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THE FERTILE WINDOW

THE FERTILE WINDOW

A MASTER'S PROJECT
SUBMITTED TO THE GRADUATE FACULTY
OF THE GRADUATE SCHOOL
BETHEL UNIVERSITY

BY
ASHLEY JENSEN

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The Fertile Window

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May 2019

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Ashley Jensen

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Abstract

Purpose: The purpose of this paper is to examine various biological indicators and tracking methods to determine which are the most accurate in identifying the fertility window for reproductive-aged women.

Theoretical Framework: The Health Belief Model is used to analyze health-related behaviors to guide health interventions. This model recognizes that humans are rational and make decisions in a complex and intricate manner. This model is useful in looking at different methods of fertility identification. In using the model, different approaches to decision making can be analyzed to determine what factors influence women to choose different methods of fertility tracking.

Research articles: Twenty-three research articles were extensively studied to answer the question of which biological indicators and tracking methods are most accurate at identifying the fertile window in reproductive-aged women.

Results: Whether the woman has regular or irregular cycles is a major determinant of what method can be successfully utilized. Additionally, the woman's desire to achieve a pregnancy and her preference regarding intensity of the necessary training are significant factors in choosing a method. Use of two biologic indicators is discussed as some research points to this being the most effective. Finally, recommended web and mobile applications are discussed with a word of caution regarding their use.

Implications for Research and Practice: Because research in this area is limited, of low quality, and inconsistent in its findings, it is crucial for nurse-midwives to have the knowledge of the various biological indicators and tracking methods that a woman can use to identify her

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fertile window. A decision tree was developed and included for the nurse-midwife to guide a woman in selecting a method that would be most appropriate for the woman to use.

Keywords: fertile window; fertile phase; ovulation detection; ovulation prediction; ovulation identification; fertility awareness-based methods; natural family planning; biological markers; certified nurse-midwife; achieving pregnancy; avoiding pregnancy.

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List of Acronyms

American College of Nurse-Midwives	ACNM
Billings Ovulation Method	OM
Certified Nurse-Midwife	CNM
Cervical Mucus Monitoring	CMM
Creighton Model Fertility <i>Care</i> System	CrMS
Electronic Hormonal Fertility Monitor	EHFM
Fertility Awareness-Based	FAB
Marquette Method	MM
Natural Family Planning	NFP
Randomized Controlled Trial	RCT
Standard Days Method	SDM
Symptothermal Method	STM

Chapter I: Introduction

Knowledge is power. When a woman is able to identify when she is fertile, she has the power to use that information in several ways. She can choose to use that information to avoid or achieve a pregnancy, or merely for the empowerment of knowing what is occurring in her own body. While generally a man is considered fertile all the time, meaning there is a potential for conception every day, a woman has only a few days in her menstrual cycle when conception is possible and she would, therefore, be considered fertile.

These fertile days can be distinguished in a myriad of ways. Monitoring the biological changes can be accomplished through observing cervical mucus, basal body temperature (BBT), salivary changes, or hormone test strips results. Additionally, an estimate of the fertile window can be determined by monitoring the menstrual cycle with calendars or web and mobile phone-based applications (commonly called “apps”). Collectively, these are known as fertility awareness-based (FAB) methods of family planning, or natural family planning (NFP). Navigating the plethora of methods can be daunting and leads the searcher to wonder which method may be the most accurate or helpful.

Reproductive Physiology

Each month a woman’s body goes through a cycle of events culminating in the release of an egg, called ovulation. If fertilized, a new life begins, and if unfertilized, the cycle starts again. This cycle repeats in a predictable fashion that allows a woman to track where she is at in her cycle and know when ovulation is occurring or has occurred.

The cycle begins with menstruation when the endometrium, or the lining cells of the uterus, are shed. Within a female ovary are thousands of eggs. Each month one of these eggs matures under the influence of follicle stimulating hormone (FSH) (King et al., 2015). As the

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developing follicle matures, it secretes estrogen. This follicular phase of the menstrual cycle varies in length but most typically is 10-14 days. Estrogen produced in the follicular phase is responsible for the proliferative effect on the endometrium and for the production of a specific type of cervical mucus. This clear, stretchy, and lubricative cervical mucus typically appears approximately six days prior to ovulation and contributes to sperm survival, nourishment, and motility (Hilgers, 2002). Without the cervical mucus, sperm die within minutes. However, in the presence of cervical mucus, sperm have been found to live five to six days. Approximately 24-36 hours prior to ovulation, estrogen levels peak. This creates a surge in luteinizing hormone (LH). Ovulation typically takes place 10-12 hours after the surge in LH.

The luteal phase of the menstrual cycle follows ovulation. This phase of the cycle is stable in length and is typically 14 days. The follicle that once housed the mature egg is now called the corpus luteum. It begins to produce progesterone. Progesterone is responsible for thickening the endometrial lining to prepare for implantation of a fertilized egg. It also thickens the cervical mucus, effectively creating a plug to inhibit sperm penetration, and is associated with a rise in BBT. This rise in temperature occurs approximately 12-24 hours after ovulation (King et al., 2015).

The effects of the reproductive hormones FSH, estrogen, LH, and progesterone, as described above, produce detectable signs that a woman can use to determine when she is at in her cycle. Researchers have studied these various biological markers and used them to develop the FAB methods of family planning by identifying the days constituting the fertile window. The fertile window is typically defined as the five to six days preceding ovulation. This correlates to the maximum lifespan of the sperm in cervical mucus, and consequently to the time during which an act of intercourse could result in a pregnancy. Because these methods do not change or

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prevent a woman's fertility, they can be used equally to achieve or avoid pregnancy. The various FAB methods, along with their protocols for identifying the fertile window, are discussed below.

Review of FAB Methods

Calendar methods. The calendar method uses the average length of the last six or more cycles to define the parameters of the fertile window (Hilgers, 2002). Currently, many variations to this method exist. The majority of web and mobile phone applications perform this calculation automatically and continue to adjust the projected fertile windows with each completed cycle (Hilgers, 2002). The Standard Days Method (SDM) is an example of the calendar-based method. For all women with regular cycles ranging in length from 26-32 days, the SDM defines the fertile window to be from days 8-19 of the cycle (Manhart, Duane, Lind, Sinai, & Golden-Tevald, 2013).

Basal body temperature methods. Under the various BBT methods, the fertile window closes after three consecutive days of a temperature rise of approximately 0.4-1.0°F (Hilgers, 2002). The exact rules defining post-ovulatory infertility vary widely from method to method. When combined with calendar methods, BBT methods are able to give users a start day to their fertile window.

Mucus-only methods. Three mucus-only methods, the Billings Ovulation Method (OM), the Creighton Model Fertility*Care* System (CrMS), and the TwoDay Method, rely solely on the observations of cervical mucus discharge at the opening of the vagina to define the fertile window (Hilgers, 2002). The first day of fertility is typically defined as the first day of the presence of cervical mucus, and the last day of fertility is three days after the last appearance of a characteristic "peak type" cervical mucus (cervical mucus that is clear, stretchy, or lubricative)

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(Hilgers, 2002). The TwoDay Method differs slightly in that a woman is considered fertile if she notes mucus of any kind on that day or the day prior (Manhart et al., 2013).

Symptothermal Method. The Symptothermal Method (STM) combines the BBT with a variety of ovulatory symptoms to help identify the boundaries of the fertile window (Hilgers, 2002). Some of the symptoms frequently used include cervical mucus, intermenstrual pain, breast tenderness, vulvar swelling, ovulation bleeding, and changes in cervical texture and configuration. The first day of fertility in this method is indicated by either a calendar algorithm or symptoms, and the last day of fertility can be identified based on BBT, other symptoms, or a calendar method algorithm (Hilgers, 2002).

Symptohormonal methods. Women may also use urinary hormone test strips that detect the presence of estrogen and/or LH hormone to identify impending ovulation. These test strips can be used either alone or in combination with some of the aforementioned methods (Hilgers, 2002). Some variations of the Marquette Method (MM) utilize a urine hormone monitor in addition to the mucus method; other variations are mucus only.

Not all methods of identifying the fertile window are created equal; neither are they equally effective. While many service programs can teach these methods, it may be difficult to know which method to choose. Unfortunately, many resources available are not based on scientific research. Healthcare providers should possess a thorough understanding of each method to be equipped to give accurate and appropriate advice to women who seek it. If they do not have the ability to teach a particular method, they should have the resources and knowledge to refer to appropriate services. This paper provides an overview of relevant literature to identify the most accurate FAB method.

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Statement of Purpose

The purpose of this paper is to examine scholarly research articles regarding FAB methods of family planning. The question for this literature review is, “What biological indicators and tracking methods are the most accurate in identifying the fertility window for reproductive-aged women?” There may not be a single most accurate method for all reproductive-aged women. Rather it may be appropriate to give different recommendations depending on the individual characteristics of the woman.

Evidence Demonstrating Need

While quite low, NPF usage is increasing. In 2008, only 1.1% of women aged 15-44 reported using NFP, but, by 2014, that number experienced a statistically significant increase to 2.2% ($p = .009$; Kavanaugh, & Jerman, 2018). Polis and Jones (2018) discussed that 2.2% may not be an accurate prevalence rate, however, as the data in the original study classified only the projected most effective method if more than one method was being used, meaning if a woman reported a FAB method in combination with condoms, only the condom use was reported. With this in mind, the prevalence rate is postulated to have increased to 3%, which is a significant increase from 1.1% (Polis & Jones, 2018).

While FAB methods of NFP are frequently used for avoiding or spacing pregnancies, they can also be used to increase the odds of conception. Zinaman, Johnson, Ellis, and Ledger (2012) found that 45% of women incorrectly estimate their time of ovulation and their estimation actually falls outside of their fertile window. They conclude that conception rates would increase if women used a prospective method to identify their fertile window. Stanford, White, and Hatasaka (2002) recommend a prospective method, such as the mucus methods, CrMS and OM, or the hormone method, ClearPlan Easy Fertility Monitor, which are able to identify the entire

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fertile window. In a study of 100 couples who conceived without the assistance of FAB methods, 50% conceived by three months, 75% by six months and over 90% by 12 months (Stanford et al., 2002). However, a similar study analyzing couples who used the CrMS found that 76% of couples conceived in the first month, and 100% by six months, supporting the theory that a prospective method of identifying the fertile window to allow for timed intercourse increases a couple's chances of conception (Stanford et al., 2002).

With the increase of NFP users in recent years and the desire among couples trying to achieve pregnancy to do so efficiently, a search for the most effective means of identifying the fertile window for these purposes is needed.

Significance to Nurse-Midwifery

While many view midwives primarily as birth attendants, certified nurse-midwives (CNM) have a much broader scope of practice. As advanced practice nurses, they have prescriptive authority and can practice as primary health care providers for the breadth of women's health issues in addition to attending births. The most recent survey in August of 2017 reported that there are 11,826 CNMs in the United States (American College of Nurse-Midwives [ACNM], 2017). A remarkable 53.3% identified reproductive care and 33.1% identified primary care as their main responsibilities (ACNM, 2017). The identification of the fertile window is a relevant discussion to CNMs since many focus their careers on reproductive and primary care, while many more incorporate reproductive care into their daily practices.

The ACNM (1997) affirms the importance of incorporating reproductive health care into a midwife's practice. In their position paper regarding reproductive care, ACNM declares that each person has the right to make individual choices regarding reproductive health. All should have access to factual, evidence-based, unbiased information about reproductive health services

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to make an informed decision. They expound on this by saying CNMs ought to be able to provide knowledgeable information regarding fertility awareness, hormonal and non-hormonal contraceptive methods, long-acting reversible contraceptives, emergency post-coital contraception, and permanent sterilization (ACNM, 1997).

The ACNM has developed the Hallmarks of Midwifery, which characterize the art and science behind midwifery. These Hallmarks include incorporation of scientific evidence into clinical practice, empowerment of women as partners in health care, advocacy for informed choice, shared decision-making, and the right to self-determination, and evaluation and incorporation of complementary and alternative therapies in education and practice (ACNM, 2007). Educating women in methods of identifying her fertile window promotes these hallmarks. By being well versed in all methods of family planning, a midwife can present all evidence-based methods to support a woman's goals for her reproductive life. By doing this, it allows a woman to be a partner in her health care where she knows she is choosing the best method for herself in this joint decision-making process. Lastly, as a hormone free, natural option, fertility awareness-based methods can be viewed as complementary and alternative therapies, which are essential elements of midwifery care. It is the duty of the midwife to have knowledge of these therapies and methods in order to give accurate and up to date information on their safety and efficacy.

Unfortunately, studies have shown that CNMs are not well educated on these methods, nor are they prepared to give accurate information to patients who are interested. Fehring, Hanson, and Stanford (2001) received questionnaires from CNMs ($N = 450$) to discover their knowledge and promotion of NFP methods for child spacing. They discovered that midwives feel less prepared to counsel clients on NFP than oral contraception, condoms, or other methods

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of family planning. They reported only receiving minimal preparation from their midwifery education regarding NFP. Even though many methods of NFP are highly effective among motivated users, midwives projected that it would only be 70-80% effective. In the survey, 10.9% reported they would not mention NFP to their patients at all, 63.4% would mention only to select clients and 22.4% would mention to most or all clients. Although half of the CNMs felt unprepared to provide instructions to their patients themselves, only a third would refer clients to a NFP instructor (Fehring et al., 2001). A separate study reported that one in five women reported that if their healthcare provider gave them information on NFP in a positive way they would be highly likely to use the method for either achieving or avoiding pregnancy (Stanford, Lemaire, & Thurman, 1998)

UpToDate (Jennings, 2018) stated that fertility awareness-based (FAB) methods of family planning are not overly popular in the United States. They cite that one of the reasons for the low number of users could be related to a lack of information (Jennings, 2018). Few physicians and CNMs routinely educate or include this information to patients, and when they do they typically include information regarding some of the least accurate methods of fertility awareness (Jennings, 2018). The author discussed the need for a provider to screen and counsel women who are interested in using a FAB method to help them choose a method they can consistently and routinely follow. Many methods require daily actions by the woman in order for the method to be effective. In addition, Jennings (2018) highlighted the fact that with efficacy studies there is a large disparity in some methods between perfect and typical use, with the more complex methods having a wider disparity. They concluded that because of this, and the challenge of some methods, not all women may be appropriate candidates for all methods.

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In order for a provider to be able to screen a candidate for which method may be the most effective or appropriate for them, a provider must know enough information about each FAB method. If CNMs want to adhere to the position statement from the ACNM, and the recommendation from UpToDate, they must educate themselves regarding FAB methods of family planning. If women want to choose this method, providers must have the necessary tools and knowledge to screen their patients and direct them to the most appropriate method and give them the information necessary to use that method effectively.

Theoretical Framework

Theoretical frameworks in the healthcare field are a meaningful way to structure and approach interventions aimed at improving outcomes by predicting certain behaviors (Hall, 2011). The Health Belief Model (HBM), which was developed in the 1950s by Rosenstock and colleagues, is used to analyze health-related behaviors in order to help guide health interventions (Shojaei, Farhadloo, Aein, & Vahedian, 2016). The HBM recognizes that humans are rational and make decisions in a complex and intricate manner. This is a useful model in looking at different methods of fertility identification. Many different biological indicators and tracking methods are effective for identifying fertility for reproductive-aged women. By using the HBM the different approaches to decision making can be analyzed to determine what factors influence women to choose different methods of fertility tracking.

The four main constructs to the model are perceived threat, perceived benefits, perceived barriers, and cues to action (Shojaei et al., 2016). *Perceived threat* refers to the susceptibility or seriousness of a situation (Hall, 2011). For the example of tracking fertility, it may be related to the threat of an unplanned pregnancy, which gives an incentive or motivation to track fertility. It could also be tracking for the sake of achieving pregnancy in which case the perceived threat

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would be of not being able to conceive or taking a long time to conceive due to lack of knowledge of the fertile time.

Perceived benefits and *perceived barriers* are interrelated. The perceived benefit is the perception of the effectiveness, practicability, or other advantages of tracking fertility to achieve or avoid pregnancy versus the perceived barriers (Hall, 2011). Benefits could be knowledge and control of fertility, an increased chance of pregnancy due to the selective timing of intercourse, a nonhormonal option of avoiding pregnancy, or the safety of a nonintrusive and nonhormonal method of tracking fertility. Barriers may include a lack of patience to learn a system, a lack of education or knowledge to understand system instructions, the inconvenience of remembering to do something on a constant or daily basis, limited access to certain methods (if a method is not taught in a certain area or lack of provider knowledge regarding instructions for tracking fertility), or perception of lack of efficacy regarding natural methods.

Cues to action is the last construct of the HBM and incorporates internal and external stimuli. These stimuli provoke an awareness of the perceived threat (threat of pregnancy or threat of the inability to achieve a pregnancy), which serves to facilitate consideration of tracking fertility to help remediate this threat (Hall, 2011). Stimuli may be internal such as the observation of cervical mucus, abdominal pain that indicates ovulation, or an act of intercourse. These all may prompt a woman to consider her fertility. External stimuli include counseling by providers or information received by social media on natural methods of tracking fertility.

HBM postulates that before a change in behavior is initiated a change in belief is necessary (Shojaei, Farhadloo, Aein, & Vahedian, 2016). Compliance and efficacy of tracking fertility are related then to the four constructs of the HBM. Providers should structure discussions around the patient's intentions of why they want to track their cycles for identifying

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their fertility, either for the sake of achieving pregnancy or avoiding pregnancy. Investigating what their current perceptions are of the benefits and barriers of various tracking methods can help to aid in selecting the most appropriate method that will result in success for their intentions.

Summary

As providers of reproductive and primary care, nurse-midwives are in an ideal position to help women reach their reproductive goals, whether to achieve or avoid pregnancy. Women trust their providers and as such, it is the provider's duty to provide women with accurate information to help them make their own decisions. This extends to knowledge pertaining to NFP. In understanding the biological markers and tracking methods used in FAB methods of family planning, nurse-midwives can provide women with the necessary information to identify their fertile window and reach their goals. By using the HBM framework, the factors that influence decision making can be analyzed to determine a woman's perceptions and intentions, which will help the nurse-midwife to more fully understand and help her to reach her goals.

Chapter II: Methods

This chapter outlines the methods used to identify and select the research articles discussed in the literature review. These studies each relate to the use of biological indicators and tracking methods to identify the fertility window of reproductive-aged women. This chapter will discuss the search strategies used as well as the inclusion and exclusion criteria applied to those searches, and the number and type of studies found. *The Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines* (Dearholt & Dang, 2012) critiquing criteria are reviewed and will be used to critique the remaining articles.

Search Strategies

The purpose of this critical appraisal of the literature was to determine which biological indicators and tracking methods are the most accurate in identifying the fertility window for reproductive-aged women. An initial search utilizing the database CINAHL of peer-reviewed articles, written in English, with the search terms “ovulation detection” or “ovulation prediction” or “fertile window” or “fertile phase” yielded 347 results, 252 of which were from the years 2008-2018. The same search was applied to the database PubMed, which yielded 6,746 results. After limiting the results to the years 2008-2018, 1,438 results remained. The initial search limited studies to articles published in the last 10 years with the intent of including the most relevant and up to date research.

Data mining of both sets of results was performed to ensure a thorough search of current and past research on the topic. This yielded additional studies, some of which were outside of the 10-year search criteria. Many of the foundational natural family planning methods emerged during the mid to late 1900s. Further research on those methods began to appear in the 1980s and into the early 2000s. The research from these early articles have not been replicated and,

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therefore, are essential to the current discussion of identifying the fertile window in reproductive-aged women. It is supported with new research from the past 10 years to discover current trends that women today can use to assist them in their family planning intentions to either achieve or avoid a pregnancy. Duplicate studies were then removed, and the inclusion and exclusion criteria listed below were applied to the remaining articles.

Inclusion and Exclusion Criteria

In reviewing studies, the following inclusion criteria were utilized: 1) research studies; 2) studies on females of childbearing age; 3) studies about fertility awareness-based methods of natural family planning; 4) studies regarding techniques of monitoring fertility; 5) studies on achieving pregnancy; 6) studies on avoiding pregnancy; and 7) studies with participants from countries with similar economic development. Exclusion criteria were: 1) non-research studies; 2) studies on non-humans; 3) systematic reviews; 4) literature reviews; 5) studies on infertility; 6) studies on artificial reproductive technologies; 7) studies regarding women who were currently pregnant; 8) studies on pregnancy loss; 9) studies on ovulation induction techniques; 10) studies on breastfeeding women; 11) studies on women with medical conditions (ie. PCOS, endometriosis, and ovarian cancer); and 12) studies on women in perimenopause.

Number and Types of Studies Selected

The 23 articles selected for the literature review can be found in Table 1. These articles include one randomized trial, one randomized prospective comparative study, five retrospective studies, eleven prospective studies, two descriptive studies, two observational studies, and one time-to-pregnancy cohort study. The search yielded research from all over the world. The number of times a country was included in the selected research articles is as follows: United States (9), Germany (5), Philippines (4), Belgium (3), France (3), Italy (3), Peru (3), Switzerland

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(3), Sweden (3), Bolivia (2), England (2), India (2), New Zealand (2), Benin (1), Ecuador (1), El Salvador (1), Guatemala (1), Honduras (1), Ireland (1), and Spain (1). An additional two articles stated there were participants from European countries but did not specify which countries.

Natural family planning and fertility awareness services have a higher prevalence in countries with a high concentration of Roman Catholics, and as such, research on these topics has frequently been carried out with participants from these countries (Gray & Kambic, 1988). In addition to similar religious identification, the countries in the articles chosen were of comparable economic development.

Criteria for Evaluating Research Studies

Each research article was evaluated using *The Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines* (Dearholt & Dang, 2012). This model classifies research articles based on their level and quality. Level I studies include experimental studies, randomized controlled trials (RCT), and systematic reviews of RCTs. Level II studies include quasi-experimental studies and systematic reviews of a combination of RCTs and quasi-experimental studies. Level III studies can include both non-experimental studies and qualitative studies as well as systematic reviews of 1) a combination of RCT's, quasi-experimental, and non-experimental studies; 2) non-experimental studies only; and 3) qualitative studies with or without a meta-synthesis. Level IV studies are non-experimental and include opinions of respected authorities, nationally recognized expert committees, or panels based on scientific evidence. An article's quality is ranked as high, good, or low based on the consistency of the results, sample size, design, level of control, and definitive conclusion (Dearholt & Dang, 2012). The critical

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appraisal of the literature resulted in 23 total articles: two Level I and 21 Level III. Thirteen were ranked as high quality, eight as good, and two as low-quality research.

While an RCT is the gold standard for research studies, RCT's pose a great difficulty to FAB methods. Obviously, it is impossible to blind participants regarding what method they were learning, unlike different hormonal contraceptives or intrauterine devices. Aside from blinding, logistical and ethical issues arise, as many couples have a preference to which method they would want to be randomized into. This can explain in part the lack of randomized trials on this topic. Additionally, the strength of desire for either achieving or avoiding pregnancy can make the method more or less effective.

Summary

Identifying ovulation, which is often done for fertility awareness-based methods of family planning, has not been the subject of extensive research. Although the current body of research is growing, much of the research is greater than 10 years old. A thorough search of the literature was done and 23 articles were chosen and included in the final matrix. This chapter outlined the search strategies, inclusion and exclusion criteria, the number and type of articles chosen, and the criteria by which the articles were evaluated.

Chapter III: Literature Review and Analysis

The purpose of this literature review is to analyze the available data for the most accurate method of identifying the fertile window. It focuses specifically on methods that a reproductive-aged woman could perform for herself to identify her own fertile window. The major findings of each method will be described and are divided into the following categories: regular cycles, irregular cycles, mobile applications, achieving pregnancy, use of two biologic indicators, and client training.

Terminology

Perfect-use, method, or correct-use are terms used similarly by various authors to describe pregnancies which occur during cycles in which the method appears to be used perfectly. Thus, perfect-use, method, or correct-use pregnancies are only those cycles in which the method appeared to be used perfectly but a pregnancy still occurred (Manhart et al., 2013). Typical-use pregnancies are all unintentional pregnancies in all cycles of use. Therefore, typical-use effectiveness is the likelihood of conception occurring in the real world when human error is considered. In some ways, typical-use effectiveness rates can be more beneficial when comparing methods since this more accurately reflects real-world usage as few couples are perfect all of the time.

Comparing pregnancy rates among the different research studies is difficult, as the same methodologies for reporting pregnancy rates or effectiveness totals are not utilized. Many studies use the Pearl Index, which reflects the number of failures, or unintended pregnancies, among all the cumulative years of exposure (Koch et al., 2018). The challenge with the Pearl Index is that it does not consider the realities of failure over time. It assumes that the failure rate will remain constant, when in reality, with contraception, and specifically FAB methods, the most fertile

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couples, or less motivated couples, will conceive early on. Conversely, those who do not conceive, and continue with the method may have lower fertility, but overall their experience level and expertise will increase with time making the method more effective. This makes comparing studies of different lengths problematic since studies of longer duration will likely have a lower Pearl Index (Hilgers, 2002). Life table analysis, developed to combat the limitations associated with the Pearl Index, provides the number of failures, or the effectiveness rate, for each month of use; it is also able to provide a cumulative failure rate for a specific length of exposure (Hilgers, 2002). Kaplan-Meier survival rate is a specific methodology of life table analysis.

Synthesis of Major Findings

Regular cycles. Many natural family planning methods have not been proven effective in preventing or achieving pregnancy if a woman has irregular menstrual cycles. Eight of the studies examined specifically excluded women if they did not have regular cycles (Arévalo, Jennings, & Sinai, 2002; Sinai, Lundgren, & Gribble, 2012; Fehring, Schneider, Raviele, Rodriguez, & Pruszynski, 2013; Günther et al., 2015; Frank-Herrmann et al., 2007; Wade et al., 1981; World Health Organization, 1981; Ecochard, Duterque, Leiva, Bouchard, & Vigil, 2015). Because women with irregular cycle lengths have been excluded, these methods should not be recommended to women unless she has regular cycles.

Standard Days Method. The SDM studies (Arévalo et al., 2002; Sinai et al., 2012) had a high dropout rate for women with irregular cycles. In a prospective cohort study, Arévalo et al. (2002) found that 28% of the participants ($N = 478$) from Bolivia, Peru, and the Philippines had to be removed from the study due to having two cycles outside of the 26-32-day range needed to effectively use the method. Life table analysis found first-year, correct-use pregnancy rates to be

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4.8 per 100 women. However, when all cycles were analyzed, including those from women who had two cycles outside of the 26-32-day range, the first-year pregnancy rate substantially increased to 12 per 100 women (Arévalo et al., 2002). Sinai et al. (2012) conducted a long-term prospective cohort study to examine the long term efficacy of the SDM. Participants ($N = 1,659$) from Bolivia, Peru, Philippines, Benin, Ecuador, Honduras, and India were screened for cycle length. The number of women removed due to irregular cycles decreased from 40.8% in the first year alone to 8.3% in the following two years, and the efficacy of the system increased with time (Sinai et al., 2012). Life table analysis was used to calculate pregnancy rates. Data was gathered from two separate studies ($N = 1659$) and revealed a typical-use pregnancy rate of 12.0-14.1 per 100 women after year one, 3.7-5.2 after year two, 3.4-5.9 after year three (Sinai et al., 2012).

Marquette Method. Only one of the four MM studies excluded women with irregular cycle lengths (Fehring et al., 2013). In this prospective randomized clinical trial, the efficacy of a fertility algorithm was compared in combination with either the electronic hormonal fertility monitor (EHFM) or cervical mucus monitoring (CMM). Women with menstrual cycles outside of a 21-42-day range were excluded. A total of $N = 667$ couples from the United States were randomized into the two groups. They found that the rate of pregnancy in the CMM group was nearly triple the rate of pregnancies in the EHFM group ($p < 0.0048$, with $p < 0.05$ considered statistically significant) (Fehring et al., 2013).

Symptohormonal. Visualizing salivary changes from estrogen through a handheld microscope is an extension of the symptohormonal method. Günther et al. (2015) examined the effectiveness of such a method through a prospective comparative study. They too excluded women with cycles outside of a 25-35-day range. Among the $N = 74$ participants from Germany,

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it was discovered that both saliva and LH tests will detect the fertile window, but saliva will become positive 24 hours before LH (Günther et al., 2015).

Symptothermal Method. The two STM studies (Frank-Herrmann et al., 2007; Wade et al., 1981) found the method to be effective but similarly excluded women with menstrual cycles outside of a specified range. Frank-Herrmann et al. (2007) conducted a prospective, observational longitudinal cohort study, and only included women from Germany with regular cycles ranging from 22-35 days ($N = 900$). However, they did allow 20% of cycle lengths to be outside of this range. After 13 cycles of use, Kaplan-Meier survival analysis yielded a perfect-use pregnancy rate of 0.43 per 100 women and an unintended pregnancy rate, where unprotected intercourse occurred during the fertile window, of 7.47 per 100 women ($p < 0.00001$). Typical-use pregnancy rates, which included all pregnancies during use, was 1.62 per 100 women (Frank-Herrmann et al., 2007). Wade et al. (1981) limited cycle length to 24-36 days in a randomized prospective comparative study of the OM and the STM. Out of the $N = 430$ women from the United States in the study, they found Pearl Index pregnancy rates of 34.9 for the OM and 16.6 for the STM, concluding that the STM was more effective among women with regular cycle lengths (Wade et al., 1981).

Mucus-only methods. Two studies regarding mucus-only methods found CMM to be an effective means of identifying the fertile window among women with regular cycles of a particular range (World Health Organization, 1981; Echochard et al., 2015). The OM was inspected in a prospective cohort study with women ($N = 725$) from New Zealand, India, Ireland, Philippines, and El Salvador with regular cycle lengths ranging from 25-35 days (World Health Organization, 1981). Method-related Pearl Index pregnancy rates for 13 cycles was 2.2 pregnancies per 100 women-years, and 19.6 pregnancies per 100 woman-years for user-related

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pregnancies (World Health Organization, 1981). In their observational cohort study, Ecochard et al. (2015) found that cervical mucus observations at the opening of the vagina could be used as a clinical proxy for ovulation among woman ($N = 107$) from France, Italy, Germany, Belgium, and Spain with regular cycles spanning 24-34 days.

Irregular cycles. While some methods cannot effectively be used by women if they have irregular length cycles, both the CrMS, and the MM have been studied in a population of women of all cycle lengths. The MM does have some exclusions for breastfeeding and post-pill, but CrMS can be used in any life situation including post-pill, breastfeeding, or perimenopause while still maintaining its effectiveness (Doud, 1985; Fehring, Lawrence, & Philpot, 1994; Howard & Stanford, 1999; Fehring, Schneider, & Barron, 2008; Fehring, Schneider, Barron, & Raviele, 2009; Fehring & Schneider, 2017).

Creighton Model FertilityCare System. None of the three CrMS studies excluded women for any cycle reasons. These studies demonstrated low unintended pregnancy rates (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999). A prospective cohort study by Doud (1985) looked at the effectiveness of the CrMS among women of all reproductive categories ($N = 378$) from the United States. Method-use pregnancy rates were found to be 0.9 per 100 women at 12 months of use, and typical-use pregnancies were 3.8 (Doud, 1985). In their prospective descriptive cohort study, Fehring et al. (1994) also included women of all reproductive categories ($N = 242$) from the United States. Using a life table analysis, the researches calculated method-use pregnancy rates to be 1.2 per 100 women at 12 months of use, and typical-use pregnancy rates to be 2.0 (Fehring et al., 1994).

Howard and Stanford (1999) conducted an observational cohort study of the CrMS with women of all reproductive categories ($N = 701$) from the United States. Using life table analysis

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they calculated the total pregnancy rate to be 17.12 per 100 women at 12 months of use and the method-related pregnancy rate was 0.14. Notably, they did not exclude couples who were planning a pregnancy which many other studies exclude, which should explain why the total pregnancy rate is higher than the other CrMS studies. The pregnancy rate for couples planning a pregnancy was 12.84 per 100 women at 12 months of use (Howard & Stanford, 1999).

Marquette Method. Four studies on the MM were included in this appraisal of the literature, and three of these included women of all cycle lengths. However, unlike CrMS they did have some exclusions for post-pill and breastfeeding. (Fehring et al., 2008; Fehring et al., 2009; Fehring & Schneider, 2017). Fehring et al. (2008) excluded breastfeeding women in their retrospective evaluation in the United States. They found that the lowest pregnancy rates resulted when the EHF_M was used. Kaplan-Meier survival analysis yielded typical-use pregnancy rates of 9.2 per 100 women at 12 months of use for those who used the EHF_M alone or in combination with BBT and CMM ($n = 99$; Fehring et al., 2008). Fehring et al. (2009), while excluding women who were post-pill, concluded similarly in their retrospective cohort comparison in the United States. With the Kaplan-Meier survival analysis, they found the typical-use unintended pregnancy rates were 12.3 for the group that utilized EHF_M and CMM ($n = 313$; Fehring et al., 2009). Fehring and Schneider (2017) only excluded women who were breastfeeding and found somewhat lower pregnancy rates than the previous two studies in a prospective cohort study conducted with women from United States and Europe. Kaplan-Meier survival analysis calculated typical-use pregnancy rates of 6 per 100 users at 24 cycles of use for the group that used EHF_M alone ($n = 212$; Fehring & Schneider, 2017).

Mobile applications. Mobile and web applications have gained popularity in recent years. These can be an attractive means of fertility tracking, but not all applications are effective.

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Some require outside training to use the application as an effective method of family planning (Scherwitzl, Hirschberg, & Scherwitzl, 2015; Scherwitzl, Danielsson, Sellberg, & Scherwitzl, 2016; Duane, Contreras, Jensen, & White, 2016; Setton, Tierney, & Tsai, 2016).

The studies investigating NaturalCycles (Scherwitzl et al., 2015; Scherwitzl et al., 2016) revealed this mobile application to be accurate in identifying the fertile window and effective as a means of pregnancy prevention. A retrospective investigational pilot study among women from Switzerland and Sweden not planning a pregnancy found that a mere 0.05% of the fertile days were falsely attributed to the fertile window, and only one unintended pregnancy occurred among all participants ($N = 317$; Scherwitzl et al., 2015). Following the pilot study, a retrospective observational study of $N = 4054$ women from Sweden revealed a method-use Pearl Index pregnancy rate of 0.5 pregnancies per 100 woman-years and a typical-use Pearl Index of 7.0 (Scherwitzl et al., 2016). They concluded that while effective, it requires abstinence or protection on fertile days. This rule may require consistent teaching for some women, while other women simply may not comply which gives way to lower system effectiveness (Scherwitzl et al., 2016).

Two descriptive comparative studies (Duane et al., 2016; Setton et al., 2016) critiqued numerous web and mobile fertility applications on their ability to identify the fertile window. Duane et al. (2016) found that of $N = 39$ applications, 29 were able to predict the fertile window, but only six received a perfect score on accuracy or had no false negatives when fertile days were identified as infertile. These six applications that scored perfectly were Ovulation Mentor, Sympto.org, iCycleBeads, LilyPro, Lady Cycle, and myNFP.net. Applications that did not correctly identify the fertile days were NFP Charting Ovulation, Symptopro, Fertility Pinpoint,

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Kindara, Groove Fertility Pro, FEMM, NFP Project Caruso, Charting App, Lady Time, and Knowhen (Duane et al., 2016).

Several applications that did not perfectly predict the fertile window but recommended training prior to using the application still scored high on accuracy. Notably, NaturalCycles was able to predict the fertile window but was ranked number 15 out of 29 (Duane et al., 2016). Setton et al. (2016) discovered only one website ($n = 20$) and three applications ($n = 33$) which were able to exactly predict the precise fertile window based on a standardized data set. The majority of the websites (74%) and applications (75%) predicted fertile days that were within the actual fertile window. Duane et al. (2016) concluded that most applications are not designed for helping couples avoid pregnancy. Neither are they founded on the precise evidence-based FAB methods from which they may be derived. However, some can still be useful for couples who are experienced in the FAB methods of family planning (Duane et al., 2016).

Achieving pregnancy. Prospective methods of identifying the fertile window are more reliable for couples desiring to achieve a pregnancy. Five studies appraised prospective methods for this intent (Evans-Hoeker et al., 2013; Bigelow et al., 2004; Colombo & Masarotto, 2000; Ecochard et al., 2015; Günther et al., 2015).

Four studies analyzed how the utilization of CMM could impact pregnancy rates (Ecochard et al., 2015; Evans-Hoeker et al., 2013; Bigelow et al., 2004; Colombo & Masarotto, 2000). An observational cohort study by Ecochard et al. (2015) established that among their participants ($N = 107$) from France, Italy, Germany, Belgium, and Spain, cervical mucus observations at the opening of the vagina could be used as a clinical proxy for ovulation. Peak mucus, which is clear, stretchy, or lubricative as opposed to any kind of mucus, was identified as being more specific and identified the fertile window 96% of the time and the ovulation window

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88% of the time (Ecochard et al., 2015). Evans-Hoeker et al. (2013) conducted a time-to-pregnancy cohort study to determine if CMM increased the cycle specific probabilities of conception. They found that among their population of women from the United States trying to conceive without known infertility ($N = 331$), the use of CMM statistically significantly increased the likelihood of pregnancy ($p = 0.02$). As the CMM frequency increased, so did the chance of pregnancy ($p = 0.01$). Overall, 23% conceived in the first cycle and 53% conceived by the sixth cycle. CMM was more likely to occur among women who were younger ($p = 0.01$) and nulligravid ($p = 0.002$). The authors concluded that CMM is more effective for timing intercourse than the calendar method since the beginning of the fertile window is able to be determined prospectively (Evans-Hoeker et al., 2013). Bigelow et al. (2004) findings expound further on this conclusion in their prospective cohort study from Italy, Switzerland, Germany, France, England, and Belgium, stating that pregnancy probability increases with an increased ranking of cervical mucus, with transparent, stretchy, slippery mucus receiving the highest ranking ($p < 0.01$). When intercourse occurs on the day that the highest ranked mucus is present in the six-day fertile window, pregnancy is much more likely to occur without regard to its relation to ovulation. However, the most fertile mucus is most often noted two days before the estimated ovulation day ($p = 0.020$; Bigelow et al., 2004; Colombo & Masarotto, 2000).

Saliva is postulated to be a resource for women to prospectively identify their fertile window and maximize their chances of conceiving (Günther et al., 2015). A prospective comparative study determined that among their voluntary participants from Germany ($N = 74$), the saliva test *Geratherm ovu* was as accurate as LH tests in identifying ovulation and changes 24 hours before LH gives a positive reading. Estrogen, which is responsible for cervical mucus

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changes, is also accountable for the changes in saliva and rises just prior to the LH surge (Günther et al., 2015).

Use of two biologic indicators. FAB methods that use two biologic indicators of fertility as a double check for the beginning and end of the fertile window are more effective than just one. The MM and STM are two methods that combine more than one biologic indicator of fertility (Fehring et al., 2008; Fehring et al., 2009; Fehring et al., 2013; Fehring & Schneider, 2017; Frank-Herrmann et al., 2007; Wade et al., 1981).

Marquette Method. The MM gives women the option of using two biological indicators, consequently, a number of studies have been carried out to ascertain if higher effectiveness rates can be achieved by using CMM, EHF_M or a combination of both methods (Fehring et al., 2008; Fehring et al., 2009; Fehring et al., 2013; Fehring & Schneider, 2017). In a retrospective evaluation from the United States, Fehring et al. (2008) concluded that the additional use of the EHF_M enhances the efficacy of the MM for avoiding pregnancy. Kaplan-Meier survival analysis yielded typical-use pregnancy rates of 9.2 per 100 women at 12 months of use for those who used the EHF_M alone or in combination with BBT and CMM ($n = 99$) and 12.2 for those who did not use the EHF_M at all ($n = 105$; Fehring et al., 2008). Fehring et al. (2009) concluded similarly after evaluating the differences in pregnancy rates between those that utilized EHF_M and CMM or CMM only in their retrospective cohort comparison from the United States. With the Kaplan-Meier survival analysis, they found that the typical-use unintended pregnancy rates were 12.3 for the EHF_M group ($n = 313$) and 22.8 for the CMM group ($n = 313$), a statistically significant difference ($p < 0.05$; Fehring et al., 2009).

On the other hand, two studies (Fehring et al., 2013; Fehring & Schneider, 2017), concluded that EHF_M alone was superior when comparing EHF_M and CMM. In their

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prospective randomized clinical trial from the United States, Fehring et al. (2013) used the Kaplan-Meier survival analysis and calculated the typical-use pregnancy rate as 7 pregnancies per 100 users for the EHFMM group ($n = 289$) and 18.5 for the CMM group ($n = 292$); this is nearly triple those of the EHFMM group ($p < .0048$; Fehring et al., 2013). Fehring and Schneider (2017) utilized a prospective cohort study methodology for their research with participants from the United States and Europe and calculated pregnancy rates with the Kaplan-Meier survival analysis. The typical-use pregnancy rate was 6 per 100 users at 24 cycles of use for the EHFMM alone ($n = 212$), 19 for the CMM only ($n = 118$), and 18 for the combined EHFMM and CMM ($n = 333$). They concluded that simplified and objective methods of identifying fertility with the EHFMM alone seem to be the most effective for avoiding pregnancy (Fehring & Schneider, 2017; Fehring et al., 2013).

Symptothermal Method. Two studies (Frank-Herrmann et al., 2007; Wade et al., 1981) demonstrate that using the STM, which combines at least two biological indicators to identify the fertility window, is effective for avoiding pregnancy. Frank-Herrmann et al. (2007), in their prospective observational longitudinal cohort study, had participants from Germany ($N = 900$) monitor CMM, BBT, and apply a calendar algorithm. Kaplan-Meier survival rates were utilized to calculate a typical-use pregnancy rate of 1.62 per 100 women at 13 cycles of use when abstinence was observed during the fertile window and 2.02 when a barrier method was used during that time. Perfect-use pregnancy rate was 0.43, and the unintended pregnancy rate when there was unprotected intercourse during the fertile window was 7.47 which was statistically significant ($p < 0.00001$). Wade et al. (1981) performed a randomized prospective comparative study in the United States and found that the STM was more effective than the OM. Pearl Index pregnancy rates for 12 months was 34.9 per 100 women-years for the OM ($n = 619$) and 16.6 for

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the STM ($n = 628$). The authors did not try to classify pregnancies into a method or user failure; therefore, these results were not reported (Wade et al., 1981).

Client training. The amount of client training required for the different FAB methods varies from intense training over the course of a year to something that can be instructed quickly during the course of a standard office visit (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999; Fehring et al., 2008; Fehring et al., 2009; Fehring & Schneider, 2017; World Health Organization, 1981; Sinai et al., 2012; Arevalo et al., 2002; Arevalo et al., 2004; Koch et al., 2018, Scherwitzl et al., 2015; Scherwitzl et al., 2016). The CrMS, MM, and OM have varying follow-up structures for clients; however, most cite individual training of at least a year in duration (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999; Fehring et al., 2008; Fehring et al., 2009; World Health Organization, 1981).

The CrMS has an individualized in-depth training program for users which requires a one-hour introductory session and eight follow-up sessions within the first year. The program is standardized and includes follow-up quizzes and a cycle review given at the fourth and sixth follow-up session to review the progression of the cycle (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999).

The MM can also require intense training for users. Training can be conducted in person which involves a one-hour introductory session and five follow-up sessions within the first year (Fehring et al., 2008; Fehring et al., 2009). It can also be taught online. Users are granted access to downloadable charts, protocols, and instructions as well as quick start instructions. They can access forums on the website and receive consultation by NFP teachers, an OB/GYN, and a bioethicist. In this case, there is no set duration of training (Fehring & Schneider, 2017).

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The prospective multicenter cohort study on the OM by the World Health Organization (1981) demonstrated that the method does require training. They noted that many from their study were illiterate or poorly educated and yet 91% of the total participants from New Zealand, India, Ireland, Philippines, and El Salvador ($N = 725$) were able to identify their fertile window by cervical mucus observations (World Health Organization, 1981).

Conversely, the SDM, TwoDay Method, Daysy monitor, and NaturalCycles application are easy to use and require little to no training for users (Sinai et al., 2012; Arvalo et al., 2002; Arevalo et al., 2004; Koch et al., 2018; Scherwitzl et al., 2015; Scherwitzl et al., 2016). The SDM can be taught quickly at an office visit to women with regular cycles ranging from 26-32 days. These women are instructed that their fertile window is from days 8-19 and that they should abstain or use protection on those days (Sinai et al., 2012; Arvalo et al., 2002).

The TwoDay Method is taught by instructing women to ask herself each day if she has noticed any cervical mucus that day or the day prior. If she has, then she should consider herself fertile. If not then her chances of conception are very low. Using life table analysis, the method pregnancy rate in a prospective, nonrandomized, multicenter study of $N = 450$ women from Guatemala, Peru, and the Philippines, was found to be 3.5 per 100 women after 12 months of use and a total pregnancy rate of 13.7 (Arevalo et al., 2004).

Daysy is a fertility monitor that calculates BBT and applies an algorithm to estimate the days of fertility (Koch et al., 2018). Fertile days are displayed by a red light on the monitor, infertile days by a green light, and a yellow light indicates the application is unsure. A retrospective cohort study of current users in Europe of the DaysyView application ($N=798$) found that the use of the application increased the effectiveness of the Daysy device (Koch et al., 2018). Perfect-use 12-month Pearl Index pregnancy rate was 0.753 per 100 women-years, and

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typical-use was 1.252. The combination of the BBT Daysy device with the DaysyView application gives the users the ability to visually see the data which reduces the risk of inaccurate or misinterpretation of data and thereby improves usability and higher accuracy of the device (Koch et al., 2018). Because the device does the calculation itself, it requires virtually no instruction. However, women should be cautioned that to achieve maximal effectiveness, protection or abstinence should be used on days when the application gives a yellow or red light (Koch et al., 2018).

Finally, the NaturalCycles mobile application can be easily taught by instructing a woman to monitor her BBT and input it into the application. The application then tells her whether she is currently fertile or not. She should be instructed that consistent abstinence or protection be used on days the application indicates as fertile (Scherwitzl et al., 2015; Scherwitzl et al., 2016).

Critique of Strengths and Weaknesses

Weakness. This literature review, while comprehensive suffers from many weaknesses. Some of these will be described below including poor study design, variance in statistical analysis, the large variance in pregnancy rates, CrMS study variances, inconsistencies with the MM, and major flaws in the Daysy monitor study.

Poor study design. Unfortunately, research regarding methods for women to identify their fertile window is both limited and inconsistent. Among the research that does exist, the number of RCTs, which is the gold standard for research, is scant. Because of the lack of RCTs, self-selection was seen in the majority of research studies, which increases the bias. Further, the two RCT articles that were included had high discontinuation rates. Fehring et al., 2013 in their prospective randomized clinical trial on the MM had a 59.4% discontinuation rate for the EHF

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group and 63.4% for the CMM group. Wade et al., (1981) in their randomized comparison had a high discontinuation rate as well with 73.7% of OM and 63.6% of the STM group dropping out. The second largest dropout group was from pregnancy with a total of 22.4% of the OM participants and 11.2% of the STM participants dropping out due to pregnancy ($p < 0.01$; Wade et al., 1981).

Variance in statistical analysis. For studies that look at the effectiveness of a certain FAB method, different statistical analysis for calculating pregnancy rates makes it impossible to directly compare studies. Further, they are inconsistent in how they have decided which pregnancies to include as method or user pregnancies which compounds issues in comparison.

Large variance in pregnancy rates. In addition to different statistical analysis, a wide variation in pregnancy rates reported in the studies further confounds evaluation and comparison between the different methods. Even among studies of the same method, a wide variance was found. For the SDM a typical-use pregnancy rate range of 3.4-14.1 was reported (Arévalo et al., 2002; Sinai et al., 2012). The STM method had an even wider range of 1.62-16.6 among typical-use pregnancies (Frank-Herrmann et al., 2007; Wade et al., 1981). Mucus-only methods reported typical-use pregnancy rates between 13.7-34.9 (World Health Organization, 1981; Wade et al., 1981; Arevalo et al., 2004). The CrMS ranges between 2.0-17.12 for typical-use pregnancies and 0.14-1.2 for method-use pregnancies (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999). The MM reported typical-use pregnancies between 2-12.3 (Fehring et al., 2008; Fehring et al., 2009; Fehring & Schneider, 2017). Overall among all studies examined a range of typical-use pregnancies of 1.252-34.9 and a range of correct-use pregnancies of 0.14-4.8 was found.

CrMS study variances. Another challenge is presented when looking at how pregnancies are reported, specifically among the CrMS studies. The cited range among the three articles

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found method-use pregnancy rates to be between 0.14-1.2 and typical-use pregnancy rates as low as 2 per 100 women (Doud, 1985; Fehring et al., 1994; Howard & Stanford, 1999). The CrMS is unique in that it takes into account the couples intentionality in the cycle of conception. If a couple knowingly has intercourse during the fertile window it is categorized as an achieving related pregnancy regardless of whether or not they stated they were achieving or avoiding pregnancy at the beginning of the cycle. This takes into account the reality that couples change their mind and the ability of FAB methods to allow a couple to change their intentions from day to day. None of the other studies utilize this method of calculating pregnancies though, which creates a challenge when trying to directly compare to other studies.

MM inconsistencies. There were also inconsistencies in the findings on the MM which present a challenge in summarizing recommendations. Fehring and Schneider (2017), and Fehring et al. (2013) concluded that the use of the EHF_M alone was an effective FAB method for avoiding pregnancy. This contradicts the earlier conclusions of Fehring et al. (2009), and Fehring et al. (2008) that recommend the EHF_M in combination with CMM and/or BBT increases the effectiveness of the MM because it acts as a double check for the beginning and end of the fertile window. It is not surprising that Fehring et al. (2013) concluded this in their prospective randomized study since the comparison was between CMM alone and EHF_M alone. Naturally, neither conclusion would result in a recommendation to use the EHF_M in combination with another method as this was not being studied. Fehring and Schneider (2017) in their prospective cohort study also concluded that the EHF_M alone was more effective than in combination with other methods. The main difference for this study was that they had an additional comparison group than the other two studies. In this study, they compared the difference between the EHF_M alone, the EHF_M in combination with CMM, and CMM only (Fehring and Schneider, 2017).

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The other two studies (Fehring et al., 2008; Fehring et al., 2009) did not have a separate group for the EHF_M alone but compared between 1) those that used the EHF_M alone or in combination with CMM or BBT, or 2) CMM alone. Together these three studies conclude that the use of the EHF_M in some fashion is superior to a method that does not use the EHF_M.

Flaws in *Daisy* article. It should also be noted that while the study on the *Daisy* monitor reported perfect-use Pearl Index pregnancy rate of 0.753 and a typical-use Pearl Index pregnancy rate of 1.252, the study was quite flawed (Koch et al., 2018). One major weakness of this study was that they excluded all users with less than 13 cycles of use which eliminated all pregnancies that occurred in the first 13 cycles. Further, 64% of users reported concurrent use of another form of contraception which makes it challenging to report the true effectiveness of the *Daisy* monitor alone. Lastly, only 17 of the 798 users were under the age of 20, therefore, generalization cannot be applied to the younger population (Koch et al., 2018).

Irregular cycles. The last weakness found was revealed in the study on the SDM by Sinai et al. (2012) in which close to half of the women were removed from the study due to cycle lengths outside of the 26-32 day range. Hilgers (2002) reports that only 5-12% of women have 28-day cycles and that the average duration of cycles is a range of 25-37 days. While this is similar to the range needed to use the SDM it is slightly broader which could explain why so many women were excluded. This is a challenge for many FAB methods in which women with irregular, long, or short cycles cannot reliably use the method as was revealed in this chapter.

Strengths. There are many strengths to this study which will be demonstrated below. These include the prospective and standardized nature of the majority of the study designs, heterogeneity of the participants, the inclusion of studies for women with irregular cycles, the large variety of methods presented, and the inclusion of studies utilizing technology.

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Prospective and standardized. While only a few studies in this review were randomized controlled trials ($n = 2$), many were prospective studies ($n = 11$), which is stronger than retrospective ($n = 5$), observational ($n = 2$) or descriptive studies ($n = 2$). Further, most had standardized teaching of each method among all participants which help to serve as control by ensuring all participants were taught the same information in the same manner.

Heterogeneity. Among all studies, there was great heterogeneity among participants which assists in making generalized conclusions and recommendations. The studies also included participants from all over the world and from different lifestyles. The diversity of participants gives reassurance that any woman can find a method that can work successfully.

Irregular cycles. The recognition that not all women have regular cycles was demonstrated through the inclusion of studies with women of all cycle lengths. The importance of this is seen through the work of Sinai et al. (2012) on the SDM in which nearly half of the women were removed from the study due to cycle lengths outside of the 26-32 day range. Hilgers (2002) reports that only 5-12% of women have 28-day cycles and that the average duration of cycles is a range of 25-37 days. While this is similar to the range needed to use the SDM it is slightly broader which could explain why so many participants had to be removed. Many studies excluded women for a variety of cycle lengths, therefore it was important to ensure some of the studies appraised in this literature review included women with cycles outside of these ranges.

Variety of methods presented. Another strength which appears in this literature review is the variety of methods available for reproductive-aged women to identify their fertile window. Women are individual and unique with different needs, desires, and preferences. This fact is

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appreciated in the many methods presented to ensure that each woman can find a method that most suits her.

Inclusion of technology. Including studies with modern technology is an additional strength of this review. Several more recent articles were included that looked at the use of mobile applications. This current generation uses and relies frequently on mobile applications. The development of FAB methods that utilize them is relevant and adaptive to changing trends. Therefore, including studies with those methods was necessary to provide the most up to date and relevant research.

Summary

The major findings include an examination of which studies are proven effective for women with regular and irregular cycles. Various studies on mobile applications were reviewed showing that some can be effective but caution should be used. Prospective methods for identifying the fertile window were analyzed with regard to its efficacy for achieving pregnancy. FAB methods that used two biological indicators instead of one were studied. Lastly, the FAB methods that require more intense training versus those that can be taught quickly were reviewed. Further research is needed in this area, preferably with life table analysis so that studies can be compared directly. If possible, rigorous randomized controlled trials should be undertaken to bolster the strength of FAB methods as more women are seeking to use them. In synthesizing the literature for this project, it is not possible to recommend a single method of identifying the fertile window for all reproductive-aged women. However, in Chapter 4 the implications of the current research findings will be analyzed and applied to the research question.

Chapter IV: Discussion, Implications and Conclusions

The purpose of this literature review was to examine methods of self-identification of the fertile window for reproductive-aged women. Identification of the fertile window is highly practical, capable of being utilized to either achieve or avoid pregnancy. Application of the *Johns Hopkins Research Evidence Level and Guide* (Dearholt & Dang, 2012) assisted in the selection and appraisal of the 23 scholarly peer-reviewed articles shown in the matrix. These articles were evaluated on their research methodology, results, strengths, limitations, as well as implications for use in this literature synthesis. This chapter will include a synthesis of the literature and implications for nurse-midwifery practice. Additionally, critical areas of future research will be addressed, as well as integration and application of the HBM framework.

Literature Synthesis & Implication for Midwifery Practice

The research question this review of the literature explores is: What biological indicators and tracking methods are the most accurate in identifying the fertility window for reproductive-aged women? Through the critical appraisal of the literature, a great deal of information and understanding related to the use of the various methods was identified. The variance on which methods are reliable for the length of the cycle, the amount of client training required to learn the method and the differing purposes of why a woman may want to identify her fertile window reveals that there is not one single method that is most effective for all reproductive-aged women. Utilizing the information from the 23 research articles made it possible to develop a decision tree. The diagram shown in Figure 1 provides a useful and meaningful tool which allows providers to counsel and educate women in choosing the method that may be the most appropriate for them.

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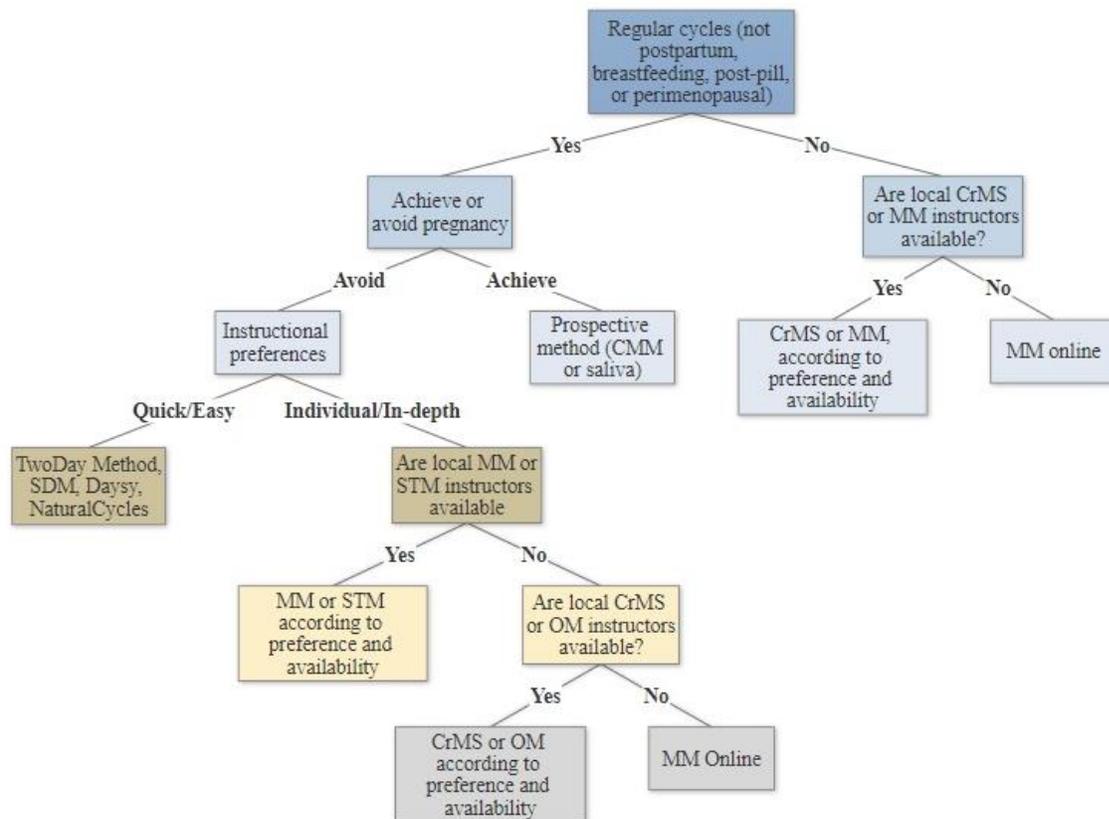


Figure 1. Decision tree for providers to help a woman choose the most appropriate fertility awareness-based method for identifying their fertile window. CrMS = Creighton Model FertilityCare System; MM = Marquette Method; CMM = cervical mucus monitoring; SDM = Standard Days Method; STM = symptothermal method; OM = Billings Ovulation Method.

When helping a woman decide which method will be most suited for her individual needs, four major questions are asked: (1) does she have regular cycles; (2) is she wanting to achieve or avoid pregnancy; (3) what kind of training does she need or want; (4) are local instructors available to teach the preferred or chosen method.

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The first pertinent question to ask is, “does she has regular cycles?” If the answer is yes then the provider should ascertain what intention she has for wanting to identify her fertile window. If it is to achieve pregnancy, she should be directed towards a prospective method that utilizes CMM as the research from chapter 3 revealed (Evans-Hoeker et al., 2013; Bigelow et al., 2004; Colombo & Masarotto, 2000; Ecochard et al., 2015). Monitoring saliva could also potentially be used as a valid prospective method, although only one research article was identified that used this method (Günther et al., 2015).

If she states her intention is to avoid pregnancy than it should be determined if the patient prefers a simple method, able to be utilized immediately, or does she need or desire someone to teach her a method individually. The provider should also use their clinical judgment in helping her choose a method that might be the best suited for her. Such items to consider include whether she seems like she could consistently adhere to an intense regimen that requires daily action, whether she can financially afford the cost of individual training or the cost of some of the devices such as an EHFMM or Daysy monitor. A method may have a high use effectiveness rate, but this implies that it is being used correctly nearly all of the time, therefore, it is the duty of the provider to guide her in choosing the most appropriate method that she will actually be able to carry out in her daily life.

There are several effective methods that can be taught quickly at an office visit. The TwoDay Method relies on the knowledge of the CNM to educate during an office visit as it does not have an application. Additional methods include the Daysy Monitor, and NaturalCycles, both of which are both available on iOS and Android. Finally, the SDM can be utilized through the iOS and Android application iCycleBeads which was proven to be effective by Duane et al. (2016). In-depth and personalized training can be utilized through the CrMS, MM, and OM. The

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articles discussed in chapter 3 do not specifically talk about the training requirements for the STM, but individual training can be obtained in this method through the Couple to Couple League International and Northwest Family Services. Individuals can also read and learn about the STM through various books, websites, and mobile applications on their own, though it should be noted that the two studies that looked at the STM state that the participants were taught the method by instructors (Frank-Herrmann et al., 2007; Wade et al., 1981). Duane et al. (2016) did find four web and mobile applications for the STM that were effective including Sympto.org, and myNFP, which are both available on iOS, Android and the web; Lady Cycle which is only available on Android, and LilyPro which is only available on iOS. Six articles from the critical appraisal of the literature revealed that the MM and STM which use two biological indicators of fertility for identifying the fertile window are more effective than just one. Thus, these methods should be viewed as the first line among the four methods that have individual and in-depth client training as is shown in Figure 1 (Fehring et al., 2008; Fehring et al., 2009; Fehring et al., 2013; Fehring & Schneider, 2017; Frank-Herrmann et al., 2007; Wade et al., 1981). The websites for finding local instructors for the CrMS, MM, OM, and STM can be found in Appendix B. If there are no local instructors for CrMS, MM, OM, or STM, the MM can be utilized through their online platform.

If she does not have regular cycles the two options available to her include the CrMS and MM. The MM studies were inconsistent in what participants they kept in their study from different reproductive categories including post-pill, breastfeeding, and perimenopausal status, therefore, caution should be used with women in these categories (Fehring et al., 2008; Fehring et al., 2009; Fehring & Schneider, 2017). CrMS, however, did not exclude any of these women from their three studies and still demonstrated high effectiveness rates, consequently, it may be

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more prudent for women of these categories to utilize CrMS, if available as the first line. If CrMS local instructors are not available, MM would be a good alternative. If neither CrMS or MM instructors are locally available the MM can be learned entirely online.

The decision tree in Figure 1 can be used by providers to guide patients through the numerous FAB methods thereby offering an informed decision-making process where a woman can choose the method most suited for her needs. This does require a midwife to have knowledge of these methods. It is not necessary for the midwife to be trained in teaching each of these methods but knowledge of how the method works in addition to some of the strengths and weaknesses of each method should be understood. Knowing which methods have local instructors, and having those instructors' contact information, can also be helpful to make the decision-making process more efficient.

Obtaining knowledge on the various methods of FAB is not difficult but it will take self-determination for midwives to learn on their own time. *The Complete Guide to Fertility Awareness* (Knight, 2017) is an excellent resource providing the science and research behind each method as well as the basic instructions of its use. The internet also has countless resources to learn about each method including an abridged version of Knight's book found in an online published chapter by Pyper & Knight (2004) from the book *Gynecology and Obstetrics*. Lastly, Fertility Appreciation Collaborative to Teach the Science (FACTS) is a collaborative project with the goal of providing information on FAB methods within the medical community (FACTS, 2019a). They hold several one-day long conferences each year entitled "Modern Fertility Awareness for Family Planning and Women's Health" to inform medical providers on the newest research and how providers can apply it to their practices (FACTS, 2019b). In addition, their website has thorough explanations, user-friendly handouts, and links to the various

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evidence-based methods (FACTS, 2019a). The links to the websites mentioned above can be found in the reference list.

Recommendations for Future Research

Gaps in current research were identified throughout this review of the literature. The most prominent gaps are the lack of current and adequate research regarding FAB methods of NFP. The research that does exist from the past 10 years has inconsistent results and is of low quality. Grimes et al. (2012) conducted a systematic review of all randomized controlled trials (RCT) of any FAB method used for avoiding pregnancy and only found three trials at that time. Of these trials, high discontinuation rates, poor methods, and poor reporting made determining pregnancy rates impossible. They concluded that the comparative efficacy of FAB methods of contraception remains unknown. Manhart et al. (2013) performed a systematic review of peer-reviewed clinical studies published since 1980 ($N = 29$) that examined the effectiveness of FAB methods to avoid pregnancy. Peragallo Urrutia et al. (2018) in their comprehensive systematic review of $N = 53$ studies on FAB methods for avoiding pregnancy found that evidence for each method is small and many were of low quality. They found that not all studies had correctly calculated perfect-use estimates and could, therefore, not be included in the review. They conclude that women should be cautioned in the method they are using if it has not undergone a standardized prospective effectiveness study, and some have had no studies performed on them at all. Further, with the surge of new internet-based applications, users should be cautioned that though it may be of similar design to a current FAB method, the effectiveness estimates may not apply as modifications could have occurred (Peragallo Urrutia et al., 2018).

Women are becoming increasingly more interested in the hormonal workings of their bodies and many are making an intentional move to living artificial hormone free lives. Research

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needs to reflect this interest, especially as these women may not be seeking FAB methods of family planning for religious reasons as did many of the participants the studies included. Additionally, with the surge of technological advances in the past 30 years, research needs to consider these changes and incorporate more research on FAB methods that utilize technology. It is encouraging that some of the most current research articles explore technological advances, such as mobile applications and medical devices, but further research is urgently needed. Grimes et al. (2012), Manhart et al. (2013), and Peragallo Urrutia et al. (2018) all found that research on FAB methods of family planning are limited, of low quality, and utilize different means of pregnancy classification and analysis making comparison impossible. Future research should include RCTs if possible, and utilize the same method of reporting pregnancy rates, ideally with life table analysis as it has fewer limitations and would then allow pregnancy rates to be directly compared between studies.

Application and Integration of Theoretical Framework

When considering the use of a FAB method to identify the fertile window, the HBM offers a unique way to analyze what is necessary to make it a successful method for each woman by looking at perceived threats, perceived benefits, perceived barriers, and cues to action.

Perceived threats are a major motivation that drives a woman to take the time and effort to monitor her fertility. Two main threats identified in this paper have been either the threat of an unplanned pregnancy or the length of time it may take to conceive a desired pregnancy.

Perceived benefits include the ease of learning a method and its subsequent use, the low-cost of many of the methods, and the high effectiveness rates which are comparable to many of the hormonal contraception options. Perceived barriers encompasses the cost of individualized training, the cost of an EHFEM or Daysy device, the need for consistency of each method to

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achieve maximal effectiveness, the inability to successfully learn a method, the lack of local instructors to teach a method, or the lack of support from a partner. Lastly, cues to action are seen clearly through the external stimuli of providers counseling a patient on FAB methods. Other external stimuli include reminders or notifications from a downloaded mobile FAB method application. Internal stimuli include pondering whether she is fertile or infertile prior to an act of intercourse or the symptoms she notices such as cervical mucus.

The core ideology of the HBM is that women are intelligent and capable of making rational and complex decisions. It is the duty of the midwife to give appropriate information and counsel to help her make those decisions through the incorporation of scientific evidence and informed choice. Knowing what the woman's individual perceived threats, perceived benefits, perceived barriers, and cues to action are, is vital for giving pertinent information related to FAB methods. For example, if her perceived threat is that it will take a great deal of time to conceive it does not make sense for the midwife to provide information on a calendar method as this is not proven to be the most effective method for achieving a pregnancy. If she has limited financial resources it may not be appropriate to counsel on the Daysy monitor as it costs several hundred dollars to purchase. Midwives must be sensitive to the individual needs, concerns, and personality of each woman they see in order to provide them with the necessary tools to carry out their goals for their reproductive life, and the HBM lays a foundation for the midwife to do that precise thing.

Conclusion

The purpose of this review was to investigate the various biological markers and tracking methods that can be utilized for identifying the fertile window in reproductive-aged women. Using the *Johns Hopkins Research Evidence Level and Guide* (Dearholt & Dang, 2012), 23

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scholarly peer-reviewed articles were thoroughly appraised and examined. The articles were scrutinized for their implications into nurse-midwifery practice. The information presented shows the desperate need and opportunity for further research on this topic in order to be relevant to the women of this generation. Integration and application of the theoretical framework showed the crucial elements needed to guide the discussion pertaining to FAB methods. This review will inform CNMs and other healthcare professionals on how to educate reproductive-aged women on the numerous methods of identifying their fertile window and to assist them with choosing the method that will be both satisfying and effective for their current desires.

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Appendix A

Literature Review Matrix

Matrix 1

Source: Scherwitzl, E.B., Hirschberg, A.L., & Scherwitzl, R. (2015). Identification and prediction of the fertile window using NaturalCycles. <i>European Journal of Contraception & Reproductive Health Care</i> , 20(5), 403-408. doi:10.3109/13625187.2014.988210			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To determine if the web and mobile application, NaturalCycles could identify a woman's ovulation day and fertile window to use as a form of natural family planning (NFP)</p> <p>Sample/Setting: Participants recruited from Switzerland and Sweden through advertisements and clinic collaboration that gave advice on birth control. Ages 18 - 40, sexually active, not pregnant, not using another method of birth control, at least 30 days of BBT recorded.</p> <p>Total users selected were 317.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Retrospective investigational pilot study</p> <p>Method: Users input basal body temperature (BBT) and date of menstruation into Natural Cycles application on the phone, tablet or laptop. Luteinizing hormone (LH) test results are optional. Cervical mucus and protected or unprotected intercourse optional. Based on the data algorithm gives either red (fertile) or green (non-fertile) icon each day. Algorithm adapts each month to typically give more green days the more data that is received. Messages sent to remind the user to measure BBT.</p> <p>Instruments: Basal thermometer, LH test strips, NaturalCycles mobile application.</p>	<p>1) 0 pregnancies following unprotected intercourse on green days. 1 pregnancy from unprotected intercourse on a red day before ovulation.</p> <p>2) The study strongly indicates correct ovulation day and therefore, fertile window identified. 0.05% green days falsely attributed during the fertile window.</p> <p>3) Users who used hormonal contraception in the last few months have more red days but increase with continued use. No difference after 3 months.</p> <p>Conclusion: The study shows the ability of NaturalCycles to accurately identify ovulation day and fertile window. Allows a database that can analyze data automatically and interact with participants with real-time messages or notifications.</p>	<p>Strengths: 1) Performed in a real-life environment without training or supervision. 2) Minimal selection criteria generated a good study population.</p> <p>Limitations: 1) Diminished oversight into the quality of recorded data and participants history. 2) No comparison group in design. 3) Self-selection bias 4) No randomization 5) Too small of a sample size to yield valid Pearl Index.</p>
<p>Author Recommendations: A further prospective study with larger sample-size to determine Pearl Index and validate the safety of method and compare to other fertility monitors as well as hormonal contraception.</p>			

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Implications:

While only a pilot study, this study does show good evidence that a simple mobile application can be an effective means for women to monitor their fertility in order to identify ovulation and therefore the fertile window.

Matrix 2

Source: Fehring, R. J., & Schneider, M. (2017). Effectiveness of a natural family planning service program. <i>MCN, The American Journal of Maternal/Child Nursing</i> , 42(1), 43-49. doi:10.1097/NMC.0000000000000296			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: The purpose of the study was to examine the extended use effectiveness of the online nurse-managed Marquette Method (MM), an online system of natural family planning (NFP) in women seeking to avoid pregnancy.</p> <p>Sample/Setting: Total participants selected were 663.</p> <p>Inclusion criteria female, use site to avoid pregnancy, at least 1 cycle of charting, not breastfeeding, and 18 years older. Recruited through an online announcement of the new website in an NFP discussion board for healthcare professionals. Website spread through snow-ball means after that.</p>	<p>Study Design: 24-month Prospective cohort study of a university-based online website</p> <p>Method: Website gave access to downloadable menstrual cycle charts, protocols, instructions on how to observe and chart, instructions on avoiding and achieving pregnancy, and Quick Start Instructions to begin charting immediately. Once registered gain access to online forums and consultation from the MM nurse NFP teachers, an OB/GYN and bioethicist. Daily charting includes sections for charting the menstrual flow, electronic hormonal fertility monitor (EHFM) results, self-observed cervical-vaginal mucus and acts of intercourse. The EHFM and cervical mucus are charted as either low (L), high (H) or peak (P) fertility. After charting the system will automatically indicate the fertile phase based on the information given. EHFM detects rising levels of urinary estrogen to give an indication of high fertility level and detects luteinizing hormone to give an indication of peak fertility level. Cervical mucus monitoring (CMM) instructions were to check daily whenever voiding and at the end of the day and to</p>	<p>1) Correct use unintended pregnancies were calculated to be 1.6 per 100 users at 12 and 24 cycles of use. 2) The total or typical use pregnancy rate was 2 per 100 users at 12 months and 6 per 100 at 24 cycles of use for the EHFM alone. 3) With EHFM and CMM the rates were 18 pregnancies per 100 women over 24 cycles of use and 19 per 100 over 24 cycles with the CMM alone. 4) 70% of unintended pregnancies were reported as a conscious decision to deviate from the instructions to avoid a pregnancy.</p> <p>Conclusion: An online system of NFP developed and managed by nurses can be very effective for a couple wanting to avoid pregnancy. Simplified methods of NFP (EHFM alone) seems to be the most effective means.</p>	<p>Strengths: 1) Not much external control and frequent monitoring unless the participants requested it which more closely simulates a typical-use effectiveness study and how the MM would work in a non-research context. 2) The study did not eliminate women with irregular cycle lengths, short or long cycle lengths, and older women with very irregular perimenopausal cycles, which most NFP effectiveness studies do. 3) Participants represented all 50 states and 5 foreign countries.</p> <p>Limitations: 1) No direct follow-up with participants over the extended time period. It was not recorded whether participants stopped charting or if they continued with paper charts. 2) Results depended upon the participants to be honest in their acts of intercourse, but it's assumed there was underreporting.</p>

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<p>Level of Evidence: III</p> <p>Quality: B</p>	<p>record the mucus and low, high or peak based on the most fertile level of mucus observed that day.</p> <p>Each pregnancy was evaluated by 2 nurse NFP teachers. Correct use pregnancy if no recorded acts of intercourse during the estimated fertile phase. Incorrect use pregnancy if acts of intercourse during the estimated fertile phase or missing data that would not allow the system to determine the fertile phase.</p> <p>Instrument: Swiss Precision Diagnostics (SPD) EHF, CMM, Marquette online web charting system.</p>		<p>3) Women were mostly all well educated (80% with college degrees), Euro-American (85%) and Catholic (93%).</p> <p>4) The EHF is \$200 for the initial purchase and around \$20-40 per month for test strips, which could be a limitation for participants.</p> <p>5) No comparison group in design.</p> <p>6) Self-selection bias</p> <p>7) No randomization</p>
<p>Author Recommendations: Development of a fertility app that is based on the MM system of NFP that can be synced to the web page system to allow more ease and consistency in charting. This app would also include social networking.</p>			
<p>Implications: This study is useful for clinical practice. It shows a simple method of NFP that allows users to monitor their fertility using an EHF. This provides them with an estimation of their own fertile phase, which can be an effective means of avoiding (or achieving) pregnancy. Unfortunately the cost of the EHF might be an issue for some patients.</p>			

Matrix 3

Source: Evans-Hoeker, E., Pritchard, D.A., Long, D.L., Herring, A.H., Stanford, J.B., & Steiner, A.Z. (2013). Cervical mucus monitoring prevalence and associated fecundability in women trying to conceive. <i>Fertility & Sterility</i> , 100(4), 1033-1038. doi:10.1016/j.fertnstert.2013.06.002.			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To see if the use of cervical mucus monitoring (CMM) in women trying to conceive is associated with an increased cycle specific probability of conception.</p> <p>Sample/Setting: A population-based cohort of 331.</p> <p>Women trying to conceive for three months or less, ages 30-44 years without known infertility.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Time-to-pregnancy cohort study.</p> <p>Method: Introduced to the use of an online daily diary to record vaginal bleeding, intercourse, results of testing for the fertile window, and pregnancy test results. Cervical mucus (CM) charted as types 1-4, but no instructions on CMM weren't required to perform CMM and weren't given any other information regarding its use to identify the fertile window. Continue until first positive pregnancy test or 4 months of charting. After 4 months complete diary once per months for up to 12 months or until pregnancy occurred.</p> <p>Instrument: Online daily diary</p>	<p>1) Women who performed CMM in the first cycle were younger ($P=.01$), more likely to use LH monitoring ($P=.01$).</p> <p>2) Women who performed CMM consistently tended by nulligravid ($P=.002$).</p> <p>3) Cycles in which women consistently performed CMM was statistically significantly more likely to result in a pregnancy and showed higher cumulative pregnancy rates compared with cycles were women did not perform CMM ($P=.02$).</p> <p>4) Trend of increasing fecundability with increasing frequency of CMM noted ($P=.01$).</p> <p>5) 23% conceived in the first cycle and 53% by 6 months.</p> <p>Conclusion:</p> <p>1) Use of any CMM (42%) is more common than the use of LH (27%) or BBT (30%) but CMM less consistent than other methods.</p> <p>2) CMM decreases with increasing maternal age</p> <p>3) Increasing consistency of CMM associated with increasing fecundability</p> <p>4) CMM more effective for the timing of intercourse than calendar method since the</p>	<p>Strengths:</p> <p>1) Use of daily diary which helps to minimize recall bias.</p> <p>2) CMM not included in instructions and was reported prospectively before pregnancy.</p> <p>3) A standardized protocol for pregnancy testing increased likelihood and accuracy of outcome reporting.</p> <p>Limitations:</p> <p>1) Lack of information regarding the recruitment process.</p> <p>2) Daily diary could be considered informative since it included the description of CM types.</p> <p>3) Cohort was well educated, lacked women of younger reproductive ages, and only included women early in their attempts to conceive.</p> <p>4) Analysis did not adjust for alcohol or caffeine consumption which could have detrimental effects on fertility.</p> <p>5) No comparison group in design.</p> <p>6) Self-selection bias</p> <p>7) No randomization</p>

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		beginning of fertile window is determined prospectively.	
<p>Author Recommendations: Findings support the need for an RCT of CMM in women of all reproductive ages in general population.</p>			
<p>Implications: Identifying the fertile period through means of CMM significantly increases a couple's chances of conception. Understanding this and being able to offer this to patients is a vital tool for a midwife in assisting them in achieving their reproductive goals.</p>			

Matrix 4

Source: Scherwitzl, E.B., Danielsson, K.G., Sellberg J.A., Scherwitzl, R. (2016) Fertility awareness-based mobile application for contraception. <i>European Journal of Contraceptive Reproductive Health Care</i> , 21(3),234-241. doi:10.3109/13625187.2016.1154143.			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: The purpose of the study was to determine the mobile-based application called Natural Cycles used in conjunction with a basal thermometer is effective for women wanting to avoid pregnancy</p> <p>Sample/Setting: Total of 4054 women. Recruited from women who had registered to use the Natural Cycles mobile-based application to avoid pregnancy. Aged 18-45 from Sweden. Participants had to have had the app for 3 months, enter data for at least 20 days, be at least 18 years old and not planning conception during the study.</p>	<p>Study Design: Retrospective observational study</p> <p>Method: the mobile app requires documentation daily basal body temperature (BBT) and date of onset of menstruation, luteinizing hormone test results are optional. Information can be input on a smartphone, tablet or computer. The algorithm gives days as either red (unsafe) or green (safe) for intercourse to avoid pregnancy. Green days are given in a conservative manner usually more red days per cycle than the empirical value of 6. 0.05% probability of a green day given in error of the fertile window. The algorithm uses previous cycles and data to give future predictions in subsequent cycles. The app generates reminders to record temperatures and use protection on fertile days.</p> <p>Pregnancy was determined by user's data and by online questionnaires.</p>	<p>1) Method Failure: Green day is given in the fertile window in a cycle where a pregnancy was identified - regardless of if she had charted intercourse or unprotected intercourse during a red day later during the cycle. 2) 34% of women discontinued the application prior to the end of the study. 3) A Pearl Index of 7.0 was given for typical use. Pearl Index score of 0.5 for method failure, or perfect-use. 4) Of the 143 cycles where pregnancy did occur, 51% of women reported unprotected intercourse during the fertile window and only 3% reported protected intercourse.</p> <p>Conclusion: 1) Natural Cycles as a contraception proves to have a good algorithm with only 0.05% probability of a green day being falsely attributed to the fertile window and the Pearl Index for perfect-use at 0.5 confirms that green days are considered highly safe days. The perfect use rate is comparable to other similar devices and for the STM. 2) The Pearl Index of 7.0 for typical use pregnancies are significantly lower than other fertility awareness-based methods which have Pearl Index rates of 24.0. The main reason for these typical use</p>	<p>Strengths: 1) Loose inclusion/exclusion criteria which allowed the study participants to represent the general population of women. 2) Because pregnancy status could be directly determined by data from the application this lowered the amount of recall bias that may be present in other studies. 3) Pregnancy status could be determined for 98.5% of participants meaning the retention bias was low and follow-up rate high. 4) Large sample size</p> <p>Limitations: 1) Short duration. The study ended less than 5 months after the last participant was recruited meaning the average cycles per user was low at only 6.3 cycles. 2) Expected one-year discontinuation rates were 56% which is similar to other fertility awareness-based methods, but worse than oral contraception or long-acting reversible contraception. 3) No incentives and the contraception was not</p>

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<p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Instrument: Natural Cycles mobile application, basal thermometer, LH tests. An online questionnaire that answering if they became pregnant was a mandatory answer but had other questions included as well.</p>	<p>pregnancies was reported to be a conscious deviation from abstaining or using some sort of protection on fertile days.</p> <p>3) A low number of green days (<50%) did lead to higher dropout rates for users.</p> <p>4) Surveys at the end showed a very high satisfaction by users at 83%, although only 30% completed the survey.</p>	<p>free which could negatively impact continuation rates.</p> <p>4) Since intercourse was not a mandatory item to log, a calculation of perfect/imperfect-use could not be made.</p> <p>5) Participants were women from ages 20-35 which means the results can not be generalized to other age groups such as teenagers.</p> <p>6) Self-selection bias</p> <p>7) Not randomized</p> <p>8) No comparison group</p> <p>9) Effectiveness measured in Pearl rates which has more limitations than life table analysis</p>
<p>Author Recommendations:</p> <p>Further studies with longer time span and be prospective. Authors are interested in performing a randomized, prospective clinical trial that would more closely compare it to combined oral contraceptive pills which would yield a Pearl Index with less selection bias. They would also like to compare the effectiveness and user experience of Natural Cycles with other fertility awareness-based methods and hormonal contraception.</p>			
<p>Implications:</p> <p>Users were very satisfied with the method. It seems to be an improvement on traditional fertility awareness-based methods as it does not require subjective assessment, which removes failure due to human error. Because abstinence or consistent protection needs to be used during the red days, consistent teaching needs to be done for users. Thus it may not be a good system for those who will not comply with that rule. Overall, it could be a reasonable choice for women wanting a natural system with a 7.5% pregnancy rate over 12 cycles.</p>			

Matrix 5

Source: Fehring, R. J., Schneider, M., Raviele, K., Rodriguez, D., & Pruszynski, J. (2013). Randomized comparison of two internet-supported fertility-awareness-based-methods of family planning. <i>Contraception</i> , 88(1), 24-30. doi:10.1016/j.contraception.2012.10.010			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To compare two internet-supported fertility awareness-based methods (FABM) of natural family planning (NFP) to determine which is more effective and acceptable in avoiding pregnancy.</p> <p>Sample/Setting: 667 couples selected and randomized.</p> <p>Participants recruited through online ads, list serves, and fertility blogs and social networking sites. between ages 18-42, regular cycles between 21-42 days, no history of hormonal contraception for the past 3 months, at least 3 cycles since breastfeeding weaning. Male partners with no known fertility problems between 18-50 years old.</p> <p>Level of Evidence: I</p> <p>Quality: B</p>	<p>Study Design: 12 month (13 cycles) prospective randomized clinical trial</p> <p>Method: Couples randomized by computer generation. Electronic hormonal fertility monitor (EHFM) group or cervical mucus monitoring (CMM) group.</p> <p>EHFM group received Clearblue Easy Fertility Monitor (CBFM) and instructed to push button M on the first day of the period. 10-20 daily urine tests performed and monitor displays either, “low,” “high,” or “peak” fertility. Results recorded on electronic fertility chart in addition to all acts of intercourse and all days of menstrual bleeding.</p> <p>CMM group instructed to think about how the mucus felt, look at mucus when going to the bathroom and at bedtime and check every day and chart most fertile mucus observed in the electronic fertility chart.</p> <p>Online charting indicated a fertile phase in light blue based on the</p>	<p>1) Pregnancies intentional only when couple stated using to the method to achieve. Perfect use (method) failures when couples followed instructions. All others were user failures.</p> <p>2) Final participant numbers were 197 in the EHFM group and 160 in CMM group.</p> <p>3) Perfect use: 0 pregnancies per 100 for the EHFM group and 2.7 per 100 for the CMM group.</p> <p>4) Total pregnancy rate was 7 for EHFM group and 18.5 for the CMM group.</p> <p>5) The rate of pregnancy in mucus group 2.96 times that of monitor group ($p < .0048$).</p> <p>6) Continuation rates at 12 months were 40.6% for EHFM group and 36.6% for CMM group. Reasons for discontinuation were, “lost to follow up,” “no longer interested,” and “wishing to achieve pregnancy.”</p> <p>Conclusion:</p> <p>1) Online charting system with the use of the EHFM method of NFP compared to CMM is more effective.</p> <p>2) EHFM provides objective measures of</p>	<p>Strengths:</p> <p>1) Randomized 2) Good sample size 3) Comparison group</p> <p>Limitations:</p> <p>1) High discontinuation rates limit the generalization of results. 2) Study participants mostly homogenous: white, middle class, educated couples. 3) A monetary incentive for turning in charts</p>

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	<p>algorithm and instructed to avoid all genital contact on all days of the fertile window.</p> <p>All pregnancies confirmed by three professional nurse FABM teachers</p> <p>Instruments: CBFM, electronic fertility chart</p>	<p>fertile window compared to CMM.</p>	
<p>Author Recommendations: Future studies using an online system to compare other FABM like the Standard Days method or the Two Day Method, or other older calendar-based formulas. Also could use this information to enhance subfertility.</p>			
<p>Implications: This study is useful to clinical practice, showing that a more simple method of a FABM which allows users to objectively monitor their fertility with an EHFm provides them with an estimation of the fertile phase, This can be an effective means of avoiding pregnancy. Additionally, because it is a randomized clinical trial it can more reliably be trusted and applied to practice.</p>			

Matrix 6

Source: Setton, R., Tierney, C., & Tsai, T. (2016). The accuracy of web sites and cellular phone applications in predicting the fertile window. <i>Obstetric Gynecology</i> , 128(1), 58-63. doi:10.1097/AOG.0000000000001341			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Examine the validity of fertility websites and apps that are used by patients to assist with conception, by comparing predicted fertile window to the actual fertile window of a standard 28-day cycle.</p> <p>Sample/Setting: No human subjects. Google search, Google play app search and Apple's App store for "ovulation calendar" and "fertility calendar." Top 20 websites and 33 apps were chosen. 7 apps repeated on Google Play and Apple iOS.</p> <p>Level of Evidence: III</p> <p>Quality: B</p>	<p>Study Design: Descriptive comparative study of web and mobile fertility applications</p> <p>Method: Last menstrual period of January 1, 2015. If prompted given info that cycle length was 28 days and 4-day long period. The fertile window and predicted date of ovulation generated by site were recorded. Predicted dates of ovulation compared with the assumed actual date of ovulation (cycle day 15). Fertile window compared with the assumed fertile window of the 5 days before ovulation (cycle days 10-15).</p> <p>Instruments: Top 20 free website and apps for ovulation and fertility calendars.</p>	<p>1) If cycle day 15 chosen for ovulation, the app or website deemed accurate. Inaccurate if any other day was chosen. If cycle days 10-15 chosen for the fertile window, then considered accurate.</p> <p>2) Some calendars did not specify a single day for ovulation. 10 websites and 23 apps gave predicted day of ovulation. 8 of the websites and 20 of the apps were correct in giving cycle day 15 as predicted day.</p> <p>3) Only 1 website and 3 apps predicted the precise fertile window of cycle days 10-15. 5 website and 5 apps gave windows that included some of the actual fertile window days, but not all 5 of them. 15 websites and 26 apps had fertile windows that contained days after ovulation.</p> <p>4) 74% of all predicted fertile days by the website and 75% of all predicted fertile days by app were within actual fertile window.</p> <p>Conclusion: The study showed that website and apps are generally inaccurate and unreliable at predicting the actual fertile window and</p>	<p>Strengths: 1) Simplicity that each app or website was given the same information to give a simple conclusive look at how that system uses that information to yield a fertile window and predicted day of ovulation.</p> <p>Limitations: 1) Only top 20 free websites and 33 apps used. 2) Search terms were limited, other search terms may have yielded different results may result in a researcher selection-bias 3) Actual names of applications not listed which makes it difficult to make recommendations.</p>

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		day of ovulation. Only 4 were exactly accurate.	
<p>Author Recommendations: Further studies to assess the clinical effectiveness of websites and apps by reviewing actual pregnancy rates in patients who use them. Also should look in these studies if the predicted fertile window and ovulation are based on the menses lengths.</p>			
<p>Implications: While only a descriptive study and not clinical or cohort study, this is a good report to give caution to the various apps and websites that the general population has access to. Specifically they all seem to use different algorithms, but these algorithms may not be based on scientific research. This is important information to give to patients who may be accessing them and relying on them for their fertility needs.</p> <p>For women with regular cycles prediction of the fertile window from these applications should be used with caution. If wanting to use for achieving pregnancy, many of the applications counsel intercourse on days that are not actually fertile, including days after ovulation which is known to be infertile. This is especially true if couple abstains for several days prior to the fertile window to increase sperm count and the identified day may be too early to be conducive to conception.</p> <p>As a provider, it may be helpful to counsel patients that other methods of fertility identification are more reliable and backed by scientific research (ie. ovulation test strips or symptom monitoring).</p>			

Matrix 7

Source: Günther, V., Bauer, I., Hedderich, J., Mettler, L., Schubert, M., Mackelenbergh, M. T., . . . Alkatout, I. (2015). Changes of salivary estrogen levels for detecting the fertile period. <i>European Journal of Obstetrics and Gynecology and Reproductive Biology</i> , 194, 38-42. doi:10.1016/j.ejogrb.2015.08.007			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To see if the saliva test, <i>Geratherm ovu</i> control as accurate as luteinizing hormone (LH) tests for identifying ovulation.</p> <p>Sample/Setting: 74 voluntary participants.</p> <p>Females with regular cycles (25-35 days) and not using any hormonal contraception or intrauterine devices, not pregnant or breastfeeding.</p> <p>Level of Evidence: III</p> <p>Quality: C</p>	<p>Study Design: Prospective comparative study</p> <p>Method: Geratherm ovu control, a small plastic handheld microscope used in morning or afternoon at least 3 hours after eating, drinking, smoking or brushing teeth. A drop of saliva placed on the lens of a microscope, ready to view in 10-15 minutes. 3 possible results were dot pattern and lines indicating no ovulation, small ferning pattern or crystals with the spots and lines which indicates ovulation in the next 3-4 days and ferning which indicates ovulation is about to happen or just happened. Test performed cycle days 5-22 and record not fertile, transitional or fertile on a table.</p> <p>The EXACTO urinary LH tests done at the same time advised not to drink 2 hours before to concentrate urine, but morning urine not permitted because too highly concentrated. Test positive when line visible both in control and test window</p>	<p>1) LH sharply rises on the 10th day with max on 17th day and plateau till 18.5th day of the cycle and then sharp decline till 22nd day.</p> <p>2) Positive saliva curve almost parallel with LH curve, max on the 16th day.</p> <p>3) Max positive saliva was on 16th day and 17th day for LH because of estrogen peaks before LH peaks.</p> <p>Conclusion: Saliva and LH tests both detect fertile window of the menstrual cycle. Because saliva changes are from estrogen, saliva will be positive 24 hours before LH.</p> <p>LH. Consequently, the saliva test can be used as an ovulation test and help women maximize their chances of conceiving. There is also a high congruence between LH and saliva in the pre- and post-ovulatory period, indicating that the saliva test can also be used for contraception purposes.</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) User-friendly, inexpensive test 2) All participants reported data <p>Limitations:</p> <ol style="list-style-type: none"> 1) Small sample size 2) Short study period 3) Self-selection bias 4) Not randomized 5) No comparison group 6) Lack of information regarding the recruitment process.

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	<p>meaning ovulation will take place in the next 24-36 hours. If positive, test repeated after 6-8 hours to prove ovulation.</p> <p>Instruments: <i>Geratherm ovu</i> control and EXACTO test for urinary LH.</p>		
<p>Author Recommendations: One day difference in changes in hormones are advantages of saliva test that can identify fertile period earlier.</p>			
<p>Implications: This test is cheap, easy to use for women at home, and can identify the oncoming fertile period 1 day sooner than LH tests. This can be advantageous for both achieving and avoiding pregnancy. However, there are many things that could change the saliva content, such as meds and hydration status, which could falsely change the results and make it less accurate.</p>			

Matrix 8

Source: Fehring, R. J., Schneider, M., Barron, M. L., & Raviele, K. (2009). Cohort comparison of two fertility awareness methods of family planning. <i>The Journal of Reproductive Medicine</i> , 54(3), 165-170. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/19370902			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: The purpose of the study was to determine if the electronic hormonal fertility monitor (EHFM) combined with cervical mucus monitoring (CMM) is more effective than CMM alone in avoiding pregnancy.</p> <p>Sample/Setting: Total participants were 638.</p> <p>Women who wanted to learn how to use a method of fertility awareness-based method (FAM) of natural family planning (NFP) to avoid pregnancy in Saint Augustine, Florida; Atlanta, Georgia; St. Louis, Missouri; and Milwaukee, Wisconsin.</p> <p>18-44 years, no known fertility issues, no hormonal contraception in last 3 months</p> <p>Level of Evidence: III</p>	<p>Study Design: Retrospective cohort comparison</p> <p>Method: 315 taught EHFM aided method of NFP. 318 taught CMM only FAM. 1 hour intro session, monthly individual follow-up for the first three months and follow-up after until the couple assessed to be able to use the method autonomously. Taught to track and chart natural fertility indicators including self-observation of cervical mucus only or cervical mucus with the info collected from the EHFM that measures urinary levels of both estrogen and LH.</p> <p>For CMM only FAM, the start of the fertile window was present of cervical mucus. for EHFM beginning was either cervical mucus or “high” reading on the monitor, whatever was first.</p> <p>End of the fertile window for CMM only was 3 full days past the last observation of peak mucus and end of the fertile window for</p>	<p>1) 12-month correct use unintended pregnancy rate for EHFM group 2.0% and for CMM group was 2.8%. The 12-month total pregnancy rate for EHFM group 12.3% and for CMM was 22.8%.</p> <p>2) In reduced data set for regular cycles only (N=413), 12-month correct use unintended pregnancy rate for EHFM was 2.3% and 3.0% for the CMM group. The total unintended pregnancy rate for EHFM was 12.0% and for CMM group was 23%</p> <p>3) The significant difference in total unintended pregnancies between two groups ($p < 0.05$).</p> <p>Conclusion: FAM that uses 2 biologic indicators (CMM + EHFM) of fertility as a double check for beginning and end of the fertile window is more effective than just one (CMM alone).</p>	<p>Strengths:</p> <p>1) Different groups were very similar, other than a significant difference in age (>80% white, Catholic, at least high school education and middle to upper socioeconomic class). But similarities helps to be confident in the results that there were no other factors contributing to the differences in the unintended pregnancy rates.</p> <p>2) Good sample size</p> <p>3) Taught the methods prospectively and was standardized among participants</p> <p>Limitations:</p> <p>1) Significantly older mean age in EHFM group compared to CMM which could mean that the older females in EHFM were more consistent with the use of FAM as they may have completed their families already. Additionally, there is a decline in fertility after age 35, so the slightly older age in the EHFM could have aided the method results.</p> <p>2) No randomization</p> <p>3) Self-selection bias</p>

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Quality: A	EHFM was 3 full days past last observation of peak mucus or peak reading on the monitor, whichever came last. Instruments: ClearBlue Easy Fertility Monitor		4) No comparison group
Author Recommendations: Verification of these findings by randomized, controlled trial.			
Implications: Using both EHFM and CMM can be a good double check for women to confirm the days of their fertile window. CMM alone can be a confusing biological marker for women to observe, but with combination with the EHFM, which is subjective, it can lead to a more effective system.			

Matrix 9

Source: Sinai, I., Lundgren, R. I., & Gribble, J. N. (2012). Continued use of the Standard Days method. <i>Journal of Family Planning & Reproductive Health Care</i> , 38(3), 150-156. doi:10.1136/jfprhc-2011-100097			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Examine long-term effectiveness of the Standard Days Method (SDM), especially with the effect of cycle irregularity on continuation in second and third years of use.</p> <p>Sample/Setting: Data used from two sources: SDM efficacy trial followed for 13 cycles, this study followed them for 2 more years past initial study period.</p> <p>1659 total participants.</p> <p>Women in Bolivia, Peru and the Philippines who previously participated in the efficacy trial.</p> <p>Introduction studies from Benin, Ecuador, Honduras and two sites in India asked to participate in long-term studies, 468 continued to long-term studies, 91 completed year 3.</p>	<p>Study Design: Long-term prospective cohort study.</p> <p>Method: SDM works best for women with cycle ranges of 26-32 days. Fertile window is from days 8-19 for every use, every cycle. To avoid pregnancy users avoid unprotected intercourse during these days.</p> <p>After initial studies ended, follow up interviewed at 3,6,12,18 and 24 months. Each follow-up standard questionnaire to find out if they were still using SDM and what their satisfaction was and if there were any problems. Self-reported pregnancies and pregnancy eval were given to determine if it was planned or unplanned.</p> <p>Providers withdrew participant if they had 2 cycles outside of range during the 1-year study period.</p> <p>Instruments: Calendar for recording menstrual cycles. Coital logs for efficacy study.</p>	<p>1) In the long-term follow up it was not known if the method was used correctly in the cycle where pregnancy occurred or if unprotected intercourse occurred during the fertile window.</p> <p>2) Typical use pregnancies from efficacy study: -12.0% after year 1 -5.2% after year 2 -3.4% after year 3.</p> <p>3) Typical use pregnancies for method introduction studies: -14.1% after year 1 -3.7% after year 2 -5.9% after year 3.</p> <p>Conclusion: SDM method compares to other user-directed methods such as condoms after 1 year but effectiveness is much better in the second and third year compared to other methods. However, it does require cycle regularity of 26-32 days.</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Closely resembled regular service delivery conditions without intense follow up of efficacy study. 2) Large sample size over a diverse patient population to generalize to the population 3) High continuation rates (67%) <p>Limitations:</p> <ol style="list-style-type: none"> 1) Underreporting of out-of-range cycles and pregnancy tests since follow up was every 3-6 months and no calendar or coital logs were required to be kept. 2) A decision to do long-term study was made after some of the method introduction studies ended so with some participants there were less than 3 years contributed to the study. 3) Not randomized 4) No comparison group

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<p>Level of Evidence:III</p> <p>Quality: A</p>			
<p>Author Recommendations: There were methodological limitations which makes the results approximations. No future studies are planned or suggested though.</p>			
<p>Implications: The simplicity of this system could be very appealing, especially for patients with historically regular and consistent cycles. Its ease in learning would make it a simple family planning option for a midwife to offer to a patient at the time of an appointment. This can also provide a bridge to other more modern family planning methods.</p>			

Matrix 10

Source: Ecochard, R., Duterque, O., Leiva, R., Bouchard, T., & Vigil, P. (2015). Self-identification of the clinical fertile window and the ovulation period. <i>Fertility & Sterility</i> , 103(5), 1325.e3. doi:10.1016/j.fertnstert.2015.01.031			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To determine the sensitivity and specificity of the self-identified fertile window through observation and testing of cervical mucus, basal body temperature, hormone studies, and ultrasounds.</p> <p>Sample/Setting: Total of 107 patients.</p> <p>Recruited from 1996-1997 from 8 natural family planning (NFP) clinics in France, Italy, Germany, Belgium, and Spain. Aged 19-45, with previous cycles of 24-34 days. Excluded if a runner, breastfeeding or postpartum of less than 3 months. See pg 1320 for a full list of exclusion criteria</p> <p>Level of Evidence: III</p> <p>Quality: B</p>	<p>Study Design: Observational cohort study of the biological markers of ovulation.</p> <p>Method: Cervical mucus (CM) assessed 2-3x/day. A recorded sensation of dry, moist, wet and slippery; an appearance of white/yellow and clear; consistency of tacky, creamy and stretchy. Given a 4 point score with peak mucus being 4 points given to wet, slippery sensation with or without an appearance of clear, stretchy mucus. Last day of peak mucus is peak sign and fourth day after peak sign beginning of the postovulatory phase.</p> <p>Basal body temperature (BBT) taken daily when waking before activity. Recorded in the chart with date, cycle day and anything that could affect temperature. Third consecutive day of high temp above coverline considered the start of the postovulatory phase.</p> <p>Serial transvaginal ultrasounds (TVUS) with follicle measurements performed by a single physician per center. TVUS began the first day</p>	<p>1) Biological Fertile Window (BFW) based on TVUS identified day of ovulation is 6-day period and includes the ultrasound-identified day of ovulation.</p> <p>2) Ovulation window (OW) is the last 2 days of BFW from TVUS which includes the day before and day of ovulation.</p> <p>3) Mean duration of the clinical fertile window (CFW) 11 days.</p> <p>4) All 6 day of BFW included within the mucus-mucus CFW in 69% of cycles, 72% of mucus-BBT CFW and 6% of peak mucus CFW.</p> <p>5) All 2 days of OW included in mucus-mucus CFW in 98% of cycles, 99% of mucus-BBT CFW and 58% of peak mucus clinical window.</p> <p>6) LH and FSH not completely correlated with mucus observed before ovulation. But both E1-3-G and PDG significantly ($P < .05$) correlated with mucus observed. E1-3-G with mucus before and after ovulation and PDG with mucus immediately before and after ovulation. The ratio of E1-3-G/PDG correlated</p>	<p>Strengths:</p> <p>1) Good sample size 2) A heterogeneous group that is able to generalize to the general population. 3) Good review of the literature.</p> <p>Limitations:</p> <p>1) Peak symptoms only available in 67% of cycles which limited the total number of cycles that could be observed. 2) Recruiting techniques are not described. 3) No randomization 4) No comparison group 5) An extensive amount of data points for each participant to do which may have been why the completed cycles of data were not very high.</p>

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	<p>CM observed or LH surge on LH home test, whichever came first. Performed every other day until follicle 16mm and then daily until evidence of ovulation. Estimated day of ovulation determined by the day of max follicular enlargement and then next day evidence of rupture.</p> <p>Daily first-morning urine collected for quantitative analysis of estrone-3-glucuronide (E1-3-G), pregnanediol-3alpha-glucuronide (PDG), LH and FSH.</p> <p>Instruments: A daily chart for recording. Basal body thermometer, TVUS, LH tests.</p>	<p>with mucus changes to a greater degree.</p> <p>Conclusion: 1) Peak mucus can be very useful for identifying both BFW and OW. Identification of any kind of mucus is perfectly sensitive but not specific as the mean average days of fertility was 11. Suggest use of peak-mucus instead which gives fertile window 96% of the time and OW 88% of the time if using to achieve pregnancy. 2) In a clinical setting, giving couples instruction on observing CM at the vulva as a clinical surrogate marker of ovulation may be effective at identifying ovulation.</p>	
<p>Author Recommendations: More research to correlate with cycles outside of the 25-32 day cycles. Higher motivation needed for women to be more rigorous in observations.</p>			
<p>Implications: This article points out the difference between which method of observation is most useful for identifying the BFW and OW. A tool that has higher specificity such as peak-mucus observations would be good to suggest to couples trying to conceive whereas a mucus-mucus observation is more sensitive to suggest to couples wanting to use it to avoid pregnancy.</p>			

Matrix 11

Source: Fehring, R. J., Lawrence, D., & Philpot, C. (1994). Use effectiveness of the Creighton Model Ovulation Method of natural family planning. <i>Journal of Obstetric, Gynecologic, and Neonatal Nursing</i> , 23(4), 303-309. doi:10.1111/j.1552-6909.1994.tb01881.x			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: The purpose is to determine what the use effectiveness is of the Creighton Model ovulation method in both avoiding and achieving pregnancy.</p> <p>Sample/Setting: The total population of couples was 242.</p> <p>323 couples enrolled in Marquette University Nursing Center natural family planning (NFP) program from October 1984 to May 1992. After removing some who were taught only for fertility awareness, were infertile, using condoms during fertile periods, and pregnant at the time of introductory session 242 couples remained. 2,284 cumulative months of use. Couples excluded if infertile, used condoms during the fertile time, or pregnant at onset.</p>	<p>Study Design: Prospective descriptive cohort study</p> <p>Method: All 242 couples taught the Creighton Model which includes an hour-long introductory session, 8 follow-up sessions in the first year (first four every 2 weeks, fifth 1 month later, then every 3 months after). The model has a rigorous teacher training program. Program standardized with 26-page follow-up form, picture dictionary of terminology and observations, user manual and case management book for the teacher. At 4th and 6th follow up couples given a true or false quiz to review knowledge and a review of the progression of the cycle. Every pregnancy evaluated with a pregnancy evaluation within the first 3 months of pregnancy.</p> <p>Instruments: Fertility chart, fertility monitoring stamps.</p>	<p>1) 65 pregnancies in the 242 couples during the 12 months. 2) Method effectiveness for avoiding pregnancy 0.0 per 100 couples (100%) at 1st month, 0.4 (99.6%) at 6th month and 1.2 (98.8%) at 12 months. 3) Use effectiveness for avoiding pregnancy was 0.0 per 100 couples (100%) at first month, 1.2 (98.8%) at 6th month and 2.0 (98.%) at 12 months. 4) Use effectiveness for achieving pregnancy was 13.6 per 100 couples at 6 months and 24.4 at 12 months. 5) Discontinuation rate of 20.2%, 17.4% for personal reasons, 1.2% to use artificial method, 0.8% due to difficulty avoiding genital contact, 0.4% switch to another natural method, 0.4% lacked confidence in the method.</p> <p>Conclusion: 1) Rates similar to those obtained in 3 previous studies of the effectiveness of the Creighton Model. The range of method effectiveness at 12 months from studies 98.8-99.9%. 2) Use effectiveness at 12 months from all 4 studies 94.8-98.0%. The higher percentage in this study,</p>	<p>Strengths: 1) All taught by teachers who went through the program so each couple taught in the same exact manner. 2) Results matched up with previous studies and could be compared. 3) Prospective design. 4) Not excluded if had cycles other than regular. 5) 80% continuation rate.</p> <p>Limitations: 1) Small, homogenous sample. Mostly college educated, white and Roman Catholic. 2) Self-selection bias 3) Not randomized 4) No comparison group 6) Pregnancy rates classified according to Creighton model classification which does not count pregnancies that were unplanned/unintended if the user had correct information on how to use the system but decided not to use it according to their original intent (achieving-related pregnancy)</p>

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<p>Level of Evidence: III</p> <p>Quality: B</p>		<p>attributed to improving training programs for teachers as years go by.</p> <p>3) Creighton Model is an effective method of NFP and is continuing to be more effective as time goes by.</p> <p>4) During 1-year period 1 out of 5 couples stop using the method to avoid and adopt the method to achieve pregnancy. 4 of 5 of those will conceive. Use effectiveness for achieving pregnancy of 4 studies over 12 months ranges from 13.1-24.4.</p>	
<p>Author Recommendations: Additional research should include larger numbers and more diverse populations. Additional qualitative research should also be done in the decision-making processes and behaviors couples use when planning a pregnancy. Other studies should be done with other forms of NFP to make comparisons, but the NFP method must be standardized in the same manner as Creighton in order to make true comparisons.</p>			
<p>Implications: This method can be confidently recommended with its high effectiveness rates in avoiding pregnancy and teaches couples on any given day when they are fertile or infertile. If they have intercourse on a day of fertility they are abandoning the method as a means of avoiding pregnancy and adopting the method as a means of achieving pregnancy.</p>			

Matrix 12

Source: 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. <i>Human Reproduction</i> , 19(4), 889-892. doi:10.1093/humrep/deh173			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To calculate the day-specific probabilities of pregnancy and to determine if the probability increases with the successive increase ranking of cervical mucus.</p> <p>Sample/Setting: Total participants were 782.</p> <p>Data was taken from European Study of Daily Fecundability which recruited participants from 1992-1996. Women from 7 European centers providing natural family planning (NFP) and fertility awareness services. 18-40 years old, at least one menses after cessation of breastfeeding or delivery, not taking any hormones affecting fertility, no history of fertility problems, and required not to use any sort of barrier method.</p> <p>Level of Evidence: III</p>	<p>Study Design: Prospective cohort study</p> <p>Method: Women kept a daily diary of basal body temperature (BBT), cervical mucus and intercourse. Cervical mucus scored from 1 (no discharge and dry) to 4 (transparent, stretchy, slippery). BBT was kept to estimate the day of ovulation (last day of hypothermia, an accurate marker of ovulation day).</p> <p>Instruments: Basal body thermometer.</p>	<p>1) Cycles excluded if insufficient BBT data to determine ovulation, no reported intercourse during fertile window, days in the fertile window which there was intercourse but no recorded mucus observation. Started with 6,724 menstrual cycles with 487 pregnancies and after removing those listed ended with 1,473 cycles with 353 pregnancies.</p> <p>2) An increasing trend of pregnancy probability with increases in mucus score - a consistent steady increase in probability with each increasing unit of mucus score ($p < 0.01$).</p> <p>3) Probability higher when intercourse occurred on any day with type 4 mucus in the 6-day fertile window rather than timing related to ovulation.</p> <p>Conclusion: Pregnancy is much more likely to occur when the most fertile mucus is present in the 6-day fertile window, irrespective on when that occurs in relation to ovulation. Although, the most fertile mucus is most prevalent 2 days before the estimated ovulation day.</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Large sample size 2) A diverse population which gives better generalization to the general population. 3) Data collected prospectively 4) Relatively simplistic mucus categorization made it easy to learn and yielded a high return of data. <p>Limitations:</p> <ol style="list-style-type: none"> 1) It does not describe how the participants were instructed on mucus observations which makes it harder to apply this information to make recommendations. 2) No control 3) No randomization 4) No comparison group

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Quality: A			
Author Recommendations: None			
Implications: Instructing patients on the nature of cervical mucus and the use of basic observations can significantly improve their likelihood of conception. Being able to identify the beginning and subsequent days of the fertile window will more likely result in pregnancy if intercourse occurs on those days.			

Matrix 13

Source: Frank-Herrmann, P., Heil, J., Gnoth, C., Toledo, E., Baur, S., Pyper, T., . . . Freundl, G. (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. <i>Human Reproduction.</i> , 22(5), 1310-1319. doi:10.1093/humrep/dem003			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Review the effectiveness and acceptability of the symptothermal method (STM) a fertility awareness-based (FAB) method of family planning.</p> <p>Sample/Setting: Total participants were 900.</p> <p>1985 - 2005 participants enrolled by volunteer basis through self-selection in collaboration with German NFP study center. Enrolled 1599 women and collected 35,996 menstrual cycles. A cohort of 900 women with 17, 638 cycles met selection criteria. Couples had to have the intent to avoid pregnancy, record all sexual activity, not use any barrier method, between 19-46 years old, regular cycles (22-35 days), no history of infertility, and at least 3 months post breastfeeding,</p>	<p>Study Design: Prospective, observational longitudinal cohort study</p> <p>Method: Taught STM by accredited teachers from Arbeitsgruppe NFP, which is standardized. Participants used the STM which included recording cervical secretion patterns, changes in basal body temperature (BBT) and application of calculation rule. Fertile window is calculated by 2 parameters to have a double check system. First fertile window is identified by either first appearance of cervical secretion or the 6th day of the cycle for the first 12 cycles and then it would be the earliest BBT rise in the past 12 cycles minus 7 to identify first fertile day (minus 8 rule). The last fertile day is identified by either the evening of the third day after cervical secretion peak day or evening of third higher temp reading, all higher than last 6 readings, the last one being 0.2 degrees</p>	<p>322 women used STM only and 509 used STM with occasional use of barriers at the fertile time (STM mix). 69 did not document sexual behavior and were excluded.</p> <p>Unintended pregnancy rate 1.79 per 100 women after 13 months of use (no difference between learning phase and rest of use). Perfect use (abstinence), the unintended pregnancy rate 0.43 per 100 women at 13 cycles. Unintended pregnancy rate with unprotected intercourse during fertile window 7.47 per 100 women at 13 cycles ($p < 0.00001$).</p> <p>Conclusion: STM that uses two indicators of fertility (BBT + cervical secretions) to identify fertile window is effective and acceptable. The overall rate of unintended pregnancies 1.8%. Perfect use (abstinence) 0.4% pregnancy rate per year (0.4 unintended pregnancies per 100 women)</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Large database. 2) Low number lost to follow-up (6.7%). 3) Inclusion of data from teaching phase which many studies exclude. 4) Documentation of all sexual behavior and classification of pregnancies as intended or unintended according to intention before conception. 5) Use of advanced analytical methods 6) Differentiated between those that use barriers at the fertile time and those that did not which can help serve as a comparison. <p>Limitations:</p> <ol style="list-style-type: none"> 1) High effectiveness may be related to the high motivation of self-selected individuals and motivated teachers who agreed to participate. 2) Self-selection bias 3) Not randomized 4) 60% were 19-29 years old which makes it hard to generalize results to all reproductive-aged women.

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delivery or use of oral contraception.	Celsius higher than previous 6.		
Level of Evidence: III	Instruments: BBT		
Quality: A			
Author Recommendations: Cannot compare to studies carried out in developing countries due to very different social setting and infrastructure - further studies with STM for comparison of these other methods that are used in developing countries.			
Implications: For my future midwifery practice offering STM could be a highly effective choice for a patient who wants to use a natural method. However, it would seem to require the instruction by a qualified accredited teacher in order to reach the highest effectiveness.			

Matrix 14

Source: Doud, J. (1985). Use-effectiveness of the Creighton Model of NFP. <i>International Review of Natural Family Planning</i> , 9, 54-72.			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Determine the use-effectiveness of the Creighton Model Ovulation Method of natural family planning (NFP) as a means of achieving and avoiding pregnancy.</p> <p>Sample/Setting: Total participants were 378 couples (2,364 couple months of use)</p> <p>Women who were clients at St. Francis Regional Medical Center's NFP department in Wichita, Kansas were recruited.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Prospective cohort study</p> <p>Method: All clients taught a standardized method by accredited practitioners from Creighton University. Individual follow-up sessions performed at 2, 4, 6, 8, 12, 24, 36, and 52 weeks. Standardized vaginal discharge recording system and picture dictionary taught and days of fertility and infertility and instructed that using a day of fertility was using the method as a means to achieve pregnancy. Clients who use concomitant use of barriers omitted from the study.</p> <p>Instruments: Creighton fertility chart and stamps</p>	<p>1) Method effectiveness - 99.4 at 6 months - 99.1 at 12 months</p> <p>2) Use-effectiveness as means to avoid pregnancy - 97.3 at 6 months - 96.2 at 12 months</p> <p>3) Use-effectiveness as means to achieve pregnancy - 19.9 at 6 months - 28.0 at 12 months</p> <p>4) Total pregnancy rate at 12 months was 31.8. - 28.0 were achieving pregnancy - 0.9 method related - 1.4 using related - 0.6 teaching related - 0.9 using/teaching related</p> <p>Conclusion: Results compare favorably to Hilgers' study and to effectiveness studies on artificial methods of contraception. Also reflects the quality of teacher training program.</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Good sample size. 2) All cycle lengths included rather than just regular cycles as many other NFP studies use. 3) A standardized method of teaching among all participants. 4) Adequate study time. 5) low discontinuation rate (14.2% at 6 months and 16.9% at 12 months) <p>Limitations:</p> <ol style="list-style-type: none"> 1) A rather homogenous group which makes it hard to generalize to the population. 2) Not randomized 3) No comparison 4) Self-selection bias 5) Pregnancy rates classified according to Creighton model classification which does not count pregnancies that were unplanned/unintended if the user had correct information on how to use the system but decided not to use it according to their original intent (achieving-related pregnancy)
Author Recommendations: None			
Implications: If taught by a trained practitioner, the Creighton model allows a very effective method of NFP for couples. The advantage of Creighton to other fertility awareness-based methods is that it teaches couples when they are fertile and infertile on any given day. It is not based on any sort of calendar method so it can be used very effectively for long or irregular cycles or for any other reproductive category.			

Matrix 15

Source: Wade, M., McCarthy, P., Braunstein, G., Abernathy, J., Suchindran, C., Harris, G., . . . Uricchio, W. (1981). A randomized prospective study of the use-effectiveness of two methods of natural family planning. <i>American Journal of Obstetrics and Gynecology</i> , 141(4), 368-376. https://doi.org/10.1016/0002-9378(81)90597-4			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Evaluate two methods of natural family planning (NFP): the ovulation method (OM) based on the Billings method and the Symptothermal Method (STM).</p> <p>Sample/Setting: Total participants were 430</p> <p>Women age of 20-39 years, regular menstrual cycles (24-36 days), not pregnant, stable couple relationship, and stated the intention to avoid pregnancy for 2 years.</p> <p>Randomized into either OM or STM. From Los Angeles and Orange County areas of Southern California. 1,247 randomized (619 in OM and 628 in STM). Only 191 (OM) and 239 (STM) continued to study phase for a total number of 430 participants.</p>	<p>Study Design: Randomized prospective comparative study</p> <p>Method: After randomization trained in either OM or STM. Couples could drop out during training in the first month, after 3-5 months of training couples who demonstrated accurate charting and proper use were asked to enter the formal study. If not, by fifth month they were dropped. Evaluated monthly to assure accurate charting and troubleshoot if needed and pregnancy test taken. No formal training programs in Southern California for either method, therefore, teachers were those who currently use the system or previously used - additional training provided after recruitment. Quality control by periodic on-site observation of teaching sessions.</p> <p>Instruments: OM charts adapted from Atlas of Ovulation Method by Billings.</p>	<p>1) A major reason for dropout was voluntary withdrawal (43.8% for OM and 43.6% for STM). The second major reason was pregnancy (22.4% for OM and 11.2% for STM) which was statistically significant ($p < 0.01$).</p> <p>2) Cumulative pregnancy rate 26.7% for OM and 10.9% for STM.</p> <p>3) 12 month Pearl rates from the beginning of training: 34.9 pregnancies per 100 women-years for OM and 16.6 for STM. From the beginning of entry into the formal study: 39.7 for OM and 13.7 for STM.</p> <p>Conclusion:</p> <p>1) A difficulty with interpretation of mucus symptoms contributing factor in 17.6% of STM and 35.7% of OM pregnancies. The largest category of pregnancies occurred in both groups when participants didn't follow the rules.</p> <p>2) STM superior to OM of NFP with use-effectiveness.</p> <p>3) Dropout rates high. The major cause for voluntary dropout during the training session was lack of interest or dissatisfaction with the</p>	<p>Strengths:</p> <p>1) Randomization that eliminates selective bias 2) Balanced groups based on demographics. 3) Individual and standardized teaching in groups</p> <p>Limitations:</p> <p>1) Recruitment difficulties resulted in an overall smaller number than anticipated. 2) Dropout rates for both methods high. (73.7% for OM and 63.6% for STM). Dropout group lived together a shorter amount of time, more sexually active prior to training, and fewer children than those who completed training ($p < 0.05$) 2) If volunteers unable or unwilling to adhere to methodology, encouraged to drop out - gives difficulty in actual rates of use-effectiveness. 3) Effectiveness measured in Pearl rates which has more limitations than life table analysis</p>

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<p>Level of Evidence: I</p> <p>Quality: B</p>		<p>method and during the formal study was an unplanned pregnancy. 4) 6 OM and no STM pregnancies classified as method pregnancies after extensive review.</p>	
<p>Author Recommendations: Further studies on motivation and acceptance of abstinence during the fertile phase of cycle necessary before NFP will be acceptable to a larger proportion of the population</p>			
<p>Implications: This study points some of the issues presented when teaching methods of NFP to couples that must be overcome to achieve high effectiveness of a NFP system. Adequate teaching on the nature of abstinence during fertile phase needs to be given in order for a couple can know this is when effectiveness is at its highest and not to be shocked when beginning the system. Additionally, this study points out how the identification of cervical mucus and its interpretation can be difficult where a system that offers standardized interpretation may be of more value. Regardless, the STM does show with this study to be an effective means of avoiding pregnancy if taught and used correctly.</p>			

Matrix 16

Source: World Health Organization. (1981). A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. <i>Fertility & Sterility</i> , 36(5), 591-598. https://doi.org/10.1016/S0015-0282(16)45856-5			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To determine the effectiveness of the OM of family planning.</p> <p>Sample/Setting: Total participants were 725.</p> <p>Women with regular cycles (23-35 days), proven fertility, who had successfully learned the OM.</p> <p>Recruited from 5 centers in New Zealand, India, Ireland, Philippines, and El Salvador invited to participate.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Prospective multicenter cohort study to determine the effectiveness of the ovulation method.</p> <p>Method: Rules of OM those of Billings method out of Atlas of Ovulation Method with exception all mucus days in preovulatory phase regarded as fertile. Abstain from intercourse on days of menstruation, alternate dry days preovulatory (reduce confusion of seminal fluid) and during the fertile period.</p> <p>Pregnancy eval for each pregnancy and determination of reason: method-related pregnancy, inadequate teaching, inaccurate application of instruction, conscious departure from rules, and uncertain.</p> <p>Instruments: Record of symptoms of cervical mucus, menstruation, and days of intercourse.</p>	<p>1) Average duration fertile period 9.6 days. Mean number of days of abstinence 15.4.</p> <p>2) 7,514 cycles of observation. Pearl rate 2.8 pregnancies per 100 women (1300 cycles). 111 user-related pregnancies, 89 from conscious departure and 20 from an inaccurate application. Use-related pearl rate 18.9.</p> <p>3) 10,215 total cycles (including the 3 cycles of teaching and 13 cycles of effectiveness) Pearl rates: 2.2 method failure, 0.5 for uncertain, 19.6 user-related pregnancies. 15.4 Pearl rate for conscious departure.</p> <p>4) Those that discontinued who had an intention of spacing pregnancies was 43.0% while those who discontinued and had stated they had no intention of expanding their families was 29.1%, which was significant ($p < 0.001$)</p> <p>Conclusion: Very low method-related pregnancy rates of the OM of NFP. Overall a relatively high use-related pregnancy rate. 91% assessed as having an excellent or good grasp of the method and being able</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Groups were heterogeneous and cross-cultural from 5 countries, therefore, conclusions can be applied to the general population. 2) Good sample size. 3) Data gathered prospectively 4) Teaching was standardized between the different centers. <p>Limitations:</p> <ol style="list-style-type: none"> 1) High discontinuation rate - 45.9% 2) Effectiveness measured in Pearl rates which has more limitations than life table analysis 3) Self-selection bias 4) Conclusions only applicable to regularly ovulating women of proven fertility who had not used OM before and were motivated to use OM. 5) Users were screened through a teaching phase before the study began. 6) No randomization 7) No comparison groups.

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		to describe their fertile period by cervical mucus observations which is encouraging of a diverse population and some from developing nations.	
<p>Author Recommendations: Further analysis into why the more socioeconomic developed countries had higher method-related pregnancies. Further research into ways in which couples can be assisted to follow the OM rules.</p>			
<p>Implications: Some of the study participants were illiterate or poorly educated, yet a large percentage (92%) were deemed to be able to use the self-observations of cervical mucus to identify fertile period. This can be encouraging when recommending a natural family planning method that nearly anyone is capable of learning. When used correctly without conscious departure it has a very low method-related pregnancy rate at 0.5 per 100 women.</p>			

Matrix 17

Source: Howard, M. P., & Stanford, J.B. (1999). Pregnancy probabilities during use of the Creighton Model Fertility Care System. <i>Archives of Family Medicine</i> , 8, 391-402. doi:http://dx.doi.org/10.1001/archfami.8.5.391			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Evaluate pregnancy probabilities with Creighton Model Fertility Care System (CrMS)</p> <p>Sample/Setting: Total participants were 701 couples (6947.5 couple months).</p> <p>Recruited from St. Joseph's Hospital Natural Family Planning program in Houston Texas from 1982-1989. Excluded if there was a history of infertility, pregnant at the onset of use and women who were not genitally active when they began using the system. No other inclusion or exclusion criteria were used.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Observational cohort study of couples who had begun using CrMS until they completed 18 months, became pregnant or left for another reason.</p> <p>Method: No separate learning phase for study. Contributed until 18 months of follow-up, pregnant or left for some reason.</p> <p>Daily charting of vaginal discharge according to CrMS protocol. External observations only. Abstain from genital contact for the first month of observations (though not followed by all users). Follow up at 2, 4, 6, 8, 12, 24, 36, and 52 weeks. Individualized sessions and tailored for individual circumstances. Fertility begins the first appearance of mucus and ends at end of the fourth day after peak day (last day of clear, stretchy or lubricative mucus). Average mucus discharge lasts 5-6 days. Special instructions for breastfeeding, oligo-ovulatory states, and</p>	<p>1) At 12 months probabilities per 100 couples: method-related 0.14, user and/or teacher error 2.72, achieving-related behavior 12.84, unresolved 1.43 and total pregnancies was 17.12 (but this number includes pregnancies that other studies would exclude, for example, pregnancies that were intended and planned).</p> <p>2) The probability of leaving study other than pregnancy was 27.39 per 100 couples at 1 year. Lost to follow up was 12.4. Leaving did not necessarily mean discontinuation of CrMS.</p> <p>Conclusion: 1) Results comparable to other methods of NPF and most pregnancies were user-related, specifically genital contact during the known fertile time. A regular cycle is not needed. 2) A common mechanism of user-related pregnancies occurred when couples had genital contact on days they believed to be infertile but on review of their chart were deemed to be fertile. 3) The best comparison would be extended-use</p>	<p>Strengths: 1) No attempt was made to exclude couples who were wishing to achieve a pregnancy or asking participants to commit to avoiding a pregnancy which many studies would have excluded which would inflate the numbers of pregnancies in comparison to other NFP studies. 2) Included women of all reproductive categories (including breastfeeding, breastfeeding-weaning, post-pill, long cycles...etc). 3) All taught by highly trained instructors and standardized teaching methods. 4) Probabilities made with life table analysis which has fewer limitations than the Pearl Index 5) No separate learning phase 6) Good sample size</p> <p>Limitations: 1) Gross probabilities from this study cannot be directly compared with net probabilities or Pearl rates from other studies. 2) All couples included and proven fertility was</p>

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	<p>chronic vaginal discharge. Taught genital contact on the day of fertility adopting method as a means of achieving pregnancy.</p> <p>Avoiding-related occurs despite correct use as understood by the couple.</p> <p>Instruments: Creighton Model fertility chart and fertility stamps</p>	<p>pregnancies, though not all studies produce this data.</p> <p>4) Lowest pregnancy for uncomplicated regular cycles (13.98 per 100 couples at 12 ordinal months).</p> <p>5) Perfect use in first year chance of pregnancy less than 1%. Accounting for errors by either user or teacher in the first year would be 3-4%. Those of normal fertility who select days of fertility to have genital contact have a very high chance of achieving pregnancy. This study shows that probability of those who started CrMS would be pregnant in 1 year was 17%.</p>	<p>not required, no known history of infertility though.</p> <p>3) Lack of info about how many couples who had genital contact during fertile time did not conceive.</p> <p>4) Lack of info about the timing of weaning and return of menses.</p> <p>5) Inability to compare pregnancy probabilities directly with studies on contraception because this study included couples who may have been planning a pregnancy.</p> <p>6) No randomization</p> <p>7) Self-selection bias</p> <p>8) No comparison group</p>
<p>Author Recommendations: How intention relates to sexual behavior among NFP users. Studies of NFP and contraception report pregnancies with extended-use pregnancies because it has better comparisons among all methods. Further research to define exact probabilities for adjusted achieving-related and adjusted avoiding-related pregnancies. Further research on CrMS in postpartum couples specifically.</p>			
<p>Implications: While most calendar-rhythm methods and other methods of NFP are only studied and effectively used for regular cycles this proves to be still effective in other reproductive life situations. Particularly, post-pill (96% of women had used at some point, and 29.1% used immediately prior to starting CrMS). which can result in a delay of fertility. This is practical for many real-life situations in which a person may be seeking NFP. CrMS proves to be reliable and effective even in these other life-circumstances.</p>			

Matrix 18

Source: Arévalo, M., Jennings, V., Nikula, M., & Sinai, I. (2004). Efficacy of the new TwoDay Method of family planning. <i>Fertility and Sterility</i> , 82(4), 885-892. doi:10.1016/j.fertnstert.2004.03.040			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To determine the efficacy of the TwoDay Method.</p> <p>Sample/Setting: Total participants were 450 (3,928 cycles).</p> <p>Women from 5 different sites in Guatemala, Peru, and the Philippines. Aged 18-39 years, living in union, had a previous pregnancy, 3 months post breastfeeding or oral contraception use, or 6 months post hormonal contraception injection.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Prospective, nonrandomized, multicenter study to test the efficacy of the TwoDay Method.</p> <p>Method: Women taught the TwoDay Method which asks each day if they noticed secretions today or yesterday. If yes to either she should consider herself fertile and should use protection. If none today or yesterday chances of conception very low.</p> <p>Interviewed every cycle to assess use and pregnancy status (3 times in the first cycle) until 13 cycles completed. If cycle longer than 42 days, removed from the study. Removed if <5 days or >14 days of secretions.</p> <p>Institute for Reproductive Health trained 5-10 health service providers in each site to offer TwoDay Method. Screened potential participants, taught usage and collected data.</p> <p>Instruments:</p>	<p>1) Mean number of days with secretions 12.1, suggests a degree of false positives (days identified as fertile that are actually infertile).</p> <p>2) Of the 450 who entered, 52.7% completed all 13 cycles and 99% planned to continue method. Of those that left, 15.7% were asked to leave study for method or study-related reasons.</p> <p>3) End of the first cycle only 2% reported trouble detecting secretions. 93.6% no reported intercourse during days identified as fertile. 2.9% backup method used on fertile days. 3.9% unprotected intercourse on fertile days.</p> <p>4) 53.2% of pregnancies occurred when unprotected intercourse on fertile days, 12.8% when using withdrawal, 8.5% with condoms on fertile days. only 12 (25.5%) occurred in cycles with no intercourse reported on fertile days.</p> <p>5) First-year pregnancy rate 3.5 with the correct use of the method. 6.5 if include use of condoms or withdrawal during fertile days. All pregnancies in cycle give pregnancy rate 13.7 for the first year.</p>	<p>Strengths:</p> <p>1) Culturally and socioeconomically diverse participants (some rural indigenous, urban, semi rural and a large city)</p> <p>2) Proven fertility with at least one previous pregnancy.</p> <p>3) No learning period included. All cycles of learning included in study results.</p> <p>4) Excluded cycles with no intercourse so results are conservative</p> <p>5) Prospective data collection.</p> <p>Limitations:</p> <p>1) Reliance on women to accurately report acts of intercourse and backup methods. Under-reporting suspected.</p> <p>2) The requirement of monthly follow-up and coital log necessary for data collection may have increased correct use and continuation rates.</p> <p>3) Removing women for study reasons may artificially reduce the failure rate (15.7% removed).</p> <p>4) No randomization</p> <p>5) No comparison</p> <p>6) Self-selection bias</p>

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	Diary card for recording answers to algorithm and acts of intercourse.	<p>Conclusion: Compares well with other more complex fertility awareness-based methods. Shows that clients can correctly identify fertile period by learning to recognize cervical secretions and correctly use this method to avoid pregnancy.</p> <p>Effective, easy to teach, learn and use.</p>	
<p>Author Recommendations: Additional research on the viability of offering both the TwoDay Method and Standard Days Method in same programs. Study delivery issues when offering through regular service delivery, with the option of barrier method use on fertile days and without keeping a coital log. Examine efficacy and acceptability of method to couples in specific subgroups.</p>			
<p>Implications: Many NFP programs are complex and take a significant amount of time to teach and learn. There are specific training programs that a woman or couple must go through to know her fertile period. The TwoDay Method does eliminate that in that it is very easy to learn. Many study participants were poorly educated or illiterate altogether which makes this appealing to women who are less educated.</p>			

Matrix 19

Source: Arévalo, M., Jennings, V., & Sinai, I. (2002). Efficacy of a new method of family planning: The Standard Days Method. <i>Contraception</i> , 65(5), 333-338. doi:https://doi.org/10.1016/S0010-7824(02)00288-3			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To determine the efficacy of the Standard Days Method (SDM)</p> <p>Sample/Setting: Total participants were 478 (4,035 cycles). Women from 5 sites in Bolivia, Peru, and the Philippines. Regular cycles ranging from 26-32 days. Ages 18-39.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Prospective cohort study to test the efficacy of the Standard Days Method.</p> <p>Method: Instructed on SDM which teaches days 8-19 (12) are fertile and they should avoid unprotected intercourse on those days. No more than twice in a 12 month period to have a shorter or longer cycle than 26-32 days.</p> <p>Institute for Reproductive Health trained 5-10 workers in the SDM. Each participant had a counseling session on instructions of metho. Each user was given a string of 32 beads (CycleBeads) to represent the day of the cycle. First bead red, next 6 are brown (non-fertile), next 12 white (days 8-19 considered fertile) and last 13 are brown (non-fertile). Each day move a rubber band to mark the day in the cycle. If cycle lasted less than 26 or longer than 32 days, advised contacting the provider. Advised not to have unprotected intercourse</p>	<p>1) Cycles excluded that did not include intercourse or when another method of family planning used on other days than 8-19 (non-fertile) days. 2) 46% completed 13 cycles. The largest group to leave was 28% who were removed after having 2 cycles outside the 26-32 day range. 3) Correct method use (no intercourse on days 8-19) reported in 92% of cycles. 4) First-year pregnancy rate 4.8 with the correct use of the method (no intercourse on days 8-19). With condom or withdrawal, first-year pregnancy rate higher at 5.7. All cycles and all pregnancies for 1-year is 12.</p> <p>Conclusion: SDM effective method of family planning. The first-year pregnancy rate of less than 5% with correct use. Compares well to other user-controlled methods available. Shows how easy the method is to learn and use to avoid unplanned pregnancy.</p>	<p>Strengths: 1) Heterogeneous study population. 2) Culturally and socioeconomically diverse participants 3) No learning phase, all pregnancies included from the entrance to study. 4) Prospective data collection</p> <p>Limitations: 1) Reliance on women to accurately report acts of intercourse and barrier methods. Under-reporting suspected. 2) Monthly follow-ups may have increased correct use of the method. 3) Self-selection bias 4) No randomization 5) No comparison</p>

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	<p>on days 8-19. If 2 cycles outside of 26-32 days advised to use another method and withdrawn from the method.</p> <p>Interviewed each cycle until 13 cycles or left the study. Follow-ups occurred in their home to minimize loss to follow-up</p> <p>Instruments: CycleBeads, a coital log indicating which days used and which method for protection and calendar to mark first day menses.</p>		
<p>Author Recommendations: Research studies to address how best to offer family planning like the SDM in another context outside of traditional family planning programs.</p>			
<p>Implications: The simplicity of the SDM makes it very easy to use. The ability for the CNM to teach this method in a single setting such as the annual exam makes it possible for the woman to leave knowing what to do. However, it requires that women know the average lengths of their cycles. It is not to be used with irregular cycles, short or long cycles. This limits its use, but provided they have regular cycles between 26-32 days this is an effective and easy system to offer.</p>			

Matrix 20

Source: Colombo, B., & Masarotto, G. (2000). Daily fecundability: First results from a new data base. <i>Demographic Research</i> , 3(39). doi:10.4054/DemRes.2000.3.5			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Determine the daily probability of conception among healthy subjects.</p> <p>Sample/Setting: Total participants were 881.</p> <p>1992-1996, 782 women recruited in 7 European Family planning centers (Milan, Verona, Lugano, Dusseldorf, Paris, London and Brussels). Aged 18-40 years old, in a stable relationship, at least one period after breastfeeding cessation, not taking any hormonal medication affecting fertility. Additional 99 added retrospectively from a prospective study in Auckland, New Zealand from 1979-1985. Total of 7017 cycles. 5490 from European study centers only.</p> <p>Level of Evidence: III</p> <p>Quality: A</p>	<p>Study Design: Prospective multicenter cohort study to produce daily pregnancy probabilities.</p> <p>Method: Each woman asked to record days of period and any physical disturbances (illness, lack of sleep...etc). Record basal body temperature (BBT) on the chart until clear post-ovulatory rise. Observe and chart cervical mucus (CM) by coding 0-4 based on the description, daily during the cycle. Record every act of intercourse and whether protection was used, and what kind.</p> <p>Three over six rule used to determine BBT shift and post-ovulatory infertility. CM peak day last day best quality mucus (day 0).</p> <p>New Zealand study: Proven fertility - instructed how to recognize fertile period from cervical mucus changes. Record BBT daily. Only one act of intercourse during the fertile phase.</p>	<p>1) On average, peak mucus symptom occurs 0.31 days before last low-temperature day in European group.</p> <p>2) No one of the 350 intercourse episodes of the third day of the high BBT resulted in a conception.</p> <p>3) BBT reference day may be a slightly better marker of ovulation day than CM as it is less prone to error.</p> <p>4) Max level of conception second day before the shift in BBT or peak day of CM.</p> <p>5) Peak CM day not the one with max fecundability, 4 days preceding the reference day appear most relevant for cycle fecundability.</p> <p>6) The pattern of conception is concentrated and falls after a continuous rise extended over 5 days, the max is at day -2 approaching 0 ($p=0.020$).</p> <p>7) The difference in the level of fecundability of women with proven versus unproven fertility group was very significant ($p=0.014$).</p> <p>Conclusion: 1) Couples attempting pregnancy should maximize intercourse frequency during the four days preceding the first</p>	<p>Strengths:</p> <ol style="list-style-type: none"> 1) Groups were very homogeneous which eliminates any impact of confounding factors. 2) Reliability about type and timing of acts of intercourse which gives confidence to results. 3) Large sample size. 4) Data gather prospectively 5) Advanced statistical analysis <p>Limitations:</p> <ol style="list-style-type: none"> 1) Probable errors in BBT or CM which results in different reference (ovulation days) which would result in different measurements of fecundability rates. 2) Homogenous groups make it more difficult to make recommendations to the general population 3) No randomization 4) No comparison group 5) Self-selection bias 6) Participants added only added after the instruction phase.

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	<p>Instruments: A chart to record menses, BBT, CM, and intercourse.</p>	<p>upward shift of BBT or peak mucus day. 2) Couples wanting to avoid pregnancy unsafe period may be 11-12 days, typically 8 days before reference point 3) The maximum daily fecundability estimated in the BBT window is .255 which corresponds to an average number of 3.92 cycles needed for obtaining a pregnancy, while after one year 2.2% subjects remain without success. 4) Couples with at least three acts of intercourse in the same window reach a proportion of .227 conception cycles on the whole. This corresponds to 4.41 cycles for a pregnancy and 3.5% of failures in a year.</p>	
<p>Author Recommendations: Longitudinal analysis of consecutive cycles within women needed to make clusterization of subjects and in clarifying the impact of physiology and behavior on outcomes.</p>			
<p>Implications: When attempting to identify post-ovulatory infertility, the use of BBT may be a better indicator than CM. This information may be useful for couples wanting to avoid pregnancy specifically in that once this is determined there is no risk of conception occurring. Additionally when counseling couples who wish to achieve a pregnancy knowing either or both the BBT or CM could greatly enhance their chances of conception. Specifically counseling when, based on this data, is the best time to focus their intercourse efforts.</p>			

Matrix 21

Source: Fehring, R., Schneider, M., & Barron, M. (2008). Efficacy of the Marquette Method of natural family planning. <i>MCN, The American Journal of Maternal Child Nursing</i> , 33(6), 348-354. doi:10.1097/01.NMC.0000341254.80426.32			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Determine the effectiveness of the Marquette Method (MM) of NFP.</p> <p>Sample/Setting: Total participants were 204 (1,034 couple months of use). Women from four clinical sites in the United States. Excluded if breastfeeding, being treated for infertility, older than 42 years of age.</p> <p>Level of Evidence: III</p> <p>Quality: B</p>	<p>Study Design: 12-month Retrospective evaluation of the Marquette Method.</p> <p>Method: All received introduction session and monthly follow-up sessions for the first 3 months and then at 6 and 12 months with pregnancy evaluation for each pregnancy.</p> <p>Users could use any or all of the following analytes to determine fertility: 1) Use of electronic hormonal fertility monitor (EHFM) that measures estrone-e-glucuronide (E3G) and luteinizing hormone (LH) in the urine and reports either low, high or peak. High is when a threshold of E3G is detected, a peak is when the threshold of LH detected. 2) Basal body temperature 3) Cervical mucus</p> <p>Instruments: ClearBlue or ClearPlan EHFM, basal body thermometer.</p>	<p>1) 1 correct use pregnancy which is a 0.6% 12-month correct use pregnancy rate. 2) Total unintended pregnancy rate was 10.6%. For those that used the EHFM alone or in a combination (n=99) unintended pregnancy rate 9.20%, meaning it is 90.8% effective at 12 months of use. 3) For those that did not use EHFM at all the 12-month unintended pregnancy rate was 12.2 meaning it is 87.8% effective at 12 months of use.</p> <p>Conclusion: 1) Perfect-use of 0.6% is very comparable to other methods of NFP and even the condom or oral hormonal pill. 2) The typical use of 10.6% compares well to other studies of MM. 3) The use of the EHFM increases the efficacy of the MM.</p>	<p>Strengths: 1) Did not limit by cycle length which most studies do which could give better results. 2) Because it was retrospective more closely relates to a real-life situation. 3) Participants all taught with standardized teaching method. 4) Participants were followed prospectively</p> <p>Limitations: 1) A homogenous group, mostly white, middle class with at least high school education and Catholic. 2) Small sample size. 3) Retrospective decreases control over extraneous variables. 4) Is not a randomized comparative study. 5) MM can be time-consuming for professional nurses to teach and women and couples to learn. 6) Self-selection bias</p>

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Author Recommendations:

Randomized comparison study to determine the efficacy between methods of NFP. Randomized comparison study to determine what combination of analytes is more effective. Simplification of a system to allow easier/quicker teaching - which should be tested for efficacy.

Implications:

In a clinical setting, use of the EHFMM can be a helpful adjunct especially for those that have difficulty assessing the subjective biological markers, whereas the EHFMM is objective and the monitor gives a definitive result to go by. This study shows that overall the MM is an effective method of NFP and by using the EHFMM it can be even more effective when used with other markers of fertility to determine the fertile window. The MM needs to be taught by trained nurses, however, not all geographic locations may have a trained instructor. Further, it requires many follow-up sessions. If the follow-up scheduled is not adhered to effectiveness of the system may suffer.

Matrix 22

Source: Duane, M. Contreras, A., Jensen, E.T., & White, A. (2016). The performance of fertility awareness-based method apps marketed to avoid pregnancy. <i>Journal of the American Board of Family Medicine</i> , 29(4), 508-511. doi:10.3122/jabfm.2016.04.160022			
Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: To evaluate and rate fertility apps designed for couples to avoid pregnancy.</p> <p>Sample/Setting: 39 apps from iTunes, Google and Google Play (56 other applications excluded)</p> <p>Level of Evidence: III</p> <p>Quality: B</p>	<p>Study Design: Descriptive comparative study of web and mobile fertility applications</p> <p>Method: Each app rated based on the criteria to evaluate medical apps by Family Practice Management. Rated each app for 10 criteria (authority, accuracy in the method, accuracy in observations, support, adaptability, cost/pricing, ease of use, confidentiality, developer/sponsor & platforms available on).</p> <p>Standardized dataset of 7 cycles of daily fertility observations which were obtained from real data cycle was used to determine the accuracy in identifying potential fertile days.</p> <p>If an app did not predict fertile day but recommended prior FABM training apart from the app it scored high on accuracy.</p> <p>Instruments: iTunes and Google Play stores, Google.</p>	<p>1) 29 apps predicted fertile days and 10 did not. 2) Apps that correctly identified fertile days ranked according to score: 1 Ovulation Mentor* 2 Sympto.org* 3 iCycleBeads* 4 LilyPro* 5 Lady Cycle* 6 myNFP.net* 7 MyFertilityCharts.com 8 CycleProGo 9 2Day Method 10 Ova Ova 11 OvaGraph 12 OvuView 13 FemCal 14 Ovatemp 15 Natural Cycles 16 Cyclendar 17 My Fertility MD 18 Menstrual Cycle Woman Log 19 Menstruation & Ovulation 20 Cycles 21 iCyclus 22 Period Log 23 Period Pace 24 Period & Ovulation Calendar 25 Pink Pad Pro 26 Fertility Calendar 27 Fertility Clock 28 Woman Calendar 29 Fertility & Ovulation</p> <p>3) Apps with * had either a perfect score on accuracy or no false negatives (days</p>	<p>Strengths: 1) Each app was given the same information which makes conclusions easy to draw. 2) Names of applications included so specific recommendations can be made. 3) Large number of applications identified in search (n = 95). 4) Specific criteria for rating and scoring each application.</p> <p>Limitations: 1) List of search terms not included which means there could be a potential researcher self-selection bias if search terms were limited. 2) Limited conclusions drawn related to the score and how it translates to real-life usage.</p>

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		<p>classified as infertile when they were fertile).</p> <p>4) Apps that did not correctly identify fertile days ranked: 1 NFP Charting Ovulation 2 Symptopro 3 Fertility Pinpoint 4 Kindara 5 Groove Fertility Pro 6 FEMM 7 NFP Project Caruso 8 Charting App 9 Lady Time 10 Knowhen</p> <p>Conclusion: 1) Majority of apps are not designed for avoiding pregnancy or are not founded on evidence based FAB methods. 2) Attractive apps are not necessarily effective and vice-versa. 3) At least one app with a perfect score in each FAB method category (Except symptohormonal) 4) Apps that do not predict fertile days can still be useful for experienced NFP users.</p>	
<p>Author Recommendations: None</p>			
<p>Implications: This study demonstrates how dependent young people have become on information technology. Comparing various applications shows that not all of them are equally reliable or accurate. Limited data exist regarding actual human studies of the effectiveness of FAB method apps, therefore, patients should be cautioned when they choose to use these applications for their family planning needs. This study is specifically helpful as it found one application for each type of FAB method which gives patients something to choose from based on what sort of method they are interested in utilizing.</p>			

Matrix 23

Source: Koch, M.C., Lermann, J., van de Roemer, N., Renner, S.K., Burghaus, S., Hackl, J., ... Thiel, F. C. (2018). Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: Results of a retrospective efficacy study of Daysy and DaysyView app. *Reproductive Health*, 15(1), 37. doi:10.1186/s12978-018-0479-6

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Purpose/Sample	Design (Method/Instruments)	Results	Strengths/Limitations
<p>Purpose: Evaluate feasibility, satisfaction, and failure rate of Daysy device and DaysyView app as a FAB method.</p> <p>Sample/Setting: Total participants were 798 (4738 cycles).</p> <p>Recruited from current registered users of the DaysyView application.</p> <p>Level of Evidence: III</p> <p>Quality: C</p>	<p>Study Design: 13-cycle retrospective cohort study of current users of the DaysyView application.</p> <p>Method: All Daysy international purchases who already had registered and had a DaysyView account received an invitation.</p> <p>Daily temperature Green light - Infertile Red light - Fertile Yellow light - unsure</p> <p>Method-related pregnancy is a pregnancy that occurred during unprotected intercourse on a green day (infertile phase)</p> <p>Perfect-use pregnancy is a pregnancy that occurred when there was no unprotected intercourse on the red days (fertile phase)</p> <p>The Pearl Index represents the number of failures per 100 woman-years exposure.</p> <p>Instruments: Daysy BBT device and DaysyView App</p>	<p>1) Typical-use related pregnancy rate is a Pearl Index of 1.252 (2.707% pregnancy probability)</p> <p>2) Method related pregnancy rate is Pearl Index of 0.626 (2.2% pregnancy probability)</p> <p>3) Perfect-use pregnancy rate is Pearl Index of 0.753 (2.19% pregnancy probability)</p> <p>4) Unprotected intercourse during fertile time has pregnancy probability of 10.82%</p> <p>Conclusion:</p> <p>1) Digital analysis of temperature data, the monitors can reduce the risk of inaccurate or misinterpretation of data.</p> <p>2) They can remind the user of the risk of pregnancy by showing a red (fertile) day but don't reduce the risk of the user choosing to use another contraceptive method or unprotected intercourse.</p> <p>3) Daysy with the combination of the DaysyView app improves usability and leads to higher engagement of a highly accurate device.</p>	<p>Strengths:</p> <p>1) Researchers blinded to personal data of users.</p> <p>2) Kaplan-Meier approach used to calculate overall effectiveness to take into account varying durations of use.</p> <p>3) Good sample size</p> <p>Limitations:</p> <p>1) Self-selection bias</p> <p>2) Pearl Index has more limitations than life table analysis</p> <p>3) Not mandatory to report whether and when users had protected or unprotected intercourse</p> <p>4) Only 17 users under the age of 20, therefore, cannot make a general recommendation for this age group.</p> <p>5) No randomization</p> <p>6) No control or comparison group</p> <p>7) Excluded users with less than 13 cycles of data and those pregnancies from those cycles</p> <p>8) Only 13% of users agreed to complete the survey (798 out of 6278)</p> <p>9) Pregnancies were only verified if the user reported a pregnancy as unwanted but it's not clear if every data set was evaluated and so unintended but wanted pregnancies may have</p>

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			<p>been missed or pregnancies that ended in an abortion.</p> <p>10) Retrospective survey not able to capture changing pregnancy intention which could change effectiveness rates.</p> <p>11) No inclusion or exclusion criteria</p> <p>12) 64% reported concurrent use of a contraception which makes it difficult to report true effectiveness rates of Daysy.</p>
<p>Author Recommendations: None</p>			
<p>Implications: While the results of this study seem appealing and they boast of high effectiveness there are a lot of flaws in the study which make it difficult to ensure the rigor of the study and therefore, it's results. Pregnancies were excluded if that resulted in less than 13 cycles of data and it's unsure whether each data set was analyzed for evidence of pregnancy.</p> <p>While it may still be an effective device for FAB method users this study does not give us an accurate picture of what those rates are. Patients should be cautioned that while this device is minimal effort on the part of the user it's effectiveness may not be known.</p>			

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Appendix B

Local FAB Method Instructors

Creighton Model Fertility*Care* System: <https://www.fertilitycare.org/>

Marquette Method: <https://www.marquette.edu/nursing/natural-family-planning-classes.php>

Billings Ovulation Method: <https://www.boma-usa.org/find-a-boma-usa-teacher.html>

Symptothermal Method:

- Couple to Couple League International: <https://register.ccli.org/>
- SymptoPro: <https://www.symptopro.org/about-us/find-an-instructor.html>