2012

A review of fertility awareness based methods of birth control

BOSTON UNIVERSITY

SCHOOL OF MEDICINE

Thesis

A REVIEW OF FERTILITY AWARENESS BASED METHODS OF BIRTH CONTROL

by

CAITLIN F. JACOWSKI

B.S., University of Notre Dame, 2009

Submitted in partial fulfillment of the

requirements for the degree of

Master of Arts

2012

Approved by

First Reader

Linda J. Heffner, M.D., Ph.D.
Professor of Obstetrics and Gynecology

Second Reader

Theresa A. Davies, Ph.D.
Assistant Director, M.A. in Medical Sciences Program
Adjunct Assistant Professor of Biochemistry

ACKNOWLEDGEMENTS

I would like to sincerely thank Dr. Heffner and Dr. Davies for their help in the completion of this thesis. I would also like to extend special thanks to my family and friends who supported me and helped to revise and structure this project. I appreciate everyone's support and encouragement; it has been invaluable during the completion of this thesis project.

A REVIEW OF FERTILITY AWARENESS BASED METHODS OF BIRTH CONTROL

CAITLIN F. JACOWSKI

Boston University School of Medicine, 2012

Major Professor: Linda J. Heffner, M.D., Ph.D., Professor of Obstetrics and Gynecology

ABSTRACT

Women who are interested in controlling the timing of their pregnancies have many birth control and family planning options. The majority of women use exogenous forms of contraception, including oral contraceptive pills, hormone shots or patches, intra-uterine devices, or barriers such as condoms, sponges or diaphragms. Many of the exogenous methods have negative side effects including allergic reactions and increased risk of blood clotting, and cancer. Additionally, there can be religious objections to these methods. In an attempt to provide women other, natural, birth control options, an array of methods have been developed over time using knowledge of a woman's menstrual cycle.

These methods are referred to as fertility awareness based methods because they track various symptoms of a woman's menstrual cycle to determine when she is fertile. Changes in the cervix, cervical mucus secretions, and basal body temperature indicate the fertile window when a woman is most likely to get pregnant. To avoid pregnancy, women using fertility awareness based methods abstain from unprotected intercourse during their fertile windows. Using cycle length and observed physical changes, six methods have been developed. The goal of this thesis is to review and compare the methods.

Of the developed methods, the Standard Days method is a calendar method with an average method effective rate of 95% and an average typical-use effective rate of 88%. The Billings Ovulation method, a cervical mucus only method, has an average method effective rate of 98.5% and an average typical-use effective rate of 82%. The Creighton Model of Fertility Care System, also a cervical mucus only method, has an average method effective rate of 99% and an average typical-use effective rate of 87%. A simpler, cervical mucus only method is the TwoDay method which has an average method effective rate of 96% and a typical-use effective rate of 91%, higher than the other cervical mucus methods, likely due to its ease of use. The symptothermal method uses a combination of symptoms to create a double-check system for entering and exiting the fertile window. The method effective rate is the highest at 99.5% and the average typical-use effective rate is 95%. This method is the most effective, but also the

most difficult to learn. Finally, the Marquette Model uses cervical mucus and an electronic fertility monitor to indicate the fertile window. The average method effective rate is 97.8% and the average typical-use effective rate is 83%.

The fertility awareness based methods of birth control show method effective rates comparable to many of the exogenous forms of birth control. The typical-use effective rates are generally lower than other forms of birth control because success requires appropriate abstinence by the users, which some users find difficult. Inconsistencies in definitions of what constitutes an unintended pregnancy affect the reported failure rates among the methods making it difficult to compare them. Future studies are that evaluate all the methods using consistent terminology and exclusion criteria are needed. Ultimately, the natural methods can be effective for highly motivated couples who wish to use a birth control method that is natural, has no side effects, and can, in many instances, improve martial communication and relationships.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

BIP	Basic Infertile Pattern
BOM	Billings Ovulation Method
BBT	Basal Body Temperature
CBM	Calendar Based Method
CEFM	ClearBlue Easy Fertility Monitor
CrMS	Creighton Model Fertility Care System
E3G	Estrogen Metabolite
EDR	Early Day Rules
EHFM	Electronic Hormonal Fertility Monitor
FAB	Fertility Awareness Based Method
FSH	Follicle Stimulating Hormone
FWHC	Feminist Women's Health Center
IPPF	International Planned Parenthood Federation
IUD	Intra Uterine Device
LH	Luteinizing Hormone
MM	Marquette Method
NFP	Natural Family Planning
OM	Ovulation Method
PR	Peak Rule
SBM	Symptom Based Method
SDM	Standard Days Method

STM	Symptothermal Method
WHO	World Health Organization

INTRODUCTION

Family planning methods have recently become popular topics in the United States debate on health. Commonly, women use oral contraceptives, patches, intrauterine devices (IUD), and barrier methods such as diaphragms – all exogenous forms of contraception. A large subset of women are interested in alternative, natural forms of birth control whether it be for religious reasons or fear of the risks associated with other forms of birth control. For these reasons, an array of natural methods has been designed based on knowledge of a woman's menstrual cycle.

FEMALE MENSTRUAL CYCLE

The female menstrual cycle has been fairly well characterized and has relatively predictable hormone patterns and physical markers. In adolescence, the reproductive axis begins to function in a rhythmic, cyclical pattern, with the ovaries responding to two hormones, Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH), secreted by the pituitary. Ovarian follicles start to mature with stimulation by FSH and continue to grow due to estrogen secretion. This estrogen is a stimulus for LH. The interacting hormones display a characteristic LH surge, small FSH surge, fall in estrogen, and an increase in progesterone which occurs just prior to ovulation (Owen, 1975). LH and FSH levels are low during the luteal phase with a high level of progesterone.

Several physical indicators coincide with these hormonal changes. The changes in estrogen levels correspond to changes in the properties of a woman's cervical mucus secretions. When estrogen levels are low, such as during the early follicular phase, the mucus is "scanty and viscous, relatively high in protein content" (Owen, 1975). When estrogen levels are higher, such as during the later follicular phase around ovulation, mucus "becomes thinner and more watery, and increases dramatically in quantity (up to 30-fold) and in mucin content." Another characteristic of cervical mucus that has been studied is 'spinnbarkeit' which refers to the elasticity of the mucus. The spinnbarkeit of cervical mucus increases during the follicular phase and can stretch up to 15 cm around ovulation (Hilgers, 2004). These characteristics of the mucus determine sperm survival and transport (Bigelow et al., 2004).

Another physical marker of hormonal changes during the menstrual cycle is basal body temperature (BBT). A rise of 0.63°F above an individual's average body temperature occurs on or soon after ovulation and remains elevated until menses (Owen, 1975). When a woman's temperature stays elevated for three consecutive days, her fertile period is over (Royston & Abrams, 1980). All these factors are integrated into Figure 1.

Other factors observed are cervical position and cycle regularity. Increasing knowledge of the hormonal and physical changes associated with the female

menstrual cycle led to the development of Fertility Awareness Based (FAB) Methods that incorporate one or a combination of several of these signs of fertility to either achieve or avoid pregnancy. These methods were developed mostly as a response to religious opposition to artificial birth control methods (J. Billings, 2002).

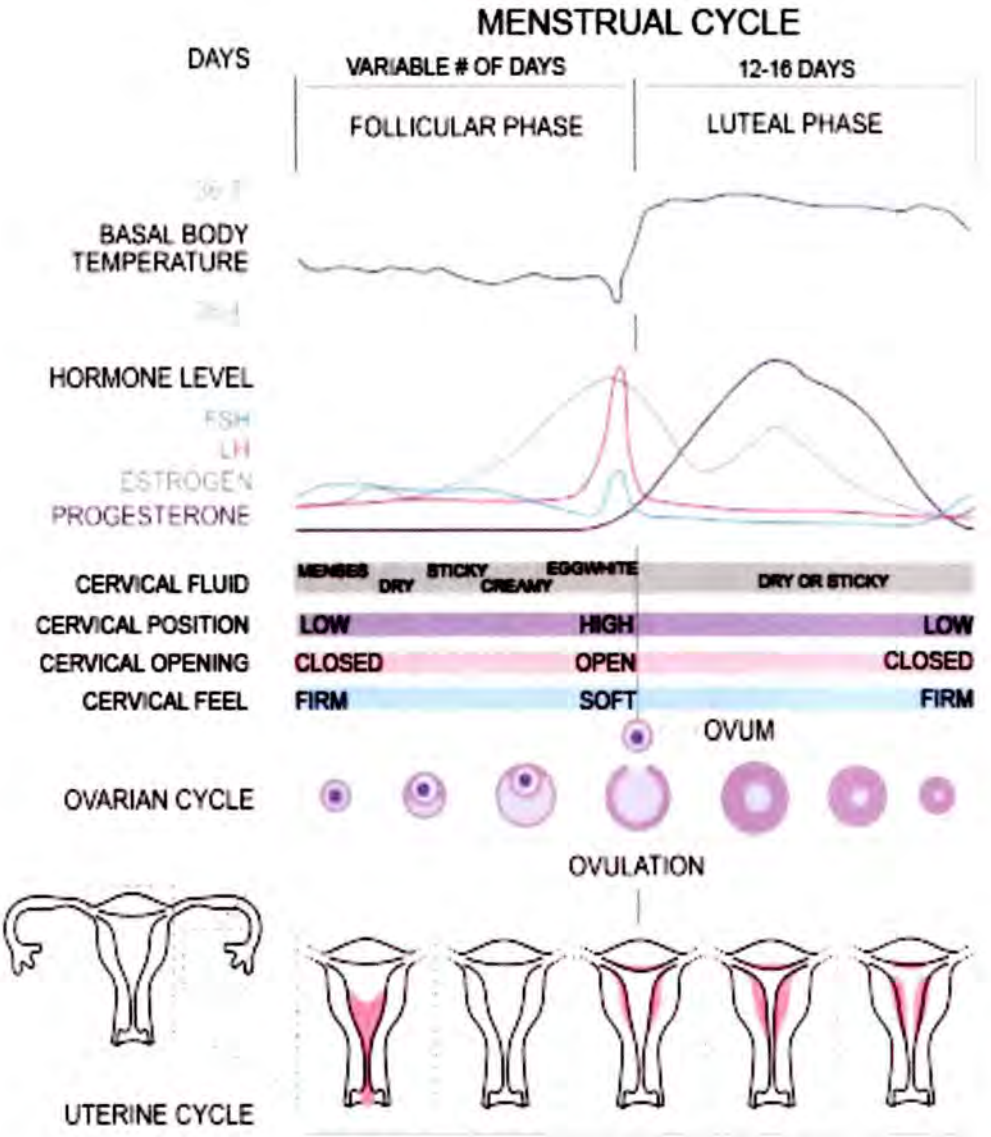

Figure 1. Hormonal and Physical Patterns of Menstrual Cycle. Luteinizing Hormone (LH) levels and Follicular Stimulating Hormone (FSH) surge just before or during ovulation while progesterone levels characteristically peak just following ovulation. Estradiol has a peak just before ovulation and another, smaller in the mid luteal phase. The cervical fluid around ovulation has characteristics of high spinnbarkeit, low proteinous, and similar to eggwhites.. Basal body temperature (BBT) rises above the normal mean temperature and stays elevated until the next menses. The cervix moves higher, opens, and gets soft around ovulation and descends and becomes firm again following ovulation. These symptoms can be monitored to indicate a woman's fertile and infertile times (Figure taken from Wikipedia contributors, 2012).

FERTILITY AWARENESS BASED METHODS

From the information known about the ovulatory cycle and the times during a women's cycle that she is considered fertile and infertile, many methods were developed to assist women in either achieving or preventing pregnancies. These methods can be broken down into two main categories: calendar based methods (CBM) and symptoms-based methods (SBM) ("Fertility awareness methods," 2012). According to the International Planned Parenthood Federation (IPPF), CBMs are those which "track the days of menstrual cycle to identify the start and end of the fertile time" and SBMs as those which observe physical indicators of fertility such as cervical secretions, BBT, and cervical position (2012). While the rhythm method is considered a CBM, the Standard Days Method (SDM) is the only CBM with scientific verification and thus only the SDM that will be discussed here (Arévalo, Jennings, & Sinai, 2002). A tool entitled 'CycleBeads' was developed to assist those following the SDM by providing a visual aid to follow one's cycle (Cycle Technologies, 2012). Several SBMs have arisen, including the Billings Ovulation Method (BOM), Creighton Model of Fertility Care System (CrMS), Two Day Method (TDM), symptothermal method (STM), and the Marquette Model (MM) system (J. Billings, 2002; Hilgers, 2004; Kippley & Kippley, 1996; Marquette University, 2012; Sinai, Jennings, & Arévalo, 1999). All methods require that couples refrain from unprotected intercourse during the fertile window. Some methods require complete abstinence (no back up barriers) and are referred to as natural family planning (NFP).

A woman interested in a natural method of family planning has many options, but the questions remain of how effective are these methods and which one, if any, is best. The effectiveness of FABs is controversial and few comparisons of the various methods have been conducted. The goal of this study is to conduct a comprehensive literature review of the various methods of natural birth control and compare and contrast them. The study will look at each method's efficacy and compare it with the others. Finally, there will be an analysis of which method is most beneficial based on effectiveness, ease of use, and other influencing factors.

CALENDAR BASED METHODS

STANDARD DAYS METHOD

The Standard Days method was developed by researchers at the Institute for Reproductive Health at Georgetown University. The development of the SDM was an attempt to devise a method which balanced

> "the need to provide effective protection from unplanned pregnancy while restricting the identified fertile period to as few days as possible" (Arévalo, Jennings, & Sinai, 2002).

Investigators observed that for 89% of women, ovulation occurred within +/- 3 days of the cycle midpoint ("Natural Family Planning - the Standard Days Method," n.d.); when taking into consideration that sperm can survive up to 5 days after intercourse, the investigators created the SDM and defined potentially fertile days as days 8-19 of the menstrual cycle (Arévalo, Sinai, & Jennings, 1999). The developers did acknowledge that the method is only effective for those women whose cycles range between 26 to 32 days (Arévalo et al., 2002). Women with two or more cycles lasting fewer than 26 days or longer than 32 are discouraged from using SDM as a method of family planning. Using data obtained by a World Health Organization (WHO) study of the ovulation method, the researchers estimated timing of ovulation, analyzed probability of pregnancy due to unprotected intercourse outside of the fertile window, and analyzed probability of pregnancy due to unprotected intercourse on various cycle days

relative to ovulation (Arévalo, Sinai, & Jennings, 1999). The results confirmed that the Standard Days Method would be an effective form of birth control.

Standard Days Method tracks a woman's individual cycles and instructs her to avoid unprotected intercourse on days 8-19 of her cycle if trying to avoid pregnancy (Arévalo et al., 2002). Using a calendar, the woman marks the first day of her period with the number 1 and circles it. On the same day the following week, she will mark the calendar with the number 8, circle it, count out to number 19, mark the calendar with the number and circle, then draw a solid line through days 8-19 ("Natural Family Planning - the Standard Days Method," n.d.). On days 8-19, the woman should practice abstinence or use another form of protection if engaging in sexual intercourse. When the next period starts, she should mark her calendar with the circled 1 and count the total number of days of the preceding cycle and annotate this on the calendar with a square. An example is illustrated in Figure 2.

Figure 2. Standard Days Method Calendar. The number 1 is circled and indicates day one of menstrual bleeding. Days 8-19 are considered to be fertile days and thus are annotated on the calendar with a line through the dates to indicate the user should avoid unprotected intercourse during these times. When a new menstrual cycle begins, the number 1 is again recorded and the total number of days of the previous cycle are counted and tracked. SDM is only effective for women whose cycle are consistently between 26-32 days long, so this last step is important for long term efficacy of the method. Figure taken from "Natural Family Planning - the Standard Days Method," n.d.

The developers of this method were interested in creating a method that was simpler than other methods by eliminating the necessity of monitoring physical fertility signs or completing complicated computations thus making this method more readily available to populations with lower educational opportunities or limited access to family planning resources (Arévalo et al., 1999). In an effort to increase simplicity of the method, the group at Georgetown also developed a mnemonic device, called cycle beads, to help track fertile and infertile days

(Arévalo et al., 2002). CycleBeads are a ring of beads containing four different colored beads to help users recognize important days relating to the SDM method (Figure 3). On the first day of menstrual bleeding, the ring is moved to the red bead. The user then moves the ring one bead forward every day. When the ring reaches white colored beads, this is an indication of entering the fertile window, and thus signals the couple to avoid unprotected intercourse during these days. Once the ring re-enters the brown region of beads, it is safe for the couples to engage in unprotected intercourse. The dark brown bead is a visual signal to help identify any cycles lasting fewer than 26 days. When menses begins again, the ring is moved back to the red bead and the process begins again (Cycle Technologies, 2012). CycleBeads aid the SDM by being a visual reminder of the fertile windows to assist women in tracking their own fertility. The advantage of CycleBeads is their ease of use, and accessibility. Currently CycleBeads are available as beads themselves, which commonly range in cost from $10-$20 and can be used online through the CycleBeads website (Cycle Technologies, 2012) at a cost if $12.00 for a yearly subscription. A smartphone app is also available for $2.99 ("App Store - iCycleBeads - Plan or Prevent Pregnancy," 2012). Figure 4 shows that CycleBeads are currently available on six continents and over 50 countries worldwide, many through Non-Government Organizations. The simplicity of the method, both for teachers and users, and availability of resources makes the SDM an attractive natural family planning method.

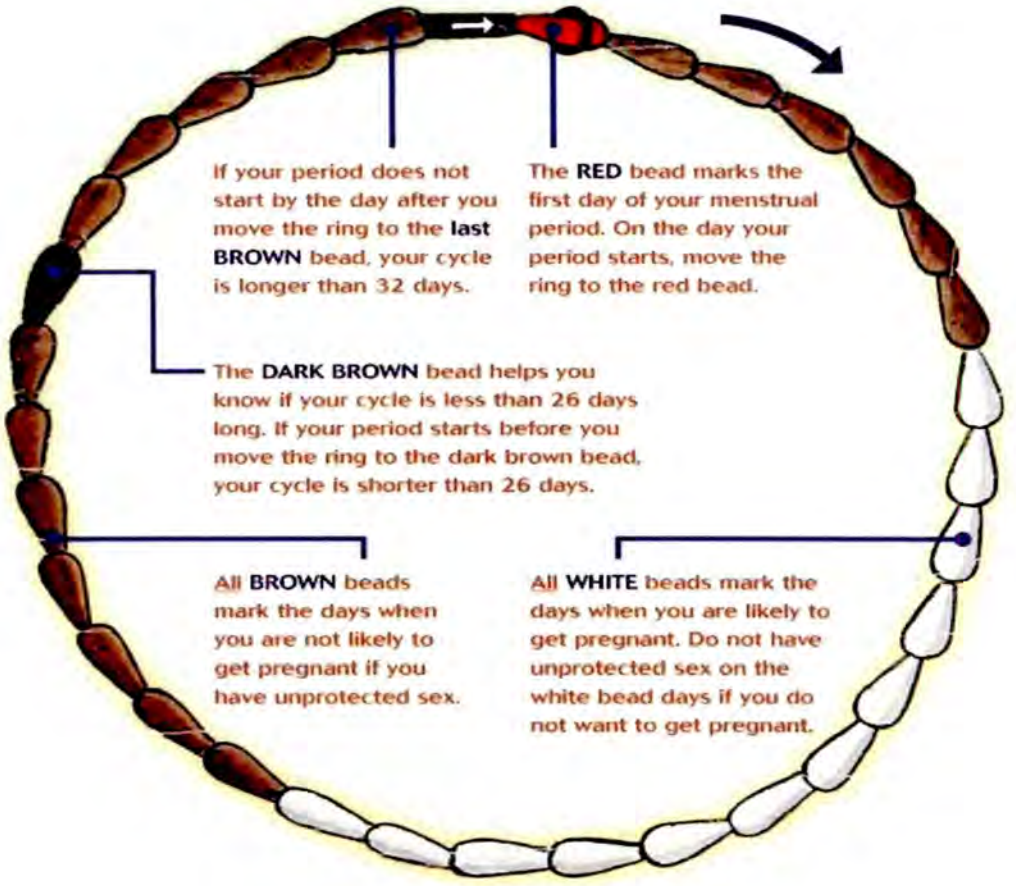

Figure 3. Standard Days Method CycleBeads. CycleBeads were developed by investigators who developed the Standard Days Method of family planning. It is a visual representation of a woman's menstrual cycle with each bead representing a day in the cycle. The red bead represents the first day of menstrual bleeding. Brown beads symbolize days where a couple can engage in unprotected intercourse with little probability of getting pregnant. White beads represent the fertile window and indicate days a couple should not engage in any unprotected intercourse to avoid pregnancy. The dark brown bead is a marker to help notice any cycles shorter than 26 days. The ring is placed at the red bead at the beginning of menstruation and moves forward one bead every day until the beginning of the subsequent menstrual cycle. Figure taken from Gribble, Lundgren, Velasquez, & Anastasi, 2008.

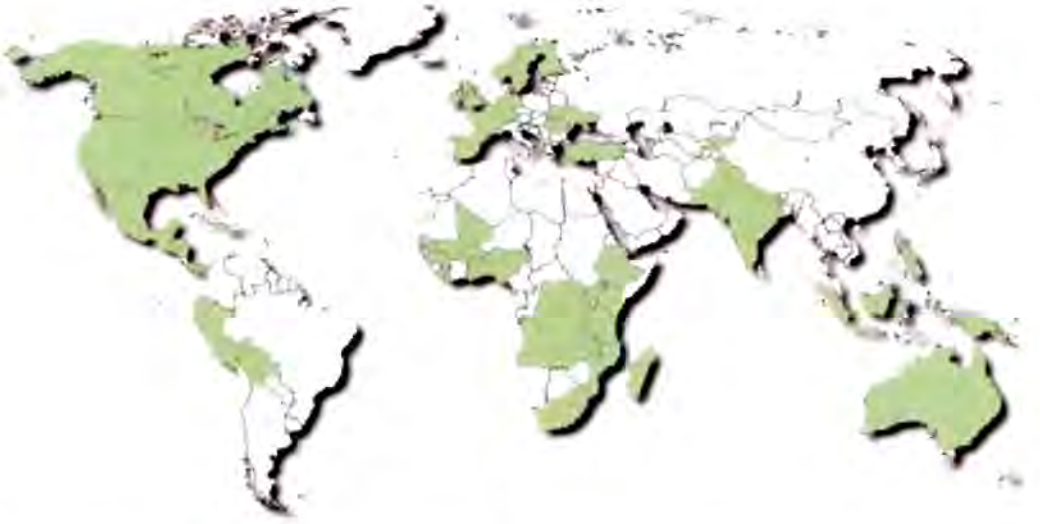

Figure 4. Cyclebeads Availability Worldwide. CycleBeads are available on 6 continents and in over 50 countries. Many are provided by Non-Government Organizations (NGOs), or health ministries or providers or can be purchased for a small fee. Their availability and ease of use make the SDM a feasible option for a wide range of the world's populations. Figure taken from ("Where in the World Are CycleBeads?," 2010).

Ease of use would be meaningless if the method was not also effective at avoiding pregnancy with use. Arévalo, Jennings, and Sinai tested the efficacy of the SDM among 478 women in Bolivia, Peru, and the Philippines (2001). Forty-six percent of those who began the study completed the full 13 cycles for a total of 4035 cycles. Only 43 pregnancies occurred over the course of the investigation and 65% of those were associated with the participant engaging in unprotected intercourse sometime during days 8-19 (Arévalo et al., 2002). A total of 15 participants became pregnant with correct use (no intercourse during days 8-19) and the majority of those occurred within the first three cycles. The results of the study showed that, with correct use, the rate of pregnancy was five

in every 100 women or 95% effective at preventing pregnancy. With typical use, the pregnancy rate was 12 in every 100 women, or 88% effective at preventing pregnancy.

In another study, the SDM method was introduced to a diverse cohort of women (n=1646) from across the globe, including Africa, South America, and Asia, and reached women of various educational levels (Gribble, Lundgren, Velasquez, & Anastasi, 2008). The results showed a typical use success rate of 14.1 pregnancies per 100 women. In yet another study conducted in Peru, researchers found a 12 month typical-use rate of 10 pregnancies per 100 women (n=1200) (Arévalo, Yeager, Sinai, Panfichi, & Jennings, 2010). SDM does seem to be effective at avoiding unplanned pregnancies, comparable with other methods of family planning and other modern family planning and artificial methods of contraception. The results also indicate that SDM has the potential to be an effective method of birth control for a diverse population of women across the globe.

SDM does have its disadvantages. It is slightly less effective than methods that track physical symptoms of fertility such as ovulation or symptothermal methods (Pallone & Bergus, 2009). For the majority of users of SDM, they can begin practicing the method immediately, but those who are switching from hormonal birth control, including oral contraceptives, hormonal injections and others should

wait to begin until they have had two consecutive menstrual cycles between 26-32 days and then can begin on the third cycle (Cycle Technologies, 2012). Following a pregnancy, SDM should only be employed as a primary method of birth control after a woman has experienced four periods, with the most recent one lasting between 26-32 days. The main negative aspect of the SDM is that the method is only applicable to those having regular cycles between 26 and 32 days. Women who have two or more cycles longer or shorter, or one cycle greater than 42 days are instructed to find another method of pregnancy prevention (Pallone & Bergus, 2009).

SYMPTOMS-BASED METHODS

OVULATION METHODS

Ovulation methods of birth control were developed based on an understanding of cervical mucus as a biomarker of fertility and rely on user observations of cervical secretions to determine the fertile days during the menstrual cycle. As estrogen levels rise, the cervical mucus becomes increasingly more lubricative, clear, and stretchable. The knowledge regarding the typical cyclical changes in cervical mucus secretions led to the development of two different fertility awareness methods: The Creighton Model of Fertility Care System (CrMS), and the Billings Ovulation Method (BOM). Both methods rely exclusively on cervical mucus observations to determine a user's fertile window (E. Billings, 2006; Hilgers, 2004). While the methods are similar, there are specific distinctions between the two and the idiosyncrasies and individual efficacy rates of each will be presented following the general discussion of the ovulation method.

Both ovulation methods are based on self-determination of the peak day of fertility based on observations of the cervical mucus pattern. Periodic observations of an individual's cervical secretions are charted to keep record over the course of each cycle. At the first indication of any cervical secretions, even those that are opaque or tacky, a couple should abstain from intercourse or genital contact. The peak day corresponds to the last day of fertile type mucus,

identified by a subsequent day of little or no mucus (E. Billings, 2006; Hilgers, 2004). Several studies have shown that peak day occurs within +/- 3 days of ovulation and thus is often associated with the most fertile time of the cycle (Fehring, 2002). Intercourse should be avoided until three days after the peak day. Fehring found that "self-determination of the peak day of cervical mucus is a very accurate means of determining peak fertility and a fairly accurate means of determining the day of ovulation and the beginning of the end of the fertile time."

BOM and CrMS require detailed charting, using colored stamps to indicate days of menses, dry days (days of no mucus), and fertile days (Figure 5). Generally speaking, red stamps correspond to menstrual bleeding and green stamps indicate infertile days of the pre and post-ovulatory period. White baby stamps represent the days within the fertile window, and yellow stamps often represent days of mucus exhibiting unchanging patterns, which do not indicate fertility (E. Billings, 2006). The stamp color systems for the two methods vary slightly, so it is important to enroll in an instruction course to learn the nuances of a specific method and the appropriate charting system. A trained instructor can help the user identify these conditions and help address them or refer the user to a physician for further treatment. It is vital, for either method to be successful, to be taught by a trained instructor. The instructor can serve as a point of contact for any questions or peculiarities that might arise during its use.

The benefits of the ovulation methods exist in the charting methods. As users learn characteristics of fertility and infertility, the methods can be used for pregnancy avoidance or pregnancy achievement. The methods allow natural, seamless transition from avoidance into achievement. Another benefit of the ovulation method charts is the ability to unveil physiologic abnormalities in the fertility system, including anovulatory conditions, miscarriage, or low progesterone states, through specific, identifiable chart patterns (Hilgers, 2004). A significant benefit is that ovulation methods are functional for women with variable cycle lengths and those with variable hormonal states, such as pre-menopausal and breastfeeding women (Pallone & Bergus, 2009).

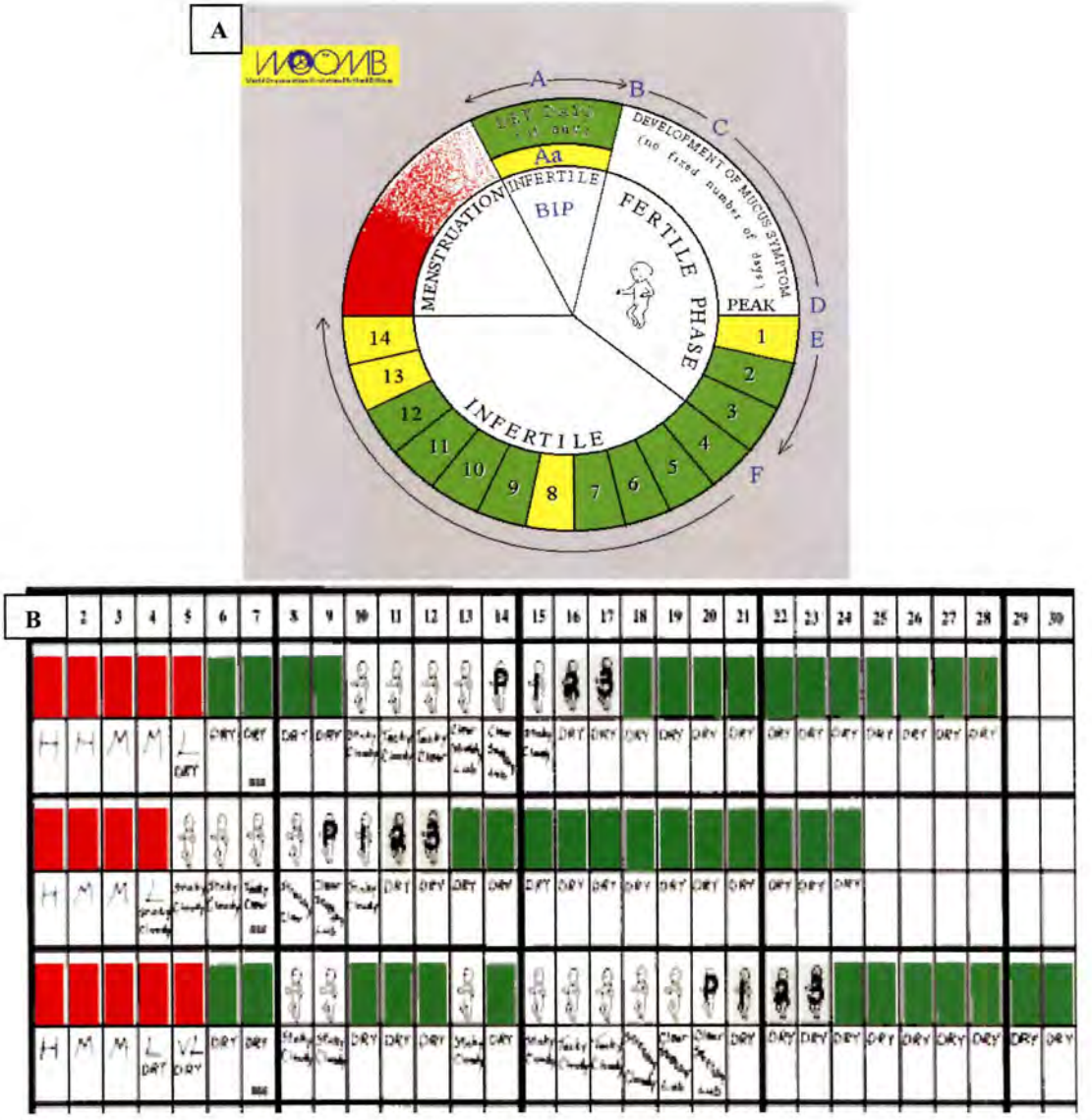

Figure 5. Ovulation Method Charts.
A The Billings Ovulation Method (BOM) circular diagram. This illustrates the cycle and the associated charting stamps and symbols used by BOM. Red is for menstruation, and green is for dry, infertile days. Yellow is for days of mucus that has no changing patterns and white signals fertile days. Figure was taken from E. Billings, 2006a.
B is an example of the Creighton Model Fertility Care System (CrMS) chart. It is similar to the BOM chart and helps the woman track which days she presents cervical mucus secretions signifying fertility. Figure was taken from Hilgers, 2004.

Some research has even shown that usage of the ovulation methods of family planning may successfully be used for child sex selection. The results on this topic vary widely. McSweeny reported a 94.9% success rate among 99 participating couples (2011). Couples having successive days of intercourse on peak day and the days following (ovulation) successfully selected males 96.3% of the time, while couples engaging in intercourse several days before the peak and not again until four days post-peak selected females with a success rate of 88.9%. Other studies have shown that fewer males and more females births occur with conceptions around ovulation and the reverse ratios among conceptions before and after ovulation (France, Graham, Gosling, Hair, & Knox, 1992; Guerrero, 1975; Perez, Eger, Domenichini, Kambic, & Gray, 1985). Other studies have found no significant difference in gender based on timing of intercourse (Gray et al., 1998; Wilcox, Weinberg, & Baird, 1995)

BILLINGS OVULATION METHOD (BOM)

The BOM was initially developed by Drs. Evelyn and John Billings based on scientific research completed by James Brown and Erik Odeblad (J. Billings, 2002). It was the main ovulation method taught before the introduction of the CrMS. The BOM uses subjective descriptions; the user charts the sensations she feels at the vulva and anything she sees (E. Billings, 2006). The BOM instructs women to identify her own Basic Infertile Pattern (BIP) which is an unchanging pattern corresponding to infertility. A changing pattern in cervical

secretions is considered an indication of fertility. BOM places emphasis on vulvar sensations, and has made the claim that even blind women can successfully use this method of family planning. BOM encourages its users to be aware of vulvar sensations at all times during the day while engaging in normal activities. A feeling of slipperiness is an important indication of fertility, and thus, if trying to prevent pregnancy, all intercourse and genital contact should be suspended until 3 days following the peak day. Billings defines the peak day as the last day of slippery sensation at the vulva, which may also be swollen and have heightened sensitivity (E. Billings, 2006).

A set of four rules govern when participants can engage in intercourse. These rules are broken into two categories: Early Day Rules (EDR) and the Peak Rule (PR). The first EDR states that "there should be abstinence from intercourse and all intimate genital contact during the days of heavy menstrual bleeding" (Billings Life - Leaders in Fertility Education, n.d.) because bleeding, especially in short cycles can mask the presence of fertile mucus. The second EDR states that a couple can engage in intercourse on alternate evenings only, once the BIP is established. The third EDR explains that if any change from BIP occurs, including any bleeding or mucus, the couple should abstain from intercourse while continuing to chart and wait to see how her symptoms progress. If the BIP returns, the couple should wait an additional 3 days and then can resume with the EDR rules. Once the woman experiences her peak day, she will then follow

the PR. The PR states that on the fourth morning following the peak day, a couple can engage in intercourse on any day and at any time for the remainder of the cycle until menses begins again.

A study conducted in India initially consisting of 2059 women found that the failure rate among perfect users of BOM was 1.1 pregnancies per 100 users at 12 months with a retention of 1815 women and 1.5 per 100 users at 21 months with a retention of 867 women (Bhargava, Bhatia, Ramachandran, Rohatgi, & Sinha, 1996). These numbers are comparable to exogenous methods of contraception. The typical use failure rate showed a higher incidence of unintended pregnancies with 10.5 pregnancies per 100 users at 12 months and 15.9 per 100 users at 21 months. The study also showed that a significantly higher proportion of users under the age of 25 had unintended pregnancies than those older than 25.

In the United States, information about the success rate of the Billings Ovulation Method was compiled from 6 sites (Klaus et al., 1979). A total of 1139 women entered the study. Over the course of a year (n= 7420 cycles), a method-failure rate of 1.29 pregnancies per 100 women was reported with a user-failure rate of 20.05 pregnancies per 100 women. Over 2 years, there was a reported method-failure rate of 1.17 pregnancies per 100 women and a user-failure rate of 18.01 pregnancies per 100 women.

The World Health Organization conducted a study of 725 women from five study centers, 54.1% of whom completed the study (1981). The study reported a method-effective rate of 2.3 pregnancies per 100 women per year. The typical-use rate was 22.3 pregnancies per 100 women per year the majority of which were due to conscious departure from the method rule.

CREIGHTON MODEL OF FERTILITY CARE SYSTEM (CrMS)

Dr. Thomas Hilgers, who designed the Creighton Model of Fertility Care System, claims the CrMS to be a 'standardized modification' of the BOM (E. Billings, 2006). According to Billings, the most significant change between the BOM and CrMS "was to the observations and interpretations of the cervical mucus." The primary distinction between the two methods is that they "differ in the way of observing, charting, and using the information." CrMS should only be used by those who have been properly trained. Training consists of an introductory session, where the method basis is explained and charting is described. Eight follow-up sessions over the course of a year ensure proper usage of the method, teacher evaluations, and individual fine tuning of the method (Fehring, Lawrence, & Philpot, 1994). The model employs standardized terminology and documentation, and education that are consistent among all users (Barron & Daly, 2001). All educators are instructed through the Creighton Model Educational Program and upon completing the requirements apply for certification by the American Academy of Natural Family Planning.

CrMS is a system employing objective observations, as opposed to the subjective descriptions used in the BOM. The observation of cervical mucus is achieved by using folded toilet paper following urination to wipe over the vulva (Hilgers, 2004). The woman should pay attention to any vulvar sensations while wiping, and then evaluate the mucus using a finger test (mucus stretched between two fingers) to determine the spinnbarkeit (stretchiness). The stretchability is compared with a standardized picture dictionary, provided at the time of initial instruction, and the user matches her secretion to one listed in the picture dictionary based on color, stretchability, density, and quantity (E. Billings, 2006). The method requires mucus observation during every trip to the bathroom and once before going to bed (Hilgers, 2004).

An additional difference between BOM and CrMS is the definition of the peak day. Hilgers defines the peak day as the final day of any mucus secretion that is lubricative, clear, or stretchy (2004). The rules of intercourse for CrMS are similar to those of BOM, however CrMS instructs women to do Kegel exercises an hour following intercourse to expel all vaginal semen and wipe with toilet paper until the area is dry.

The CrMS efficacy has been evaluated by multiple studies. A meta-analysis of five study sites with a total of 1,878 couples over the course of 17,130 couple-months found a method-effectiveness rate of 99.5% success over 18 months and

a use-effectiveness rate of 96.4% over 18 months (Hilgers & Stanford, 1998). Fehring, Lawrence, and Philpot studied 242 women from the Marquette University Nursing Center and found a method-effectiveness rate, defined as a couple who correctly used the method to avoid pregnancy but became pregnant, of 98.8% (1994). They found a use-effectiveness rate of 98.0%.

In 1999, Howard and Stanford reported results of a study of 701 women from the Houston, TX area. The results showed a total pregnancy rate per 100 users of 17.12 at 12 months and 21.26 at 18 months over 6947.5 total couple months. However, the study found only 1 unintended pregnancy with perfect method use; the majority of pregnancies were a result of intercourse occurring during known fertile times, also known as 'achieving-related' behavior (Howard & Stanford, 1999). The clinical review of multiple NFP studies completed by Pallone and Bergus calculated a 0.5% rate of unintended pregnancies with perfect use, and a 17.1% rate of pregnancies with typical use (2009).

Unlike the method-effective rate, which is defined as correctly identifying fertile days according to the method and perfectly following the rules regarding days of abstinence, the literature seems conflicted concerning the definition of a typical use error. Studies done using Dr. Hilgers' definition of pregnancy, appear to have a lower rate of typical-use unintended pregnancies because they do not count pregnancies achieved when the couple had intercourse on known days of

fertility (Fehring et al., 1994; Hilgers, 2004). If the couple willingly and knowingly risked intercourse on a day the method indicated as fertile, the couple was objectively considered to "have abandoned the model as a method of avoiding pregnancy and adopted it as a method of achieving pregnancy", whether a pregnancy was specifically desired or not. For example, the results of the World Health Organization (WHO) study done in 1981 reported an average use-effectiveness rate of 22.5 pregnancies per 100 women. However approximately 15.4% of the pregnancies occurred in couples who had 'abandoned the method' by Hilgers' standards. If those couples who chose intercourse against the method rules are factored out, the use-effectiveness pregnancy rate drops to 12.8 over 12 months or 87.2% effective at preventing pregnancies (Fehring et al., 1994). Inconsistencies in definitions of unintended pregnancies such as this are likely the cause of the vast range of values seen in the literature. While differences in effectiveness rates exist, the CrMS does seem to be an effective form of family planning, especially among those users who choose to faithfully adhere to the method. The method-effectiveness is even greater than that associated with Standard Days Method and possibly slightly higher than that of BOM.

TWODAY METHOD

Another method based on cervical secretions is the TwoDay Method (TDM), which was developed by the Georgetown Institute for Reproductive Health. Their goal was to use detection of a primary symptom of fertility, cervical mucus, but develop a method of interpretation that is easier for users to learn and for providers to teach than the other ovulation methods (Sinai, Jennings, & Arévalo, 1999). The algorithm Sinai et al. developed can be seen in Figure 6. The woman is taught to observe her vaginal secretions and ask herself two questions: 1) Did I note any secretions today and 2) Did I note any secretions yesterday? If the answer to either question is yes, the woman should consider herself fertile, and should abstain from unprotected intercourse. Secretions in this method are defined as "any substance the woman perceives as coming from her vagina, except for menstrual bleeding." Various methods can be used to detect cervical secretions, including looking for mucus on underwear or panty liners, wiping the vulva with tissue, being aware of vulvar sensations, or physically touching to feel for mucus (Jennings, Sinai, Sacieta, & Lundgren, 2011). Users are taught to note secretions in the afternoon and evening which will limit any confusion with seminal fluid from intercourse during the previous evening (Sinai et al., 1999).

Figure 6. The TwoDay Algorithm. An algorithm developed at the Georgetown Institute of Reproductive Health which teaches users to observe vaginal secretions. Every day, the woman observes her secretions and asks herself the questions depicted in the flow chart. On days she says yes to either question, she has a higher probability of pregnancy and is instructed to abstain from unprotected intercourse. If she answers no to both questions she is free to engage in unprotected intercourse. Figure was taken from (Arévalo et al., 2002)

Sinai et al. first proved the theoretical basis for their algorithm using data from the 1981 WHO study and 183 charts of women tracking their fertility using an ovulation method (1999). Based on the data, the TwoDay Method covers 96-100% of cycles when ovulation occurs the day before peak day of cervical secretions, on peak day, and the day after peak day. Eighty percent of cycles are covered by the method when ovulation occurs up to four days before peak day. On average, less than 50% of cycles with ovulation two and three days post peak are covered; the calculated probability of conception on those days, even

assuming ovulation occurs on those days, is less than 2%. According to this theoretical study, the authors concluded their algorithm was able to identify the infertile phase with few false-negatives (days identified as infertile when they are actually fertile).

To test the actual efficacy rates of the TwoDay method, researchers conducted a prospective, nonrandomized, multicenter study spanning five sites in Guatemala, Peru, and the Philippines (Arévalo, Jennings, Nikula, & Sinai, 2004). Four hundred and fifty women were admitted to the study; twenty-nine women were excluded from the study because they had a total number of days with secretions lasting less than five or longer than 14. Of the original participants, 52.7% completed the full 13 cycles and a total of 3,928 cycles were used for evaluation. Interviews conducted at the end of the first cycle showed 96.4% of women reporting ease and ability to detect the presence, or lack-there-of, of secretions confirming the ease of use of the method. At the completion of the study, only 47 pregnancies occurred, 53.2% of which were reported to have been a result of unprotected intercourse during known, method-described, fertile days. Twelve of the pregnancies were due to method failure, while 21.1% of the pregnancies occurred with couples using withdrawal or condoms during fertile periods, actions described as restricted for the purpose of the study but optional for actual use outside of the study. Thus, the method-effective pregnancy rate for women using only periodic abstinence during fertile times was 3.5 pregnancies per 100 women for 13 cycles, while the pregnancy rate was 6.3 per 100 women among those

who occasionally engaged in protected intercourse during fertile times. The typical-user effective pregnancy rate, which included all pregnancies, was 13.7 per 100 women for 13 cycles. A large percentage of the pregnancies occurred in the early cycles, and those pregnancy rates decreased if only the last 10 cycles are considered. This may indicate a learning curve among those detecting secretions for method-effective use and possibly an adjustment to periodic abstinence among those risking unprotected intercourse during fertile times (Arévalo et al., 2004).

In Peru, a study was conducted to determine if the TDM could be started at any point during a woman's cycle. One hundred and seventy-six women entered the study and 47 women left for various reasons, including abnormally short or long number of secretion days and method dissatisfaction (Jennings et al., 2011). A total of 12 pregnancies occurred over 7 cycles, 2 of which were intentional pregnancies. Only 1 pregnancy occurred in the group counseled early in the cycle (n=40) while 11 pregnancies occurred among women counseled later during their cycle (n=121). The calculated failure rate was 3.45 per 100 women counseled early in the cycle and 9.91 per 100 women for those counseled later in the cycle with no significant statistical difference between groups. These rate are comparable to the typical-use rates in previous TwoDay Method studies (Jennings et al., 2011). The study corroborated the method effectiveness and proved that starting counseling at any time during the cycle is effective.

The TwoDay Method has both its advantages and disadvantages. Based on the definition of secretions as any vaginal discharge other than menstrual bleeding, the method could present problems for women with short cycles whose fertile secretions begin at the end of menstruation and could be missed by the user. Another shortfall of the TDM occurs for women whose basic infertile pattern is constant mucus secretions. Other methods, such as Billings and Creighton, can account for this basic infertile pattern but TDM does not provide instruction on how to differentiate between infertile patterns of mucus and fertile mucus secretions. For women with a BIP with consistent mucus, it would be in her best interest to employ an alternative method. TDM also often only covers one day past the peak day despite studies showing that ovulation can occur up to three days following the peak day (Billings, Brown, Billings, & Burger, 1972). Thus, the method falls short in protecting a woman whose ovulation is two or more days past the peak day. All of these shortcomings may contribute to the slightly lower efficacy rates of the TDM.

An advantage of the TDM is the increase in days available for intercourse. The theoretical study found a mean of 9.0 days of the fertile window identified by the TDM as opposed to 9.7 days identified by the World Health Organization, who exclude the early day rules of abstinence during menses and alternating pre-ovulatory days (Sinai et al., 1999; WHO, 1981). The field study showed a mean of 13.1 days in the fertile window (Arévalo et al., 2004), which is larger than the

theoretical model, yet still encompasses fewer days unavailable for intercourse compared to previously described methods. This may lead to greater adherence to the method but may also account for the lower method-effectiveness (Dunson, Sinai, & Colombo, 2001).

Other advantages of TDM include ease of use and user satisfaction. In Peru, up to 88% of users were able to correctly identify the fertile window by secretions in the first cycle. Approximately 98% of users appropriately adhered to the method by using periodic abstinence only during fertile days (Jennings et al., 2011). Less than 1% of participants claim the TDM is difficult to learn and/or use and only 2.6% considered the method not effective. During exit interviews, more than 92% of women noted they would recommend the method to other women. Arévalo et al. reported that 99% of the women who completed all 13 cycles planned on continuing the method after the study and 50% of the women excluded from the study still intended to continue using the TDM (2004). TDM requires minimal instruction, is easily learned and incorporated into users' lifestyles, and poses no financial burden making it a sensible and propitious option for a variety of users worldwide.

MULTI-SYMPTOM METHODS

Multi-symptom methods of fertility awareness use a double-check system in which at least two distinct symptoms of fertility are used to determine the beginning and the end of the fertile window. Changes in the cervix, basal body temperature and cervical mucus are all symptoms which can indicate the fertile window (Kippley & Kippley, 1996). Recent methods have introduced the idea of using a urinary hormone monitor in conjunction with other symptom monitoring as a double check method (Fehring & Schlaff, 1998).

Following ovulation, the progesterone secreted by the corpus luteum causes a sustained rise in a woman's basal body temperature (BBT) referred to as the 'thermal shift' which is typically about 4/10 of 1^0 higher than the 'pre-shift base level' (lower temperature norm established on the six days preceding the rise) (Kippley & Kippley, 1996). Using a basal temperature thermometer, couples tracking BBT should record the woman's temperature (oral, vaginal, or rectal) every day at the same time, preferably upon waking before rising from bed. Due to circadian changes in body temperature throughout the day, it is vitally important that the temperature be taken every day at roughly the same time. When the temperature remains elevated for three consecutive days, it can be assumed ovulation has occurred and the woman is out of the fertile window.

The other common symptom monitored is the cervix. Before ovulation, the cervix is low and firm. Around the time of ovulation, the cervix softens, opens, and rises in the body. Following ovulation, the cervical os (opening of the cervix) closes tightly, moves lower, and becomes very firm. Daily examination of the cervix can indicate what phase of the menstrual cycle a woman is. The changes are gradual, and accurate interpretations can take several cycles to master (Kippley & Kippley, 1996).

Cervical mucus monitoring in multi-symptom methods is very similar to that of the ovulation methods described earlier. Users can choose to observe mucus on tissue paper, similar to the Creighton method, or by paying attention to vulvar sensations, as is done in the Billings method. The multi-symptom method also allows for monitoring of mucus internally by checking mucus at the cervical os with fingers. The charting system is less specific than either the Billings or Creighton methods. The rules regarding intercourse are the same except intercourse during menstruation is allowed unless the woman has a history of short cycles (Kippley & Kippley, 1996).

Along with a calendar determination of probable fertility, any or all of these physical symptoms can be charted to determine the fertile window. Figure 7 shows a sample chart depicting use of all three symptoms described above. Typical multi-symptom methods require at least two guidelines be applied to the

determination of the first and last day of fertility. To identify the first fertile day, the two guidelines chosen are applied and whichever occurs first identifies the earliest fertile day and unprotected intercourse should be avoided beginning then to avoid pregnancy. Similarly, for the last fertile day, two guidelines are applied and whichever occurs last identifies the final fertile day (Kippley & Kippley, 1996).

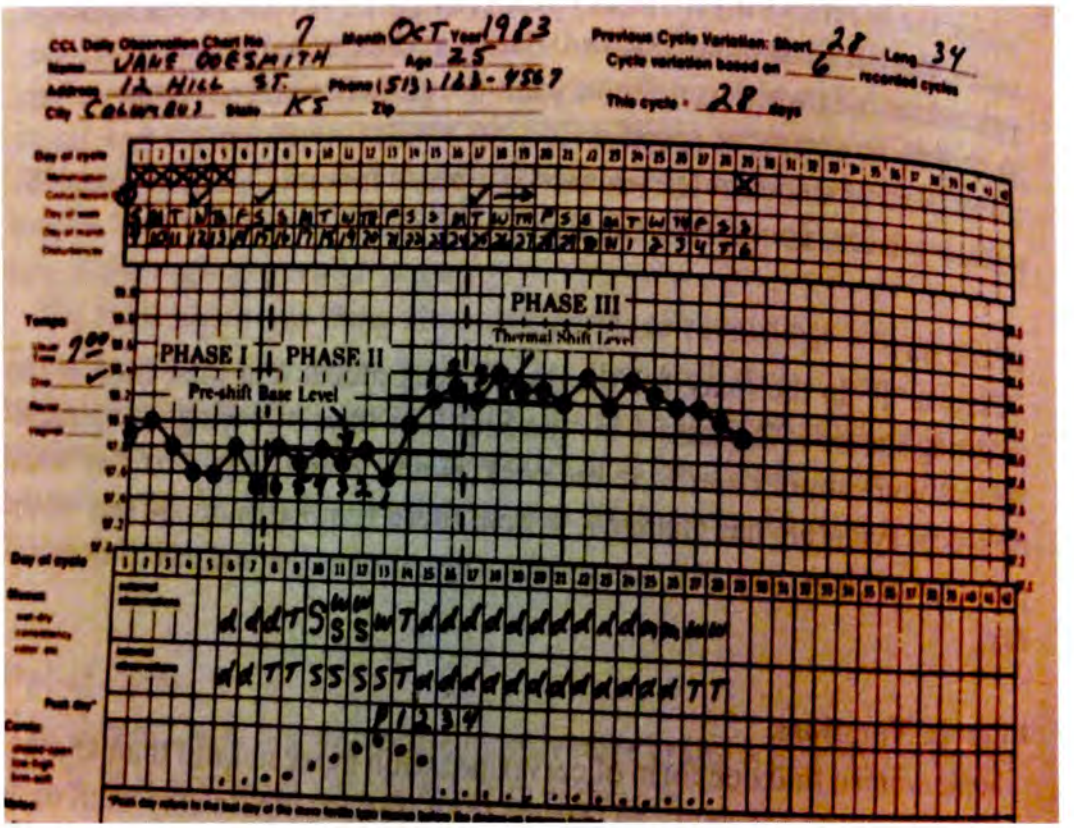

Figure 7. Multi-Symptom Method Chart. The figure depicts a sample chart of a woman using multiple symptoms as her Natural Family Planning (NFP) method. The top rows track the days of the cycle. The Upper middle rows show the basal body temperature recordings. The lower middle rows track the cervical mucus observations, both external and internal. The final rows show charting of changes in the cervix. Figure taken from (Kippley & Kippley, 1996).

SYMPTOTHERMAL METHOD

A specific application of a multi-symptom method of natural family planning is the symptothermal method (STM). The combination of symptoms used for STM is shown in Figure 8. The two symptoms used to determine the beginning of the fertile window are the calculation rule (calendar system) and cervical mucus. During the learning process, the first appearance of cervical secretion and calculation of day six of the cycle are the parameters used to define the beginning of the fertile time. Whichever occurs first is the first day of fertility. After several cycles have been charted, a more precise and individual calculation rule can be applied. Frank-Herrmann describes a calculation rule after a woman has completed 12 cycles. Following 12 cycles, a woman takes the earliest temperature rise over the past 12 cycles and subtracts seven to get the first fertile day (Frank-Herrmann et al., 2007). For example, if the earliest temperature shift across 12 cycles occurred on day 15, then subtracting seven would make day eight of the cycle the first fertile day. An alternate calculation rule is the '21 day rule of thumb' (Kippley & Kippley, 1996). After completing a minimum of six cycles, the woman takes her shortest cycle and subtracts 21 to determine the last day before the fertile window begins. For example, if the shortest cycle for a woman over six cycles was 30 days, then subtracting 21 makes day seven the last infertile day and thus abstinence should begin on day eight.

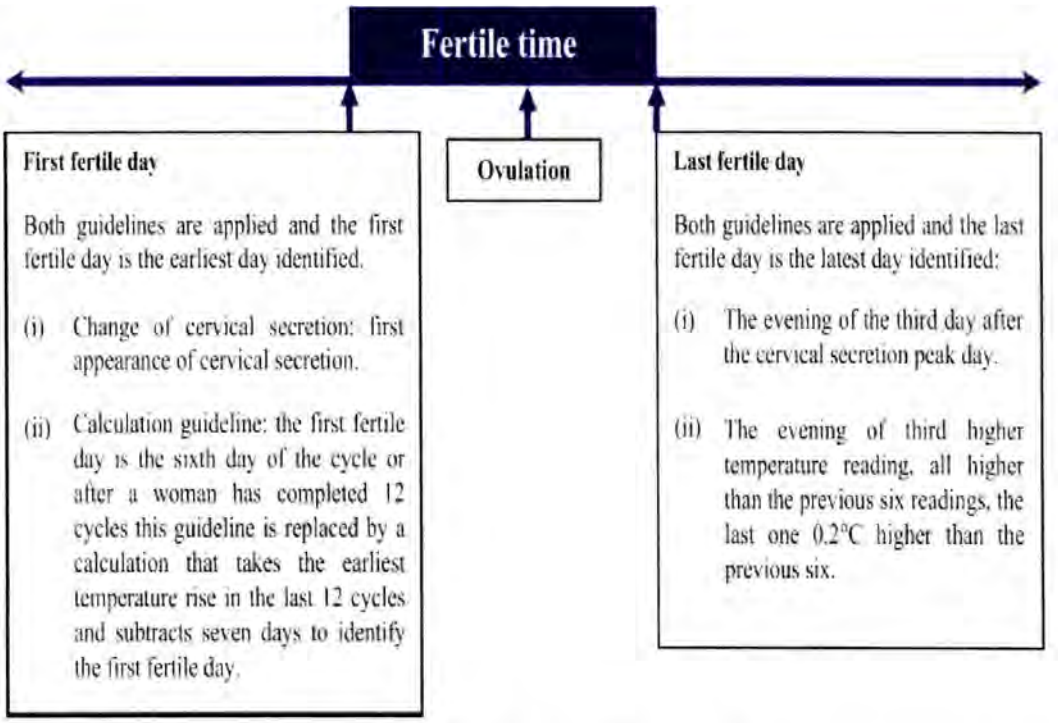

Figure 8. Symptothermal Fertility Guide. The figure depicts how the symptothermal guidelines for fertility determination are applied. The first day of fertility uses a double-check system of calendar method and cervical mucus. The last day of fertility uses a double-check system using cervical mucus and Basal Body Temperature as guidelines. To avoid pregnancy, no unprotected intercourse should occur during the fertile time. Figure taken from Frank-Herrmann et al., 2007.

The end of the fertile window is typically determined by applying the cervical mucus and BBT guidelines. A woman should abstain from unprotected intercourse until the third day after the peak day, or the third day of a higher BBT, whichever occurs last (Frank-Herrmann et al., 2007; Kippley & Kippley, 1996). Frank-Herrmann stipulates that all three temperature readings must be higher than the previous six and the third day of elevated temperature must be at least 0.2°C higher (2007). Kippley and Kippley recommend that all three be 0.4°C higher than the previous six, each one be 0.2°C above the previous six with the

final on 0.4°C higher, or all three be at least 0.1°C above the previous six with an elevated pattern and at least one being 0.4°C above the previous six (1996).

Many studies have looked into the effectiveness of the symptothermal method. Frank-Herrmann conducted a study of 900 women from the German NFP study centre to determine the efficacy of the symptothermal method (2007). At 13 cycles, 509 women remained and 9005 cycles resulted in an overall unintended pregnancy rate of 1.8 per 100 women over 13 cycles. The European Natural Family Planning Study Group looked at information from women in 15 different NFP organizations across 10 European countries (Freundl, 1999). Over a one year time span, 34 unintended pregnancies were reported from 1046 women (n=16,865 cycles) using a double-check STM. This accounts for a pregnancy rate of 2.6 per 100 women over 12 cycles. In Belgium, 71 women using STM for a total of 1240 cycles had only one unintended pregnancy that resulted from a user engaging in unprotected intercourse during a clearly defined fertile day over the course of the 12 study months (De Leizaola-Cordonnier, 1995).

Wade et al. conducted a study in which couples from southern California were randomly assigned to either the Ovulation Method (OM) (n=619) or symptothermal method (n= 628) of natural family planning (1981). Excluding the training period, women in the OM group reported 42 pregnancies over a total of 1,269 cycles for a pregnancy rate of 39.7 pregnancies per 100 women per year.

Women in the STM group reported 19 pregnancies over 1,668 cycles for a rate of 13.7 pregnancies per 100 women per year for the STM. These rates include intentional pregnancies (7.4% for OM and 9.8% for STM). While the study did not seek to differentiate between method-failure and user-failure, the author acknowledges that the largest number of method failures for both OM and STM was due to failure of couples to follow the method rules (Wade et al., 1981). The study showed that the symptothermal method was significantly more effective in preventing pregnancies than the ovulation method.

STM is more complicated to use than the other methods described above, which can be a significant disadvantage. Multiple symptoms need to be closely monitored and charted to accurately use the method. However, the double-check system can instill confidence in the user that they are appropriately identifying the fertile window. This is reflected in the lower method and user failure rates compared with other methods.

MARQUETTE MODEL

Another multi-symptom method, the Marquette Model, uses an electronic hormonal fertility monitor (EHFM) to detect rising estrogen levels and the LH surge. Because the monitors often miss the beginning days of the fertile window, the monitor is typically used with cervical mucus observations as a double-check system. Fehring, Raviele, and Schneider found that the fertility monitor tends to underestimate the fertile period while cervical mucus observations tend to overestimate the fertile period; the combination of the two can adequately indicate the fertile period while limiting the number of false positives (infertile days characterized as fertile) (2004). Developed by researchers at Marquette University College of Nursing Institute for Natural Family Planning, the method is commonly referred to as the Marquette Model (MM) and uses the ClearBlue Easy Fertility Monitor (CEFM) or similar electronic fertility monitoring devices. The devices work by monitoring changing color levels of test strips that have antibodies specific to an estrogen metabolite (E3G) and LH (Fehring, Schneider, Raviele, & Barron, 2007).

- On day one of a woman's cycle, she pushes a button on the monitor which then keeps track of her cycle day. The monitor will request urine samples periodically during her cycle. On those days, the woman will urinate on the test strip and insert it into the monitor. When the monitor detects the threshold level of E3G, the monitor displays a 'high' reading designating a day of high fertility. When the

threshold LH level is reached, the monitor will give a 'peak' reading designating the peak days of fertility. The cervical mucus observations and CEFM readings are logged on a chart to track cycles (Figure 9). If the system is being used to avoid pregnancy, unprotected intercourse should be avoided beginning on the first day of a high fertility reading or the first observation of cervical mucus. The couple should abstain from intercourse until three days following the last day of a peak fertility reading or last peak day of cervical mucus, whichever occurs latest (Fehring et al., 2007).

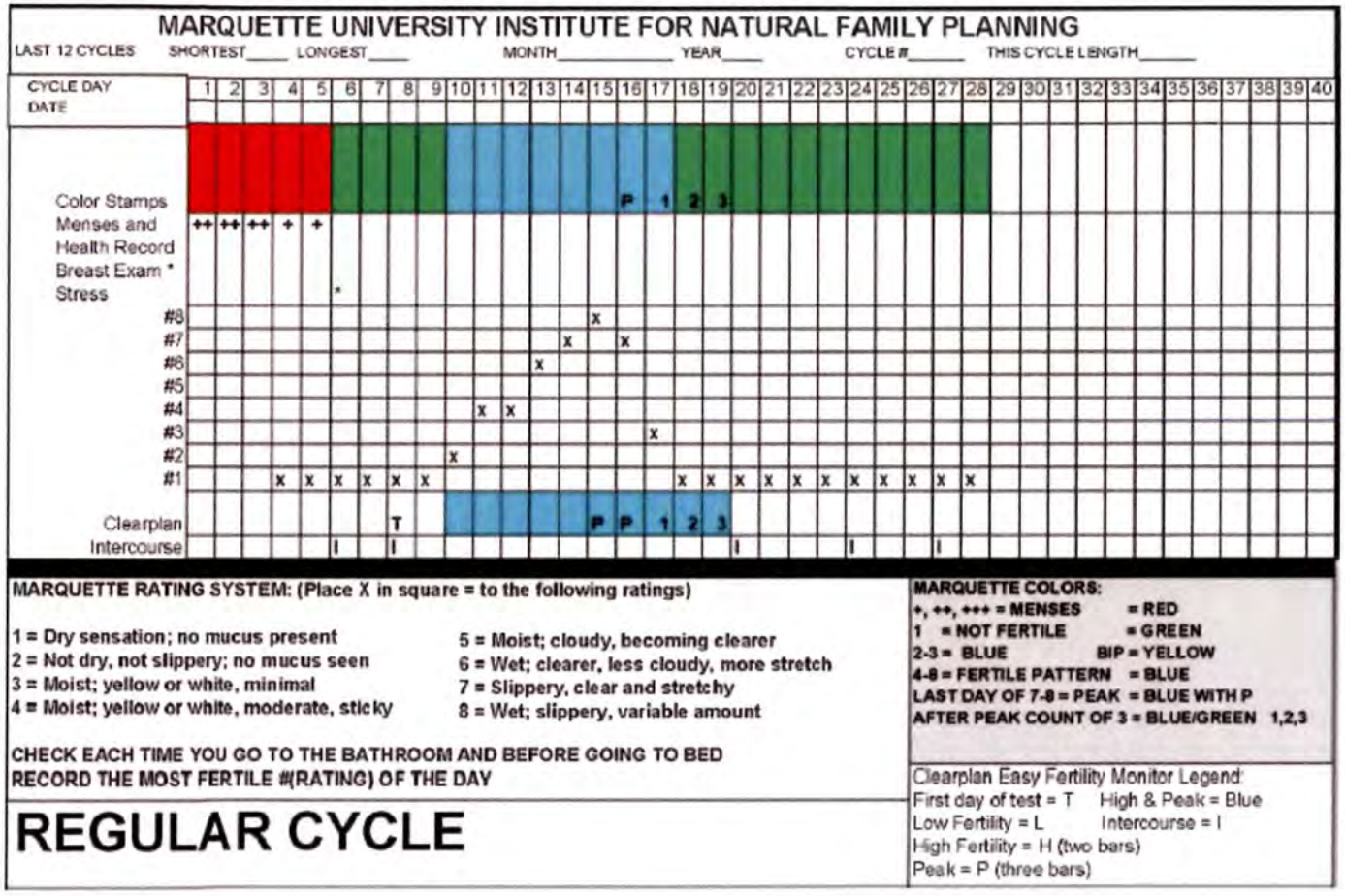

Figure 9. Marquette Model Fertility Chart. The figure depicts a typical Marquette Model chart which tracks ClearBlue Easy Fertility Monitor readings and cervical mucus. Blue days are considered fertile and thus to avoid pregnancy, abstinence from intercourse is necessary on these days. Figure taken from Fehring et al., 2007.

Several studies have been conducted to determine how effective the Marquette Model is at preventing unwanted pregnancies. Fehring's 12 month study of 195 women reported a method-failure pregnancy rate of 2.1 per 100 women over 1 year and a user-failure pregnancy rate of 14.2 per 100 women over 1 year (2007). These values are comparable to user and method failure rates of the other methods described earlier.

In another investigation, a cohort of 315 women taught to use a EHFM-cervical mucus double-check system and compared to a cohort of 318 women taught to use cervical mucus observations only (Fehring, Schneider, Barron, & Raviele, 2009). The EHFM group reported a correct-use failure rate of 2.3 pregnancies per 100 women over 12 months and a typical-use failure rate of 12.0 per 100 women over 12 months. The mucus only women reported a correct-use failure rate of 3.0 pregnancies per 100 women over 12 months and a typical-use failure rate of 23.0 pregnancies per 100 women over 12 months. Overall, there was a statistically significant difference between the unintended pregnancy rate between the two groups proving the double-check system using the fertility monitor resulted in fewer unintended pregnancies.

The MM's use of the ClearBlue Easy Fertility Monitor does serve as an effective double-check method to avoid unplanned pregnancies. It can be especially useful for women who lack confidence about distinguishing between fertile and

infertile types of mucus or peak days; the monitor can help confirm observations and decrease uncertainties. The effective rates of the MM are comparable with other methods but do not exceed the rates of other symptothermal methods. The cost is a significant disadvantage. The CEFM costs approximately $120 plus $40 for monthly test sticks. The expense of this method limits its widespread use among those interested in NFP methods.

DISCUSSION

All six methods of fertility awareness based (FAB) methods of birth control have a proven high effective rating with perfect use; however, typical-use failure rates can be much higher compared to other exogenous form of contraceptives (Trussell, 2007). The FAB methods require dedication, and motivation to strictly adhere to the rules in order to have maximum protection from unwanted pregnancy. While all contraceptives, except possibly sterilization, require correct use, women looking for a method of minimal effort and vigilance with maximum protection should probably use an alternate method. However, if a woman is interested in a natural method with few side effects and is highly motivated, and has the support of her partner, Natural Family Planning (NFP) methods of birth control could be a desirable and highly effective method. Table 1 is a summary of all the methods discussed. When used perfectly, all the methods can effectively prevent unwanted pregnancies, with methods charting physical symptoms being the most successful, especially if multiple symptoms are monitored.

Table 1. Summary of Fertility Based Awareness Methods of Birth Control

	Type	Cycle Length	Expense	Method-Rate	Typical-Rate	Reference
SDM	Calendar	26-32 day cycles only	Free CycleBeads ($10) (optional)	5	12	Arevalo 2002
					14.1	Gribble 2008
					10	Arevalo 2010
BOM	Cervical Mucus only	All	Class Fee (Variable*) Charting Materials ($4)	1.1	10.5	Bhargava 1996
				1.29	20.05	Klaus 1979
				2.3	22.3	WHO 1981
CrMS	Cervical Mucus only	All	Class Fee (variable*) Charting Materials ($4)	0.5	3.6	Hilgers 1998
				1.2	2	Fehring 1994
				>1	17.12	Howard 1999
				0.5	17.12	Pallone 2009
TDM	Cervical Mucus only	All	Free	3.5 (abstinence) 6.3 (w/ barrier)	13.7	Arevalo 2004
					3.45 (early counsel) 9.91 (late counsel)	Jennings 2011
STM	Multi-symptom	All	Thermometer ($10-15) Class Fee ($135) Annual Charts ($5)		1.8	Hermann 2007
					2.6	Freundl 1999
				0	0.96	DeLeizaola-Cordonnier 1995
					13.7	Wade 1981
MM	Multi-symptom	All	Fertility Monitor ($120) Test strips ($30/month)	2.1	14.2	Fehring 2007
				2.3	12	Fehring 2009

* Prices for instruction vary depending on location and range from $100-400; training is covered by many health insurance plans

The symptothermal method is the most effective method with both low method-failure and user-failure rates. The double-check system provides two symptoms to indicate both the beginning and end of fertility, ensuring coverage of the fertile days more completely. The double-check system reinforces the users' observations of fertility symptoms, thereby instilling confidence in the correct implementation of the method rules. This could account for the lower user-failure rate. The symptothermal method, while the most effective, is also the most complicated to learn. Users must master cervical mucus interpretations as well as learn how to record basal body temperature; users also must be able to integrate these symptoms and be able to accurately determine the fertile window and thus times of required abstinence. It is vitally important for correct usage of this method that couples be trained by certified instructors. The one time fees for the thermometer ($10) and class instruction ($135) are small and often covered by medical insurance. The only other fee is the annual cost for a year's supply of charting materials ($5/year).

The Marquette Model reports method-effective pregnancy rates higher than both the symptothermal and ovulation methods. This is likely due to the monitor's underestimation of early fertile days. However, the typical-use failure rates are slightly lower than those of the ovulation methods. This may be due to the ability of the monitor to assist women who have difficulties interpreting their cervical secretions. The monitor can increase a woman's confidence in her observations

and help with adherence to method rules regarding intercourse leading to fewer unintended pregnancies. The cost of the MM could be a major deterrent to potential users. The ClearBlue Easy Fertility Monitor costs $120 plus the monthly cost of test strips ($30/month). While this method could be useful for those wishing for an objective confirmation of their fertility status during the cycle, it is impractical for those with financial constraints or those without easy access to a monitor or testing strips.

The ovulation methods are the next most effective methods. When the Billings Ovulation Method and the Creighton Model of Fertility Care System are used appropriately with explicit adherence to the prescribed rules, the rate of unintended pregnancy is very low, rivaling most other modern methods of birth control including oral contraceptives (0.3%), intrauterine devices (0.3%), and condoms (5%) (Trussell, 2007). However, both OMs have a higher user-failure rate. This failure rate is elevated by couples consciously choosing to depart from the rules and engage in intercourse during known fertile periods. Confusion with symptom interpretation and method rules could also contribute to this failure rate. The methods are easier to learn than the symptothermal method because only one physical sign of fertility is being monitored, but adequate evaluation of cervical secretions can be difficult to learn and often takes multiple cycles to perfect. The studies by Hilgers (1998), Howard (1999), and Pallone (2009) show that CrMS is moderately more effective than BOM. The BOM relies on a

woman's subjective feelings and can be taught to women of low-literacy status and even visually impaired women. CrMS relies on objective language and comparisons, which probably accounts for the higher success rate. As in the symptothermal method, it is important to have a trained teacher to instruct new users about mucus interpretation and proper charting. The price for both BOM and CrMS includes the fee for initial classes, which varies based on location, but it usually a one-time fee between $100-$400 and is often covered by health insurance. An annual fee of $4 exists for yearly charting supplies. Users who wish to use an ovulation method will need to decide if they want a more objective (CrMS) or subjective (BOM) method.

The STM, MM, BOM, and CrMS have the added benefit of assisting with pregnancy achievement. If couples using any of the methods to avoid pregnancy decide to get pregnant, the symptoms can be used to track when the woman is most fertile and has the highest probability of achieving pregnancy. Proper charting can also be used to track gynecological health and can be used to discover fertility problems including anovulatory conditions.

The TwoDay Method, another modified method of observing cervical mucus secretions, has a slightly higher method-failure rate than the previous four methods. The TDM's rules usually only extend to cover the cycle through the evening of the first day past peak day of cervical secretions despite evidence

showing that ovulation is possible up to three days following the peak day; this is likely the cause of the higher failure rate. However, the TDM shows slightly lower typical-use unintended pregnancy rates than all other methods excluding the symptothermal method; TDM has fewer days of required abstinence and thus couples may find it easier to comply with abstaining from unprotected intercourse. The method is very easy to learn, doesn't require any charting, is thus available to couples with lower levels of education, and is free. The method can be taught in one day requiring little if any follow-up sessions. It does not apply to women who have a basic infertile pattern of consistent mucus because the method does not distinguish between fertile and infertile types of secretions.

The Standard Days Method has the highest method-failure rate of all the fertility awareness based methods. That being said, the method is still 95% effective at avoiding pregnancy when used perfectly. Similar to the TwoDay Method, the typical-use failure rate is slightly lower than the other methods, excluding the STM, probably due to the ease of use. The method only takes into account the probability of fertile time based on cycle length, assigning days 8-19 as days of abstinence. The lack of physical symptoms to indicate the fertile times increases the total number of days of abstinence which probably influences the higher method-failure rate. The SDM is only functional for women whose normal cycles fall between 26-32 days. Women with shorter or longer cycles should use an alternate method. The SDM is usually ineffective for premenopausal and

postpartum women as they often have irregular cycles. The method is very easy to learn and requires only that the woman be able to count. Fertile days can be tracked with a basic calendar and is free to learn. CycleBeads, an optional mnemonic device, can assist women to successfully use the method and cost only $10.

Table 2 summarizes the efficacy of multiple contraceptive methods (Trussell, 2007). As can be seen from the table, the fertility awareness based methods compare favorably with other exogenous methods. The typical-use pregnancy rates are within the same range as oral contraceptives and better than typical use of condoms. However, the literature detailed in this review does have a wide variety of reported values of typical-use pregnancy rates for the fertility awareness based methods. There is a lack of consistent definitions of what determines typical use. Some studies include all pregnancies resulting during the course of a study, neglecting to remove pregnancies that result from a couple's change in intention from pregnancy avoidance to pregnancy achievement. Other studies factor out those with intentions to get pregnant but include all users who consciously departed from method rules and engaged in unprotected intercourse during the fertile window which resulted in a pregnancy. Still other studies remove pregnancies resulting from departure of the rules and classify them as 'pregnancy-achieving' behavior regardless of subjective intention regarding the desire for pregnancy.

Table 2. Modern Contraceptive Rates of Pregnancy (Trussell, 2007)

Method	Percentage of women experiencing an unintended pregnancy within the first year of use		Percentage of women continuing use at 1 year[a]
	Typical use[b]	Perfect use[c]	
No method[d]	85	85	
Spermicides[e]	29	18	42
Withdrawal	27	4	43
Fertility-awareness-based methods	25		51
Standard days method[f]		5	
TwoDay method[f]		4	
Ovulation method[f]		3	
Sponge			
Parous women	32	20	46
Nulliparous women	16	9	57
Diaphragm[g]	16	6	57
Condom[h]			
Female (Reality)	21	5	49
Male	15	2	53
Combined pill and progestin-only pill	8	0.3	68
Evra patch	8	0.3	68
NuvaRing	8	0.3	68
Depo-Provera	3	0.3	56
IUD			
ParaGard (copper T)	0.8	0.6	78
Mirena (LNG-IUS)	0.2	0.2	80
Implanon	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

Because BOM and CrMS were developed as methods by religious researchers, the methods are strictly natural family planning methods whose rules require complete abstinence during the fertile window. Other methods, including SDM and TDM, allow users to use other backup methods such as condoms. The inconsistencies among the methods' studies make it difficult to directly compare them. More studies with consistent procedures, definitions, and statistical methods are needed to get a true sense of how these natural family planning methods compare to each other and other forms of birth control.

Despite the effectiveness of fertility awareness based methods, their use worldwide is quite low. According to Gray and Kambic, an average of only 10% of contraceptive users in developing countries use a natural family planning method (1988). In developed countries, an average of 7% use NFP methods. Countries with the highest prevalence of use of fertility awareness based methods were predominantly Catholic and include Peru, the Philippines, Belgium, France, and Poland. Freundl also found the highest prevalence of use of natural methods of birth control in Eastern Europe with Poland being the country with the highest percentage of users (2010).

It is highly probable that the low incidence of use of fertility awareness based methods is due to misconceptions and misinformation about them. In the majority of the cited studies, the participants were disproportionately Catholic.

Often, members of the secular society view these methods as a religious option, and associate them with the out-dated 'rhythm method' which was traditionally very ineffective. Physician's attitudes about natural methods of birth control also probably have an effect on the low use rates. A survey sent to 138 Canadian physicians showed that 94% incorrectly underestimated perfect use rates of FABs and 66% underestimated the typical-use rates (Choi, Chan, & Wiebe, 2010). When asked about their responses to patients asking for help in making a decision about contraceptive use, only a quarter of physicians polled said they mention NFP as a viable option. In the United States, only 5% of surveyed physicians (n= 295) accurately knew the perfect-use rates and less than 20% had correct knowledge about the typical-use effective rates (Stanford, Thurman, & Lemaire, 1999). This misinformation among doctors may contribute to the low usage of fertility awareness based methods. While other forms of contraception are certainly good options for some patients, the effectiveness of the methods described in this review confirm that NFP is a viable and effective method for many patients, especially given the benefits NFP offers.

Many of the current users of FABs have chosen the methods for religious purposes. However, FABs have benefits for many different women searching for birth control options. As opposed to other forms of birth control, including oral contraceptives, hormone shots, and intrauterine devices, fertility awareness based methods have no negative health side effects. Oral contraceptives have

been linked to increases in hazardous blood clots, various cancers, decreased libido, and weight gain. IUDs have been associated with Pelvic Inflammatory Disease and pelvic pain. These risks are minimal, but women with increased risk factors or those looking for hormonal free methods could find FABs an appealing alternative method of birth control. Studies have also shown that NFP methods of birth control can have a positive effect on users' marriages (Vande Vusse, Hanson, Fehring, Newman, & Fox, 2003). Of 334 couples surveyed, 75% had positive comments regarding their use of NFP reporting enhanced relationships. Couples listed improved communication, shared responsibility in family planning, an increase in respect for one another, and an increased appreciation of sexuality. Some couples did mention frustrations with abstinence and worsened relationships, but the overall response to the method was positive as may be seen in Figure 10 (Vande Vusse et al., 2003).

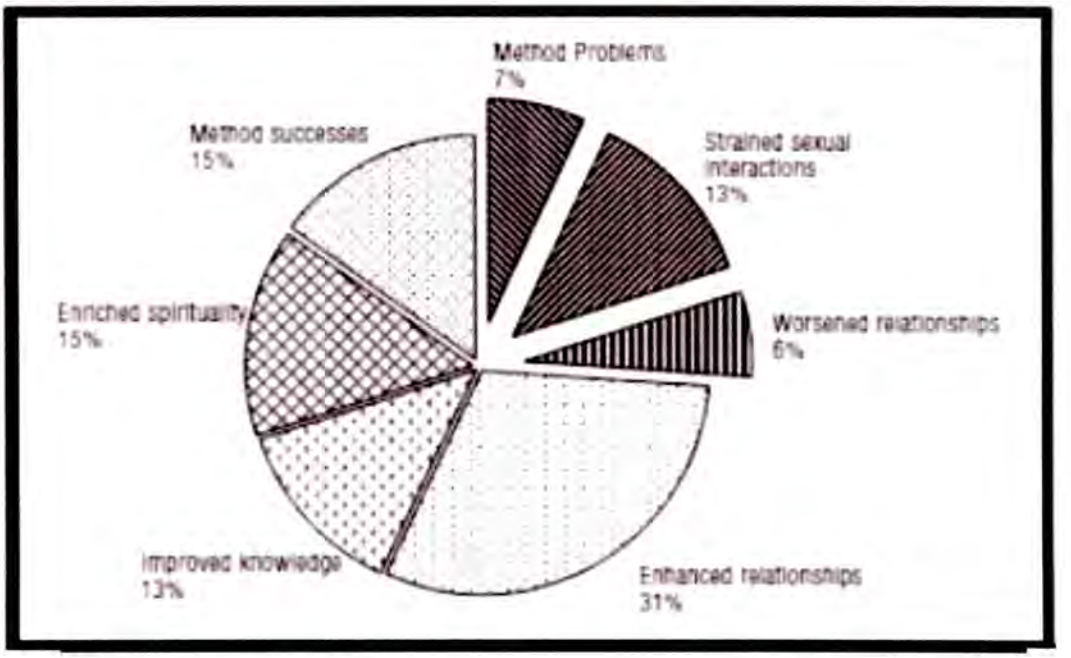

Figure 10. User Views on NFP Effects on Marital Relationship. A survey of 334 couples showed 74% positive comments about NFP use while 26% had negative feedback. Figure taken from (Vande Vusse et al., 2003).

The overall determinant regarding method success is user motivation. For any of the six methods described to be effective, users must be motivated to monitor their symptoms and abstain from unprotected intercourse during the fertile window. Breaking the rules of these methods, by design, puts the woman at significant risk of pregnancy as she is engaging in intercourse when she is most fertile. Partner cooperation can help ease some of the frustration of abstinence and couples can learn to express their love in alternate ways. Sinai and Arévalo (2006) found that users of TDM and SDM engaged in 5.6 and 5.5 average days of intercourse respectively which compared to the 5.5 acts reported for all sexually-active married women in Stover's 2001 study. Couples were also able

to modify their behavior to adequately fit the model and over time reported an increase total number days of intercourse while decreasing the number of days of intercourse during the fertile period. If users are motivated to use FABs correctly, they can serve as an effective and natural form of birth control.

Fertility Awareness Based methods have a place among the modern forms of available birth control. All the methods are effective, especially with perfect use. Couples interested in natural methods of birth control, whether for religious, health, or other personal reasons, have a variety of different FAB methods to choose from and can pick the method they find most appealing. Increases in knowledge regarding FAB methodologies and effective rates can help increase the effectiveness and widespread use of these methods of natural birth control.

REFERENCES

App Store - iCycleBeads - Plan or Prevent Pregnancy. (2012). Retrieved June 14, 2012, from http://itunes.apple.com/us/app/icyclebeads-plan-or-prevent/id401996963?mt=8

Arévalo, M, Sinai, I., & Jennings, V. (1999). A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning. *Contraception*, *60*(6), 357–360.

Arévalo, Marcos, Jennings, V., & Sinai, I. (2002). Efficacy of a new method of family planning: the Standard Days Method. *Contraception*, *65*(5), 333–338.

Arévalo, Marcos, Jennings, V., Nikula, M., & Sinai, I. (2004). Efficacy of the new TwoDay Method of family planning. *Fertility and sterility*, *82*(4), 885–892.

Arévalo, Marcos, Yeager, B., Sinai, I., Panfichi, R., & Jennings, V. (2010). Adding the Standard Days Method® to the contraceptive method mix in a high-prevalence setting in Peru. *Revista Panamericana De Salud Pública = Pan American Journal of Public Health*, *28*(2), 80–85.

Barron, M. L., & Daly, K. D. (2001). Expert in fertility appreciation: the Creighton Model practitioner. *Journal of obstetric, gynecologic, and neonatal nursing: JOGNN / NAACOG*, *30*(4), 386–391.

Bhargava, H., Bhatia, J. C., Ramachandran, L., Rohatgi, P., & Sinha, A. (1996). Field trial of billings ovulation method of natural family planning. *Contraception*, *53*(2), 69–74.

Bigelow, J. L., Dunson, D. B., Stanford, J. B., Ecochard, R., Gnoth, C., & Colombo, B. (2004). Mucus observations in the fertile window: a better predictor of conception than timing of intercourse. *Human reproduction (Oxford, England)*, *19*(4), 889–892.

Billings, E. (2006). *Some Clarifications Concerning NaproTECHNOLOGY and the Billings Ovulation Method (BOM)*. WOOMB International Limited.

Billings, E. L., Brown, J. B., Billings, J. J., & Burger, H. G. (1972). Symptoms and hormonal changes accompanying ovulation. *Lancet*, *1*(7745), 282–284.

Billings, J. (2002). The Quest - leading to the discovery of the Billings Ovulation Method. *The Bulletin of the Ovulation Method Research and Refernce Centre of Australia*, *29*(1), 18–28.

Billings Life - Leaders in Fertility Education. (n.d.). The Rules of the Billings Ovulation Method™ | How the Billings Ovulation Method™ Works. Retrieved June 14, 2012, from http://www.thebillingsovulationmethod.org/how-the-billings-ovulation-method%E2%84%A2-works/the-rules-of-the-billings-ovulation-method.html

Choi, J., Chan, S., & Wiebe, E. (2010). Natural family planning: physicians' knowledge, attitudes, and practice. *Journal of obstetrics and gynaecology Canada: JOGC = Journal d'obstétrique et gynécologie du Canada: JOGC*, *32*(7), 673–678.

Cycle Technologies. (2012). Natural Family Planning. Natural Birth Control. Plan or Prevent Pregnancy. | CycleBeads. Retrieved June 14, 2012, from http://www.cyclebeads.com/

De Leizaola-Cordonnier, A. (1995). Natural family planning effectiveness in Belgium. *Advances in contraception: the official journal of the Society for the Advancement of Contraception*, *11*(2), 165–172.

Dunson, D. B., Sinai, I., & Colombo, B. (2001). The relationship between cervical secretions and the daily probabilities of pregnancy: effectiveness of the TwoDay Algorithm. *Human reproduction (Oxford, England)*, *16*(11), 2278–2282.

Fehring, R J, Lawrence, D., & Philpot, C. (1994). Use effectiveness of the Creighton model ovulation method of natural family planning. *Journal of obstetric, gynecologic, and neonatal nursing: JOGNN / NAACOG*, *23*(4), 303–309.

Fehring, R J, & Schlaff, W. D. (1998). Accuracy of the Ovulon fertility monitor to predict and detect ovulation. *Journal of nurse-midwifery*, *43*(2), 117–120.

Fehring, Richard J. (2002). Accuracy of the peak day of cervical mucus as a biological marker of fertility. *Contraception*, *66*(4), 231–235.

Fehring, Richard J, Schneider, M., Barron, M. L., & Raviele, K. (2009). Cohort comparison of two fertility awareness methods of family planning. *The Journal of reproductive medicine*, *54*(3), 165–170.

Fehring, Richard J, Schneider, M., Raviele, K., & Barron, M. L. (2007). Efficacy of cervical mucus observations plus electronic hormonal fertility monitoring as a method of natural family planning. *Journal of obstetric, gynecologic, and neonatal nursing: JOGNN / NAACOG*, *36*(2), 152–160.

Fehring, Richard J., Raviele, K., & Schneider, M. (2004). A comparison of the fertile phase as determined by the Clearplan Easy Fertility Monitor™ and self-assessment of cervical mucus. *Contraception*, *69*(1), 9–14.

Fertility awareness methods. (2012). Retrieved June 14, 2012, from http://www.ippf.org/en/Resources/Guides-toolkits/Fertility+awareness+methods.htm

France, J. T., Graham, F. M., Gosling, L., Hair, P., & Knox, B. S. (1992). Characteristics of natural conceptual cycles occurring in a prospective study of sex preselection: fertility awareness symptoms, hormone levels, sperm survival, and pregnancy outcome. *International journal of fertility*, *37*(4), 244–255.

Frank-Herrmann, P., Heil, J., Gnoth, C., Toledo, E., Baur, S., Pyper, C., Jenetzky, E., et al. (2007). The effectiveness of a fertility awareness based method to avoid pregnancy in relation to a couple's sexual behaviour during the fertile time: a prospective longitudinal study. *Human reproduction (Oxford, England)*, *22*(5), 1310–1319.

Freundl, G. (1999). European multicenter study of natural family planning (1989-1995): efficacy and drop-out. The European Natural Family Planning Study Groups. *Advances in contraception: the official journal of the Society for the Advancement of Contraception*, *15*(1), 69–83.

Gray, R. H., Simpson, J. L., Bitto, A. C., Queenan, J. T., Li, C., Kambic, R. T., Perez, A., et al. (1998). Sex ratio associated with timing of insemination and length of the follicular phase in planned and unplanned pregnancies during use of natural family planning. *Human reproduction (Oxford, England)*, *13*(5), 1397–1400.

Gribble, J. N., Lundgren, R. I., Velasquez, C., & Anastasi, E. E. (2008a). Being strategic about contraceptive introduction: the experience of the Standard Days Method. *Contraception*, *77*(3), 147–154.

Gribble, J. N., Lundgren, R. I., Velasquez, C., & Anastasi, E. E. (2008b). Being strategic about contraceptive introduction: the experience of the Standard Days Method. *Contraception*, *77*(3), 147–154.

Guerrero, R. (1975). Type and time of insemination within the menstrual cycle and the human sex ratio at birth. *Studies in family planning*, *6*(10), 367–371.

Hilgers, T W, & Stanford, J. B. (1998). Creighton Model NaProEducation Technology for avoiding pregnancy. Use effectiveness. *The Journal of reproductive medicine*, *43*(6), 495–502.

Hilgers, Thomas W. (2004). *The Medical & Surgical Practice of NaProTECHNOLOGY*. Pope Paul VI Institute Press.

Howard, M. P., & Stanford, J. B. (1999). Pregnancy probabilities during use of the Creighton Model Fertility Care System. *Archives of family medicine*, *8*(5), 391–402.

Jennings, V., Sinai, I., Sacieta, L., & Lundgren, R. (2011). TwoDay Method: a quick-start approach. *Contraception*, *84*(2), 144–149.

Kippley, J. F., & Kippley, S. (1996). *The art of natural family planning*. Cincinnati, OH: Couple to Couple League International.

Klaus, H., Goebel, J. M., Muraski, B., Egizio, M. T., Weitzel, D., Taylor, R. S., Fagan, M. U., et al. (1979). Use-effectiveness and client satisfaction in six centers teaching the Billings Ovulation Method. *Contraception*, *19*(6), 613–629.

Marquette University. (2012). Marquette University | Natural Family Planning. Retrieved June 14, 2012, from http://nfp.marquette.edu/

Natural Family Planning - the Standard Days Method. (n.d.). Retrieved June 14, 2012, from http://www.natural-family-planning.info/standard-days-method.htm

Owen, J. A. (1975). Physiology of the Menstrual Cycle. *The American Journal of Clinical Nutrition*, *28*(4), 333–338.

Pallone, S. R., & Bergus, G. R. (2009). Fertility awareness-based methods: another option for family planning. *Journal of the American Board of Family Medicine: JABFM*, *22*(2), 147–157.

Perez, A., Eger, R., Domenichini, V., Kambic, R., & Gray, R. H. (1985). Sex ratio associated with natural family planning. *Fertility and sterility*, *43*(1), 152–153.

Prospective European multi-center study of natural family planning (1989-1992): interim results. The European Natural Family Planning Study Groups. (1993).*Advances in contraception: the official journal of the Society for the Advancement of Contraception*, *9*(4), 269–283.

Royston, J. P., & Abrams, R. M. (1980). An objective method for detecting the shift in basal body temperature in women. *Biometrics*, *36*(2), 217–224.

Sinai, I., Jennings, V., & Arévalo, M. (1999). The TwoDay Algorithm: a new algorithm to identify the fertile time of the menstrual cycle. *Contraception*, *60*(2), 65–70.

Stanford, J. B., Thurman, P. B., & Lemaire, J. C. (1999). Physicians' knowledge and practices regarding natural family planning. *Obstetrics and gynecology*, *94*(5 Pt 1), 672–678.

Trussell, J. (2009). *Contraceptive Technology. Nineteenth Revised Edition.* Ardent Media, Inc.

Vande Vusse, L., Hanson, L., Fehring, R. J., Newman, A., & Fox, J. (2003). Couples' views of the effects of natural family planning on marital dynamics. *Journal of nursing scholarship: an official publication of Sigma Theta Tau International Honor Society of Nursing / Sigma Theta Tau*, *35*(2), 171–176.

Where in the World Are CycleBeads? (2010).*Birth Control Beyond Hormones!* Retrieved June 14, 2012, from http://birthcontroloptions.onsugar.com/Where-World-CycleBeads-14967803

WHO. (1981). A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. *Fertility and sterility*, *36*(5), 591–598.

Wikipedia contributors. (2012, June 13). Menstrual cycle. *Wikipedia, the free encyclopedia*. Wikimedia Foundation, Inc. Retrieved from http://en.wikipedia.org/w/index.php?title=Menstrual_cycle&oldid=497315387

Wilcox, A. J., Weinberg, C. R., & Baird, D. D. (1995). Timing of sexual intercourse in relation to ovulation. Effects on the probability of conception, survival of the pregnancy, and sex of the baby. *The New England journal of medicine*, *333*(23), 1517–1521.

VITA

[redacted]