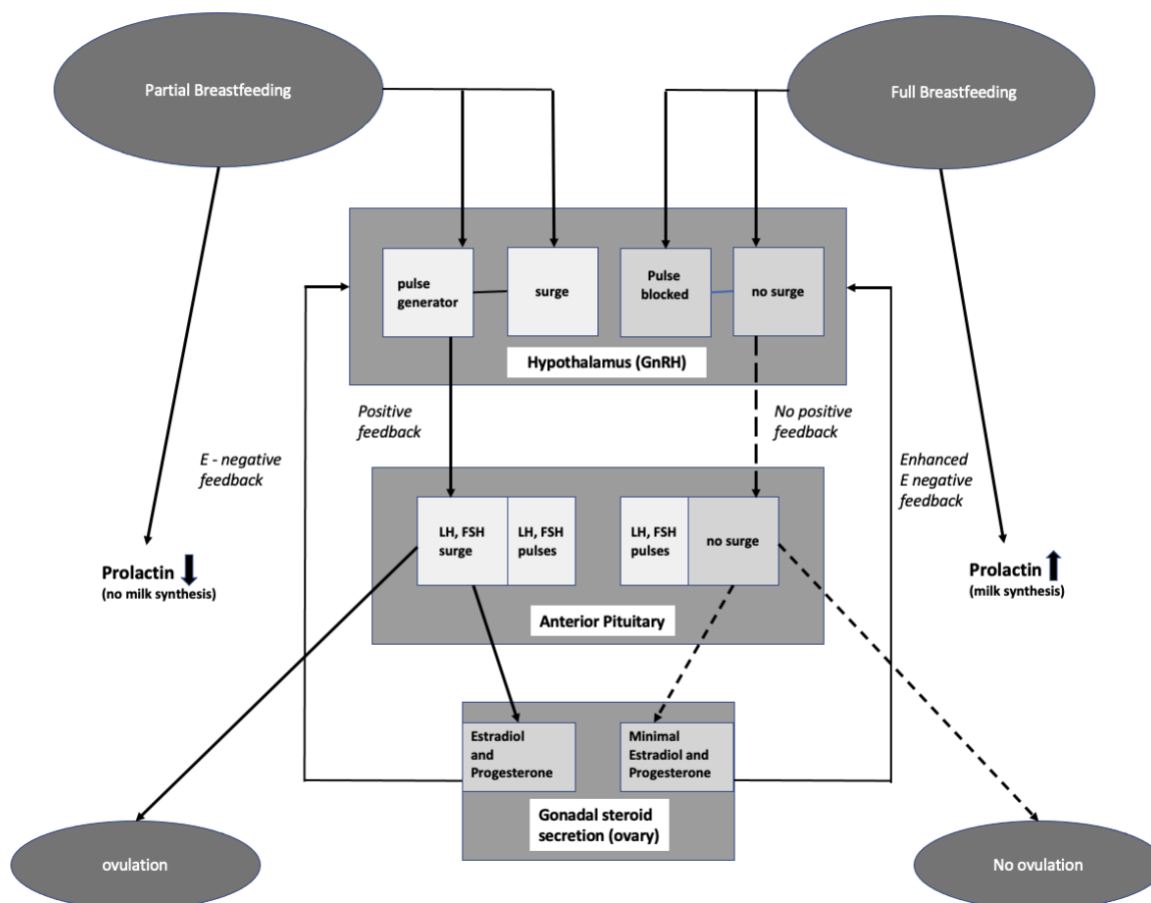
Note: Hypothalamic-pituitary-ovarian axis and Suckling Induced Reflex Theory (SIRT) (model adapted from Schneider, 2004; Johnson, 2013)

In the first months of lactation, when the infant finishes breastfeeding, prolactin levels drop, minimally. With each breastfeeding event, prolactin levels are elevated. Slight drops in prolactin levels occur at the end of each breastfeeding event. However, with each breastfeeding event prolactin levels rise again. Thus, since prolactin levels do not drop completely each breastfeeding episode has an additive effect on prolactin levels. Moreover, frequent nursing in the first few weeks postpartum has a step-like rise effect on the prolactin levels. This step-like rise in prolactin is the pattern that is thought to

maintain suppression of ovulation in Lactogenesis stage III for months (Johnson, 2013; Lawrence & Lawrence, 2016b).

Therefore, Lactogenesis stage III is marked by elevated prolactin levels, a well-established supply of mature milk, and suppressed GnRH pulsatility. With suppression of the GnRH generator pulsatility, ovulation and pregnancy cannot occur (Lawrence & Lawrence, 2016c; McNeilly, 2001b).

As the infant grows and breastfeeds less, prolactin levels drop, removing the block on the GnRH pulse generator (Lawrence & Lawrence, 2016c; McNeilly, 2001b). How quickly the GnRH generator responds to dropping levels of prolactin depends on how the infant is weaned or breastfeeding is discontinued.   Infant weaning patterns vary. Weaning can be quick and sudden where breastfeeding is abrupt, and it can be slow where women replace a breastfeeding event daily with nutritional supplements, or it can be guided naturally by the infant as the baby grows. Slow weaning can take a few weeks to months. There is no set way to wean, and women wean according to their schedule and changes in life events. Weaning triggers, the transition and return to fertility (McNeilly, 2001).

The theoretical premise that women's reproductive physiologic adaptation to weaning is the body's natural way of protecting women from pregnancy too early after birth has been scientifically studied since the twentieth century (Brown, 2011; Henry, 1961; Konner, 1978; Konner & Worthman, 1980; McNeilly, 2001). Studies that used this theory and collected urine biomarkers from breastfeeding women in the transition found hormone patterns concurred with more recent studies (Bouchard et al., 2018; Brown, 2011). This section described the complex physiologic connection between breastfeeding and fertility, which started with the embryonic stage of development and ended with the physiologic events that supported the nurturing of an infant (i.e., lactation).

In this study, the RAM provided a system approach that was guided by the physiologic theory of human reproductive adaptation. Human behavior is unique, ordered, and knowable. The neurologic theory of the physiology of breastfeeding and fertility is complex, but it is ordered and repeatable. Thus,

Roy's (2009) systems model approach to physiologic adaptation provided an excellent framework for this study's methodology. The RAM was used to simplify the complex nature of how breastfeeding's *stimulus* affected women's fertility as it is processed through the reproductive neuroendocrine *regulator subsystem* and manifested through the presence of urine biomarkers.

Roy's (2009) theory of adaptation supported the scientifically known phenomenon that women's bodies naturally adapt to support the new infant and space pregnancies. This physiologic process is a function of human adaptation she referred to as one of survival, orchestrated by a higher power – God!

Philosophic Underpinnings: RAM

Roy's model of physiologic adaptation with its premises, assumptions, and propositions is implicitly rooted in Supernatural design and realism. Supernatural design, the belief that a higher power has ordered the universe and that all persons follow a common purpose, was a foundational premise for the proposed study. Realism as a philosophical belief that truth is not always visible to the human eye but is present and discoverable provided a basis for the scientific background. A premise of this study was that there is a neuroendocrine connection between breastfeeding physiology and fertility imprinted in women before they are born. Moreover, this innate human function is knowable through hormone biomarkers (Strimbu & Tavel, 2011). Thus, Supernatural design and realism were foundational for the philosophic underpinnings of this study.

In the RAM realism provided the scientific connection to the philosophy of the theory. The ancient Greeks used realism and philosophy as a systematic way of thinking and creating theory (Hussey, 2000; Wainwright, 1997). Philosophers believed that to develop theory, three principles of inquiry must be considered: ontology, epistemology, and methodology (Wainwright, 1997). These three areas of inquiry described below, discuss the philosophic connection between realism and the RAM.

Finally, Roy's (2009) use of human adaptation supported the precept that nursing practice is a caring science. Nurse's respect and value the premise of Supernatural design and understand it is intimately connected to the actions of the human person. Individual actions, therefore, are ordered toward survival. Thus, when natural processes such as suppression of fertility-related to changes in breastfeeding patterns are visible through the presence of pre-ovulatory urine hormones, this increases anxiety. Anxiety then is a stimulus that activates adaptation. This study used the RAM as a nursing theory because the method incorporated the belief of Supernatural design, realism, and human adaptation. These concepts support the belief that for women, breastfeeding is a state of wellness designed to naturally space pregnancies.

Ontology

The study of existing or being is "ontology". Through ontology, Nurses strive to understand the meaning of human behavior. For Roy (2009), human behavior is the result of adaptation to stimuli that can positively or negatively impact health. To understand human behavior, nurses borrow from philosophers of human and social sciences (Hussey, 2000; Wainwright, 1997).

Roy used the philosophy of realism to guide the development of the RAM. Realism is the idea that domains are not visible but discoverable. For Roy (2009), the ontology of realism is that humans exist within a complex world beyond the visible and tangible. Humans, therefore, process stimuli through different overlapping domains that are contextual to their being.   Roy (2009) used this concept in her systems model and referred to domains as adaptive modes.

How one interprets the adaptive modes results from multiple stimuli acting upon the individual's physiologic and social environment. For Roy (2009) behavior that affected the physiologic mode of adaptation can be known through the action of organs and systems manifested through outward signs of adaptation. Nurses, therefore, evaluate adaptation through assessment skills unique to the nursing science view of caring.

Nursing, Roy stated, understands that individuals exist in an open system influenced by environmental stimuli, events, assessment of the stimuli' effects, and the individual's adaptation to the ever-changing environment.   The ability to adapt and thrive in one's environment promotes human development and well-being. Well-being occurs when a stimulus is managed once it is processed. Therefore, the nurse's ability to assess well-being comes through astute observation, intuition, interviewing the patient, and measurement of biomarkers. Roy's use of stimuli, processing, adaptability and environment as a systems model are similar to realisms ontological precepts of event, mechanism and experiences (Wainwright, 1997).

Although realism and the RAM are similar in design, Roy has expanded on it by adding the philosophy of human adaptation in her model. In the RAM, human adaptation acknowledges an individual's right to dignity, respect of uniqueness, and unity within all Supernatural design. These principles apply to all individuals simply because they exist. For Roy (2009), nurses incorporate these values in their care by recognizing the uniqueness of individuals bound through a common purpose. According to Roy (2009), Common purposefulness, the belief that humans' actions are directed towards a mutual goal, is dictated by nature.

For Roy, the foundation of her theory is that persons with innate dignity are diverse yet have a common destiny. She calls this caring element of her theory human adaptation. Roy used the theory of human adaptation to show how individuals have a common destiny and that this commonality among individuals affirms their connection to each other, the world, and a "God-figure" (Roy, 2009, p.30). This commonality affirms the human person's connection to the world, universe, and the other. It is a commonality where patterns of human behavior can bind individuals to the other.

Human behavior and action are driven by the need for survival and are central to knowing and valuing the other. Knowledge of the other's unique essence is a common thread found in existence or being of the individual. Thus, for Roy, ontology is centered around human actions that are common or

repeatable and fundamental to human survival. This commonality ties humans to each other through a

common "cosmic unity" (Roy, p.26*)*. A unity that exists within a world that is full of mystery,

discoverable through action, adaptation, and survival. For Roy, the purpose of observing human

behavior is to understand modes of adaptation and individuals' resources that support one's health. In

nursing, the science of human adaptation couched within Supernatural design respects all living entities.

Nurse's value the uniqueness of each individual and support them within their natural environment. For

nurses, the goal of caring is to learn how to understand and support the normal, natural processes and

patterns that respect individuality, and consider human and earth resources that acknowledge the God's

presence and the individual's connections to each other and their higher power (Roy, 2009).

Epistemology

The second step to understanding social sciences and the nature of human behavior in realism is

to accept that there is a world that is known and visible and one that is not visible but is known to be

present (Wainwright, 1997). The philosophy of realism provides a framework for this knowledge, and it

supports the underlying principles in the RAM (2009). Within the RAM, realism is the structure for

knowing (epistemology) that considers the question, "how do we know what we know as nurses"? In

realism, mechanisms cannot be directly observed but are present and discoverable through theory and

inquiry (Wainwright, 1997; Williams et al., 2017).

The RAM used systems theory outputs or products of behavior to learn what is knowable

through the belief that a mechanism was present but not visible. The *regulator subsystem*, the

mechanism that processes activity, helps determine the essence of an outcome (Roy, 2009). The

essence of physiologic adaptation is observed by biologic output measurable through biomarkers

(Frederickson, 2000; Roy, 2009).

Therefore, when physiologic and psychologic adaptive behaviors are observed, they provide a

link to theoretical scientific inquiry and reveal the existence of hidden mechanisms and systems that can

be measured. Roy's use of realism, humanism, and systems approach provided a nursing science framework used to understand the physiologic effects of <u>breastfeeding</u> *stimuli* on reproductive functions.

Methodology

Finally, to study human science and behavior, a methodology is needed (Wainwright, 1997). The methodology provides a structure for theory, and a means to understand phenomena. Theory for the realist is not a method, but a methodology that constructs links from grand theory to middle range and finally to grounded theory (Wainwright, 1997; Williams et al., 2017). Similar principles that guide nursing research have been proposed by Fawcett (1999).

Fawcett (1999) described the CTE framework to provide a point of reference that guides nursing research. This study used the RAM as its conceptual framework. Breastfeeding physiology as its theoretical guide and key reproductive hormones were used to understand the menstrual cycle's parameters in the postpartum breastfeeding transition as empirical evidence for patterns unique to understanding return to fertility.

Realism's philosophic link of "explanatory mechanisms" paints a logical brush stroke over this study's CTE and methodology (Wainwright, 1997, p.1264). The RAM's systems approach to human behavior is a grand nursing theory aligned with the philosophy of realism through its description of processing subsystems that were not visible other than through adaptation. Realism supported the understanding that scientific theory can reveal the truth of a hidden, yet present, natural phenomena (Wainwright, 1997). Therefore, RAM was used to build the CTE in this study and was an important methodology that provided tangibility to the process. The process was then used to understand the phenomena of interest, which is breastfeeding physiology and its effect on ovarian activity ovulation and return to fertility.

Gaps in the Literature

Prospective and retrospective longitudinal observational studies from breastfeeding women who used CM, BBT, and urine hormones have been done since the mid-20th century. However, small sample sizes, lack of operational definitions for key variables, tedious data collection processes, and high attrition rates have negatively affected the use and dependability of these signs of NFP for breastfeeding women and their clinicians. Most research on the effectiveness of NFP during breastfeeding completed in the 1980s and 1990s focused on the development of LAM. Although the LAM was determined to be theoretically highly effective, its use effectiveness was determined to be low in a secondary analysis of survey data (Fabic & Choi, 2013). Close examination of the LAM studies in two Cochrane reviews found poor descriptions of breastfeeding and menses (Van der Wijden et al., 2008; Van der Wijden & Manion, 2015). The authors concluded there was no difference in effectiveness for the women who fully breastfed and those using the LAM. Despite this, the LAM was promoted worldwide (Finger, 1996).

The initial development of the LAM came from Brown's (2011) work. For years he continued to work on advancing the understanding of the connection between breastfeeding and urine hormones. Brown's success in collecting and analyzing these hormones used by other researchers advanced the understanding of NFP use during the postpartum/breastfeeding transition (Hatherley, 1985a; Kennedy et al., 1995).

Brown's work, which compared CM, BBT, and urine hormones, was seminal to understanding NFP methods used during the postpartum/breastfeeding transition. His work in describing the inconsistency in CM descriptions across studies showed why the use effectiveness pregnancy rates of CM methods (i.e., OM) during the postpartum/breastfeeding transition were low.

Other problems with CM studies showed variability in effectiveness rates were related to the rules used to identify the fertile time. Heterogeneity of key variables among NFP studies resulted in changes in rules, each method had different rules and descriptions of CM over the last 50 years.

Inconsistent rules and interpretable terminology have made it difficult to compare use effectiveness

rates across NFP methods (Howard & Stanford, 1999; Peragallo Urrutia et al., 2018). Among the

different OM's the inability to clarify the fertile time has been one of the greatest deficits to

understanding the use effectiveness of CM during the postpartum breastfeeding transition. The lack of

standardization of terms used to describe CM observations added to the problem of CM having high

sensitivity and low specificity as a single indicator biomarker during LA and the first few cycles is low.

Lack of specificity and high sensitivity of the CM meant long periods of unnecessary abstinence or

unintended pregnancy for women trying to avoid a pregnancy.

In a reanalysis of Brown's data, Bouchard et al. (2017) standardized descriptions of CM and used

urine hormones to confirm that CM has a low predictive value. He also found that women experienced

three different patterns of hormone activity during the transition. These patterns showed if women

were fertile or not by comparing TE and PDG levels to CM descriptions. The first pattern in the

amenorrhoeic phase showed that TE levels remained low and steady at less than 10 µg/24 hours for

several months and peaked late in the cycle. This pattern was followed by low levels of PDG and luteal

phases that were less than 11 days. In the second pattern, TE levels intermittently rose greater than 10

µg/24 hours, but PDG levels remained low, the length of the luteal phase was less than 11 days. In the

third pattern, TE and PDG levels increased during the first few months, dropped, and the women

remained in amenorrhea for several more months. With this pattern, the first TE/PDG rise during

amenorrhea was not sufficient for ovulation, but in subsequent cycles the rise did indicate ovulation

occurred.

Bouchard et al., (2018) reanalysis of Brown's data confirmed two results that had been reported

in the past. First, women experienced one of three different patterns for return to fertility. Second,

women's fertile CM signs did not correlate with urine hormone results. However, the sample size was

small (n= 26), and the data was from Brown's work from postpartum/breastfeeding women collected in

the 1970s and 1980s. The work of Brown (2001) completed in the 20th century was a good start; however, the collection of urine samples from women was tedious. In the early 2000s the CBFM was available for women to do POC fertility testing. This POC testing was added to the MM of NFP and revolutionized NFP research. The combination of POC testing and NFP protocols significantly reduced the chance of an unintended pregnancy during the postpartum/breastfeeding transition(Bouchard et al., 2013; Fehring et al., 2017; Mu et al., 2020).

Since the early 21st century researchers at the Marquette University Institute for NFP have been helping women understand the postpartum/breastfeeding transition using the CBFM. A pilot study of the original protocol modernized the use of NFP during the postpartum/breastfeeding transition. The pilot study of the modernized protocol identified how CM overestimated the fertile days compared to urine hormones (Fehring et al., 2005). In 2013, an analysis of women using the original protocol resulted in a revision of the protocol. The revised protocol added a second LH test strip during the LA phase. Women were instructed to test every 10 days with the monitor and begin the FW on day 10 in the first cycles, previously the original protocol stated the FW started on day 6 of the cycle. The start of the FW for cycle 2 was day 9, cycle 3 was day 8, cycle 4 was day 7 and by cycle 5 couples resumed starting the FW on day 6. This gave couples a few more days of infertility in the pre-ovulatory phase during the first four cycles (Bouchard et al., 2013). Studies on the original protocol found adding the CBFM to a simplified nurse managed NFP system significantly improved effectiveness rates and reduced abstinence during LA (Fehring et al., 2005). However, improved effectiveness came with added costs such as daily testing instead of every other day testing with the CBFM. Also, adding LH testing in the afternoon increased testing to twice a day. In this literature review of past methods of NFP used during the postpartum/breastfeeding transition found CM, BBT and the LAM pregnancy use effectiveness rates were high. The addition of FMU testing added to the MM NFP system significantly improved the use effectiveness rates. However, at an increased cost to the users. To understand how the protocol can be

improved it is important to identify the physiologic menstrual cycle parameters of the postpartum/breastfeeding transition. The purposes of this study were to describe the physiological breastfeeding transition to fertility from LA through the first six cycles postpartum and to evaluate the correct and typical use effectiveness pregnancy rates of the revised protocol at 12 months and 12 cycles of use.

<div align="center">**Conclusion**</div>

The RAM is a complex model that used the philosophic principles of natural design, realism, and human adaptation. Roy's (2009) understanding of natural design appreciates the order of the universe with an understanding that individuals have a common purpose of existence. Roy has named this common purposefulness of existence "veritivity," a word rooted in the Latin term "veritas", which means truth (Roy, 2009, p. 28). Realism is a philosophy of the natural science of human behavior where the output of action or biomarkers reflects the individual's physiologic adaptability to stimuli. The result of the stimuli or output is known and visible and is evidence for truth.

Searching for truth in the science of human behavior is complex. However, when the study of human behavior is approached, methodologically, truth is repeatable and knowable to science. The methodological approach in this study is the CTE framework. The study's design is governed by the RAM's physiologic conceptual theory and the Suckling Induced Reflex Theory. Evidence for the effect breastfeeding stimuli have on ovarian activity and fertility in the woman's transition from infertility to fertility were measured by the presence of estrogen and LH documented in MM NFP charts.

Chapter 3: Methodology

The purposes of this study were to describe the physiological breastfeeding transition to fertility from lactation amenorrhea (LA) through the first six cycles and to evaluate the correct and typical use effectiveness of the revised Marquette Method (MM) breastfeeding protocol. This study aimed to understand the effectiveness of avoiding pregnancy in women who used the revised breastfeeding protocol during LA through the first 11 menstrual cycles after the return of fertility. The second aim was to describe the physiologic postpartum breastfeeding transition to fertility through the first 6 menstrual cycles from women who used the revised MM postpartum breastfeeding protocol.

This study is an extension of the pilot study described in detail in Chapter 2. In this chapter the methodology used to test the aims and research questions are presented. Then a description of the studies design, sample of interest, measures, data collection, processing and the analysis are provided. A brief historical overview of what the MM NFP system was like during the time it was active provides context for the data that was analyzed. Data sets used in this study are owned and managed by nurse researchers at Marquette University Institute for Natural Family Planning (NFP).

Nurse researchers at the Marquette University Institute for NFP have helped breastfeeding women avoid pregnancy during the postpartum/breastfeeding transition since Fehring et al. (2005) published the first article of 10 women who used the original protocol. The protocol published in April 2008 in an online nurse managed NFP website was the first of its kind. Since that time, hundreds of menstrual cycle charts have contributed to understanding the benefits of adding point of care (POC) home testing with the Clearblue Fertility Monitor (CBFM) to the postpartum/breastfeeding protocol.

The MM breastfeeding protocol was reported to be 92-98% effective over 12 months of use (Bouchard et al., 2013). The two unintended pregnancies occurred at nine and twelve months of use. One pregnancy occurred during lactation amenorrhea (LA) and the other during the first cycle after menses. Examining when the peak day (PD) that is, one day after the LH surge, occurred Bouchard et al.

(2013) found that women experienced long follicular phases (i.e., ovulated late), the first few cycles postpartum. The finding was like that described in Brown's Continuum (2011). The results from the Bouchard et al. (2013) study led to a revision of the MM protocol for the first 6 cycles after LA (see Appendix A). The original protocol used by women in the 2005 study was evaluated in the 2013 cohort study for effectiveness to avoid pregnancy. These studies did not evaluate the menstrual cycle parameters in the first 6 cycles postpartum nor evaluate the revised protocol's effectiveness. The current study used the findings from Bouchard et al. (2013,2018) studies as a guide. Questions of interest included a descriptive analysis of menstrual cycle parameters in the first 6 cycles during the breastfeeding transition and then analysis of the use effectiveness of the revised breastfeeding protocol.

Design

A repeated measure pregnancy effectiveness and longitudinal descriptive analysis of menstrual cycle parameters from postpartum breastfeeding women who used the revised MM protocol during the first 6 cycles postpartum was completed. Descriptive variables measured were the length of Lactational Amenorrhea (LA)/cycle zero and the following 6 cycles, the length of the follicular and luteal phases of each cycle and characteristics of first menses. Survival analysis pregnancy rates for correct and typical use pregnancy rates through 12 months and 12 cycles of use were reported. A repeated measures quasi-experimental design was used to test the effectiveness of the revised MM postpartum breastfeeding protocol for avoiding pregnancy. The independent variable for this study was the revised postpartum breastfeeding protocol. The dependent variable was an unintended pregnancy. Correct use and incorrect use pregnancies were reported.

Summary of Aims and Research Questions

The first aim was to analyze the menstrual cycle parameters and the second aim was to address pregnancy effectiveness rates. The research questions of the first aim were to: 1) evaluate the length of

cycles, 2) evaluate the length of the pre- and post-ovulatory phases, and 3) to characterize the first menstrual bleed, considered to be the clinical sign that fertility has returned. The research questions of the second aim were to: 1) evaluate the correct use and 2) typical use pregnancy rates of the revised protocol over 12 months and 12 cycles of use.

Sample

A convenience sample of postpartum breastfeeding women who registered on the MM NFP website between July 1st, 2015 and May 1, 2019. Women were between the ages of 18-45 years old.

Minimum inclusion criteria

Women were included if they met the following criteria: (1) registered as either total or partial breastfeeding, (2) singleton birth (3) used the revised MM breastfeeding protocol, (4) provided the infant's date of birth, and (5) had at least one complete cycle postpartum.

Sample size

The estimated sample size came from prior postpartum breastfeeding studies that tested the original protocol and were published in 2013 and 2017. In the efficacy study by Bouchard et al. (2013), 198 women used the original protocol. Results showed eight total unintended pregnancies per 100 women at 12 months. For Fehring et al. (2017) a cohort comparison of 816 postpartum women, who used either the Clear Blue Fertility Monitor (CBFM) and cervical mucus (CM), only CM or both, found a total of 14 pregnancies (i.e., typical use) per 100 women at 12 cycles of use (SR = .86; SE = .019). Women who used the CBFM either with or without CM were following the original breastfeeding protocol for NFP? (Fehring et al., 2017). Both Bouchard et al. (2013) and Fehring et al. (2017) used the Kaplan-Meier survival analysis method to assess pregnancy rates.

For this study, pregnancy survival rates (SR) were calculated using the Kaplan-Meier method for survival analysis (SA). An a priori sample size of at least 50 participants were needed to achieve a

standard error (SE) of < 0.05. This estimation came from a simple non-comparison survival analysis

model described by Norman and Streiner (2000). Therefore, a minimum of 50 eligible postpartum

breastfeeding women had to complete 12 months of use for the present study. Because this study used

a design like the Bouchard et al. (2013) postpartum effectiveness study, results from that study were

also used to determine sample size.

In the Bouchard et al. (2013) study, 346 women registered, 198 started the study. About half of

the active participants (n=70) did not complete 12 months of charting. Considering this attrition rate to

have an adequate sample size, we projected a sample of 350 postpartum breastfeeding women would

be sufficient to support statistical power.

Protection of human subjects

Eligible women were contacted through email. The email sent from the Qualtrics site supplied

women with information on the research study and the reason why we were contacting them for

additional information. The email notice contained a link to the Qualtrics questionnaire. Clicking on the

link in the email brought them to the Qualtrics site and the consent to participate form. Emails were

matched to the unique username's women were assigned to in the parent study. Once women who

qualified completed the questionnaire their emails were removed, and data was de-identified. This

study was approved by the Marquette University Institutional Review Board (MU-IRB) HR-3666. The

parent study (HR 1597) has been approved by MU-IRB every year since 2008.

Setting

The setting was the online MM NFP website. The website was a platform developed specifically

for teaching women about fertility health and the MM of NFP. Women who used the website learned

the revised MM Breastfeeding Protocol and how to chart and interpret their biological signs of

fertility. The revised breastfeeding protocol instructions found on the site were accessible to women in

the discussion forum. Access to the instructions on the discussion forum were given to the women after they completed the consent form and paid for services.

<div align="center">**Measures**</div>

Description and Definition of Variables

Clear operational definitions of variables were used to describe menstrual cycle parameters. These definitions provided clear guidelines for data processing and analysis.

Menstrual cycle parameters

Menstrual cycle parameters relevant to this analysis were the cycle length, length of the follicular and luteal phase, the estimated day of ovulation (EDO), the first day of high and peak readings on the monitor, menses duration, and bleeding score. Time to points of change in the hormone patterns (i.e., low, high, and peak) from the CBFM were used to identify menstrual cycle parameters. The following were the definitions and means of determining the points of change in the menstrual cycle parameters.

Length of Cycle Zero and First Six Cycles

The length of cycle zero was determined by counting the days from the infant's date of birth to the day before the first day of menses. Once menses was found, the length of the following six cycles was determined.   In each cycle, the day of the first day of menses to the day before the next menses counted as one cycle.

Length of the Follicular Phase

The length of the follicular phase during cycle zero was determined by counting the days from the infant's date of birth up to and including the last peak day (i.e., the day after the LH surge) on the chart. If a peak day was not documented, the follicular phase could not be calculated. When women returned to cycles, the follicular phase was calculated by counting from the date of the first menses up to and including the second peak day on the chart.

Length of the Luteal Phase

In cycle zero, the length of the luteal phase was determined by counting the days from the day after the last peak on the chart up to and including the day before the first day of menses. After the first menses, the length of the luteal phase was determined by counting the days from the day after the second peak on the monitor up to and including the day before the next menses.

Time to the Estimated Day of Ovulation

The time to the estimated day of ovulation (EDO) was determined to be from the baby's birth up to the day after the first peak on the monitor. The EDO was identified as the last peak day just before menses. The time to the EDO in the following six cycles began on the first day of menses in each cycle through the second peak on the monitor.

Time to the First High and Peak on the Monitor

Time to the first high (i.e., the estrogen rises from baseline) on the monitor to the EDO or the second peak day on the monitor is the cycle's fertile time or fertile window. In this study, time to the

first high on the chart in cycle zero was calculated using the infant's date of birth. The date of the first

high was subtracted from the infant's date of birth. In the following 6 cycles, the fertile window started

with the first recorded high day in the cycle. Time to the EDO in cycle zero was calculated

using the infant's birth date subtracted from the date of the second recorded peak day in the cycle. For

the next six cycles, the time to the EDO's was calculated using the cycle day that the second

peak occurred. Once the time to the first high and the EDO was calculated, then the time to the EDO

was subtracted from the time to the first high. The difference was used to identify the length of the

fertile window for each cycle.

Menses and the Menstrual Cycle

First and next menses were identified when four or more consecutive days of bleeding had a

bleeding score of five or higher that may or may not have been preceded by a peak on the monitor. The

menses had to follow a crescendo-decrescendo or a decrescendo-crescendo-decrescendo bleeding

pattern (Daggs, 2015). The bleeding score was calculated using the MM NFP systems bleeding scores 1

to 3, with 1 = light bleeding or spotting, 2 = moderate bleeding, and 3 = heavy bleeding. The menses

score was a sum of consecutive days of bleeding using the MM NFP bleeding system (see Figure 6). The

length of the menstrual cycle was estimated using the date from the first day of bleeding (recorded as a

number) to the first day of the next series of four or more days of vaginal bleeding that met the

definition of menses 21 days apart.

Figure 6

Menses Scoring
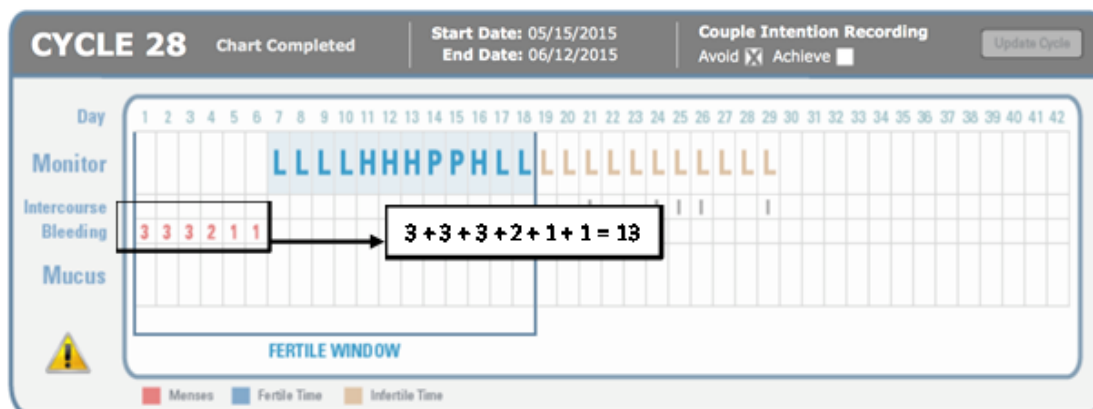
Note. This is a sample from the MM NFP fertility charting system. The menstrual cycle begins on the left of the chart and the bleeding intensity is indicated by the numbers seen in the row labeled "Bleeding". In this example the sum score of the bleeding is represented.

Instrument

Clearblue Fertility Monitor (CBFM)

The CBFM is a handheld testing device on the market for couples with cycles 21-42 days long who want to achieve a pregnancy (Swiss Precision Diagnostics GmbH, 2015). The device uses test strips to detect the biomarkers estrone-3-glucuronide (E3G) and luteinizing hormone (LH) in women's first-morning urine (Swiss Precision Diagnostics GmbH, 2015). Estrone-3-glucuronide (E3G) is the urine byproduct of the pre-ovulatory hormone estrogen. The E3G levels rise above a baseline seven to ten days before ovulation, preparing for the eventual LH surge (Catt et al., 2006). The LH surge occurs about 24-36 hours before ovulation (Barbieri, 2013; Behre et al., 2000; Swiss Precision Diagnostics GmbH, 2015).

In the mid to late 20th century, the gold standard for finding the EDO was transvaginal ultrasound (TV-US) (Barbieri, 2013). Since that time, other less invasive methods for identifying the EDO

through urine testing have been found to be reliable (Behre et al., 2000; Direito et al., 2013; Johnson et al., 2015; Roos et al., 2015). In a comparison between the CBFM and TV-US, Behre et al. (2000) found from 53 women who provided 135 menstrual cycles 97% of the time ovulation occurred when the CBFM identified the LH surge. The study also found that when the CBFM did not detect the LH surge, the cycle was anovulatory (Behre et al., 2000).

Recent studies by Johnson et al. (2015) and Roos et al. (2015) confirmed the accuracy of identifying ovulation with first-morning urine (FMU). In both studies, serum and urine hormones correlated with ovulation detected by TV-US. These studies showed that E3G and LH's urine hormones accurately detected ovulation in women in regular length cycles. The hormone E3G occurred on average about three to five days before ovulation, and the LH occurred on average one day before ovulation (Johnson et al., 2015; Roos et al., 2015). The CBFM on the market was programmed with the same E3G and LH levels found in both studies.

The CBFM provided objective pre-ovulatory signs and has been used in pregnancy effectiveness and menstrual parameter studies for the last 20 years. The device was easily accessible and designed for women to use in the comfort of their homes. Postpartum breastfeeding women who agreed to chart their daily hormone results into the MM NFP system used the CBFM. Analysis of thousands of charts from women who agreed to use the CBFM has helped improve the researcher's understanding of menstrual cycle parameters (Fehring et al., 2006; Fehring & Schneider, 2008). The addition of the CBFM to NFP research has ended the need to do TV-US or serum hormone levels to identify ovulation. The device has helped significantly reduce the cost and burden of NFP research since there is no need for urine samples to be collected and analyzed in labs.

Tools

The Marquette Method System of NFP

The MM NFP system has combined the CBFM, urine test strips, and an electronic charting system into an online family planning and fertility care management system. The MM NFP system integrated the CBFM to help women identify when urine estrogen levels were present, indicating the start of fertility. When the monitor detected elevated estrogen levels, the word "high" was displayed on the device's screen. After the monitor identified the first high day, it was programmed to find the LH surge. When the LH surge was detected, it was shown as a "peak" or smiley face on the monitor. The CBFM provides qualitative hormone tracking and lets women know when they are fertile or not. Women who used the MM NFP system are instructed to read the CBFM user manual.

Women set the monitor using the user manual instructions for the first day of menses. For women in regular cycles in the first cycle of use the monitor will request a test on the 6th day of the cycle. Daily FMU testing begins on day 6 of the cycle and will continue until the monitor indicates an LH surge or peak day. The peak day is when the monitor detected LH and ovulation is expected to occur the next day. The MM NFP system has women record the monitor results as L = low fertility; H = high fertility and P = peak fertility. That is, low estrogen levels are considered low fertility days, when estrogen levels are detected, and the ovary is preparing to release the egg this is high fertility and just before ovulation LH levels surge and this is peak fertility. Women also are instructed to record the quality of their menstrual bleeding and acts of intercourse in the fertility charting system (see Figure 1).

MM NFP Fertility Charting System. The MM NFP fertility chart system will automatically calculate women's fertile time/fertile window (FW) that is identified by a blue bracket as seen in Figure 1. In the first 6 cycles it will start the FW on day 6 unless a high or peak day is recorded prior to that day. For example, if a high or "H" is recorded on day 3 of the cycle the FW bracket will begin on day 3. The FW bracket will close 3 days after the last P on the monitor. When the first day of menses occurred, the

woman would close out the fertility chart and set her calendar to start a new chart. To close the fertility

chart, a popup window asks if a pregnancy occurred. If a pregnancy occurred, she clicked on the "yes"

button this sent a notice to the user's internal portal and to the administrative portal. When the user

completed the pregnancy evaluation the completed form stayed in the user's membership portal. All

pregnancies reported by the women were collected in an internal administrative portal. The

administrative portal listed the users unique ID. The pregnancy evaluations were accessible through the

user's portal. All data from the MM NFP system which included fertility charts, pregnancy evaluations

and demographic surveys were saved into data tables before the site was archived.

Revised MM Breastfeeding Protocol

The revised MM Breastfeeding Protocol is a version of the original MM Breastfeeding Protocol, a

comparison of the two protocols was published in Bouchard et al., (2013) and can be found in Appendix

A. The protocol was revised in response to 2 unintended pregnancies found in Bouchard et al. (2013).

The revised protocol was integrated within the MM NFP System. It was a tool developed by MM NFP

researchers and found to be 92-98% effective in helping couples avoid pregnancy during the

breastfeeding transition (Bouchard et al., 2013; Fehring et al., 2017; Fehring et al., 2005; Mu et al.,

2018). The tool is a series of instructions that guide breastfeeding women through the first 6 cycles

postpartum.

After having a baby, women are instructed to begin the protocol by the 8th week postpartum.

To start the protocol, she will set the CBFM for the morning she wants to begin testing. To set the CBFM

women will choose the earliest date possible, and this will program the monitor to test within a few

days. Once the CBFM begins requesting a test it will do so until it detects the LH surge. If an LH surge

was not detected it would request a test for up to 20 consecutive days. Women using the revised

postpartum breastfeeding protocol were instructed to test for 10 consecutive days unless a peak day

was detected.   If a peak day was found she could stop testing and wait 10 days at which time first

menses was expected. If menses did not occur the monitor would be reset, and women were instructed to begin another 10 days of testing.

When women reset the monitor by choosing the earliest date this forced the device to request a test on the 2nd day after the reset. To not miss the peak day/LH surge women were instructed to test with an LH test kit (i.e., brand preferred were Wondfo test kits). Instructions also included an optional daily evening LH test.   If menstruation occurred within the 10 days after the peak day, the CBFM was reset on the first full day of bleeding. The first 9 days of the new cycle were considered infertile if the woman was breastfeeding. That is, the start of the fertile window in cycle one was cycle day 10. In the following 5 cycles, the fertile window started on cycle days 9, 8, 7, and then day 6 (see Appendix A). By the 5th cycle postpartum, the fertile window began on day 6.

Pregnancy Evaluation

A tool was developed to rate each pregnancy with questions that identified if a pregnancy occurred with correct or typical use of the protocol (see Appendix E). The pregnancy tool used by MM NFP researchers for this study was adopted from the form used in a randomized control trial study (Fehring et al., 2013). Pregnancies were considered incorrect use when the intention recorded on the chart was "avoid," and the act of intercourse was recorded during the fertile time. Alternatively, if the pregnancy evaluation intention did not match the fertility chart in the conception cycle, this was recorded as an incorrect use pregnancy. Incorrect use also included incomplete charts where the fertile and infertile phases were not apparent or acts of intercourse were not recorded. Correct or perfect use pregnancies were determined to be pregnancies that occurred when the couple used a fertile day according to their pregnancy intention.

Qualtrics Questionnaire

An online survey managements system licensed by Marquette University was used to collect additional information from the women that met minimal criteria. The web-based survey tool provided a platform where women learned about the purpose of the study, could sign the consent form, answer a few demographic questions, and report a pregnancy that may not have been reported in the archived website.

Data Collection

This study is a retrospective analysis of data that came from postpartum breastfeeding women who registered on the archived MM website and learned the revised MM breastfeeding protocol. Therefore, a brief overview of the process these women followed provides important contextual background.

Historical Description of the Process in the Archived Website

The archived website was active in April 2008 through November 1st, 2019. During that time women learned the MM NFP system through online instructions and professional NFP nurses. Before registering, women signed a consent form. In the parent study, the consent form included an agreement to chart a minimum of 6 cycles online; however, they could withdraw from the study at any time. Women withdrew from the study when they informed researchers, they were pregnant. Lost to follow-up was recorded when women stopped charting for 12 or more months. Some women contacted the administrators of the site after having a baby to resume charting. They were provided with their previous username so they could resume charting in the same account.

After electronically signing the parent study's consent, the women paid for either 6 or 12 months of access to the site. Women accessed the site with their user identification and a password of their choosing. Paid access included the online charting system, self-tutorials for instructions on how to chart, the revised breastfeeding protocol, and a discussion forum. The women used the discussion forum to ask questions about the method, their chart, or other related concerns. Questions in the discussion forum were answered daily by professional MM NFP nurses. Women who registered into the secured online instruction system had unlimited access to the discussion forum and nurse.

Once payment was received, women completed a twenty-one-item online registration form (see Appendix F). In the form, women self-identified as totally or partially breastfeeding. After completing registration, women completed a ten-item pre-instruction fertility quiz. When the quiz was completed, access to the revised protocol and online charting became available. The online charts were linked to the user's identification number and email.

The postpartum breastfeeding women found the revised protocol in the discussion forum dashboard. In the instructions, they were to begin the protocol at 8 weeks postpartum. Other instructions were to read the user manual for the CBFM and record the online MM chart results.

Obtaining data from the MM Online Charting system

Data collection occurred in two phases (see Appendix G). The first phase will include an analysis of demographic and chart data downloaded from the archived website. Data transfer and translation began with a large data set in structured query language (SQL) format. A conversion program called MySQL Workbench was used to convert data into comma-separated values (CSV) files. The demographic data tables were filtered using the variables 1) Reproductive Category and 2) Are you breastfeeding? Once data was parsed, unique user identifiers were used to merge the demographic and chart tables to identify women who met minimal criteria.

Phase two began with emailing the women who met minimal criteria. The data set included women who registered in the archived website between July 1, 2015, and May 1, 2019. The start date chosen was one year after the revised breastfeeding protocol was published as new instructions on the archived website. The end date was selected because it occurred a month before significant changes occurred to the website, affecting outcomes. Visualization of data was completed in SPSS 27 for review.

Management of Missing Data in Fertility Charts

Errors in data, including extreme outliers, were checked by going back to the original chart or registration. Descriptive analysis was completed and reported both with and without extreme outlier variables. Further details about the management of missing fertility chart data can be found in Appendix D.

Securing Data

The data files were password-protected and stored in a OneDrive folder within Marquette University technology system and in an Amazon Web Service account owned and managed by the Institute for NFP.

Qualtrics Questionnaire a Second Collection

An email invitation with a brief description of the study and a link to the questionnaire was sent to women who met minimal inclusion criteria (see Appendix H). Demographic information items included the type of delivery, date of birth of the infant/s breastfed while using the revised protocol, health of the infant at birth, clarification of breastfeeding frequency upon registration, weaning patterns, and any unreported pregnancies. These items were necessary to understand menstrual cycle parameters and describe the population who used the revised protocol. It also gave women a second chance to report pregnancies.

Data Analysis

For the first research aim descriptive statistics were utilized to examine the menstrual cycle parameters during the breastfeeding transition. Time calculations to and from the EDO, in cycle zero and the following six cycles, were computed using the infant's date of birth, the date of the EDO, and the date of the first day of menses. The normality, mean, standard deviation, median, and 95% confidence intervals (CI) of the cycle parameters were assessed. The use of median cycle lengths and times to events described the data's degree of normality. The difference between the mean and the median was necessary for identifying to what degree the data was skewed. Outliers were shown using histograms or box plots.

To understand characteristics of first menses the number of days of bleeding and a sum of bleeding days were used to characterize menses. In the MM NFP charting system as seen in Figure 6, women recorded a one for light bleeding, two for moderate bleeding, and a three for heavy bleeding. How the sum of menses was calculated is seen in Figure 6.

To complete aim two for this study a quasi-experimental repeated-measure design was used. Pregnancies were evaluated for use effectiveness from the women who used the revised postpartum

breastfeeding protocol. The protocol was designed to help women avoid pregnancy during the

postpartum transition to fertility. In this study, the independent variable was the revised breastfeeding

protocol, and the dependent variable was the unintended pregnancy. The dependent variable

unintended pregnancies were classified as either correct or typical use at 1,3,6,9 and 12 months

and cycles of use.

Standard Kaplan-Meier survival analysis was used to determine pregnancy rates during cycle

zero and the first 12 months and 12 cycles postpartum. In this study, a table was used to show the

number of participants and pregnancies, survival rate, and standard error for each month/cycle of

interest. The dependent variable (i.e., pregnancy) was reported as a percentage for each parameter of

time and represented by the number of women who survived. Pregnancy rates per 100 women who

used the method at 1,3,6,9 and 12 month and cycles of use were reported.

As previously described in the tools section of this chapter pregnancies evaluations were located

in 1) an internal administrative portal for the MM NFP online charting system and 2) the Qualtrics

questionnaire. A date search feature in the administrative portal was used to identify pregnancies from

women who registered between July 1st, 2015 and May 1st, 2019. Each user in the portal that identified

a pregnancy occurred was evaluated. Evaluation included 1) a pregnancy evaluation and 2) a chart with

the day of conception indicated as an "I" for intercourse. Pregnancy evaluations from the user's

membership portal and the Qualtrics questionnaire were the same. All pregnancies required

a pregnancy evaluation and the original chart data for review.   Two professional MM NFP nurse

researchers reviewed both the pregnancy evaluation and the fertility chart independently. Once the

pregnancies were classified the two independent reports were compared. Correct, incorrect, and total

cycles of use were reported.

Conclusion

In this chapter the design for the study was presented. The design included a historical

overview of the original sources data collection process to provide context to this study. This study is a

retrospective analysis of chart data from women who registered in the archived MM NFP System to

learn the revised postpartum breastfeeding protocol. The chapter provided a definition of each

menstrual cycle parameter and how the data was used to identify each parameter, including how first

menses was defined. The urine biomarkers estrogen (E3G) and LH were used to identify menstrual cycle

parameters documented in MM fertility charts. A description of the reliability of the CBFM, an

instrument used by women to identify urine biomarkers, showed why the device was integrated into the

MM NFP system. The integration of the CBFM into tools like the MM NFP fertility charting system and

the revised MM postpartum breastfeeding protocol is foundational to this study.   A description of the

tools used to collect data on the effectiveness of the revised MM postpartum breastfeeding protocol

through the MM NFP systems pregnancy evaluation and fertility charts were also reviewed. These

included the pregnancy evaluation tool used by the nurse researchers to classify each pregnancy and the

Qualtrics questionnaire.   Finally, the methods of data analysis for each aim and research question were

presented. Results of the data analysis are presented in Chapter 4.

Chapter 4: Results

This study investigated pregnancy rates and menstrual cycle parameters of a revised postpartum/breastfeeding protocol taught by professional nurse researchers and educators at Marquette University College of Nursing Institute for Natural Family Planning (MUCN-INFP). These researchers have been teaching couples how to understand urine hormone signs used in a method of natural family planning (NFP) for over twenty years. The NFP method, called the Marquette Method (MM), integrated a home monitor that detected two preovulatory hormones in first-morning urine (FMU). The monitor is a handheld electronic device that uses test sticks to identify the preovulatory hormones estrogen (E3G) and luteinizing hormone (LH). The study's aim was to determine the effectiveness of the revised MM postpartum breastfeeding protocol and describe menstrual cycle parameters of the for the first 6 cycles postpartum. The purpose of the study was to identify how the protocol can be simplified to increase accessibility. Pregnancy effectiveness rates were determined using the Kaplan-Meier Method of Survival Analysis while descriptive analysis was used to understand menstrual cycle parameters and characteristics.

The revised protocol was taught by professional nurses, physicians, and other healthcare providers in the US and Canada. These professionals teach women how to interpret urine fertility signs using the Marquette Method NFP charting system. The system was designed for women in all . This study focused on postpartum/breastfeeding women who use the method to avoid a pregnancy during the first 12 months and 12 cycles of use.

A study of the MM from 10 different teaching sites in the US and Canada found the MM was 92-98% effective for women in regular or irregular length menstrual cycles and postpartum breastfeeding (Fawcett, 2013; Fawcett & Garity, 2009). The study assessed the effectiveness of the MM by reviewing the pregnancy tracking forms kept by 10 MM teachers. These MM teachers included nurses, advanced practice nurses, physicians, and physician assistants who completed the MM Teacher Training program

and had a minimum of one year of experience. For postpartum breastfeeding women, the method's

typical use was 92% effective to avoid pregnancy (Fawcett, 2013; Fawcett, 2009). Past MM studies have

shown that pregnancies often occurred during the first few cycles after fertility returned (Fawcett, 2013;

Fawcett & Garity, 2009). MM nurse scientists revised the protocol to manage the first six cycles once

fertility returned if the woman was still breastfeeding. However, the revised protocol's effectiveness

has not been specifically studied. This study aimed to 1) evaluate the effectiveness of the revised MM

postpartum breastfeeding protocol and 2) to describe the parameters of the first six menstrual cycles

during the transition to fertility in breastfeeding women.

Data Collection and Preparation Process

This study is a secondary analysis of data from postpartum breastfeeding women who used the

revised MM protocol to avoid pregnancy. Marquette University's Institutional Review Board approved

the study (HR 3666). Records came from an archived data set. Data, charts, and pregnancy evaluations

from women who registered between July 1, 2015, and May 1, 2019, were included in this study. Factors

considered for the start date of the study were 1) the publication of the protocol in the Bouchard et al.

(2013), 2) analysis of the effectiveness of the protocol published in the Fehring et al. (2017) study, and 3)

an increase in the number of posts in the website discussion forum from women using the revised MM

protocol. The end date of the study was the day before major work began on the site. Structured Query

Language (SQL) data tables came from the archived website. A diagram of the two-phased approach for

data collection and processing of the SQL dump files is described below and seen in Appendix G.

The first phase required visualizing SQL data tables in the program MySQL Workbench. The final

data tables used for analysis in this study came from two SQL files labeled "demographic and chart

data." The two data tables were exported into comma-separated values (CSV) files using the MySQL

Workbench program. CSV files were converted to Excel files for data cleaning. Women who registered

as postpartum breastfeeding and had at least one completed cycle met minimal study criteria. These

women received an invite to the study in an email formatted and sent through a Qualtrics

questionnaire. In the questionnaire, women were asked to provide additional information such as the

infant's date of birth, if the woman was using the revised MM protocol, and other information essential

to understanding menstrual cycle parameters (see Appendix H). The questionnaire was open for two

weeks. Once the questionnaire was closed, women's unique username was used to merge tables.

Women were assigned a username upon original registration in the MM charting website. This

username was provided to help maintain the user's anonymity. Once all data was collected, email

addresses connected to the usernames were removed from the data sets. The de-identified data sets

were cleaned in Excel and exported to SPSS 27 for analysis.

Researchers used SPSS to analyze pregnancy rates and menstrual cycle parameters. Pregnancy

rates were calculated using the survival analysis (Kaplan-Meier Method) function. The analysis included

total and correct use pregnancy rates calculated through 12 months and cycles of use. Menstrual cycle

parameters for the first 6 cycles were analyzed using the date computation, descriptive, and explore

functions in SPSS.

Parameters of the menstrual cycle included the length of 1) the cycle, 2) pre-ovulatory phase, 3)

post-ovulatory phase. The first cycle or lactation amenorrhea (LA) began with the birth of the infant and

ended just before the start of the first menses. This cycle was labeled cycle zero (Arevalo & Sanai,

2005), . The length of cycle zero could be a few months to years and is dependent on if or how often the

woman breastfeeds. In cycle zero, a woman is preovulatory, in the follicular phase of the cycle, and

anticipating ovulation. Like women in regular cycles, ovulation occurs once during cycle zero and is

followed by menses a week or two later. Two-thirds of women in cycle zero will ovulate before their first

menses (Campbell et al.,1993). Five days before ovulation and the day of ovulation make up the fertile

window (Wilcox et al., 2000).

The fertile window in cycle zero is 6 days per cycle. These days include the 5-day life span of the sperm and the 1-day life span of the egg. The fertile window is when women will achieve pregnancy and is identified by finding the day of ovulation and counting back 5 days (Barbaro & Scarpa, 2017; Wilcox et al., 2000). Therefore, identifying when ovulation occurred is necessary for finding the fertile window and understanding pregnancy events. Important factors considered in this study to determine pregnancy rates during the breastfeeding transition to fertility were 1) the variability in the length of the follicular or preovulatory phase, 2) two-thirds of women do ovulate before the first menses, 3) ovulation may or may not occur before the first menses, and 4) the chance that pregnancy occurs only one time during the cycle in the fertile window. Considering these four factors, this study looked at cycle zero as one cycle and reported correct and typical use effectiveness rates at 1, 3, 6, 9, and 12 months and cycles of use. Finally, a description of menstrual cycle parameters for the first six cycles were completed to learn more about these events and improve the revised MM protocol. Data collection, preparation, and analysis occurred in two phases (see Appendix G).

Phase one of the data collection process began with the data set labeled Female Registrations from the SQL dump file. Data was collected from women who registered between July 1, 2015, and May 1, 2019. Registrations marked as NULL and duplicates were removed; 546 registrations remained. Figure 7 shows the inclusion flow, which starts with 546 users. Of the 546 users, 42% (n = 232) registered as breastfeeding and had at least one chart. The 232 that met the minimal criteria were emailed the Qualtrics questionnaire.

Figure 7

Inclusion Flow Chart
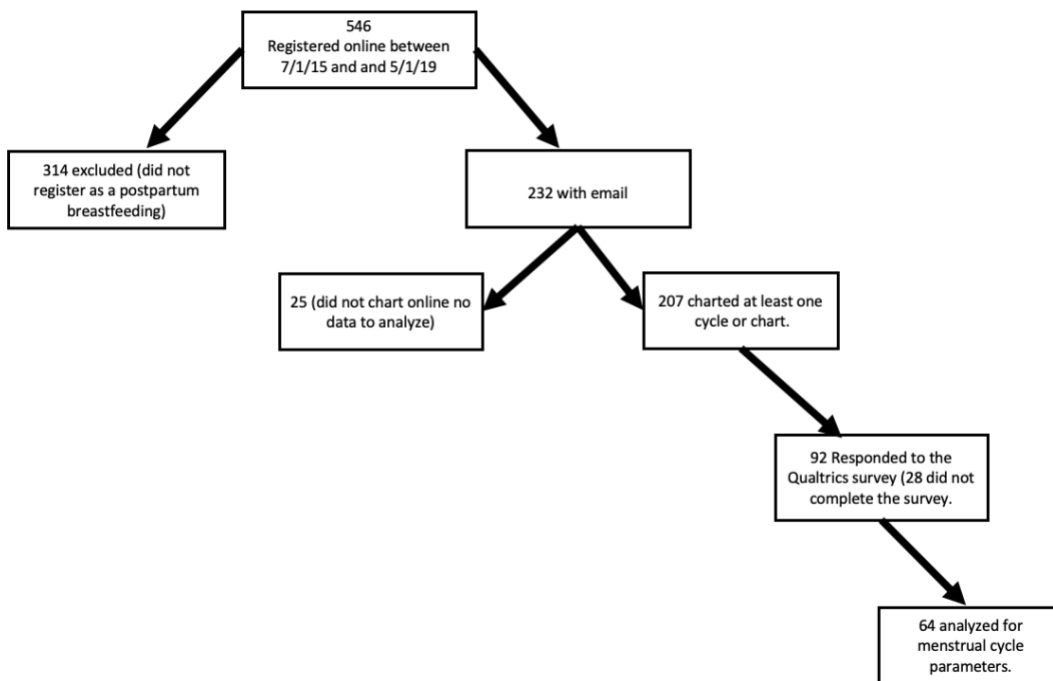
Note: The inclusion flow chart begins with the total number of women who registered from July 1st,

2015 through to May 1st, 2019. Women who registered as postpartum breastfeeding are on the right

side of the flow diagram.

Phase two of the data collection process started with a review of the charts from the 232 users.

The data was cleaned and processed in Excel. The length of cycles were found by subtracting the dates

recorded for the start and end of each cycle. When lengths of cycles calculated out as negative, the

researcher reviewed the user's original chart on the archived website.   When dates could not be

confirmed, the user was removed (i.e., *n* =25) 207 users and 216 cases were left. Nine of the users

returned to charting after having a baby and, they provided additional charts for analysis. The unique

username given to women when they first registered and started charting were used to match demographic data with the chart data. In all 207 women provided charts for 216 cases used for the pregnancy effectiveness analysis.

Of the 207 women, 92 started the Qualtrics survey, and 64 completed it. During the study a few women did email this author and indicated with extreme situation of Covid 19 lockdowns, homeschooling of children and trying to work from home they would try to complete the survey. Participants who started the survey were informed by email that the survey would remain open for two weeks. A few women did complete the survey during that time. Data cleaning and processing began the day the survey was closed.

The date computation function in SPSS 27 was used to calculate the length of cycles and follicular phases using the infant's date of birth. Analysis of cycle zero showed six cases were calculated as being negative. Because time to events cannot be negative an email was sent to the six women. All six of the cases came from women who recorded their youngest child's date of birth not the date of birth from the child they were breastfeeding when they registered. These six women were emailed a copy of their chart and asked the infant's date of birth that corresponded to when they registered and began charting. Three of six women responded to the email request and provided a date of birth. Data from the Qualtrics survey provided the information necessary for the menstrual cycle parameter analysis. Two excel data sets, 1) Qualtrics, and 2) Demographic data were merged with the menstrual cycle parameter data. Three data sets were constructed for analysis in this study. The data tables were 1) demographic data (n =207), 2) pregnancy effectiveness (n = 216) and, 3) menstrual cycle parameter data (n = 64).

Statistical Analysis

Sample

There were 207 postpartum breastfeeding women, nearly two-thirds were from the United

States, but almost one-third did not respond. Table 3 shows the women's age ranged from 21-44 years

old, they had about 3 children and were married on average for 6 years.   The profile of the women in

Table 4 shows most were Catholic, Caucasian women who delivered healthy infants and indicated they

were totally breastfeeding and well educated. Nearly 75% completed at least one year of college.

Table 3

Demographic Characteristics of the Breastfeeding Women

Variable	*n*	*M*	*SD*	Range
Age of the woman	207	31.4	5.1	21-44
Years married	190	5.9	4.6	0-18
Number of pregnancies	207	3.5	2.5	0-15
Number of children	207	2.9	2.6	0-11

Note: *n*, represents number of women. Years married is represented by the number of who responded.

Table 4

Profile of the Women

Characteristics	n (207)	Percent of participants
Religion:		
Catholic	178	86.0
Protestant	9	4.3
Other	1	0.5
No response	19	9.2
Ethnicity		
Caucasian	138	66.7
Hispanic	13	6.3
Asian	7	3.4
Other	13	6.3
No response	36	17.4
Education		
0 – 12 years	15	7.8
13 - 16 years	62	29.9
17 + years	93	44.9
No response	37	17.9
Breastfeeding status		
Total breastfeeding	113	54.6
Partial breastfeeding	82	39.5
No response	12	5.8
Baby's health at birth		
Healthy	62	96.9
Not healthy	2	3.1
Country		
USA	136	65.7
Canada	7	3.4
Other	64	30.9

Note: Baby's health at birth values came from the Qualtrics data set (N = 64).

Women who registered to learn the MM NFP system in the archived website completed a comprehensive profile (see Appendix F). The "Cycle Health and Pregnancy" area of the registration is where women indicated they were breastfeeding (see Appendix I) and at what frequency (see Appendix J). These two questions were used to identify breastfeeding women eligible for the study.   Just over half of the women registered as total breastfeeding and another two-fifths as partial breastfeeding and 12 did not respond (see Table 4). In cases where women did not respond to the frequency of breastfeeding question, they did indicate status as postpartum breastfeeding in the reproductive category question (see Appendix H).

<center>**Aims**</center>

Aim 1 - Describe the menstrual cycle parameters during the breastfeeding transition to fertility from cycle zero through the first 6 menstrual cycles among postpartum women who used the revised MM breastfeeding protocol to avoid a pregnancy.

Research Question 1. What are the mean and median times to the first high and peak day, EDO, and menses in cycle zero and the following 6 cycles?

The length of cycle zero or the time from the infant's date of birth to the first menses was a mean of 297.0 days (SD = 183.3, 95% CI [250.1, 344.0], n = 61). The median days for cycle zero was 237. Figure 8 shows cycle zero was positively skewed and trimodal with upsurges around 5 to 6 months, again around 14 to 15 months and possibly a smaller group experienced first menses at 22-24 months postpartum.

Figure 8

Trimodal Pattern of Cycle Zero by Months of Use

Months of use
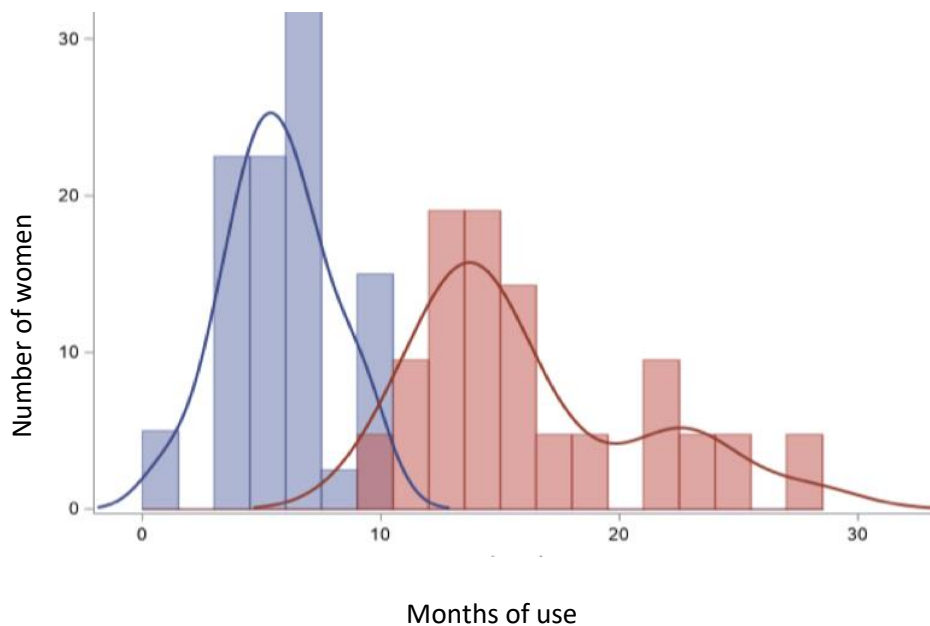
Note: The graph shows two distinct groups of women however a third group may be present. A larger

sample size is needed.

The menstrual cycle lengths for Cycle 0 and the following 6 cycles show most variability occurred

in cycles zero and one (see Table 5). Cycle 0 had greatest variability with a standard deviation of 183

days. Cycle 1 lengths had mean of 36.53 days (*SD* = 21.8, 95% CI [30.0,43.1], *n* = 45).   Cycles 2 through 6

lengths were less variable.   The difference in the number of days between the mean and median in

Cycles 2 through 6 were 1 and 2 days. Median lengths of cycles one and two were similar at 32 and 31

days. Cycles 3 through cycle 6 were an average of 30 days long, with a median length of 29 days long.

For one woman, cycle 5 was 77 days long, skewing the data to the right.

Table 5

Length of Cycle Zero through Cycle Six

Cycle	n	M	SD	Mdn	95% CI	
					LL	UL
0	61	297.0	183.3	237.0	250.1	344.0
1	45	36.5	21.8	32.0	30.0	43.1
2	38	33.9	15.2	31.0	28.9	38.9
3	36	31.1	4.8	30.0	29.5	32.7
4	37	29.9	4.2	29.0	28.5	31.3
5	31	30.0	3.7	29.0	27.5	31.4
6	31	29.5	5.3	28.0	27.5	31.4

Note. Menstrual cycle characteristics represented in days.

Cycle 0 = Lactation amenorrhea.

n represents the number of cycles.

Time to the First Estrogen Rise in Cycle Zero and First Six Cycles

The first sign of fertility (i.e., estrogen rise) in cycle zero and the next six cycles, indicated by the first high on the monitor is seen in Table 6. The first high in cycle zero occurred a mean of 162.4 days postpartum (*SD* = 129.1, 95% CI [121.6,203.1], *n* = 41).   However, the first high in cycle zero had a broad range of 35 to 705.00 days. The data was skewed to the right with a median of 126 days and a mode of 78.0 days. Once the first menses occurred, the mean first estrogen rise in cycle one occurred on cycle day 13.7 (SD = 5.9, 95% CI [11.9,15.4], *n* = 46). In the following five cycles, less variability occurred, the mean and median were one to two days apart and the first sign of estrogen and return to fertility occurred around day 13.

Table 6

Time to First Estrogen Rise Cycle Zero through Cycle Six

Cycle	n	M	SD	Mdn	95% CI	
					LL	UL
0	41	162.3	129.1	126.0	121.6	203.1
1	46	13.7	6.0	12.0	11.9	15.4
2	40	12.7	4.7	13.0	11.2	14.2
3	37	12.8	4.7	11.0	11.2	14.4
4	34	11.6	4.1	11.0	10.2	13.0
5	31	12.9	4.4	12.0	11.3	14.5
6	27	11.7	3.8	11.0	10.2	13.2

Note. Menstrual cycle characteristics represented in days.

Cycle 0 = Lactation amenorrhea.

n represents the number of cycles.

Time to the Estimated Day of Ovulation in Cycle Zero and First Six Cycles

The time to the Estimated Day of Ovulation (EDO) or the second monitor peak in cycle zero was a mean

of 251.0 days (*SD* = 158.9, 95% CI [192.5, 311.0] *n* =30) with a median of 204 days (see Table 7).   Two

extreme outliers (i.e., cases 20 and 47) charted the EDO beyond 600 days. Variability in the time to the

EDO continued in cycle one with a mean of 27.7 days (*SD* = 18.4, 95% CI [21.1, 34.4], *Mdn* = 23.5, *n* =32).

Cycles two through six were less variable with a mean time to the EDO as 20 days while the median was

one to two days from the mean.

Table 7

Time to the Estimated Day of Ovulation Cycle Zero through Cycles Six

Cycle	n	M	SD	Mdn	95% CI	
					LL	UL
0	30	251.0	158.9	204.0	192.2	311.0
1	32	27.7	18.4	23.5	21.1	34.4
2	31	22.1	7.6	21.0	19.3	24.9
3	31	20.6	4.9	20.0	18.8	22.4
4	31	19.2	4.3	19.0	17.6	20.8
5	31	18.4	3.9	17.0	16.9	19.8
6	27	18.9	4.9	17.0	17.0	20.8

Note. Menstrual cycle characteristics represented in days.

Cycle 0 = Lactation amenorrhea.

n represents the number of cycles.

Research Question 2. What are the mean and median time from the first high to the EDO and menses in cycle zero and the following 6 cycles?

Time from First Estrogen Rise to the Estimated Day of Ovulation

Once the first high (i.e., estrogen rise) was detected in cycle zero the EDO occurred a mean of 84.7 days (SD = 82.1, Mdn = 58.0, 95% CI [53.5,116.0], n = 29) later. The first high to the EDO is fertile, and a summary of the length of fertility during the transition is presented in Table 8. The number of days from the first high to the EDO was again skewed to the right in cycle zero. The days of fertility in cycle one was variable with a mean of 14.5 days (SD = 17.0, Mdn = 8, 95% CI [8.3,20.7], n = 31). Cycles two through six varied less (see Table 8).

Table 8

Time from First Estrogen Rise to the Estimated Day of Ovulation

Cycle	n	M	SD	Mdn	95% CI	
					LL	UL
0	29	84.7	82.1	58.0	53.5	116.0
1	31	14.5	17.0	8.0	8.3	20.7
2	30	8.7	5.9	8.0	6.5	11.0
3	30	8.4	4.9	8.0	6.6	10.2
4	29	7.9	4.1	8.0	6.4	9.5
5	29	6.0	3.0	5.0	4.8	7.1
6	23	6.7	3.4	6.0	5.2	8.1

Note. Menstrual cycle characteristics represented in days.

Cycle 0 = Lactation amenorrhea.

n represents the number of cycles.

Research Question 3. What are the characteristics of first menses?

Menstrual Cycle Characteristics in Cycle Zero and the Following Six Cycles

First menses was defined as when the woman recorded at least four consecutive days of vaginal bleeding that had a crescendo-decrescendo or decrescendo-crescendo-decrescendo pattern. The four or more consecutive days of bleeding had to equal a sum of five or greater and may or may not have occurred after a peak on the monitor (i.e., EDO). The EDO was defined as the approximate day of ovulation and considered the day after the first monitor peak. Women recorded vaginal bleeding as a 3 for heavy, 2 for moderate, and 1 for light flow. The sum of vaginal bleeding was determined using the

previously described recording system (see Figure 6). The mean score for first menses was 10.5 (*SD* =

3.3, 95% CI [9.5,11.4], *n* = 54). The number of days of menses was a mean of 5.5 days (*SD* = 1.6, 95% CI

[5.1,6.0], *n* = 54). Of the 48 women who provided charts for cycle zero, 30 (62.5%) had an EDO before

the first menses.

Aim Two: **Determine the correct and typical use effectiveness of the revised MM b breastfeeding**

protocol for avoiding pregnancy at 12 months and 12 cycles of use.

Descriptive Analysis of Months and Cycles of Use

A total of 207 women provided 2364 total months of use and 1647 total cycles of use. The total

months of correct use were 2142, and total cycles with correct use were 1452 (n = 216). Data analysis

showed total months and cycles of use were skewed to the right, as 207 women charted a median of 7.0

months and a mean of 10.9 (*SD* = 12.7, 95%CI [9.2,12.7]) months. The median number of total cycles of

use was 5.0, with a mean of 7.6 (*SD* = 8.5, 95% CI [6.5,8.8]) cycles of use. The mean number of correct

months of use was 9.9 (SD = 9.2, 95% CI [8.7,11.2], and the mean number of correct cycles of use was

6.7 (SD =. 7.6, 95% CI 5.7,7.7]).

A total of 19 pregnancies occurred among the 207 women. Ten women provided a pregnancy

evaluation with a conception chart. Two professional MM nurse teachers completed an Inter-rater

reliability analysis of these 10 pregnancies. Pregnancy evaluations came from either 1) Qualtrics

questionnaire or 2) the archived website. Of note, pregnancy evaluations taken from the archived

website (*n* = 6) were completed by women within weeks after they confirmed pregnancy. The Qualtrics

pregnancy evaluations (*n* = 4) were completed years after the pregnancy occurred.

A summary of the total pregnancies versus the number of pregnancies evaluated for this study is

seen in Figure 9. A total of 19 pregnancies were identified. However, to meet the criteria each

pregnancy had to have a conception chart and pregnancy evaluation. Conception charts came from the

archived website. Pregnancy evaluations came from either the archived website or the Qualtrics

questionnaire. A total of 10 pregnancies met both criteria. The PI and Co-PI completed the evaluation

separately on a rating form which was compared for inter-rater reliability. A 100% agreement was

found when the two forms were compared (see Appendix K).

Figure 9

Inclusion Flow for Pregnancy Analysis


```
                        ┌──────────────────┐
                        │  19 Pregnancies  │
                        │     (Total)      │
                        └──────────────────┘

┌──────────────────────────┐              ┌──────────────────────────┐
│  Pregnancy Evaluations:  │              │   Conception Charts      │
│      3 - Qualtrics       │              │    16 - Available        │
│      7 - Website         │              │    3 - Not available     │
└──────────────────────────┘              └──────────────────────────┘

                        ┌──────────────────┐
                        │  10  Pregnancies │
                        │     Evaluated    │
                        └──────────────────┘
```
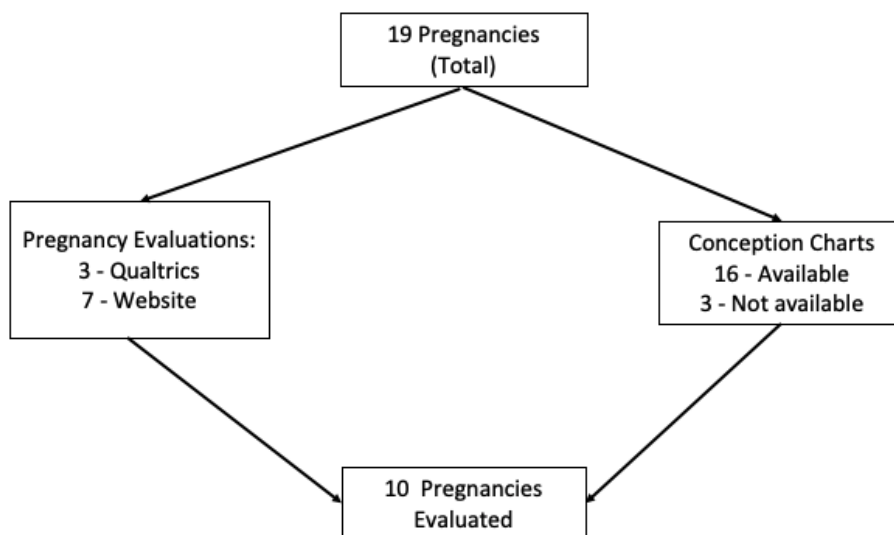
Note: For a pregnancy to be considered 1) the fertility chart where conception occurred had to be

available for review and 2) pregnancy evaluation had to be completed. Completed pregnancy

evaluations could come from the archived website or from the Qualtrics questionnaire.

Research Question 1. What is the correct use unintended pregnancy rate at 12 months and 12 cycles of use among women who used the revised MM breastfeeding protocol?

There were five unintended pregnancies. Of the five unintended pregnancies, two were correct use. Table 9 shows the correct use unintended pregnancies per 100 women at 1,3,6,9 and 12 months of use. Two correct use unintended pregnancies occurred at 12 months of use per 100 women *(SR* = .982, *SE* = .013, *n* = 66). The 12-cycle pregnancy rate for correct use seen in Table 14 shows 1.3 pregnancies per 100 users (*SR* = .987, *SE* = .009, *n* = 36).

Table 9

Survival rates per 100 women pregnant by typical and correct months of use (N = 216)

Months	Typical (2364 months of use)				Correct (2142 months of use)			
	SR	*SE*	*Preg.*	*N*	*SR*	*SE*	*Preg.*	*n*
1	1.00	.000	0	215	.995	.005	1	215
3	1.00	.000	0	170	.995	.005	0	176
6	.993	.007	1	141	.989	.008	1	145
9	.962	.019	3	93	.989	.008	0	91
12	.962	.019	0	68	.982	.013	0	66

Note: SR = survival rate per 100 women over 12 months of use, *SE* = standard error*, Preg*. = number of pregnancies per every three months of use and *N* = number of women exposed.

Research Question 2. What is the typical use unintended pregnancy rate at 12 months and 12 cycles of use among women who used the revised MM breastfeeding protocol? Analyzing by months, a total of five typical use unintended pregnancies occurred, one was outside of 12 cycles of use. Table 9 shows the SR for months of use at 1,3,6,9 and 12 months. Survival rate at 12 months was 4 per 100 women (*SR* = .962, *SE* = .019, *n* = 68).

Analyzing by cycles of use (see Table 10) the survival rate for unintended typical use pregnancies at 12 cycles of use was 6 per 100 women (*SR* = .940, *SE* = .023, *n* = 40). A summary of the five unintended pregnancies reviewed are found in Appendix L. The table shows details about where the acts of intercourse occurred on the charts that resulted in conception. The table identifies factors important for understanding each of the pregnancies. These factors included the date of the infant's birth and if this was not available when the woman started charting. Other factors considered were when were acts of intercourse recorded and how did these acts relate to the EDO. Finally, a description of the menses before the conception cycle is available. Of note one pregnancy was outside the cutoff of 12 cycles.

Pregnancy evaluations were also necessary for a full analysis. A key question in the evaluation used to identify if a pregnancy was unintended asked why the couple thought they got pregnant. The answers to the question were 1) couple decided to conceive, 2) one person decided to conceive, 3) took a chance, and 4) did not think we were fertile. Of the five couples who indicated the pregnancy was unintended, two couples recorded they took a chance, and three recorded they did not think they were fertile.

Table 10

Survival rates per 100 women pregnant by typical and correct cycles of use (N =216)

Cycles	Typical (1647 cycles of use)				Correct (1452 cycles of use)			
	SR	SE	Preg.	N	SR	SE	Preg.	n
1	.995	.005	1	216	1.00	.000	0	216
3	.990	.007	1	171	.992	.008	1	120
6	.954	.019	4	105	.992	.008	0	90
9	.940	.023	1	65	.975	.018	1	59
12	.940	.023	0	40	.975	.018	0	36

Note: SR = survival rate per 100 women over 12 cycles of use, *SE* = standard error, *Preg.* = number of pregnancies per three cycles of use, and *N* = number of women exposed.

Summary

This chapter began with an introduction to the aims and research questions of this study and how analysis of data would be arranged. Presentation of findings included several tables and figures. Appendices were used to supplement understanding of findings and the study design. The descriptive analysis of chart data was presented as tables, bar charts, histograms and box and whisker plots to show outliers and data normality.

Results of the first two research questions for Aim one that looked at menstrual cycle parameters found variability in cycles zero and one. However, in cycles two through six the parameter data were less variable with a normal distribution pattern. Characteristics of the first menstrual bleed that indicated the end of the postpartum phase occurred were identified by the EDO and occurred in over two-thirds of the women. From these women first menses was at least five days long with a sum

score of ten or higher. The next chapter will compare these findings with pilot study chart data from

postpartum breastfeeding women who used the original protocol.

Finally, aim two addressed the effectiveness of the revised protocol for avoiding an unintended

pregnancy. The two research questions looked at the correct and typical use of the revised protocol up

to 12 months and cycles of use. This study found the number of correct and typical use pregnancies

were lower for the revised protocol when compared to the original protocol.

Conclusion

Because pregnancy effectiveness rates were lower from women using the revised protocol this

supported the development of new algorithms. Postpartum breastfeeding women can use the

algorithms to know when to start the revised MM protocol, if they are in cycle zero or cycle one and

how to manage each. In chapter 5 a discussion and rationale for new algorithms is presented.

Chapter 5: Conclusion, Discussion & Future Considerations

Chapter 4 discussed the data analysis and results for this study. In this chapter, a synthesis of the results includes a summary of the study, discussion and summary of the findings, limitations of the study, suggestions for future research, and practice implications. The purpose of this study was to describe the menstrual cycle parameters in the first 6 cycles postpartum and determine the effectiveness of the revised Marquette Method (MM) postpartum/breastfeeding protocol. This chapter aims to describe how this study's menstrual cycle parameters and characteristics validated similar patterns from past studies. The patterns were then used to develop new algorithms. Finally, suggestions for future research on new web-based platforms where the algorithms can be applied are presented. Application of proposed algorithms to web-based and phone-based functions can improve the accessibility of the revised Marquette Method (MM) breastfeeding protocol. Web applications synced to an online learning platform can collect data for future analysis of the protocol. This model will support big data sets to understand the fertile and infertile characteristics of the postpartum/breastfeeding transition. This design can provide secure methods of NFP in the future that support women who want to space their pregnancies naturally.

Summary of the Study

This study was a retrospective analysis of data collected from a secure website produced by 207 women who used the revised MM of natural family planning (NFP) postpartum breastfeeding protocol to avoid pregnancy. The study aimed to determine the effectiveness of the revised MM postpartum/breastfeeding protocol and describe the menstrual cycle parameters of cycle zero through cycle six in the same cohort of women. Postpartum breastfeeding women who used the revised protocol were instructed to 1) test their first-morning urine (FMU) daily for 10 days using the Clearblue Fertility Monitor (CBFM), 2) consider the start of fertility to be day 10 in cycle one, day 9 in cycle two,

day 8 in cycle three and day 7 in cycle four and, 3) do an optional second LH test in the

afternoon (Bouchard et al., 2013). Descriptive analysis included 1) the length of each cycle, 2) the

lengths of the pre-and post-ovulatory time, and 3) characteristics of first menses. Data collection

included participant recall and secondary analysis of fertility charts taken from an archived website.

This nurse-led research study used a framework called the Conceptual Theoretical Empirical

(CTE) model (Fawcett, 2013; Fawcett & Garity, 2009). The design of the study was guided by Roy's

Adaptation Method (RAM, 2009); a theoretical model that supported the suckling-induced reflex theory

(SIRT) (Johnson, 2013) and the measurement of the pre-ovulatory reproductive neuroendocrine

hormones, estrogen (E3G) and luteinizing hormone (LH). The SIRT proposes breastfeeding frequency

affects pulsatile actions of the neuroendocrine hormone gonadotropin-releasing hormone (GnRH),

ovarian activity and the return to fertility. As a gatekeeper, GnRH regulates the hormone prolactin

responsible for breastmilk production.. Frequent breastfeeding results in low GnRH pulsatility, high

prolactin levels, and suppressed ovulation. Reduction in infant suckling diminishes, GnRH pulsatility,

increases ovarian function, chance of ovulation and eventually pregnancy is possible. Resumption of

ovarian activity and ovulation can occur before menses returns. Studies have found that two-thirds of

women do ovulate before first menses, some but not all ovulations are fertile, and some can result in

pregnancy (Arevalo & Sinai, 2005; Campbell & Gray, 1993; Eslami et al., 1990; Gray et al., 1990). Thus,

understanding hormone patterns during the first 6 cycles postpartum (i.e., the breastfeeding transition)

can help guide women to avoid pregnancy during this time successfully.

This study evaluated the presence and patterns of the two pre-ovulatory hormones, estrogen

and LH recorded in fertility charts from an archived website using the MM NFP fertility charting system.

Discussion of the Findings

Aim One: Describe the menstrual cycle parameters during the breastfeeding transition from cycle zero (i.e., lactation amenorrhea) through the first 6 cycles among women who used the MM revised breastfeeding protocol to avoid pregnancy.

Data analyzed for Aim One came from women who responded to the Qualtrics questionnaire (N = 64). Unique identifiers for the chart and demographic data tables were matched to the unique identifiers from the women who completed the questionnaire. A total of 259 cycles were analyzed. Each woman contributed an average of 4 cycles.

Research Question 1 – What is the mean and median of the menstrual cycle length, the time to the first high and peak days, estimated day of ovulation (EDO), and menses in cycle zero and the following six cycles?

Length of Cycle Zero and the First Six Cycles

The length of cycle zero or lactation amenorrhea (LA) was on average 297 days or 9.9 months (n = 61). A trimodal pattern of cycle zero showed women experienced first menses around 5, 14 and 22 months this suggested there were three separate groups of women. Past studies found that breastfeeding frequency prolonged the length of cycle zero to 9 months or more (Cooney et al., 1996; Short et al., 1991). However, the studies did not identify breastfeeding frequency. The current study had women register as either total or partial breastfeeding. Most women registered as totally breastfeeding (i.e., 72%, n = 46). However, a small group of women (n = 10) registered as partial breastfeeding. A closer look at the length of cycle zero in the women who registered as partial breastfeeding showed the time ranged from 97 to 694 days (see Figure 10).

Figure 10

Time to First Menses in Partially Breastfeeding Women (n = 10)
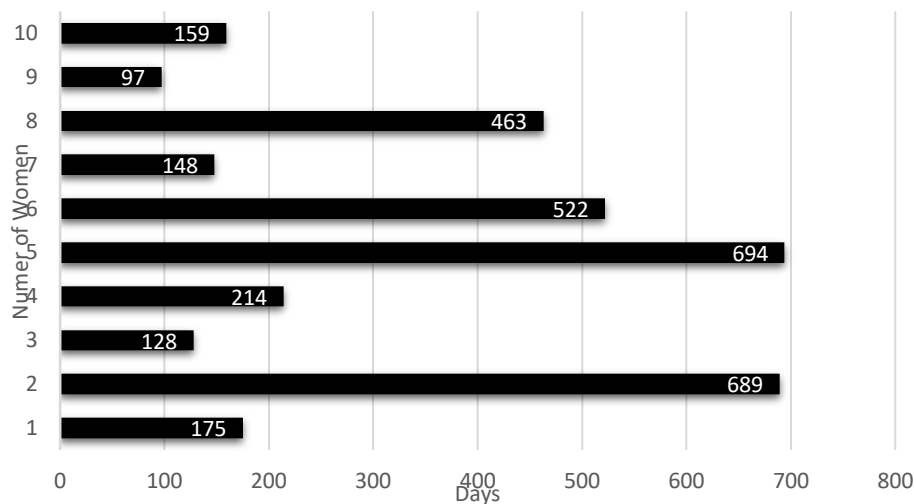
Note: Ten women that registered as partial breastfeeding. The graph represents cycle zero lengths for each of the ten women. The cycles begin at parturition and ends the day before first menses. Variability in cycle zero length and time to first menses is shown.

We expected women who registered as partial breastfeeding to have shorter cycle zero lengths. However, no association was identified. The pattern observed may be dependent on women's sensitivity to the physiologic suppression of ovulation while breastfeeding (Bouchard et al., 2018). Comparable results were found in an earlier data set taken from the archived website. The data set was analyzed for a master thesis and had 93 postpartum breastfeeding women. In the thesis study, the author evaluated data from women who used the original MM protocol (Barbaro & Scarpa, 2017). The results of the master's theses found no pattern in the length of cycle zero between the women who registered as total or partial breastfeeding. The authors of the thesis concluded it would be better to identify when women changed from total to partial breastfeeding than to use the bivariate variables of

total and partial breastfeeding (Barbaro & Scarpa, 2017). Future studies will be designed to capture

changes in breastfeeding frequency as they occur.

Cycles one and two in this study were quite variable, as seen in Table 9. However, an extreme

outlier skewed the data creating the variability. When the extreme outlier was removed, the variability

of cycle two was cut in half and the results were like those reported in the past (Arevalo et al.,

2005). Variability of cycles zero and one in this study were like the pilot study results and past studies by

Arevalo et al. (2005). In a secondary data analysis of postpartum breastfeeding women, Arevalo et al.

(2005) found the length of cycle zero ranged from 65-469 days (N = 73), and cycle one ranged from 15-

115days (n = 61). Therefore, variability of cycles zero and one during the transition are common.

A comparison of cycle lengths between women who used the original protocol and those who

used the revised protocol were similar, as seen in Figure 11. In this study, cycles zero and one had the

most variability, while cycles two through six were relatively stable. The mean length of cycle zero

differed between the two protocols by about 10 days, while the mean lengths of cycles two through six

were stable and differed by one to three days (see Figure 11).

Figure 11

Comparison of the Mean Length of Cycle Zero and the First Six Cycles of the Original and Revised Protocol.
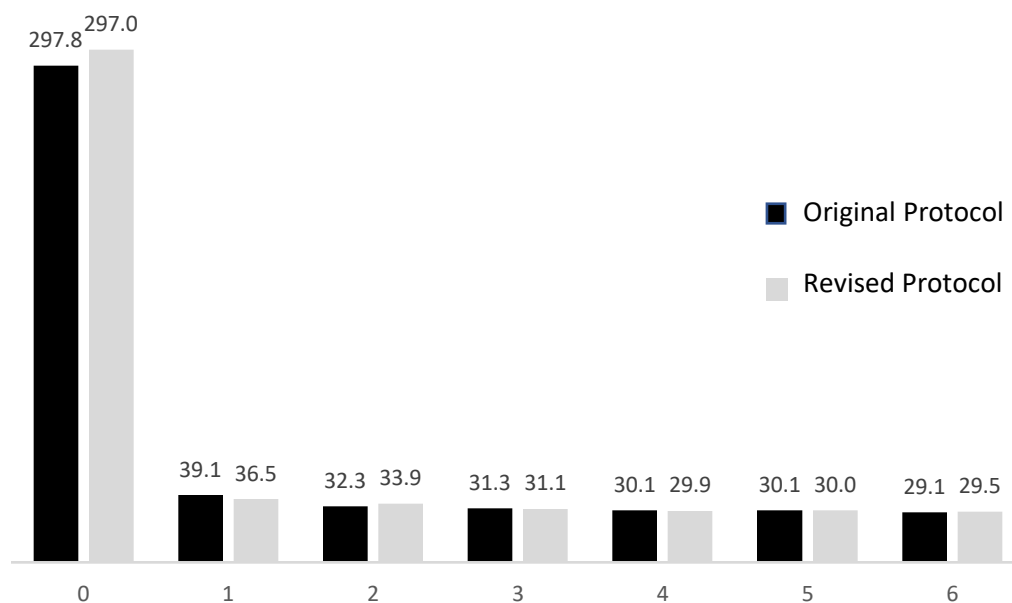
Note. The comparison between women who used the original vs those women who used the revised protocol is similar in all cycles. Unit of measurement is in days.

Time to the First High (Estrogen) in Cycle Zero and the First Six Cycles

The first high on the monitor (i.e., sign of estrogen) showed the ovary was coming out of dormancy, a sign fertility was returning. As ovarian activity resumed, the pulsatile action of the GnRH hormone increased, and estrogen levels rise. When estrogen levels reached a threshold a high was displayed on the CBFM. The first high day on the CBFM marked the rise in estrogen and was considered the start of fertility in this study. Results found the first high in cycle zero occurred around 5 months postpartum. In a similar study, the first sign of fertility occurred around 4-5 months postpartum (Bouchard et al., 2018). A Comparison between the original and revised protocols

found there was a 10-day difference (see Figure 12). The first sign of estrogen occurred earlier in cycle

zero for women using the revised protocol.

Moreover, in cycles one through six, the first high on the monitor differed by 1-3 days and was

consistently 1-3 days earlier in the revised protocol. In general, however, the mean times to the first

sign of fertility were similar between the original and revised protocol in cycles zero through six.

Figure 12

Mean Time to First Estrogen Rise – Comparing Original and Revised Protocol
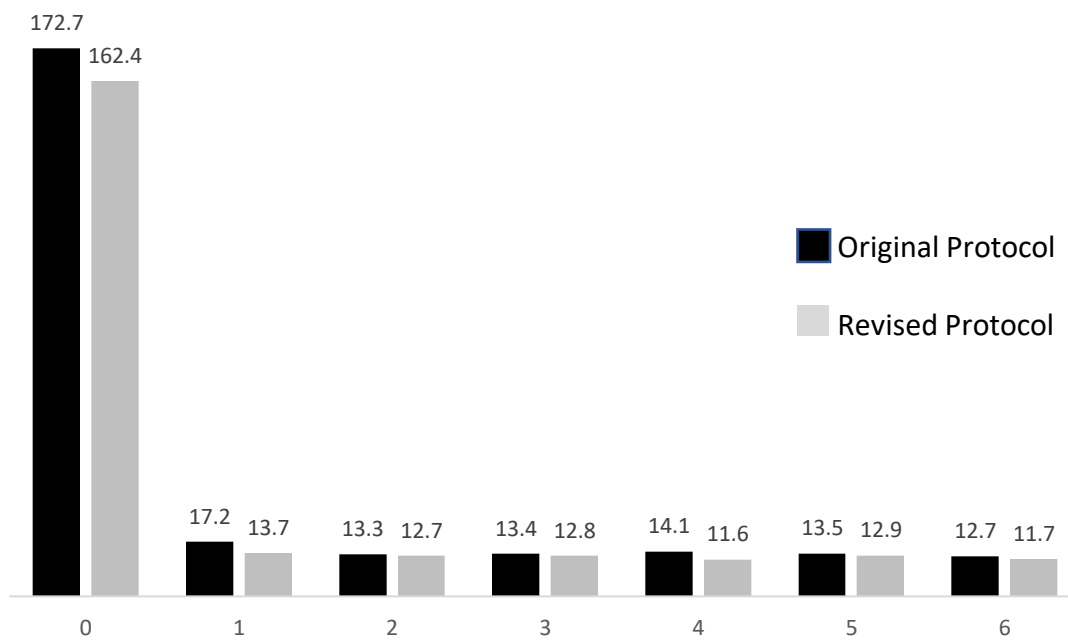
Note. Mean time in days to first estrogen rise in cycle zero and first six cycles. The comparison between

women who used the original vs those women who used the revised protocol is similar in all cycles.
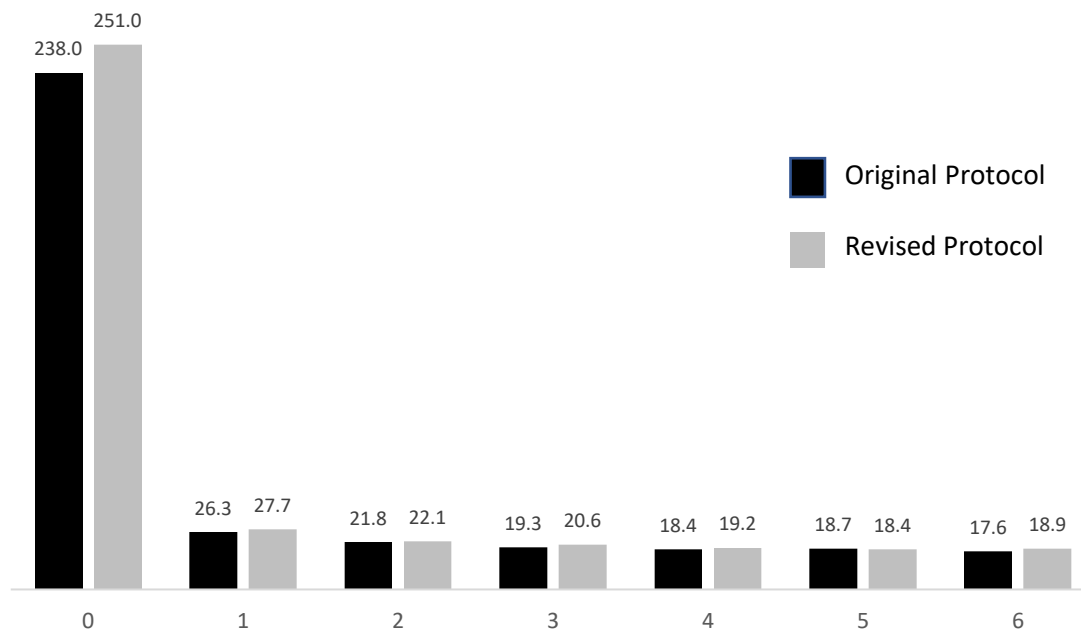
Time to the EDO in Cycle Zero and the Next Six Cycles

The time to EDO or the second peak on the monitor is the day after the monitor picked up LH. A comparison between the original and revised protocol of the mean time to the EDO is seen in Figure 14. In cycle zero, the difference between the original and revised protocol was a few weeks. However, for both the original and revised protocols, the EDO's time in cycles zero and one were significantly positively skewed while cycles two through six were normally distributed. Despite the variability, the differences in cycles zero and one between the two protocols were minimal (see Figure 13).

Figure 13

Mean Time to the Estimated Day of Ovulation Comparing Original and Revised Protocol

Note. Mean time to the EDO cycle Zero and the next 6 cycles. The comparison between women who used the original vs those women who used the revised protocol is similar in all cycles.

In cycle zero, the EDO occurred around 8 – 9 months postpartum, and in cycle one, the EDO

occurred around cycle day 27. For cycle one, the EDO's time ranged from cycle days 21 to 35 across

both protocols. This is important to note since past NFP studies have shown some women get pregnant

in cycle one (Bouchard et al., 2013; Brown et al., 1985; Fehring et al., 2017; Hatherley, 1985).

***Research Question 2 – What are the mean and median times from the first high to the EDO in cycle
zero and the following six cycles?***

Time from the First Estrogen Rise to the EDO in Cycle Zero and the Next Six Cycles

The time from the first estrogen rise to the EDO represents the average number of fertile days

per cycle and is the estimated time of fertility. The first estrogen rise indicated the ovary was becoming

active, while the EDO indicated the ovary was producing LH and ovulation occurred. A comparison

between the original protocol and the revised protocol found less fertile days in cycle zero in the revised

protocol (see Figure 15). In the revised protocol the number of fertile days in cycle zero were reduced

by about 33%. In cycle one, a comparison of the mean fertile time between the original and revised

protocol showed an increase in the number of fertile days by almost 40%. Cycles two through six show

the mean number of fertile days increased in the revised protocol by two to three days (see Figure 14).

Figure 14

Mean Time of the First Estrogen to the Estimated Day of Ovulation: Original and Revised Protocol
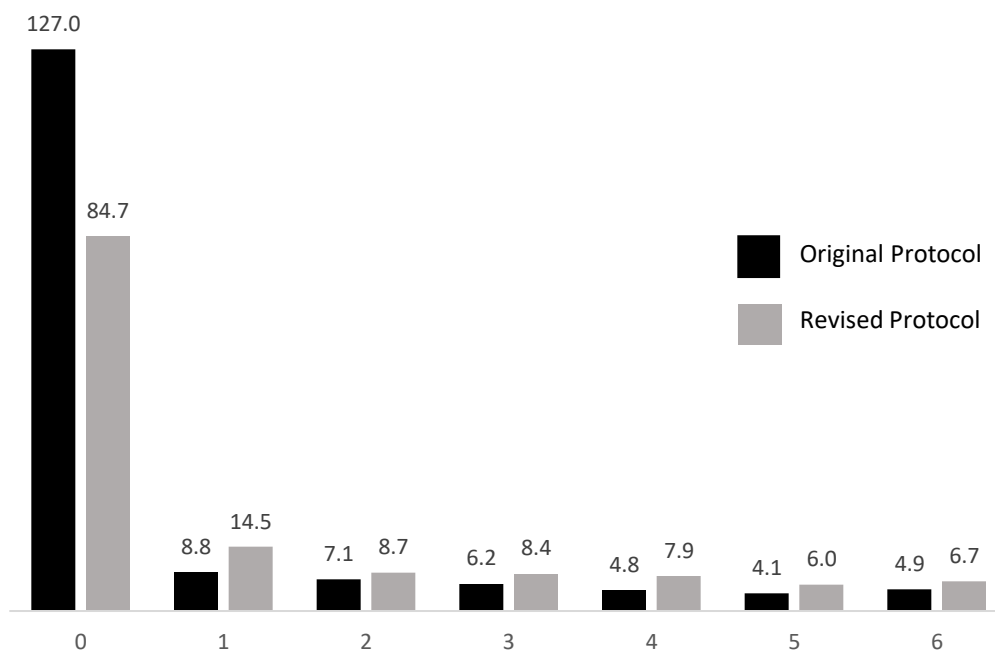
Note. Mean length of time from the first estrogen rise to the EDO in days. The comparison between women who used the original vs those women who used the revised protocol are similar in all cycles.

In this study, the fertile time began with the first high and ended with the EDO. The number of fertile days in cycle zero from women who used the revised protocol was 28.5%. In cycle one, about 39.6% of the cycle was fertile (see Figure 15). The number of fertile days for women who used the revised protocol decreased in cycle zero and then increased in cycles one through six. However, for women who used the revised protocol, the number of fertile days in cycle zero was approximately 10% higher than what was reported for the original protocol (Fehring et al., 2005).

Figure 15

Mean Length of Cycle with Mean Length of Fertile Time in Cycle Zero and the First Six Cycles of the Revised Protocol
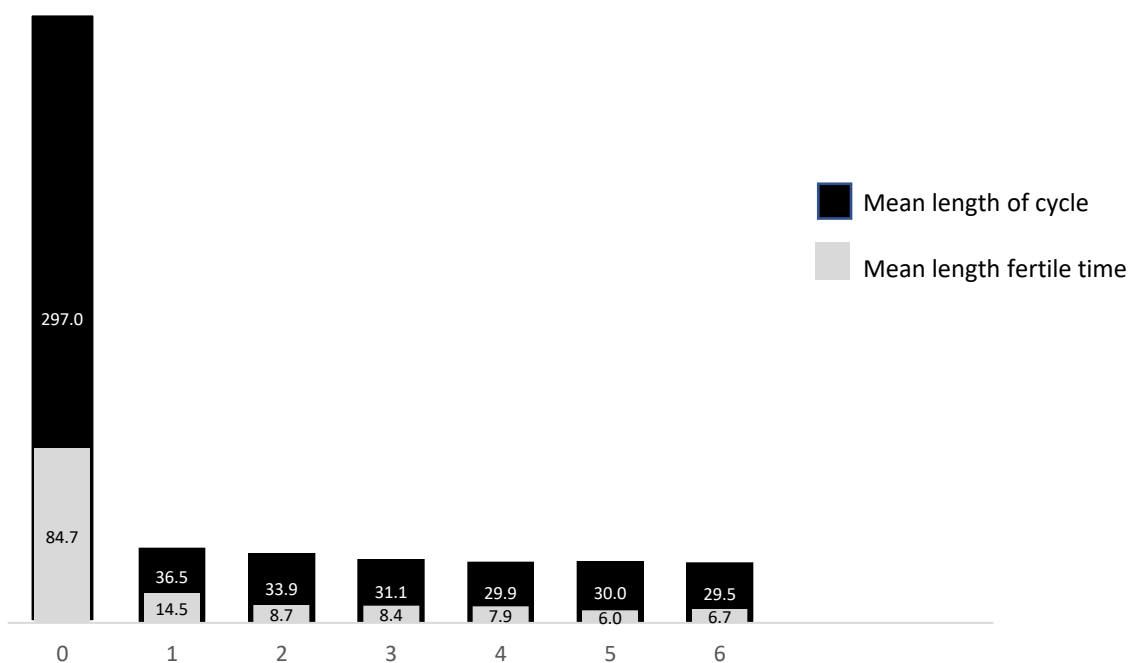
Note. Mean length of cycles with mean length of fertile time within each cycle in days.

Research Question 3 – What are the characteristics of first menses during cycle zero.

Characteristics of First Menses

        In this study, first menses was identified when women recorded a bleeding pattern of four or more consecutive days with a crescendo-decrescendo or a decrescendo-crescendo-decrescendo pattern that may or may not have been preceded by an EDO. The sum score for the consecutive days of bleeding had to be five or higher.   The numerical code women used for each day of bleeding was heavy = 3, moderate = 2, and light = 1. When four or more days of bleeding equaled five or higher this met first menses criteria. Using this criterion, almost two-thirds of the 48 women (62.5%, n = 30) had a first

menses preceded by an EDO. Similar results were reported in the past (Arevalo & Sinai, 2005; Campbell & Gray, 1993; Eslami et al., 1990).

For the pilot study from women using the original protocol, the same bleeding scoring system was used. However, in the pilot study, the bleeding had to occur 56 days after parturition, this criterion was not part of the current study. Regardless, results of this study found characteristics of first menses were like the pilot study. The number of days of bleeding were on average five days, and the sum score of these consecutive days were ten or higher. Both studies found that when women experienced an EDO before first menses vaginal bleeding was heavier than just a few days of spotting. This finding showed consistency of bleeding patterns between the two studies. The consistency in first menses characteristics across studies can be used to further clarify the definition of first menses. This clarification can help women and MM Teachers know when to start women with cycle zero instructions or cycle one instructions.

Aim Two: Determine the correct and typical use effectiveness of the revised MM breastfeeding protocol for avoiding pregnancy at 12 months and 12 cycles of use?

The revised MM postpartum breastfeeding protocol was more effective than the original protocol (Bouchard et al., 2013; Fehring et al., 2017). However, of note is the inability to know if women in this study used a second LH test during the first six cycles as suggested by the optional instructions found in the revised protocol (Bouchard et al.,2013). In the archived website fertility chart data files, this information is not differentiated. However, it was common for the MM NFP teachers to direct women who tested with the LH test strip to record these results in the chart's mucus row. This study did not assess recorded data from the mucus row on the fertility charts. Therefore, we do not know if women did a second LH test. However, this study assumed that the women who registered for the breastfeeding protocol after July 1, 2015, were using the revised protocol, and may have tested for LH in the afternoon.

Research Question 1. What were the correct use unintended pregnancy rates at 12 months and 12

cycles of use among women who use the revised MM postpartum/breastfeeding protocol?

Correct use pregnancy rates at 12 months were 2 out of 100 women (per 2142 months of use),

and correct use pregnancy rates for cycles of use were 3.0 out of 100 women (1452 cycles of

use).   Correct use pregnancy rates for women who used the original postpartum/breastfeeding protocol

reported earlier were 2 and 3 per 100 women over 12 months and 12 cycles of use (Bouchard et al.,

2013; Fehring et al., 2017). Bouchard et al. (2013) reported 2 per 100 women or a 98% correct use

effectiveness rate over 12 months of use. A secondary analysis of correct use effectiveness rates of the

postpartum/breastfeeding protocols (i.e., original and revised) completed on 816 women found a

slightly lower correct use pregnancy effectiveness rate of 3 women out of 100 over 12 months and 12

cycles of use. The current study was an extension of the earlier mentioned studies on correct use

effectiveness and the results were similar.

Research Question 2. What were the typical use unintended pregnancy rates at 12 months and 12

cycles of use among women who used the revised MM postpartum/breastfeeding protocol?

The typical use pregnancy rates were lower than the typical use pregnancy rates from the earlier

studies on the MM postpartum protocols (Bouchard et al., 2013; Fehring et al., 2017; Mu et al.,

2020). In the current study, pregnancies were 4 out of 100 women over 12 months of use and 6 out of

100 women over 12 cycles of use. These women provided an average of 10 months of charting and 8

cycles of use. Typical use rates of the revised protocol improved significantly, while, in earlier studies of

the protocol's (original and revised), there were 8 per 100 women over 12 months of use (Bouchard et

al., 2013; Mu et al., 2020) and 14 per 100 women over 12 cycles of use (Fehring et al., 2017).

Summary of the Findings

Variability in the length of cycles and time to the EDO in cycles zero and one has historically

made the management of NFP methods for avoiding pregnancy difficult for postpartum breastfeeding

couples. Analysis of menstrual cycle parameters in the pilot (N = 80) and current (N = 64) studies found

cycles zero and one to be similar in both the original and revised protocol data analysis. Comparisons of

all parameters made between the two protocols showed both had consistencies within the

variability. In both the original and revised protocol, women experienced the first estrogen rise in cycle

zero around 6 months, the EDO around 8 months, and the first menses around 9 to 10 months

postpartum.   The length of the fertile time was shorter in cycle zero for the revised protocol by about 1

month; however, it was longer by almost a week in cycle one.

This study looked at the return to fertility patterns experienced by women who used the revised

postpartum/breastfeeding protocol. The revisions published in 2013 in the protocol for cycle zero were

meant to improve use effectiveness (Bouchard et al., 2013). The revised protocol had women test their

FMU using the monitor for 10 days; a second LH test was optional in the afternoon. This study found

revisions in the protocol improved use effectiveness in cycle zero and the next 12 months and 12 cycles

of use. The findings validated the protocol's effectiveness and the consistency in menstrual cycle

parameters. The consistency in parameters suggested patterns could be used to develop new

algorithms. The new algorithms proposed here could simplify the protocol, decrease cost, and increase

accessibility.

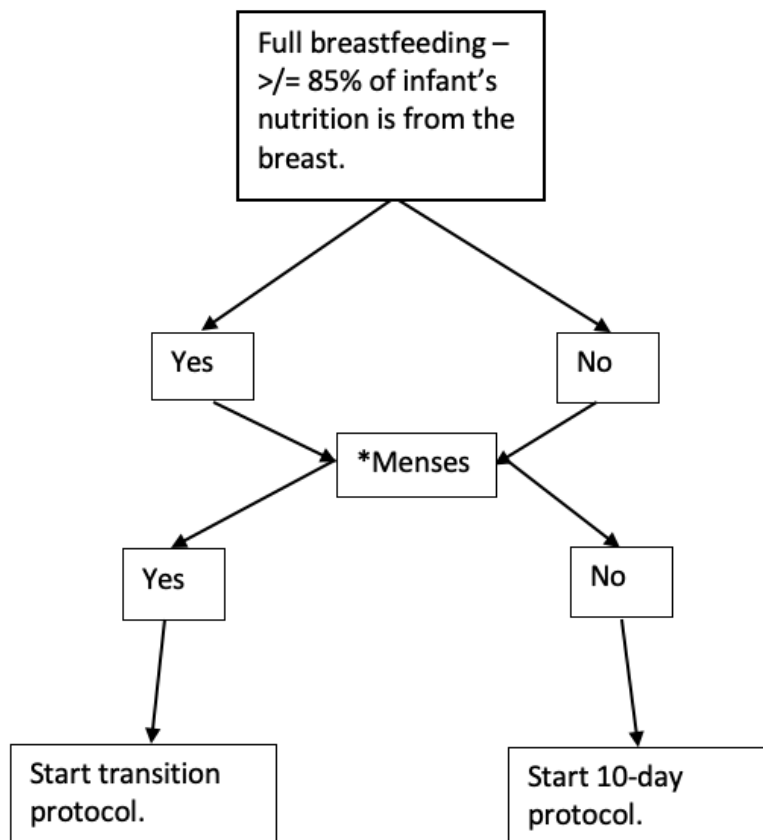**New Algorithms: Consistent Variability in Cycle Zero and One**

Consistent variability or data patterns are cornerstones in developing new algorithms and

models that can be tested (Shmueli et al., 2018). Algorithms guide data mining techniques and model

testing. Computer software developers use algorithms to develop programs that can be applied to

everyday human activity. The purpose of software programs in the healthcare field is to improve access

to care and optimize health (Devlin, 2013). Results from the pilot study and this study can be used to

develop new algorithms that can be applied to the revised MM postpartum/breastfeeding

protocol. These algorithms can help guide MM professionals and the women they teach to effectively

manage the postpartum/breastfeeding transition. Finally, adding these algorithms to the right

platforms can create databases where models can be tested, modified, and improved over time to

understand the menstrual cycle transition patterns in postpartum breastfeeding women.

A systematic approach guided by research questions from this study were used to develop three

new protocols that can support women who want to use the revised MM postpartum breastfeeding

protocol. First, an algorithm will guide women on when to begin cycle zero instructions (i.e., 10-day

protocol) or cycle one instructions (i.e., transition protocol). The algorithm used the definition of full

breastfeeding and first menses from this study. The first step in the algorithm seen in Figure 16 asks

women if they are fully breastfeeding. If the response is yes, then the next question is about menses.

That is if the pattern of bleeding is 1) crescendo-decrescendo or decrescendo-crescendo-decrescendo 2)

greater than or equal to 5 days 3) sum of the consecutive days of bleeding is greater than or equal to 10

they should start cycle one instructions.

Figure 16

New Guide for Starting the Revised MM Postpartum Breastfeeding Protocol

```
                    ┌─────────────────────┐
                    │ Full breastfeeding –│
                    │ >/= 85% of infant's │
                    │ nutrition is from the│
                    │ breast.             │
                    └─────────────────────┘
                      ↙               ↘
              ┌──────┐                 ┌──────┐
              │ Yes  │                 │ No   │
              └──────┘                 └──────┘
                    ↘               ↙
                    ┌──────────┐
                    │ *Menses  │
                    └──────────┘
                  ↙               ↘
          ┌──────┐                 ┌──────┐
          │ Yes  │                 │ No   │
          └──────┘                 └──────┘
             ↓                        ↓
    ┌─────────────────┐      ┌─────────────────┐
    │ Start transition│      │ Start 10-day    │
    │ protocol.       │      │ protocol.       │
    └─────────────────┘      └─────────────────┘
```

Note. ***Menses** = 1) Crescendo-decrescendo or Decrescendo-crescendo-decrescendo – Yes

2) Five or more days of bleeding? – Yes

3) Sum of the 5 or more consecutive days of bleeding >/= 10? Yes

Fully breastfeeding women who have not had a menses may not need to start protocol until 5 to 6

months postpartum. Check with your MM teacher for questions.

Women who did not have a first menses per the previous algorithm would start with cycle zero

instructions. Figure 18 is an algorithm for cycle zero instructions.   In both studies women did

experience more than one set of Ps on the monitor. When the monitor displayed a P the EDO followed

by first menses was expected. In both studies when the EDO was followed by first menses the luteal

phase was a mean of 8 days (see Table 6 and 16). This pattern is one of three cycle zero patterns found

by Bouchard et al (2018) and Brown (2011). That is, estrogen levels may stay elevated for months

because of an immature follicle (Velasquez et al., 2006). The elevated estrogen may trigger an LH surge

or a P on the CBFM. The algorithm in Figure 17 was developed to help women manage this situation.

Figure 17

Instructions for Management of the Revised MM Postpartum Breastfeeding Protocol: Cycle Zero Through the First Six Cycles.
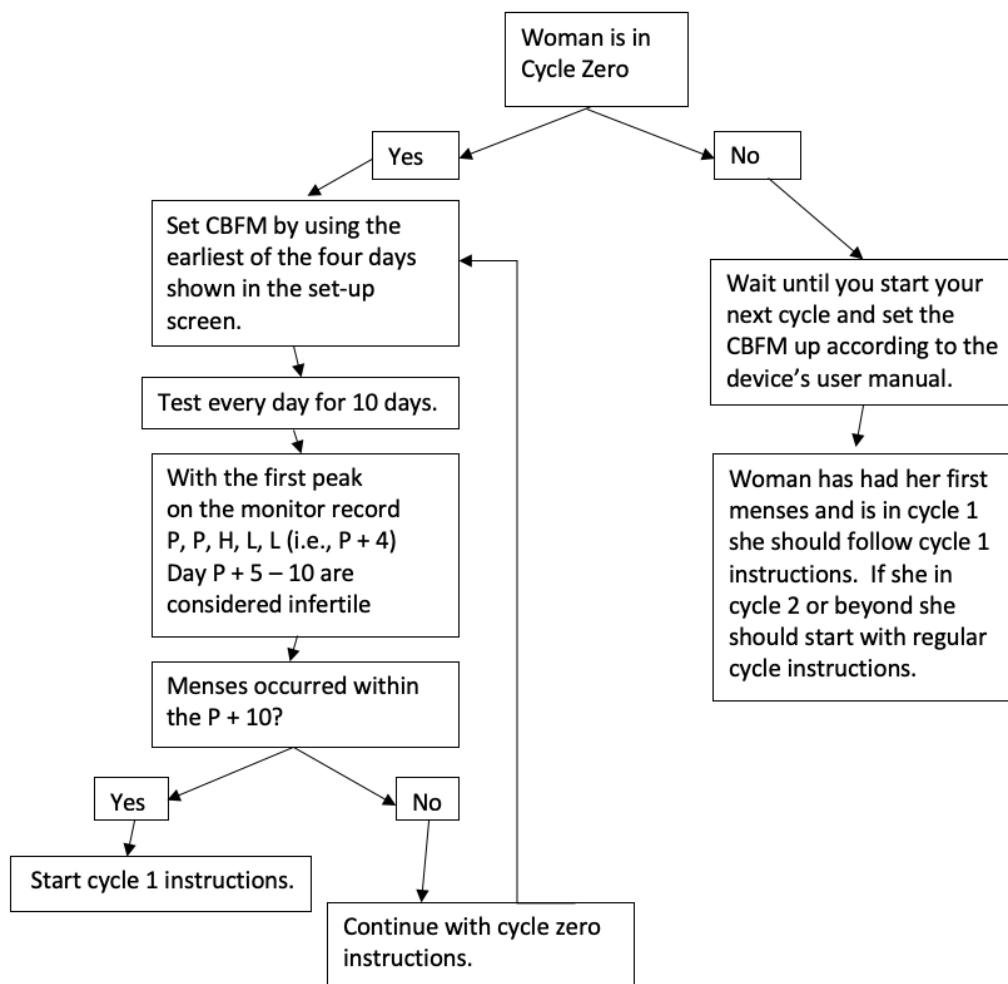

Note. Algorithm to guide the MM Teacher in how to manage cycle zero and when to begin cycle one

instruction.

Finally, in both studies where women had first menses and were breastfeeding the mean day for the EDO in cycle one was day 27. Breastfeeding studies have shown pregnancies occurred in cycles one through three postpartum (Bouchard et al., 2013; Brown et al., 1985; Fehring et al., 2017; Hatherley, 1985b). Women who used the original and revised protocol were also found to experience the EDO late in cycle one. The consistency for characteristics of first menses, time to the EDO and the length of luteal phases in both protocols were used to develop a guide for women in cycle one (see Figure 18). This study and the pilot study found patterns in the menstrual cycle parameters that were consistent and, new algorithms were developed that can be used in future research.   However, several limitations in this study design could have affected internal validity and generalizability of the study results that must be managed for future research designs.

Figure 18

New Guide for Cycle Zero to Cycle One Instructions for the Revised MM Postpartum Breastfeeding Protocol
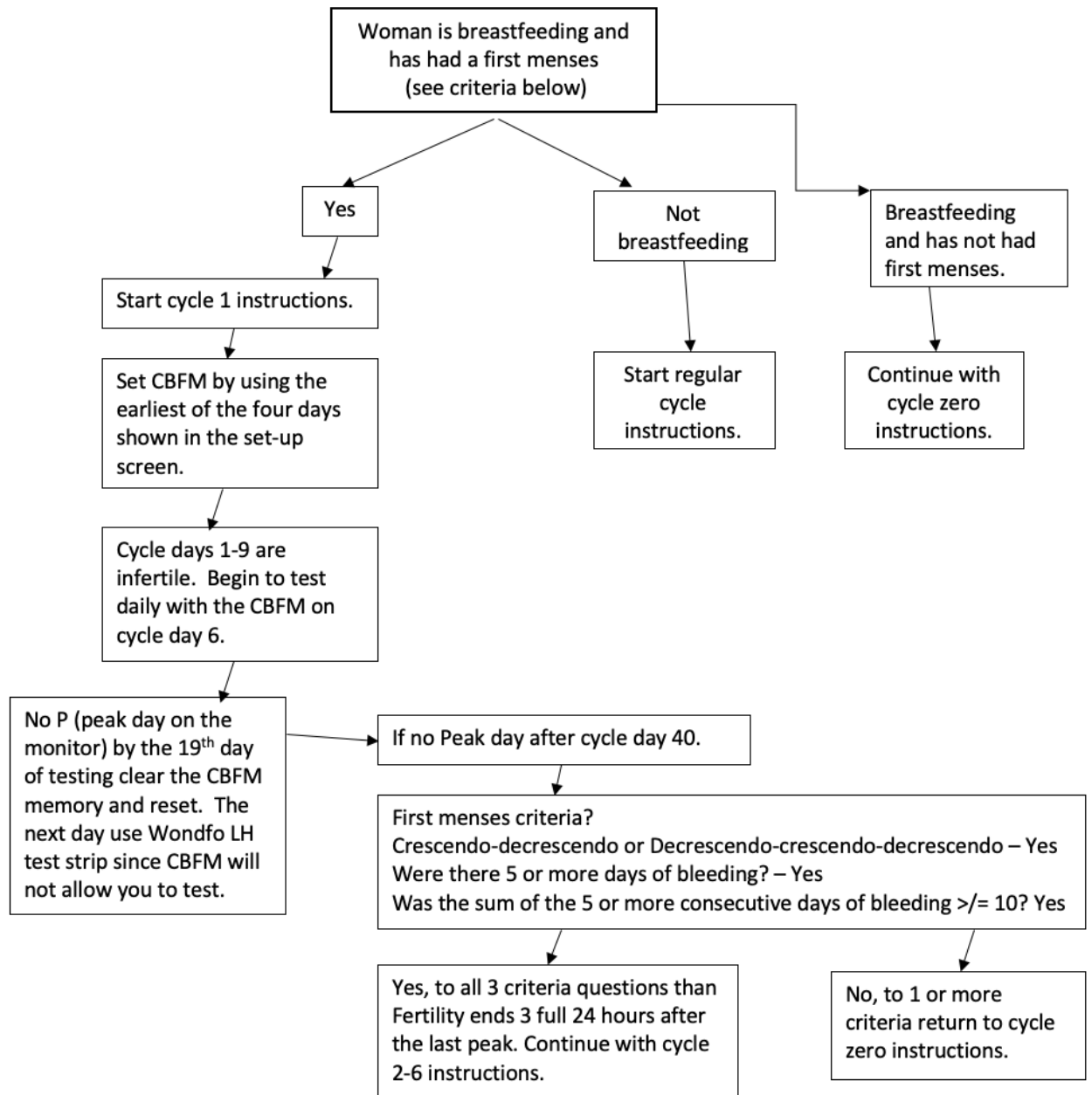
Note. This algorithm is a guide for MM teachers.

Limitations

As a quantitative cohort repeated measures study, several limitations could have affected the reliability and validity of the results (Waltz et al., 2010). Reliability is a pre-requisite for validity and depends on the condition of the validity. That is, did the measurements used in the study measure what they were intended to measure? In this study, the repeated measure was the revised protocol, and the outcome variables were correct and typical use pregnancy rates. To mitigate threats to reliability, this study used a form completed on separate occasions by two NFP nurse researchers. The nurse researchers used the form to identify correct and incorrect use pregnancies that also defined specific criteria. Criteria as seen in Appendix E is common to NFP research and has been developed over the years by MM NFP nurse researchers to decide if a pregnancy was an intended or unintended. The tool used definitions of pregnancy described by Trussell (Lamprecht & Trussell, 1997; James Trussell, 2011). However, the tool was not confirmed by other NFP researchers, a major step that is vital for avoiding research bias (Waltz et al., 2010).

A total of 19 pregnancies were found; however, 10 pregnancies had the conception chart and pregnancy evaluation, and met the studies criteria. The 9 pregnancies that did not meet the criteria and were not included would have significantly changed the results. Attrition of individuals that did get pregnant, the loss of chart data (including conception cycles), and the inability to contact women soon after pregnancy may have inflated both the correct and typical use pregnancy rates in this study. Other threats to validity were the lack of a control group, no randomization of subjects, and the use of retrospective data (Waltz et al., 2010).

Retrospective data analysis used to describe menstrual cycle parameters were affected by missing data, greater than 50% attrition rates, and data gaps. In an attempt to fill these gaps this study used a Qualtrics questionnaire. A link to the questionnaire was emailed to women (see Appendix H) requesting the date of birth of the infant they were breastfeeding, when they began supplementing

the infant's nutrition, if the infant was healthy at birth, the type of delivery and if she was nursing a

single child when she registered to use the revised protocol. Analysis of demographic data from six

women showed they supplied the wrong date of birth for the infant in the completed the questionnaire.

For example, the date of birth on the questionnaire of the youngest child occurred a few years after the

women registered to learn the revised protocol. An email was sent to these 6 women to clarify the birth

date of the child she was breastfeeding when she first registered to learn the revised protocol. Three

women responded with the correct birth date. Other data problems found in the fertility charts were

inaccurate dates for the beginning of cycles and the inability to confirm over half of these dates. When

chart dates could not be confirmed this resulted in the loss of over 50 % of the data.

Finally, the revised protocol depended on the 1) women's collection of the FMU, 2) the results

of the monitor, and 3) an optional LH test kit used in the afternoon.   The monitor instructions suggested

women collect and test their FMU. The FMU should be held in the bladder for a minimum of 4

hours. This may be challenging for postpartum breastfeeding women who are up every few hours with

the infant. Also, the monitor provided women with qualitative results of low, high, and peak.   Research

has shown the monitor can miss one out of ten LH surges (Swiss Precision Diagnostics GmbH, 2015).

Therefore, if LH surges were missed, this would affect menstrual cycle parameter results. Finally, if

women used a second LH test in the afternoon, there was no way to know this.

Even though several threats to reliability and validity listed above could have affected the results

of this study findings were consistent with past studies. In a multisite study of women who used the

breastfeeding protocol/s (n = 741) taught by 10 MM teachers, the typical use effectiveness rate was 8

women out of 100 over 12 months of use (Mu et al., 2020). In a more extensive comparison study of

816 women, typical use effectiveness rates were 14 women out of 100 over 12 cycles of use (Fehring et

al., 2017). These two studies were not able to identify the women who used the original or revised

protocol. However, this study focused on the time period when the revised protocol was routinely

taught. Therefore, since the revised protocol included a second LH test in the afternoon the results in this study were acceptable.

Suggestions for Future Research

The goals of this study were to assess the effectiveness of the revised protocol and describe menstrual cycle parameters for the first 6 cycles of the postpartum breastfeeding transition. It is evident that despite several limitations this study did find the revised protocol improved pregnancy effectiveness rates and revealed consistent menstrual cycle patterns. Data patterns of menstrual cycle parameters for both the pilot and current study were used to develop new algorithms that can be tested. Development of new algorithms were reasonable since improved pregnancy effectiveness rates validated the usefulness of the revised protocol.

Data analyzed in this study came from an archived website where women charted their daily hormone results into the MM NFP fertility charting system. The web-based fertility charting system was archived October 2019. While the website was up an IOS resident phone app was developed and released in the Apple Store (Uddin, 2013). Plans for the phone app to sync with the website were never completed. However, in 2020 development of a new and improved web-based MM NFP fertility charting system began and is slated to be released in the spring of 2021. Studies have shown women using the MM NFP protocols do find web-based charting to be highly acceptable (Bouchard et al., 2013). With over 61% of the women (Mu et al., 2020) looking for a MM NFP teacher to learn the postpartum breastfeeding protocols ongoing analysis and development of the protocols were important. New algorithms developed from the results of this study could be used to improve and simplify the protocol and the data collection process.

Conclusion and Implications for Nursing Practice

Professional nurse researchers have developed a Marquette Method system of NFP that recognized women's desire for safe, effective and natural methods of family planning during the postpartum breastfeeding transition. Thousands of women have learned to manage and chart their fertility in a web-based nurse managed fertility charting system since 2008. The findings of this study were supported by previous effectiveness studies of the MM postpartum breastfeeding protocol (Bouchard et al., 2013; Fehring et al., 2017; Mu et al., 2020). This study's design used the conceptual principles of LAM and the Suckling Induced Reflex Theory (SIRT) two theories that stated breastfeeding frequency affects ovarian and neuroendocrine activity. As breastfeeding frequency changes the change gets processed through neuroendocrine pathways and these pathways can be measured by biomarkers (Brown, 2011; Johnson, 2013; McNeilly, 2001).

The LAM and SIRT are well grounded physiologic theories affected by internal and external stimuli. This study was built with the CTE framework (Fawcett, 2013), SIRT (Johnson, 2013) and supported by the RAM. The RAM provided the overarching conceptual theory for the framework and is grounded in two philosophical premises 1) Supernatural Law and 2) Realism. Supernatural Law the idea biological patterns are ordered and purposeful to a higher power (Rice, 1999). Realism the theory that biological processes are not visible but objective results of the process that can be measured (Hussey, 2000). Together these concepts are foundational to the Roy Adaptation Method (RAM).   The science of nursing, through the lens of the RAM, is grounded in the study of human adaptation. RAM principles recognize human adaptation occur when stimuli act upon four human domains. These domains are 1) self-concept, 2) role function, 3) interdependence and 4) physiologic-physical. The design of this study looked at the physiologic domain, related to breastfeeding and how neuroendocrine feedback systems reflect hormone activity that can be measured in urine.

Reproductive neuroendocrine hormone paths are continuous and loop between the hypothalamus of the brain and the ovaries. The feedback loop is regulated by GnRH. When breastfeeding is frequent GnRH is suppressed, and the ovaries are dormant. As breastfeeding decreases GnRH activity increases, and the ovaries become active and eventually ovulation occurs. With ovarian activity the pre-ovulatory hormone estrogen rises. When estrogen levels are elevated for a few days, this triggers the LH surge and ovulation is expected a day later. This longitudinal study analyzed menstrual cycle parameters from women who charted the pre-ovulatory urine hormones. Although this study did show the revised protocol was more effective and menstrual cycle parameters during the transition were similar a prospective study with a larger sample size is warranted. A prospective study where women can quickly and easily document their fertility signs in a new MM NFP system web and phone app is being planned for 2021. The web app will be a secure data collection site where large real time data sets will be available for future analysis.

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Appendix A
Marquette Method Postpartum Breastfeeding Protocol's

Original Breastfeeding Protocol	Revised Breastfeeding Protocol – Original Monitor
1. Trigger a cycle by pushing the "m" 2. Fast-forward the monitor to day 5 3. The monitor will request 20 days of testing. 4. Test your first morning urine every other day. 5. When you see an "H" on the monitor test daily. 6. Retrigger the monitor and fast forward every 20 days. 7. Continue steps 1-6 until you have a peak reading on the monitor or resume your menses. 8. To avoid pregnancy, avoid intercourse on the high and peak days and three full days after the last peak day. 9. When your menses returns, reset the monitor and erase the memory and begin testing on day 6 when the monitor asks for a test. 10. Fertility begins on day 10 of the first cycle after the return of menses, day 9 in the second cycle, day 8 in the third cycle, day 7 in the fourth and day 6 in the fifth cycle. However, if the monitor records a high reading before these days, then fertility starts on the day of the first high reading. (Optional) Beginning on day 6 of the first menstrual cycle postpartum, women may do a second test with an LH test kit in the evening.	1. Trigger a cycle by pushing the "m". 2. Fast forward the monitor to day 5. 3. Test your first morning urine daily for 10 consecutive days. 4. When you see a "H" on the monitor continue to test daily for ten days. 5. Retrigger the monitor and fast forward to day 5. 6. Continue steps 1-5 until you have a peak reading on the monitor or resume your menses. 7. To avoid pregnancy, avoid intercourse on high and peak days and three full days after the last peak day. 8. When your menses returns, reset the monitor, and erase the memory and begin testing on day 6 when the monitor requests a test. Reset the monitor with each new cycle. 9. Fertility begins on day 10 of the first cycle after the return of menses, day 9 in the second cycle, day 8 in the third cycle, day 7 in the fourth and day 6 in the fifth cycle. However, if the monitor records a high reading before these days, then fertility starts on the day of the first high reading. 10. Starting with cycle 6 fertility begins on day 6 and ends three full days after the last peak day. 11. A second LH test can be done in the afternoon or evening. Follow instructions found in the LH test kit.

Appendix A

| Revised Breastfeeding Protocol – Touch Screen Monitor |
|---|
| 1. Trigger a new cycle by pressing the home icon and then the circle icon.
 2. Choose the earliest date the monitor will allow (usually 3 days before the current date).
 3. The monitor will request a time – select 8 a.m. the monitor will prompt you to finish the set-up.
 4. After the set-up, the monitor will display day 4.
 5. The monitor will not request a test until day 6 so consider testing with an LH test strip on day 5.
 6. Day 5 is considered fertile if the monitor does not request a test.
 7. Test your first morning urine daily for 10 consecutive days.
 8. When you see a "H" on the monitor continue to test daily for ten days.
 9. Retrigger the monitor and continue steps 1-7.
 10. Continue steps 1-7 until you have a peak reading on the monitor or resume your menses.
 11. To avoid pregnancy, avoid intercourse on high and peak days and three full days after the last peak day.
 12. When your menses returns, reset the monitor, and erase the memory and begin testing on day 6 when the monitor requests a test. Reset and clear the monitor with each new cycle.
 13. Fertility begins on day 10 of the first cycle after the return of menses, day 9 in the second cycle, day 8 in the third cycle, day 7 in the fourth and day 6 in the fifth cycle. However, if the monitor records a high reading before these days, then fertility starts on the day of the first high reading.
 14. Starting with cycle 6 fertility begins on day 6 and ends three full days after the last peak day.
 15. A second LH test can be done in the afternoon or evening. Follow instructions found in the LH test kit. |

Note. The Touch Screen Monitor has been on the market since 2015.

Appendix B
Flow Diagram for Literature Review
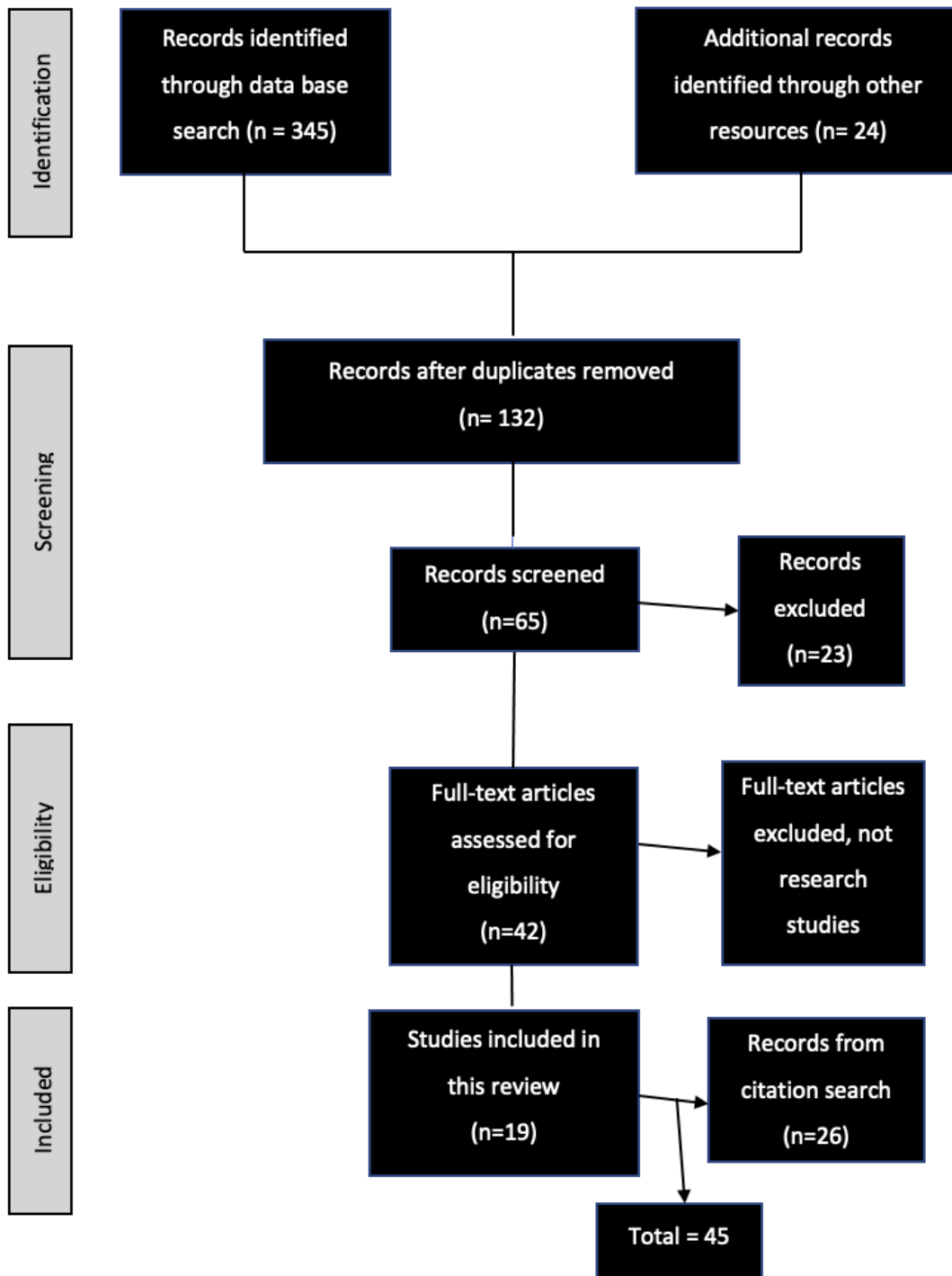
Appendix C

World Health Organization Breastfeeding/LAM studies

Authors	Title	Year published	Purpose	Sample – description and size (n).	Design	Results
World Health Organization Task Force on Methods for the Natural Regulation of Fertility	The World Health Organization Multinational Study of Breast-feeding and Lactational Amenorrhea. I. Description of infant feeding patterns and of the return of menses	1998	To describe infant breast-feeding practices from women in seven different cultures and how these practices relate to the return of menses.	Seven centers in: • Chengdu, China • Guatemala City, Guatemala • New Delhi, India • Sagamu, Nigeria • Santiago, Chile • Uppsala, Sweden • Melbourne and Sydney, Australia Breastfeeding women between 20-37 y.o., </= 3 children, breastfed one infant for three months, agree to six months of BF, literate, mother healthy weight, singleton vaginal delivery, could not leave the infant >8 hours and women had to only be breastfeeding their infant.	Prospective longitudinal cohort study. BF women entered the study at one week postpartum. Mothers completed a daily BF diary of frequency and supplements. BF event - >2 minutes and at least 30 minutes apart. 10pm-6am = night feeds. Participants followed every two weeks in their home. End point – two normal menses, pregnancy or lost to follow-up. Menses = 2 consecutive days of bleeding with one day needing sanitary care, occurring >14 days after lochia, within 21-70 days after the first	Menses – 0.8% of women had a bleeding episode > 21 days after the first. 20.7% of women had a bleeding episode < 70 days. N = 4118 (21% attrition rate) n = 3337 experienced two menses. Pregnant = 85 Age = 26.2-30.9 y.o (mean). 89% first bleed confirmed by a second and 80% of women perceived the bleeds to be menses. Difference between confirmed menses using the HRP rule and women's perception were 1-23 days.

						bleeding episode and confirmed by the woman to be her normal menstrual pattern. Confirmation of menses came if the second bleed followed the above guidelines. This is the Human Reproduction Programmed [HRP] rule.
World Health Organization Task Force on Methods for the Natural Regulation of Fertility	The World Health Organization Multinational Study of Breast-feeding and Lactational Amenorrhea. II. Factors associated with the length of amenorrhea	1998	To determine the difference in infant feeding practices related to the first menses or end of post-partum amenorrhea.	Same as above.	Same as study I but used multiple regression on 27 variables determined to affect duration of PPA.	Median for PPA = 122 to 282 days. Significant difference in breastfeeding patterns among all centers. Ten variables were significant. • 7 related to infant feeding patterns • related to parity, maternal BMI low and infant health. No supplements (or water) = highest duration of breastfeeding. Probability of first menses higher when infant received

World Health Organization Task Force on Methods for the Natural Regulation of Fertility	The World Health Organization Multinational Study of Breast-feeding and Lactational Amenorrhea. III. Pregnancy during breast-feeding	1999	To determine the effectiveness of LA for avoiding a pregnancy.	Same as above.	Same as study I but also disregarded the HRP rule if the woman discontinued the study after the first menses. That is all first menses were included but not all were confirmed by a second menses. Breastfeeding categories: Full – all nutrition from breast except vitamins/water. Partial – supplements given. Weaned – no longer breastfeeding. Survival analysis – pregnancy rates.	>\=50% of feeds. Total pregnancies: n = 64. N = 16 fully breastfeeding. N = 48 partial breastfeeding N = 18 conceived while using either NFP, withdrawal, IUD barriers or vasectomy after they were in cycles. N = 46 no contraception used. Women in Chile had higher pregnancy rates when the perception of first menses was used. Authors suggest LAM not helpful for these women. HRP rule – resulted in highest exposure to pregnancy. Effectiveness to avoid pregnancy = 1.2% (95% CI = 0-2.4%) All pregnancies in China.

World Health Organization Task Force on Methods for the Natural Regulation of Fertility	The World Health Organization Multinational Study of Breast-feeding and Lactational Amenorrhea. IV. Postpartum bleeding and lochia in breast-feeding women	1999	To describe and compare the length of lochia among bf women and does: age, parity, birth weight, frequency of breastfeeding affect duration of lochia.	Same as above. N = 3792 (92.1%) of women	Same as study I. And added: Lochia – not defined, last day of consecutive days of bleeding marked the end of lochia. Survival analysis, log rank test and Cox proportional hazards regression used. 1-2 days of no bleeding marked = bleeding free days.	Lochia – 27-33 days. 15.1 % of women had bleeding free days during lochia. 51% of Chilean women had a bleeding episode one week after lochia subsided (Mean = 3.2 days). 5.4%-63.3% had at least one bleeding episode after lochia and before 56th day. 83.4% of women bled 21-70 days after first bleed prior to 56th day.

Note. The WHO conducted one study in multiple countries that had many arms to address characteristics of return

to fertility in postpartum breastfeeding women.

Appendix D
Guidelines to Manage Missing Data

1. If greater than 10 consecutive days of charting was missed during lactation

   amenorrhea the first high that was followed by a series of highs was recorded.

2. When a single peak day was recorded, assume that there were two peak days, and

   the 2nd of these two days was the EDO. (This is because the CBFM automatically

   records a second peak after the first, even when a test has not been done and

   women will stop testing once the see the first peak day.)

3. The first high during lactation amenorrhea was considered the first day of fertility

   and recorded using the date that it occurred.

4. During the first six cycles the first high and EDO was recorded as the cycle day.

5. During the first six cycles when two or more days of charting were missed but a

   single peak day was recorded the EDO was the day after the recorded peak day.

6. If only the first day of menses was recorded, the length of the cycle was calculated

   using date transformation.

Appendix E
Pregnancy Rating Tool

Definitions and Guidelines:

1. Pregnancy occurred – The woman/man has indicated this through the chart and/ or the pregnancy evaluation.
2. Pregnancy can be determined when – The chart with the act of intercourse that resulted in the pregnancy is available and the woman completed a pregnancy evaluation in either nfp.marquette.edu or in the Qualtrics questionnaire.

Username	Intended	Unintended	Correct use	Incorrect use	Reviewer Initials

Pregnancy Classifications:

3. Perfect/correct use (method related) pregnancy criteria:
   a) Enough days of the cycle have been charted to determine the day with the act of intercourse was fertile or infertile during LA or was within the fertile window in the following first six cycles postpartum.
   b) The act of intercourse occurred on an infertile day.
   c) The intention to avoid is recorded on the chart and is the same in the pregnancy evaluation.
   d) The woman indicated she was using the revised breastfeeding protocol.
4. Typical use pregnancy criteria
   a) Inconsistent charting – The act of intercourse occurred on an untested day during LA, there is not enough days recorded to determine the fertile time/window, no act of intercourse is recorded.
   b) Intention on the chart is not the same as the intention in the pregnancy evaluation.
5. Intended pregnancy – "Achieve" is recorded on the chart when the pregnancy occurred.
6. Unintended pregnancy – "Avoid" is recorded on the chart when the pregnancy occurred.

Appendix F
Marquette Method NFP Registration Form

Natural Family Planning Female Profile

┌─ **IDENTIFICATION** ───

Name: *

Spouse's Name

Address:

City, State Zip

Work Phone:

Home Phone

Registration Date   //

1. How old were you at your last birthday? * (in years)

2. Are you? *   ▼

3. If Married, How many years have you been married?   0 ▼

4. If Engaged, When do you plan on getting married?   ▼   ▼

5. What is your religion?   ▼

6. What is your ethnicity?   ▼

7. How many school years have you completed?   0   ▼

└──

┌─ **CYCLE HEALTH AND PREGNANCY HISTORY** ────────────────────

How Tall are you?   ft.   in.

How much do you weigh?   lbs. or   kgs.

Reproductive Category: *   ▼

8. How many pregnacies have you experienced? *

9. Living Children? *

10. Miscarriages?

11. Abortions?

12. Are you currently taking any meds or vitamins? *   No ▼

└──

10/16/2019   Marquette University | Natural Family Planning | Profile

If Yes Above: Explain:

13. Please list any gynecological surgeries you have had and the dates:

14. Are you breast feeding? *   ▼

┌─ **FAMILY PLANNING PRACTICE** ──────────────────────────────

0. None	**3.** Injection	**6.** Breastfeeding	**9.** NFP.
1. Pill	**4.** Barrier	**7.** WithDrawal	**10.** Other
2. IUD	**5.** Norplant	**8.** Abstinence	

15. Among the following methods, which method are you using now? (Specify by number)

If you are not using any method, name which was the most recent method you used.

16. When did you stop using the most recent method?   ▼   ▼

└──

┌─ **FAMILY PLANNING INTENTION** ─────────────────────────────

17. Why do you want to chart your fertility? *   ▼

18. When do you want your next pregnancy to begin?

○ No More Pregnancies Desired   ○ After two years but before three years

○ Trying to become pregnant now   ○ After three years

○ Within a year from now   ○ It doesn't matter
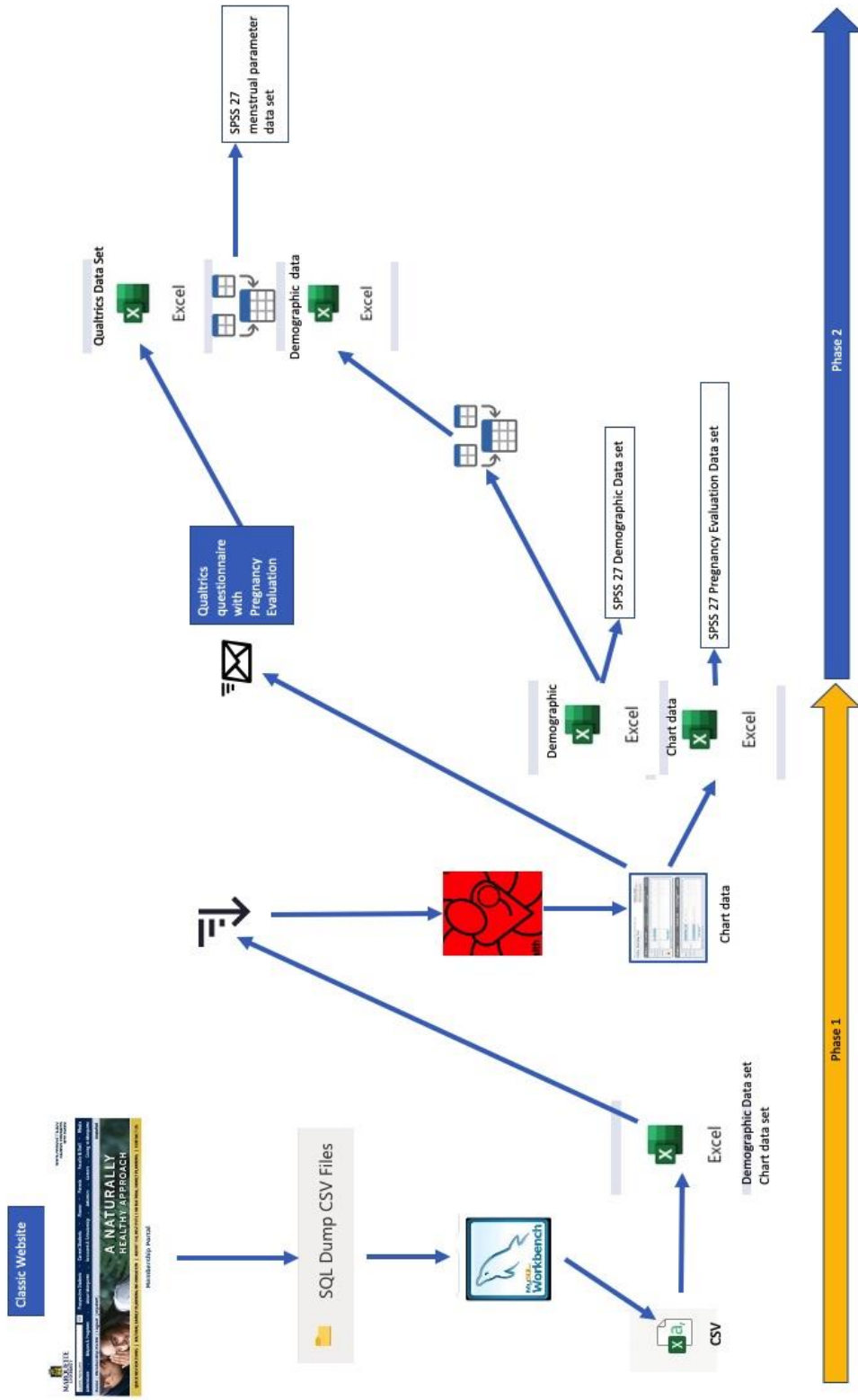
○ After one year but before two yrs   ○ Don't Know

19. Does yor spouse share this intention? *   ▼

20. If you are trying to become pregnant now, how long have you been trying? *   Years   Months

* Required

└──

Appendix G

Data Collection Process

Appendix H
Study Email (HR-3666)

MARQUETTE UNIVERSITY COLLEGE OF NURSING

INSTITUTE FOR NATURAL FAMILY PLANNING

Dear NFP Study Participant,

Thank you for your participation in the online Marquette Model study
(https://nfp.marquette.edu). You indicated on your registration form that you were postpartum
breastfeeding, or breastfeeding weaning.

We are evaluating the use of the revised postpartum/breastfeeding protocol and would like to
collect information regarding your use of the method to avoid a pregnancy. The questions have
been set up in an anonymous Survey Monkey questionnaire that will not take you more than ten
minutes to complete. Once you complete the questionnaire and your email has been matched
to the user identification you were originally given your email will be erased from the data set.
The deidentified data set will be analyzed and then stored in Marquette Universities electronic
library collection for future research.

Thank you for all you do to help us advance NFP for families such as yourself.

Richard Fehring, PhD, RN, FAAN

Mary Schneider MSN, APRN, FNP-BC (PhD Candidate)

Appendix H

Qualtrics Questionnaire

1. What is the date/s of birth of the baby/s you breastfed while using the revised Marquette
   Method Breastfeeding Protocol – record as MM/DD/YYYY

2. How many babies were you nursing during the time you charted your fertility?
   (1-10)

3. Choose one of the two breastfeeding patterns that best describes the type of
   breastfeeding you were doing when you registered on the website to learn the
   protocol. The two choices you had were:

   a. Total breastfeeding – This means baby was receiving breastmilk from the breast
      at least 85% of the time in a 24-hour period.
   b. Partial breastfeeding – This means baby was receiving breastmilk less than 85%
      of the time in a 24-hour period.

2. What month, day, year did you start providing bottles or solid foods for your
   baby?
   MM/DD/YYYY

3. What month, day, year did you completely stop breastfeeding?
   MM/DD/YYYY

4. Was the baby healthy that you breastfed during the time you charted on this
   Website?   If not, please provide a brief description of the illness and length of
   time your baby was ill.

5. Did you deliver this baby vaginally or by c-section?

6. Did you get pregnant using the revised breastfeeding protocol?   Yes   or   No

7. If you did get pregnant using the revised protocol and have not had this
   pregnancy evaluated please let us know by completing the pregnancy evaluation
   below.

Appendix I
Registration Form: Reproductive Category

Natural Family Planning Female Profile

---IDENTIFICATION---

Name: *

Spouse's Name

Address:

City, State Zip

Work Phone:

Home Phone

Registration Date   //

1. How old were you at your last birthday? * (in years)

2. Are you? *

3. If Married, How many years have you been married?   0 ⌄

4. If Engaged, When do you plan on getting married?   ⌄   ⌄

5. What is your religion?

6. What is your ethnicity?

7. How many school years have you completed?   0   ⌄

---CYCLE HEALTH AND PREGNANCY HISTORY---

How Tall are you?   ft.   in.

How much do you weigh?   lbs. or   kgs.

Reproductive Category: *   ✓

8. How many pregnacies have   Regular (25-35 days)

9. Living Children? *   Long (More than 35 days)

        Short cycles (Less than 25 days)

10. Miscarriages?   Post Hormonal

11. Abortions?   Pill or Injection

12. Are you currently taking   Post Partum (Breastfeeding)

        Post Partum (Not Breastfeeding)

If Yes Above: Explain: Post miscarriage

13. Please list any gynecologi   Pre-menopause (40 yrs or older)

        Other

14. Are you breast feeding? *   ⌄

---FAMILY PLANNING PRACTICE---

0. None	**3.** Injection	**6.** Breastfeeding	**9.** NFP.
1. Pill	**4.** Barrier	**7.** WithDrawal	**10.** Other
2. IUD	**5.** Norplant	**8.** Abstinence	

15. Among the following methods, which method are you using now? (Specify by number)

If you are not using any method, name which was the most recent method you used.

16. When did you stop using the most recent method?   ⌄   ⌄

Appendix J
Registration Form: Breastfeeding Status

Natural Family Planning Female Profile

IDENTIFICATION

Name: *

Spouse's Name

Address:

City, State Zip

Work Phone:

Home Phone

Registration Date   //

1. How old were you at your last birthday? * (in years)

2. Are you? *

3. If Married, How many years have you been married?   0

4. If Engaged, When do you plan on getting married?

5. What is your religion?

6. What is your ethnicity?

7. How many school years have you completed?   0

CYCLE HEALTH AND PREGNANCY HISTORY

How Tall are you?   ft.   in.

How much do you weigh?   lbs. or   kgs.

Reproductive Category: *

8. How many pregnacies have you experienced? *

9. Living Children? *

10. Miscarriages?

11. Abortions?

12. Are you currently taking any meds or vitamins? *   No

If Yes Above: Explain:

13. Please list any gynecological surgeries you have had and the dates:

14. Are you breast feeding? *

   ✓

   No

   Partial (Baby gets food and breast feeding)

   Total (Baby gets only breast milk)

   N / A

FAMILY PLANNING PRACTI

0. None	3. Injection
1. Pill	4. Barrier
2. IUD	5. Norplant

15. Among the following methods, which method are you using now? (Specify by number)

If you are not using any method, name which was the most recent method you used.

16. When did you stop using the most recent method?

Appendix K
HR-3666 Pregnancy Evaluation Tool and Reliability Form: Results

Definitions and Guidelines:

1. Pregnancy occurred – The woman/man has indicated this through the chart and/ or the pregnancy evaluation.
2. Pregnancy can be determined when – The chart with the act of intercourse that resulted in the pregnancy is available and the woman completed a pregnancy evaluation in either nfp.marquette.edu or in the Qualtrics questionnaire sent to the user's email.

Pregnancy Classification Table using the criteria below:

Username	Intended	Unintended	Correct use	Incorrect use	Reviewer Initials
Nfp9923		x		x	RJF/ms
Nfp10029	x				RJF/ms
Nfp10151		x		x	RJF/ms
Nfp10162	x				RJF/ms
Nfp10183		x	x		RJF/ms
Nfp10968	x				RJF/ms
nfp10203		x		x	RJF/ms
nfp10750	x				RJF/ms
nfp10269	x				RJF/ms
nfp10041		x	x		RJF/ms

Pregnancy Classifications Criteria:

3. Perfect/correct use (method related) pregnancy criteria
   a.   Enough days of the cycle have been charted to determine the day with the act of intercourse was fertile or infertile during LA or was within the fertile window in the following first six cycles postpartum.
   b.   The act of intercourse occurred on an infertile day.
   c.   The intention to avoid is recorded on the chart and is the same in the pregnancy evaluation. The woman indicated she was using the revised breastfeeding protocol.

4. Typical use pregnancy criteria
   a.   Inconsistent charting – The act of intercourse occurred on an untested day during LA, there is not enough days recorded to determine the fertile time/window, no act of intercourse is recorded.
   b.   Intention on the chart is not the same as the intention in the pregnancy evaluation.

5. Intended pregnancy – "Achieve" is recorded on the chart when the pregnancy occurred.
6. Unintended pregnancy – "Avoid" is recorded on the chart when the pregnancy occurred.

Appendix L

Unintended Pregnancies Included in Survival Analysis

UserID	Infant DOB or chart start date.	Month of preg. r/t when chart started.	Cycle of preg. r/t when chart started.	Act/s of I (r/t EDO or 2nd peak day, e.g. P+/-)	Comments
9923	20-May-15 (inf. DOB)	Aug-2016	5	P − 4 or P + 3	I's on CD 8,9 and 10; FW started CD 7; Pregnancy occurred 15 months pp.
10041	28-Feb-16	Jun- 2016	4	P + 5	FW started CD 7, act of I on CD 21.
10151	20-Nov-15	Aug-2016	3	P + 3	No menses recorded.
10183	7-Jul-16	Jul-2016	?	P + 6	Menses score 10 over 5 days in pregnancy chart. FW CD6 – CD24. No I's during FW.
10203	7-Jul-16 (inf. DOB)	July-2018	16	P − 5 or P + 8	Outside of SA cutoff = 12 months or cycles.

Note. This is a detailed description for each pregnancy and the reasons for each pregnancy classification.

MARQUETTE UNIVERSITY GRADUATE SCHOOL
DISSERTATION APPROVAL FORM

Chairperson / Director: Submission of this form indicates that the student has satisfactorily completed the Dissertation Defense, and is submitting the dissertation in its final, approved form. This completed form must be delivered to the Graduate School with the final dissertation. If you need assistance completing this form, please contact the Graduate School at 414-288-7137.

STUDENT INFORMATION

Name	Mary M. Schneider	MUID	002-96616
Program	Doctoral	Defense Date	March 30, 2021
Dissertation Director	Linda Piacentine		

Title: Effectiveness of a postpartum breastfeeding protocol for avoiding pregnancy and descriptive analysis of the physiology of the *post partum transition*

A. DISSERTATION DEFENSE

1. The committee voted by a number of [3] to accept and [0] to NOT accept this dissertation.

(Attach any comments, if necessary. A failed defense requires comments.)

☐ Approved with no changes   ☒ Approved pending required changes due by ___

☐ Failed defense   ☐ Approved with recommended changes

2. If the vote is not a unanimous acceptance, the approval of the Department Chairperson is required to allow the student to pass with a non-unanimous vote

☐ Approve   ☐ Disapprove

Signature: *Mary Schneider*   Date: 4/26/21

3. Committee Members: Your signature indicates that you agree with the above indicated results.

TYPED NAMES		SIGNATURES	
Dissertation Director	Linda Piacentine, PhD, RN	Dissertation Director	*Linda Piacentine*
Committee Member	Richard Fehring, PhD, RN	Committee Member	*Richard Fehring*
Committee Member	Thomas Bouchard, MD	Committee Member	*Bouch*
Committee Member		Committee Member	
Committee Member		Committee Member	

B. DISSERTATION FINAL SUBMISSION

This is to certify that all required changes have been made, the dissertation is accepted and approved for submission to the Graduate School

Dissertation Director Signature: *Linda Piacentine*   Date: 4-20-2021

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