The Marquette Model:

An Evidenced-based Electronic Hormonal Fertility Monitor Aided Method of

Family Planning

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Introduction

We (faculty and professional nurses at Marquette University College of Nursing, Milwaukee, Wisconsin, United States of America) have been offering professional services in natural family planning (NFP) since 1985. From 1985-1998 we offered a cervical mucus based method of NFP called the Creighton Model System CrM. In 1998, an Institute for Natural Family Planning (INFP) was established at Marquette for the purpose of providing professional education, research and service in natural family planning and in 1999, a new method of NFP (called the Marquette Model or MM) was developed and launched. This method entails the integration of electronic hormonal fertility monitoring along with traditional natural markers of fertility.

The purposes of this paper are; 1) to provide physiological and practical reasons for developing a new system of NFP, 2) to provide evidence for the effectiveness of this new system of NFP, and 3) to provide evidence for applying this system of NFP to special reproductive circumstances.

Foundations of the Marquette Method of NFP

In the early 1980s, faculty at Marquette University College of Nursing had the intention of starting a natural family planning training program for professional nurses. A number of models of NFP were explored for this purpose including the Billings Ovulation Method and the Creighton Model System of NFP. We chose the CrM system for Marquette since it was highly developed and structured. It also had a very develop curriculum that could be replicated and it was associated with a sister Jesuit University, i.e., Creighton University in Omaha, Nebraska, USA. We obtained a grant from the Marquette University religious commitment fund to send faculty and other health professionals through the CrM NFP teacher training program.

We started offering CrM NFP services at Marquette University and at area Catholic Hospitals in 1984. Eventually, this author became the president of the Creighton Model Academy of Natural Family planning and conducted an effectiveness study of the CrM system as was provided by the CrM certified NFP teachers at Marquette University (Fehring, Lawrence, and Philpot 1994).

However, when we started to develop the CrM courses for college credits and present the proposed curriculum to the College of Nursing curriculum committee, we found resistance to the idea and to the proposed courses. One problem was that a CrM NFP teacher training course would require two theory courses and two practicums. That many courses for the NFP teacher training program would be very difficult to get through College and University approval. Another reason is that there are ethical requirements for providing CrM services that we were not able to meet at our University, i.e., we could not reject students enrolling for the courses and training program if they were on hormonal contraception or did not follow Catholic Church teaching on human sexuality. However, the major reasons was that we needed a system of NFP that we could develop, research, and modify without violating CrM standards, in other words we needed our own system of NFP.

Another reason for developing a new system of NFP was that the CrM system is rather complex to use and requires very intensive work for the provider. In addition, mucus only methods, such as the CrM, are at times confusing both for the user and provider and only moderately effective in helping couples avoid pregnancy. Our CrM providers were finding a number of early dry mucus day pregnancies among their users and often having NFP fertility charts from users with white baby stamps on the majority of days indicating long bouts of abstinence. Subsequently we found out that mucus only systems can have an average of 17 days

of required abstinence for those women/couples seeking to avoid pregnancy (Colombo 1998).

However, the main reason for developing a new method of NFP was for the ability of the faculty

and staff at Marquette University to have flexibility of developing and researching a system of

NFP without having to receive permission from the developer of another system of NFP. In

addition we needed to develop a NFP teacher training program for health professionals in which

the courses fit within the University system. We needed flexibility of developing own NFP

teacher training program for health professionals.

In the meantime, Marquette NFP researchers investigated other natural indicators of

fertility and technology that could aid a woman in using a method of NFP and that could be used

with a new system of NFP. We investigated two devices that measured salivary vaginal

electrical resistance. One such device, called the OvaCue fertility monitor (formally called the

Cue) is sold and marketed (both in magazines and on the Internet) in the USA as a device to

achieve pregnancy and for use with NFP. The OvaCue fertility monitor is a hand held device that

is designed to measure salivary and vaginal electrical resistance. The OvaCue monitor provides a

predictive marker (a peak in salivary resistance readings) about 5-7 days before ovulation and a

vaginal electrical resistance nadir followed by a rise in vaginal electrical resistance readings as a

confirmation of ovulation. Because the CUE both predicts and confirms ovulation it can

potentially be used as a method to avoid or achieve pregnancy, i.e., as a means of or an assistive

device for NFP. The device is marketed and developed by Zetek Corp in Aurora Colorado. We

(Fehring and Gaska 1996) studied the OvaCue and found a strong significant linear correlations

between the peak in OvaCue salivary readings and the LH surge ($r = 0.79$, $p < 0.0I01$) and a

strong linear association between the vaginal electrical resistance nadir readings and the LH

surge ($r = 0.84$, $p < 0.001$). We also tested an older device that measured vaginal electrical

resistance (called the Ovulon) and felt there was some potential for the device but it is not manufactured, marketed or sold in the United States (Fehring and Schlaff 1998). However, since the OvaCue and Ovulon are invasive devices, they might not appeal to many women. There is potential for spread of infection if the vaginal probe for the monitors are not kept clean or shared among women. I commented in the1996 study that further research needs to take place with the OvaCue method. That recommendation still stands, furthermore, there never has been any study with the OvaCue to determine the efficacy or effectiveness of the monitor in helping women/couples to either avoid or achieve pregnancy. European researchers also suggested that the OvaCue Fertility Monitor utilizing the algorithm on which it currently is based cannot be recommended for natural family planning (Freundl, Bremme, Frank-Herrmann, Baur, Godehardt and Sottong 1996).

Over the past twenty years there have been numerous miniature microscope type devices that were developed and marketed for NFP. These devise are designed to observe changes in salivary ferning patterns that are purported to reflect the fertile window of the menstrual cycle. The changing patterns of salivary ferning are thought to reflect the changes in estrogen levels from a developing follicle much like what happens with the changes in the characteristics of cervical mucus. Women, who use these microscope type devices, lick a small microscope lens, let the saliva dry and then view the ferning pattern with the miniature microscope. There are three general patterns of ferning, i.e., no ferning which indicates an infertile time, a mixed pattern with some ferning which indicates potential fertility or transitional fertility, and then peak fertility when there is a clear ferning pattern that takes up the whole field of view.

I (Fehring 1998) published a study in which the Lady Free Biotester was compared with the self-observation of cervical-vaginal mucus and the self-detection of luteinizing hormone

(LH) in the urine. Twelve seasoned Creighton Model NFP teachers (with an average age of 36.7 years and who have used NFP for an average of 12 years) observed their cervical mucus on a daily basis, tested their urine for LH with the OvuQuick ovulation detection kits, and observed salivary and cervical mucus ferning patterns (with the Lady Free Biotester) for two menstrual cycles. The results showed that there was a very strong correlation between the LH surge in the urine and the peak in self-observed cervical-vaginal mucus ferning and salivary ferning. However, there was no definable beginning and end of the fertile time based on salivary ferning patterns. Some women in the study were able to observe what would be peak ferning patterns throughout some of the menstrual cycles. We did not recommend use of these microscope devices for use with NFP.

In 1990, Carl Dejarrsi, one of the developers of the hormonal birth control pill in the United States, predicted that in the future women would be able to monitor their own reproductive hormones in order to determine the fertile and infertile time of their menstrual cycles. He called this new method "Jet Age" natural family planning. In the late 1990s, Unipath Ltd. (Bedford, England) introduced two new electronic fertility monitors to help women determine their window of fertility (May 2001; Genuis and Bouchard 2010; Bouchard and Genuis 2011). The Persona fertility monitor was developed for women or couples wishing to avoid pregnancy and the Clearblue Easy Fertility Monitor (CBEFM) for couples choosing to achieve a pregnancy. The Persona monitor consists of a hand held electronic device and disposable test strips that were designed to detect urinary luteinizing hormone (LH) and a urinary metabolite of estrogen, i.e., estrone-3-gluconeride (E3G) from early morning urine samples. The monitor picks up a rising threshold level of urinary estrogen as the beginning of the fertile period and the urinary LH + 3 days surge as the end of the fertile period. The monitor displays a "green"

light to indicate the infertile days and a "red" light to indicate fertile days. The Persona also has a built in calendar formula when the LH surge is missed in order to determine the end of the fertile phase for those cycles. Persona is not available in the United States.

The CBEFM was also designed to identify a woman's fertile period by tracking the changing levels of estrone-3-glucuronide (E3G), the urinary metabolite of estradiol and by identifying the urinary surge of luteinizing hormone (LH) (Genuis and Bouchard 2010). The CBEFM however has a higher threshold level of detecting E3G levels than the Persona and thus has a shorter pre-LH phase and overall a shorter fertile phase to target the optimal days to achieve a pregnancy. The CBEFM was designed to read the result of anti-body impregnated test sticks to identify changes in the hormone levels and provide the user with a reading of "low", "high" and "peak" fertility. The "high" reading is triggered by the detection of rising levels of urinary E3G and the "peak" of fertility by the urinary surge of LH.   At a minimum, the monitor will indicate at least one day of "high" fertility and two days of "peak" fertility. However, in a very few women the day of the estrogen rise coincides with the day of the LH surge. The user therefore goes straight from "low" to "peak". In addition some women may only see "low" and "high" signals, particularly if they miss tests or have an infertile and anovulatory cycle.

German researchers conducted a study to determine the accuracy of the ClearPlan Easy Fertility Monitor (i.e., an earlier name for the monitor) (Behre, Kuhlage, and Gassner, et al. 2000). They monitored 53 women to detect daily serum levels of LH and estradiol and employed transvaginal ultrasound to ascertain the precise day of ovulation. The 53 women volunteers contributed 150 cycles of data with use of the CBEFM of which one cycle was determined to be anovulatory. Of the remaining 149 cycles, there were 135 cycles (90.6%) in which the CBEFM detected an LH surge, and there was an ultrasound confirmed ovulation. In

those 135 cycles, ovulation occurred 97.0% of the time during a three-day period that included

the two "peak" days plus the next day "high" on the CBEFM.   There were no ultrasound-

detected ovulations before the monitor "peak" days. They also found that in 92% of the cycles,

the first "high" reading on the monitor reading coincided with the serum estradiol rise day.

Another study with 30 healthy women volunteers showed that a Japanese-made version of the

CBEFM called the Clearview Primera Fertility Monitor (Mitsui Pharmaceuticals, Inc., Tokyo,

Japan) indicated up to 5 days of "high" fertility readings in 58.6% of the cycles (i.e., 17 out of 39

cycles) before the Clearview Primera Fertility Monitor "peak" reading and in 92.8% of the

cycles (i.e., 24 of 29 cycles) in a laboratory determined urinary LH peak (Tanabe, Susumu, and,

et al., 2001).   The authors of this study concluded that the device will allow couples to use the

information to time intercourse for the best prospects of achieving pregnancy.

The CBEFM is currently sold and marketed in the United States only for women and

couples who wish to achieve pregnancy. However, the information provided by the monitor

could be used inversely for avoiding pregnancy as an off product use. In greater than 70% of the

cycles, the monitor will provide 5 or more days of "high" and "peak" fertility and in 85% 4 days

or more. If a user avoids intercourse during the "high" and "peak" fertility days and at least 1-

day after, there should be less than a 30% chance of pregnancy using the monitor alone. This is

because sperm live 3 days in good cervical mucus and in rare cases up to 5 days and once a

woman ovulates she is only fertile from 12-24 hours. So at a minimum the fertility monitor

alone provides the user with a 1-3 day warning before ovulation takes place.

To use the CBEFM monitor as a method to avoid pregnancy alone would require the use

of another marker to help define the beginning of the fertile phase in those cycles that the

monitor underestimates the actual beginning. Use of the CBEFM and cervical mucus monitoring

together as a means to avoid might be beneficial. Having two markers to estimate the beginning, peak and end of the fertile time could be thought as a double check. A recent European study that compared a double check method (cervical mucus and a calendar count) with a single check method found that the double check method was somewhat more effective in helping couples to avoid pregnancy (European Natural Family Planning Study Group, 1999). However, a down side is that this makes the method more complex and has the risk of un-correlated signs of fertility, e.g., the peak in mucus and the peak in LH are not correlated. Teaching couples and women how to monitor the two signs of fertility and to interpret them makes the process a lot more complex. The complexity increases when the mucus signs are unclear and/or the CBEFM "peak" is not detected. The complexity of using both markers might also decrease the compliance with instructions and continuation of use. Users of the CBEFM and the Persona have found the ease of use as a single measure of fertility to be high (Severy 2001).

Based on a recommendation from Michael Zinaman, MD a reproductive endocrinologist from Loyola University School of Medicine at that time we (i.e., the Marquette University faculty) decided to develop a system of NFP that integrated the new technology of the CBEFM with a traditional mucus only type method. Clinicians and researchers from Marquette and other Universities, and some master NFP providers met to develop a new system of NFP called the Marquette Model or MM. The first MM system of NFP involved using the CBEFM as a second check for the beginning, peak, and end of the estimated fertile phase along with cervical mucus. The beginning of the fertile phase was either the change of mucus observations from baseline or a High reading on the monitor, which ever came first. The end of the fertile phase was three full days past the Peak day of cervical mucus or the last Peak reading of the monitor – which ever came last.

In order to provide a new system of NFP we also had to develop a user manual, a charting system, a registration, a follow-up, and a pregnancy evaluation form. We also developed three powerpoint sessions that included information on what is NFP, information on reproductive anatomy and physiology, instructions in how to observe cervical mucus, how to use the CBEFM, how to chart indicators of fertility, and how to use this information to avoid or achieve pregnancy. Other content in the second and third session included how to use NFP with special circumstances (i.e., post- partum, coming off hormonal contraception, and during perimenopause). We also included information on marital dynamics, benefits of using NFP, and church teaching on human sexuality. Developing graphics for all materials was also a difficult task, since we did not want to violate any copyright status from other models of NFP.

The next step was to develop a MM teacher training program and have the courses approved by faculty at the College of Nursing and at the University level. Since the Marquette University College of Nursing is a professional school, we only intended to offer the Marquette University NFP teacher training program for health professionals, i.e., professional nurses, physicians, certified nurse midwives, nurse practitioners, and physician assistants. We currently offer a NFP theory course and a NFP Teacher Training practicum. In the year 2000 we placed both courses in an online platform and now offer the courses only online. In 2013 we developed and began to offer an online NFP medical application course as well.

Evidence for the Effectiveness of the Marquette Method(s) of NFP

Since we developed a new system NFP we also needed to determine how effective this system of NFP was in helping couples avoid and achieve pregnancy. In 2007, we (Fehring, Schneider, and Raviele) published the first prospective cohort efficacy study of the MM. The participants for this study were 195 couples who sought NFP services at 5 clinics in 4 USA cities

(i.e., Atlanta, Madison, Milwaukee, and St. Louis). All 195 couples were taught how to use the monitor, self-observe their cervical mucus, and document their findings on a fertility chart. The participants were asked to avoid pregnancy for 12 months, to record on their charts their pregnancy intention before each menstrual cycle, to record all acts of intercourse, and to return completed charts to their NFP teachers.

The mean age of the female participants was 29.5 years (range 19-42) and the male partners 31.1 (range 18-49). The participants were primarily Catholic, married, and at least high school educated. The study period was between 1999 and 2006 and generated 1,795 documented months of use with a mean of 9.2 months per couple. Survival analysis (Kaplan-Meier) was used to determine correct use and total cumulative unintended pregnancy rates. There were 26 total unintended pregnancies, 3 with correct use. The correct use unintended pregnancy rate was 2.1% per 100 users over 12 months of use, and the total unintended pregnancy rate was 14.2% over 12 months of use. Of the 195 couple participants, 102 remained for the entire 12 months of the study. Of the 93 who discontinued from the study, 30 (15.4%) were lost to follow-up, and 19 (9.7%) left to achieve a pregnancy. The researchers concluded that the use of this dual method of NFP can be as effective as other fertility awareness-based methods of NFP. However, comparative studies are needed to confirm this conclusion.

In 2008 we published a retrospective effectiveness study of the MM and in 2009 a cohort comparison study between users of the MM and users of the CrM (Fehring, Schneider, and Barron 2008; Fehring, Schneider, Barron, and Raviele 2009). The 2008 retrospective study involved 204 couples (i.e., women with a mean age of 28.6 and their male partners, with a mean age of 30.3) who were taught NFP (by health professionals, physicians and nurses) at four sites in the United States (Saint Augustine, Florida, Atlanta, Saint Louis, and Milwaukee). Health

professionals helped the couples decide which combination of fertility indicators, i.e., basal body temp (BBT), cervical mucus monitoring (CMM), or CBEFM fit best with their lifestyle and reproductive needs. There were a total of twelve unintended pregnancies, only one with correct use. The twelve month correct use pregnancy rate was 0.6 (i.e., 99.4% survival) and the typical use (total pregnancy rate) was 10.6 (i.e., 89.4% survival) per 100 users. The researchers concluded that, when used correctly, the MM system of NFP is a very effective means of avoiding pregnancy.

The retrospective cohort comparison study involved couples who were taught the MM method of NFP in comparison to the CrM system of NFP (Fehring, Schneider, Barron, and Raviele 2009). The participants for this study came from the same four clinic sites as the previous study and involved 313 couples who were taught how to avoid pregnancy with the CBEFM plus CMM and another 315 who used CrM CMM only. Both methods involved standardized group teaching and individual follow-up. All unintended pregnancies were reviewed by health professionals, pregnancy rates (over 12 months of use) were determined by survival analysis, and comparisons of unintended pregnancy rates were made by use of the Fisher exact test. The researchers found a total of 28 unintended pregnancies with the CBEFM plus CMM group and 41 with the CrM CMM only group. The 12 month correct use pregnancy rate of the CPEFM group was 2.0%, and the total pregnancy rate was 12.0%, in comparison with a 3.0% correct use and 23.0%, total pregnancy rate with the CMM only group. There was a significant difference in the total pregnancies between the two groups applying the Fisher Exact test ($p < 0.05$). The researchers concluded that the CPEFM aided CMM method was more effective than the CrM CMM only method.

Although both studies involved retrospective chart audits of the NFP methods utilized, all of the couples were taught the methods prospectively with standardized formats and follow-up sessions. Even so, both studies have limitations in that they were not randomized clinical trials. The differences in results of the EPEFM plus CMM with CMM could only be due to factors other than use of the methods to avoid pregnancy – including investigator bias. However, the results do confirm earlier studies that compared CMM only with CMM plus BBT, and with later highly effective cohort studies of CMM plus BBT and calendar formulas as double checks for the beginning and end of the fertile phase of the menstrual cycle.

About the time these effectiveness studies were published we realized that our current system of NFP (called Marquette Model I) was still rather complex to learn, use, and teach. MMI requires three group sessions in the first three months, 15 minute follow-up sessions at the second and third month, and then a follow-up session at six months and 12 months of use. Furthermore, since it was a new system of NFP and we did not have many MM providers around the country, we wanted to provide greater access to this new system of NFP. To make the system easier to use and teach, we simplified the mucus ratings to Low, High and Peak based on the mucus characteristics (Fehring 2005). We also developed a simple algorithm for the system that applies to either the mucus ratings or the monitor levels of fertility. Our simple fertility algorithm is as follows:

TO AVOID PREGNANCY: Do not have intercourse during fertility

1. Fertility BEGINS on day 6 during the first 6 cycles; After 6 cycles of charting then

2. Fertility BEGINS on the earliest day of PEAK during the last 6 cycles minus 6 days

3. Fertility ENDS on the last PEAK day plus THREE full days; After 6 cycles

4. Fertility ENDS on the last PEAK day of the last 6 cycles plus THREE full days

We subsequently received a large federal and private foundation grant to develop a Web-based program to teach couples the MM of NFP online and to provide online consultation – i.e., to provide ease of access. This web site was launched in 2008. This online Web based program is in the English and Spanish languages. This online site (http://nfp.marquette.edu) includes information on NFP, user forums, automatic menstrual cycle charting systems, protocols for special reproductive circumstances (e.g., monitoring fertility during the postpartum breastfeeding transition), and online support from professional nurses and physicians. The online system of the Marquette Method now has over 10,500 women who have registered on the site. Up until Mary of 2015, these services were provided free of charge, even though they required 30 minutes to three hours per day of professional consultation.

The Marquette University College of Nursing NFP web site also has free information on fertility, a short instructional video, downloadable digital menstrual cycle charting systems, access to protocols for special circumstances (e.g., using NFP while breastfeeding), instructions on how to observe and chart natural indicators of fertility, and instructions for achieving and avoiding pregnancy. A unique aspect of the information section of the web site is a one page simple Quick Start Instructions that can be read in five minutes and allows the user to begin charting and use a NFP method. Women who register on the web site have access discussion forums and consultation from professional nurse NFP teachers, an obstetrician gynecologist with expertise in the use of NFP, and a bioethicist. The online charting system also notifies the user of possible health problems, including unusual bleeding, infertility, pregnancy, and cycle dynamics that are out of the norm.

Two professional nurses manage the online program and visit the online site every day to answer questions in the online forums, to provide one-on-one private consultation with participants, and to monitor the site for inappropriate responses. Forum and private questions are answered within 24 hours of being posted. The nurses also notify the web site physician consultant or bioethicist when questions are directed towards their expertise. The web site is periodically updated by the nurses with research on fertility, suggestions on how to manage health problems like polycystic ovarian disease, and how to optimize fertility.

The online charting system has designated sections for recording the results of either the CPEFM or self- observed cervical-vaginal mucus or both (as estimates of the fertile phase of the menstrual cycle) and provides spaces for recording the results as either L = low, H = high, or P = peak fertility. The charting system provides a pop-up window for the user that illustrates the three fertility levels provided by the fertility monitor or the cervical-vaginal mucus observations. The charting system also has a place to record menses on a scale of 1-3 with 1 = light; 2= moderate; and 3=heavy menstrual flow and a row for recording acts of intercourse (= I). The top of the chart has room for recording intention of use (to achieve or avoid pregnancy) for each cycle. The charting system automatically indicates (in light blue) the fertile phase (based on a built in fertility algorithm) as the user charts. There is no guessing as to whether the day is either fertile or not.

The participants can use the charting system and the MM model of NFP with either the use of the CBEFM, use of cervical mucus monitoring (CMM) or both (CBEFM + CMM). The online system automatically calculated the estimated fertile window based on the algorithm of the beginning of the fertile phase was day 6 for the first 6 cycles, then after 6 cycles, the earliest Peak minus 6 days. The end of the fertile phase is three full days past the last Peak recording of

CBEFM, CMM or both. The CBEFM detects a rising level of urinary estrogen to provide a High

fertility level and a threshold level of urinary luteinizing hormone to provide a Peak recording.

Users of the CBEFM used a test strip with first morning concentrated urine that was read by the

CBEFM (Swiss Precision Diagnostics, SPD). Participants who used CMM are asked to check

daily for low, high, or peak rated mucus whenever voiding and at the end of the day and to

record the most fertile level of cervical mucus observed.

The electronic charting system automatically notifies the user of the possibility of a

pregnancy when the post ovulatory phase of the charted menstrual cycle goes beyond 19 days.

The charting system will then prompt the user to take a pregnancy test. The online system also

launches a pregnancy evaluation form that the user is asked to complete. Two professional nurse

MM NFP teachers evaluate all pregnancies that occur among the participants. The NFP teachers

review the charting system for the days of fertility, the days of recorded intercourse, and the

information on the pregnancy evaluation form. Each participant is asked to record on their

fertility chart before each new cycle of charting their intention of either achieving or avoiding

pregnancy. A determination is made if intercourse occurred during the fertile time as designated

by the online charting system and MM protocols.

In 2011 we published a pilot study to determine the effectiveness of the web site system

in helping women avoid pregnancy (Fehring, Schneider, and Raviele 2011). We then conducted

a randomized comparison study, with a sister research web site, that compared use of the

CBEFM with monitoring cervical mucus changes as indicators for the fertile phase (Fehring,

Schneider, Raviele, Rodriguez, and Pruszynski 2013). We found with the 6-month pilot study

of the university based online NFP web site that among the 217 users avoiding pregnancy, there

was 1 unintended pregnancy with correct use (98% survival rate) and 9 total unintended

pregnancies providing a typical use survival rate of 89%. For those achieving pregnancy (N=38) the 6 months pregnancy rate was 60%. We concluded that the online NFP system seems to provide adequate acceptability and the ability to meet pregnancy intentions comparable to in-person teaching of NFP methods.

We then published the first randomized comparison of two Natural Family Planning (NFP) methods since the 1980s (Fehring, Schneider, Raviele, Rodriguez, and Pruszynski 2013). The aim of this study was to compare the efficacy and acceptability of two Internet-supported fertility awareness based methods (FABM) of family planning.   This study involved recruiting 667 women and their male partners and randomizing them into either the CBEFM group or a cervical mucus monitoring (CMM) group. Both groups utilized a web site with instructions, charts, and support. Acceptability was assessed online at 1, 3, and 6 months. Pregnancy rates were determined by survival analysis. We discovered that the CBEFM participants (N=197) had a total pregnancy rate of 7 per 100 users over 12 months of use compared with 18.5 for the CMM group (N=164). The log rank survival test showed a significant difference ($p < .01$) in survival functions.   Mean acceptability for both groups increased significantly over time ($p < .0001$). Continuation rates at 12 months for the monitor group were 40.6% and the mucus group 36.6%. We concluded that in comparison with the CMM, the CBEFM aided method of NFP was more effective. All users had an increase in acceptability over time but the results are tempered by the high drop-out rate.

We also found with a study involving the same participants in the randomized study described above that there was a big influence of motivation on the MM effectiveness demonstrated that motivation was a big factor in NFP effectiveness (Fehring, Schneider, Raviele, Pruzynski 2014). The 358women and (their male partners) indicated "how much" and "how

hard" they wished to avoid pregnancy on a scale of 1-10 before each menstrual cycle charted over 12 month of use. This motivation scale is used in the National Survey of Family Growth as a measure of motivation. In this study there were 28 pregnancies among the low motivation participants (N=60) and 16 among the high motivation participants (N=298). At 12 months of use, there were 75 pregnancies per 100 users for the low motivation group and only 8 for the high motivation group. There was an 80% greater likelihood of a pregnancy with the low motivation group (($\chi 2 = 25.5$, $p < .001$) OR = 1.80; 95% CI = 1.61-1.90). We concluded that high motivation to avoid pregnancy by both the female user of a behavioral method of family planning and her male partner is required for high efficacy. Assessing motivation of both the woman and her male partner before prescribing NFP methods is recommended. Another study with the same participants was conducted to compare the length of required abstinence between use of the CBEFM and cervical mucus monitoring (CMM) and found use of the CBEFM required significantly less abstinence than CMM (Fehring and Schneider 2014).

The efficacy and effectiveness studies of the MM system of NFP for avoiding pregnancy are based on use of NFP through twelve months or twelve to thirteen menstrual cycles of use. However, Trussell (2011) has pointed out that effectiveness of methods of family planning and in particular those that require behaviors for effectiveness will have multiplying un-intended pregnancy rates over time. Furthermore, there have been few extended use effectiveness studies with NFP methods. Researchers at the Georgetown University Institute for Reproductive Health conducted a study on the extended use of the Standard Days Method and found that the method continued to be effective two to three years after initiation of use to avoid pregnancy (Sinai, Lundgren, and Gribble, 2012). Therefore, we sought to determine and compare the extended use effectiveness (i.e., at 12 and 24 menstrual cycles of use) of the MM online system

of NFP among women (and subgroups of women) seeking to avoid pregnancy (Fehring and

Schneider 2017). We conducted a 24 month prospective effectiveness study of a university

based online web site with 710 women seeking NFP services and utilizing an online charting

system. Participants had a mean age of 30.03 years (*SD* = 5.4), 2.4 children (*SD*=2.0), 52% were

post-partum, and 47% had regular menstrual cycle lengths. Participants tracked their fertility

online with either cervical mucus monitoring (CMM), CBEFM monitoring, or both (CMM +

CBEFM). Unintended pregnancies were validated by professional nurses. We found among 710

non breastfeeding women there were 2 unintended pregnancies per 100 at 24 cycles of correct

use and 15 pregnancies at 24 cycles of typical use. However, the 225 women using the CBEFM

had a typical use unintended pregnancy rate of 6 at 24 cycles of use in comparison with the 129

women using CMM that had a typical use pregnancy rate of 19 at 24 cycles and with the women

(*n*=357) using both CMM+CBEFM that had a pregnancy rate of 18 at 24 cycles of use. We

concluded that our online fertility education system provides adequate ability to meet pregnancy

intentions. We also concluded that use of the CBEFM to estimate the fertility among non-

breastfeeding women provides the most secure method of avoiding pregnancy.

Applying the Marquette Model of NFP to Special Reproductive Circumstances.

The Marquette University web site NFP system also facilitated studies to determine the

effectiveness of special protocols for postpartum women (Bouchard, Schneider and Fehring

2013), effectiveness to avoid pregnancy among women transitioning through perimenopause

(Mu and Fehring 2014), and the effects of focused intercourse during the estimated fertile

window with couples wishing to achieve pregnancy (Fehring and Mu 2014). In addition, the

web site facilitated the provision of women's health beyond family planning in that the

professional nurses managing the Web site and user forum answer many related health questions

(e.g., assessing and managing polycystic ovarian syndrome and unusual uterine bleeding) with

(as of February, 2016) over 20,000 posts. In essence these studies demonstrated that the online

NFP Web site was a system of providing women's health care and the use of the menstrual cycle

as a vital sign for women's health.

Postpartum Breastfeeding

Use of NFP during special circumstance, especially postpartum breastfeeding can be very

difficult. During the postpartum breastfeeding transition to fertility, there is a great variability

among women in the time to return to fertility from about two months to well over 12. The

natural signs of fertility, and in particular mucus observations and basal body temp changes are

difficult to use and sometimes useless. Current methods of NFP do not do well in helping

women and couples to avoid pregnancy during the transition and in fact may increase the

unintended pregnancy rate. Mucus observations can be in difficult to use in estimating the fertile

phases during the postpartum, as mucus is often not associated with fertility or mucus

observations are unable to discern and differentiate.

In dealing with the problem of using NFP during the postpartum transition, we

(Marquette researchers and others, i.e., Fehring, Schneider, and Barron 2007) developed a

protocol for using the CBEFM and creating pseudo menstrual cycles based on the 20 day testing

period of the fertility monitor. Women essentially asked women to create 20 day cycles, until

they have their first LH surge and then first menses. The protocol was tested successfully with

ten women and then with a prospective 12-month longitudinal cohort study among 198

postpartum women aged 20 to 45 who were taught the postpartum protocol for avoiding

pregnancy with either online or in-person instruction (Bouchard, Fehring, and Schneider 2013).

The CBEFM was used to identify the fertile period by testing for urinary changes in estrogen and

luteinizing hormone (LH), and the results were tracked on an online website. During lactational amenorrhea, urine testing was done in 20 day intervals. When menses returned, the monitor was reset at the onset of each new menstrual cycle. Participants were instructed to avoid intercourse during the identified fertile period. Kaplan-Meier survival analysis was used to calculate unintentional pregnancy rates through the first 12 months postpartum. We found there were 8 unintended pregnancies per 100 women at 12 months postpartum and with correct use, there were 2 unintended pregnancies per 100 women at 12 months. We concluded that the online postpartum protocol may effectively assist a select group of women to avoid pregnancy during the transition to regular menstrual cycles.

We subsequently conducted a larger postpartum breastfeeding study (Fehring, Schneider, and Bouchard 2017) to analyze the effectiveness of an online nurse managed natural family planning (NFP) program among breastfeeding women (and sub-groups of these women). This study was a longitudinal comparative cohort study of breastfeeding women who as before used the Marquette University online NFP education program and menstrual cycle charting system. The participants were 816 women (mean age 30.3; $SD = 4.5$) who registered to use the online NFP system and indicated they were breastfeeding. The participants tracked their fertile time with either the CBEFM or with cervical mucus monitoring or both fertility indicators. All unintended pregnancies were evaluated by professional nurses and pregnancy rates as determined with survival analysis. We found that the correct use pregnancy rates were 3 per 100 users over 12 cycles of use and typical rates were 14 per 100 at 12 cycles of use. At 12 cycles of use, total pregnancy rates were: 16 per 100 for CBEFM users (N = 379), 81 per 100 among mucus only users (N = 45), and 14 per 100 for CBEFM plus mucus users (N = 390). We

concluded that use a nurse managed online NFP program for women can be effective in helping women avoid pregnancy while breastfeeding especially with correct use and consistent use.

Perimenopause

Use of natural family planning (NFP) by peri-menopausal women (i.e., those who are 40 years age and above) can be a challenge. NFP during the perimenopause is difficult because the menstrual cycle becomes more variable and the natural signs of fertility are difficult to track.. Furthermore, the peri-menopause is a time of a woman's and couples' life when they usually have completed their family size. There is also the greater chance of having a child with congenital abnormalities such as downs syndrome during the later reproductive ages. Although fertility of women decreases with age there still is a concern with unintended pregnancies especially among women with apparent ovulatory menstrual cycles.

We conducted a study to determine the efficacy of using natural family planning (NFP) methods to avoid unintended pregnancy among women of perimenopause age (i.e., 40 – 55 years old) (Fehring and Mu 2014). We used a secondary analysis of data from two prospective observational cohort studies among 160 women who used our university based in-person or online NFP service program to avoid pregnancy from January 2001 to November 2012. The women participants utilized either a hormonal fertility monitor, or cervical mucus monitoring or both to estimate the fertile phase of their menstrual cycles. Survival analysis was used to determine the pregnancy rate over 12 months of use. We found a total of 5 unintended pregnancies among the participants. The typical use pregnancy rate was 6 per 100 women over 12 months. The monitor alone participants (n=35) had a 12-month pregnancy rate of 3, the participants (n=73) who used mucus alone had a pregnancy rate of 4, and the participants (n=42) who used the fertility monitor plus mucus had a pregnancy rate of 6. We concluded that NFP

methods can be effective for older women to avoid an unintended pregnancy with correct use and adequate instructions. The pregnancy rate most likely was affected by diminished fertility and motivation to limit family size.

Achieving Pregnancy

One of the benefits of using a method of NFP is that it can be useful in helping couples to achieve a pregnancy, especially among couples with sub-fertility. We (Marquette researchers) conducted two studies that involve understanding the benefits of using NFP is focusing intercourse on the most fertile days of the menstrual cycle. Our first study involved comparing pregnancy rates when women have intercourse on self-estimated high and peak fertile days and when they only have intercourse on low fertile days during the fertile window (Mu and Fehring 2014). We used a prospective observational cohort study design and a convenience sample of 124 women who utilized our online charting websites to achieve pregnancy from January 2010 to November 2012. The participants used the CBEFM or self-observed cervical mucus or both to determine fertility during the estimated fertile window. Pregnancy rates were determined with Kaplan-Meier survival analysis and Chi square analysis was used to evaluate the efficacy of achieving pregnancy between two different intercourse patterns. We found a pregnancy rate of 87 per 100 women at 12 months when intercourse happened on high or peak days and 5 per 100 when intercourse occurred only on low days of the fertile window. Chi square analysis showed a greater proportion of pregnancies with intercourse on high and peak fertile days of the menstrual cycle ($x^2 = 40.2$, $p < .001$, df =1). We concluded that focusing intercourse on high or peak fertile days during the estimated fertile window enhances the probability of achieving a desired pregnancy. We also concluded that the Marquette online fertility charting system is effective in

assisting women to determine their fertile window and target intercourse accordingly to achieve pregnancy.

Finally, we conducted a study among women and couples seeking to achieve pregnancy with focused intercourse during the fertile phase of the menstrual cycle (Bouchard, Fehring, and Schneider, pending publication 2018). The aim of this study was to determine the effectiveness of achieving pregnancy with natural fertility indicators among women seeking to achieve pregnancy with a 12-24 month prospective effectiveness study of 256 volunteer women aged 20-43 (mean age 29.2 years) seeking to achieve pregnancy. Participants identified their fertile window with either the CBEFM, cervical mucus monitoring, or both, and recorded their observations on an online fertility-tracking system. Pregnancies were validated by nurses with an online self-assessed pregnancy evaluation form. Survival analysis was used to determine pregnancy rates. We found there were 150 pregnancies among the 256 participants with an overall pregnancy rate of 78 per 100 women over 12 menstrual cycles. There were 54 pregnancies (68%) among the 80 women using the fertility monitor, 11 pregnancies (46%) among the 24 women using mucus monitoring, and 90 (63%) among the 143 women using both mucus and monitor. The 12-cycle pregnancy rates per 100 women were 83 (monitor group), 72 (mucus group), and 75 (mucus and monitor group). The 12-cycle pregnancy rate among those women (181) attempting pregnancy the first time was 84 over 12 months of trying versus a rate of only 55 for those 67 women who had attempted before entering this study. Pregnancy rates reached 100% at 24 cycles of use for those women using the hormonal fertility monitor. We concluded use of the hormonal fertility monitor alone seems to offer the best natural estimate of the fertile phase of the menstrual cycle for women wishing to achieve a pregnancy. Focusing intercourse through 24 menstrual cycles can be beneficial for achieving pregnancy.

Future Research and Conclusion

Our current research effort is to conduct a large multiple site effectiveness study of the MM of NFP. We now have multiple health care professionals providing MM NFP services in the United States and Canada who either provide in person NFP services or distance education NFP services or both. Some of these providers have over 500 couples. Conducting a multiple site effectiveness study would help to not only validate the MM method but also our NFP teacher-training program for health professionals. Furthermore, this study would allow us to determine if there are differences in in-person provision of NFP services versus distance education.

We also recently launched MM I-Phone and Android fertility monitoring apps named "Marquette Fertility". The fertility monitoring apps allow for in-putting data from multiple natural indicators of fertility, i.e., CBEFM, LH tests, cervical mucus observations, and BBT. These apps will eventually be synced to a new MM web site for couples and providers. We intend to conduct a large prospective efficacy study of this new system in helping women and couples avoid or achieve pregnancy. Finally, we are also investigating the use of urine progesterone (P) test strips that are designed to help women self-confirm ovulation. We are testing protocols with use of the P test to confirm ovulation post the mucus peak day or the day of the LH surge. The P test confirmation of ovulation could be very helpful in clarifying the status of fertility in various situation, e.g., to confirm the first ovulation postpartum and after aberrant LH surges or Peak days of mucus among women struggling with polycystic ovarian syndrome .

In conclusion, we (the faculty and staff of the Marquette University College of Nursing Institute of NFP) been developing, modifying the MM system of NFP for the past twenty years.

We have a consistent record of collecting research evidence for our system of NFP and will continue to do so. In the Table 1 are listed the MM studies that have investigated the effectiveness or efficacy of the MM system of NFP for helping couples avoid or achieve pregnancy. In addition, we have conducted a number of studies to help understand the parameters of the menstrual cycle and the fertile window of the menstrual cycle (Fehring, Raviele, and Schneider 2004; Fehring, Schneider and Raviele 2006; Fehring and Schneider 2008), to understand the variability of the menstrual cycle after discontinuing hormonal contraception (Nassaralla, Stanford, Daly, Schneider, Schliep, and Fehring 2011), to determine the effects of lifesyle on the phases of the menstrual cycle (Lasquety, Rodriguez, and Fehring 2012), to understand the spiritual and marital dynamics in practicing NFP (VandeVusse, Hanson, and Fehring 2003; Fehring and Rodriguez 2013) and to investigate health professional's knowledge of NFP methods (Fehring 1995; Fehring, Hanson, and Stanford 2001). Having a NFP Institute at a University and being consistent in conducting research evidence for our system of NFP helps to bring credibility for NFP in general.

References

Behre, H. M., J. Kuhlage, and C. Gassner, et al. (2000). Prediction of ovulation by urinary hormone measurements with the home use Clearplan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. *Human Reproduction*, 15: 2478-2482.

Bouchard, T.P, and S.J. Genuis. (2011). Personal fertility monitors for contraception. *CMAJ*. 183(1): 73-76.

Bouchard, T. R. Fehring, and M. Schneider. (Pending publication 2018). *Frontiers in Medicine*.

Bouchard, T, M. Schneider, and R. Fehring. (2013). Efficacy of a new postpartum transition protocol for avoiding pregnancy. *Journal of the American Board of Family Medicine*. 26: 35-44.

Colombo, B. (1998). Evaluation of fertility predictors and comparison of different rules. *Genus,* 54 (1998): 153–167.

Djerassi, C. (1990). Fertility awareness: jet-age rhythm method? *Science,* 248(4959): 1061-1062.

European Natural Family Planning Study Groups. (1999). European multi-center study of natural family planning (1989-1995): Efficacy and drop-out. *Advances in Contraception*, 15: 69-83.

Freundl, G., M. Bremme, P. Frank-Herrmann, S. Baur, E. Godehardt, and U. Sottong. (1996). The CUE Fertility Monitor compared to ultrasound and LH peak measurements for fertile time ovulation detection. *Advances in Contraception,* 12(2): 111-121.

Fehring, R. (1995). Physicians' and nurses' knowledge and use of natural family planning. *The Linacre Quarterly,* 62(4), 22-28.

Fehring, R**.** (1998). Evaluation of the Lady Free Biotester in determining the fertile period. *Contraception*, 57(5): 325-328.

Fehring, R. (2005). New low and high tech calendar methods of family planning. *Journal of Nurse Midwifery and Women's Health,* 50: 31-37.

Fehring, R. (2009). Efficacy and efficiency in natural family planning services. *The Linacre Quarterly*, 76: 9-24.

Fehring, R. and N. Gaska. (1996). A comparison of the Ovulation Method with the CUE Ovulation Predictor in determining the fertile period. *Journal of the American Academy of Nurse Practitioners,* 8: 461-466.

Fehring, R., and Q. Mu. (2014). Cohort Efficacy Study of Natural Family Planning among Perimenopause Age Women. *Journal of Obstetrics, Gynecology, and Neonatal Nursing*. 43(3): 351-8.

Fehring, R. and D. Rodriguez. (2013). Spiritual care of couples using natural family planning *The Linacre Quarterly*, 80(3): 225-238.

Fehring, R. and W. Schlaff. (1998). Accuracy of the Ovulon fertility monitor to predict and detect ovulation. *Journal of Nurse Midwifery*, 43(2): 117-120.

Fehring, R. J. and M. Schneider. (2008). Variability in the hormonally estimated fertile phase of the menstrual cycle. *Fertility and Sterility,* 90(4): 1232-1235.

Fehring, R. and M. Schneider. (2014). Comparison of abstinence and coital frequency between two natural methods of family planning. *Journal of Midwifery and Women's Health,* 59: 528-532.

Fehring, R. and M. Schneider. (2017). Extended effectiveness of an online natural family planning service program. *MCN The American Journal of Maternal Child Nursing,* 42(1): 43-49.

Fehring, R., L. Hanson, and J. Stanford. (2001). Nurse-midwives' knowledge and promotion of lactational amenorrhea and other natural family planning methods for child-spacing. *Journal of Nurse Midwifery and Women's Health,* 46(2): 68-73.

Fehring, R., D. Lawrence, and C. Philpot. (1994). Use-effectiveness of the Creighton Model ovulation method of natural family planning. *Journal of Obstetric, Gynecologic & Neonatal Nursing, 23*(4): 303-309.

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

Fehring R., M. Schneider, and M. L. Barron. (2008). Retrospective efficacy of the Marquette Model of natural family planning. *The American Journal of Maternal Child Nursing,* 33(6): 348-354.

Fehring, R.J., M. Schneider, T. and Bouchard. (2017). Effectiveness of an Online Natura Family Planning Program for Breastfeeding women. *Journal of Obstetrics and Gynecologic and Neonatal Nursing,* 46(4): e129-137.

Fehring, R., M. Schneider, and K. Raviele. (2006). Variability in the phases of the menstrual cycle. *Journal of Obstetric, Gynecologic & Neonatal Nursing,* 35(3), 376-384.

Fehring, R., M. Schneider, and Raviele, K. (2007). Efficacy of hormonal fertility monitoring as A method of natural family planning. *Journal of Obstetric, Gynecologic, & Neonatal Nursing,* 36(2): 152-160.

Fehring, R, Schneider, M, & Raviele, K. (2011). Pilot Evaluation of an Internet-based Natural Family Planning Education and Service Program, *Journal of Obstetrics, Gynecology, and Neonatal Nursing,* 40(3): 281-291.

Fehring, R., M. Schneider, M.L. Barron, and J. Pruszynski. (2013). The influence of motivation on the efficacy of natural family planning. *MCN The American Journal of Maternal Child Nursing,* 38(6): 352-358.

Fehring, R., M. Schneider, M. L, Barron, and K. Raviele. (2009). Cohort comparison of two fertility awareness methods of family planning. *Journal of Reproductive Medicine,* 54: 165-170.

Fehring, R., M. Schneider, K. Raviele, D. Rodriguez, and J. Pruszynski. (2013). Randomized comparison of two Internet-supported fertility awareness based methods of family planning, *Contraception,* 88(1): 24-30.

Genuis, S.J., and T. P. Bouchard. (2010). High-tech family planning: reproductive regulation through computerized fertility monitoring. *Eur J Obstet Gynecol Reprod Biol,* 153(2):124-30.

Lasquety, M.G., D. Rodriguez, and R. Fehring. (2012). The influence of BMI levels on phases of the menstrual cycle and presumed ovulation, *The Linacre Quarterly*, 79(4): .451-459.T

Nassaralla, C. L., J. B. Stanford, K. D. Daly, M. Schneider, K. C. Schliep, and R. J. Fehring. (2011). Characteristics of the menstrual cycle after discontinuation of oral contraceptives. *Journal of Womens Health*. 20 (2): 169-177.

Lieva, R., U. Burhan, E. Kyrillos, R. Fehring, R. McLaren, C. Dalzell, and E. Tanguay E. (2014). Use of 'Ovulation Predictor Kits' as adjuncts when using fertility awareness based methods: A pilot study. *Journal of the American Board of Family Medicine,* 27(3): 427-429.

May, K. (2001). Home monitoring with the ClearPlan Easy Fertility Monitor for fertility awareness. *Journal of International Medical Research*, 29(Suppl 1): 14A-20A.

Mu, Q., and R. Fehring. (2014). Efficacy of achieving pregnancy with fertility focused intercourse. *MCN The American Journal of Maternal Child Nursing,* 39(1): 35-40.

Sinai, I., R. I., Lundgren, and J. N. Gribble. (2012). Continued use of the Standard Days Method. *J Fam Plann Reprod Health Care,* 38(3): 150-156.

Severy, L. J. (2001). Acceptability of home monitoring as an aid to conception. *Journal of International Medical Research*, 29(suppl):28A-34A.

Tanabe K, N. Susumu, K, Nishii, I. Ishikawa, and S. Nozawa (2001). Prediction of the potentially fertile period by urinary hormone measurements using a new home-use monitor: comparison with laboratory hormone analyses. *Human Reproduction*, 16: 1619-1624.

Trussell, J. (2011). Contraceptive failure in the United States. *Contraception*, 83(5): 397-404.

VandeVusse, L., L. Hanson, and R. Fehring. (2003). Couples' views of the effects of natural family planning. *Journal of Nursing Scholarship,* 35: 171-176.

Table 1:

Perfect and Typical Use Unintended Pregnancy Rates per 100 Women Over 12 Months of Use With Use of the Marquette System of NFP

Study	NFP Method	Indicators	Length*	Perfect	Typical
Fehring, et al.(2007)	Marquette (MM)	Mucus/Monitor	(21-42)	2	13
Fehring, et al.(2008)	MM	Mucus/Temp/LH	(21-42)	1	11
Fehring, et al.(2009)	MM vs CrM	Mucus/Monitor	(21-42)	2	12/23
Fehring, et al.(2011)	MM	Mucus/Monitor	(21-42)	2	9
Fehring, et al.(2013)	MM	Monitor/Mucus	(21-42)	0	7/19
Bouchard, et al.(2013)	MM Postpartum	Monitor	Variable	2	12
Fehring, et al.(2014)	MM Perimenopause	Monitor/Mucus	Variable	1.5	5
Fehring, et al.(2017)	MM	Monitor/+Mucus	Variable	1.6	4/7

* Range of length of menstrual cycles in study.