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Note that the "Current Medical Research" feature focuses on issues relevant to natural family planning and the beginning of life. This piece is complemented by medical reviews published in The National Catholics Bioethics Quarterly, which focus more on other areas of general medical interest including end-of-life issues. — Ed.

Natural Family Planning

Go to:

First Randomized Clinical Trial of Natural Family Planning in More Than 20 Years

Reviewed for CMR by Thomas Bouchard

Fehring et al. (2012) have published the first randomized comparison of two natural family planning (NFP) methods since the 1980s. Grimes et al. (2012), in a systematic review of fertility awareness-based methods for avoiding pregnancy, identified three randomized controlled trials that have been published: Medina et al. (1980), comparing the Ovulation Method to the Sympto-Thermal Method in Colombia; Wade et al. (1981), comparing the Ovulation Method to the Sympto-Thermal Method in Los Angeles; and Kass-Annese et al. (1989), comparing use of a vaginal sponge with and without a calendar plus Basal Body Temperature Method. There have been many observational cohort studies since that time, but Fehring et al.'s study would be the first randomized trial registered with ClinicalTrials.gov.

This 12-month prospective trial, published in the journal *Contraception*, recruited 667 couples randomized to use either a ClearBlue Fertility Monitor (CBFM) with an algorithm or a mucus-based method with an algorithm. The CBFM is a handheld monitor that detects both estrogen and luteinizing hormone (LH) in the urine, and displays the following readings—low (no hormone change), high (estrogen change above baseline detected), or peak (LH above threshold detected). The cervical mucus monitoring group monitored changes in their mucus using a three point scale (low, high, peak, similar to the readings on the CBFM). Both groups received online instructions in the use of an algorithm in addition to the monitor or mucus observations to establish the fertile window. Both groups charted online, and pregnancies were evaluated based on the couple's intention at the beginning of each cycle; motivation to avoid pregnancy on a scale of 1–10 was also evaluated in each cycle. Pregnancies were classified as "perfect-use failure" when the instructions were followed, and "user failure" when instructions were not followed. Acceptability of the method was evaluated with a survey and continuation rates were measured.

Total unintended pregnancy rates (including perfect use and user failure) were 7 per 100 women at one year for the monitor group and 18.5 per 100 women at one year for the mucus group, which was significantly different based on a hazards regression model. Perfect-use unintended pregnancy rates were 0 per 100 women at one year for the monitor group and 2.7 for the mucus group, with no significant difference between these rates. Acceptability survey scores for both methods increased over time, and there was no difference in acceptability between the two groups. Continuation rates went from 82.2 percent at 3 months to 40.6 percent at 12 months for the monitor group and from 66.4 percent at 3 months to 36.6 percent at 12 months for the mucus group; there was no difference in continuation rates between the groups. The most common reasons were "lost to follow-up," "no longer interested," and "wishing to achieve pregnancy."

The authors concluded that both monitor and mucus-based methods had low perfect-use unintended pregnancy rates, and showed that the monitor group had fewer total unintended pregnancies than the mucus group. These rates are better than those reported by Trussell (2011) in his evaluation of fertility awareness-based methods. They comment that the high discontinuation rates were related to initial non-participation, as well as being "lost to follow-up," "no longer interested," and "wishing to achieve pregnancy."

Comments Fehring et al. need to be congratulated for their rigorous randomized comparison of two methods of NFP. Their

comparison of a “high tech” (using a urine fertility monitor) and a “low tech” (using mucus) method with the combination of an ovulation-based algorithm, highlights the success of the newer method of NFP versus the traditional “gold standard” method of observing mucus. Those with experience in mucus-based methods may be interested by the higher total unintended pregnancy rate in the mucus group, even with the use of an algorithm as a “double check” in this group. The difference between perfect use and total (perfect use as well as incorrect use) unintended pregnancy rates highlights the fact that when presenting NFP methods to users, it is important to quote “real-world” pregnancy rates that include both correct and incorrect use of the method (rather than the “ideal” numbers of perfect use). Trussell should be happy to see these results so that he can update his oft quoted contraceptive failure rates for fertility awareness methods.

There were no differences in method acceptability between the groups, which suggest that both high-tech and low-tech methods represent viable options for different couples, depending on their needs. The initial and ongoing expense of the monitor may represent an obstacle to some which the authors do not discuss; however, because the study was funded this would not have been an issue for the study participants. As a personal reflection, the monitor may be a more acceptable method for NFP-naive users and medical professionals, who often place more credence in a test result than a physiologic sign; on the other hand, the mucus-based method may be more acceptable to NFP-experienced users who have seen many decades of successful use of mucus-based methods and may be skeptical of the use of new technologies in NFP.

The continuation rates are problematic, but are not out of keeping with other NFP studies with high discontinuation rates. The initial non-participation rates are unfortunate since 19 percent of the recruits did not provide any charts at all although they received a free fertility monitor, and one has to question their motivation to participate. Those “lost to follow-up” are particularly difficult to track since their recruitment was online and there is no face-to-face time with most participants; this is one of the flaws with an internet-based approach to recruitment. Those who discontinued for “wishing to achieve pregnancy” are inevitable in a population inclined to use NFP.

Fehring et al. mention in their methods recording couples' motivation for avoiding pregnancy. This is an important variable in the evaluation of pregnancy intention. They do not mention this anywhere else in their results or discussion, and it is of interest. I would be very interested in seeing the results of the motivation analysis in these two groups of participants. The inclusion of motivation in this randomized study is another example of the thoroughness with which Fehring et al. have developed this, the first randomized trial of NFP methods in over 20 years, and will be a model for NFP studies in the years to come.

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Obstetrics-Gynecology Residents Report Limited Experience with Natural Family Planning

Go to:

One of the essential components of good obstetrics and gynecological care is the provision of correct information on family planning methods. Therefore, having knowledge (and experience[1]) with all methods of family planning would be important for an obstetrics-gynecology (OBGYN) residency program. Researchers involved with (OBGYN) residency therefore sought to determine the knowledge and training that OBGYN residents obtain with specific reference to barriers and over-the-counter (OTC) family planning options (Miuklavcic and Isaacs 2012).

The researchers first developed and validated an 18-item questionnaire on knowledge and exposure to OTC family planning methods using Virginia Commonwealth University OBGYN residents. The 18 items included five questions on condom use, three on use of the diaphragm, and three on the use and counseling of spermicides. Other questions were on demographics, year in residency, and whether they wanted to learn about these methods. Included among the items was whether they ever counseled about natural family planning (NFP) and if they ever advised the use of cycle beads. They then randomly selected 50 of the 253 OBGYN residency programs in the United States and contacted the directors of the programs to help distribute the questionnaires and to help with compliance in taking the survey. They mailed out 959 surveys and received 202 (21%) of which four were

excluded due to false responses.

The researcher discovered that only 16.8 percent of the residents reported receiving formal lectures on condoms, 15.5 percent on diaphragms, and 12.3 percent on spermicides. The survey did not include a question on whether they received formal education on NFP or cycle beads. However, 49.5 percent reported counseling on NFP and 8.7 percent on cycle beads. What was meant by counseling in the use of NFP was not defined and could include that they were not effective or should only be used for helping to achieve pregnancy. The most discussed OTC family planning methods among the respondents were use of spermicide foams (93.2%) and gels (86.1%). Surprisingly, only 57 percent felt they had adequate knowledge to counsel about condoms. The researchers concluded that OBGYN residents receive little formal training on OTC family planning methods and need to seek more education on these methods to be adequately trained in an essential component of their practice.

Comments The fact that they only had a 21 percent survey return rate limits the generalizability of these results. We also do not know if the residents only counseled use of NFP to achieve pregnancy or talked only about their faults, i.e., a 49.5 percent rate is fairly high. It would have been beneficial if the questionnaire also included whether they received formal education on NFP methods.

Endnote

Go to:

1. OBGYN residents need to know about all methods of family planning, however, should only counsel use of morally acceptable methods.

Source

Miuklavcic, A. Y., and C. R. Isaacs. 2012. Obstetrics-Gynecology resident education regarding barrier and over-the-counter contraceptives: A national study. *Journal of Women's Health* 21: 1196–2000.

Few Low-Income Women at Title X Clinics Receive Information on NFP

Based on the knowledge that few (i.e., less than 1%) of federally funded Title X clinic patients report using natural family planning (NFP), researchers at the University of Missouri, Kansas, wished to determine the knowledge and opinions about use of NFP to prevent or plan a pregnancy among women attending such clinics (Witt, McEvers, and Kelly 2013). Their research purpose was also influenced by the assumption that knowledge of fertility and NFP could be better integrated into preconception planning for those couples desiring pregnancy.

In order to determine knowledge of fertility and opinions of NFP, the researchers surveyed women who attended federally funded family planning centers in 13 states. A questionnaire was distributed to administrative personnel at these centers via email and the personnel were asked to provide the surveys to their patients. Through this method, they were able to obtain 465 completed questionnaires with 374 in English and 91 in the Spanish language.

The survey included questions on history of family planning methods, attitudes about contraception, the influences of contraceptives, information received about NFP, and knowledge about fertility. The NFP questions addressed whether the patients received information about NFP or fertility awareness-based methods and for what purpose. They were also asked when they thought was the most fertile time in a woman's menstrual cycle.

The researchers found that only 20.8 percent (i.e., 94 of the respondents) had ever been informed about NFP at a Title X family planning clinic and only 9.1 percent had ever asked for or received information. Furthermore, only 37 percent ($N = 174$) had correct knowledge of the fertile time of the menstrual cycle. The authors also reported that 40 percent of those who believed they knew the fertile time of their menstrual cycle actually had a correct response but did not report how many of the participants this represented. The researchers concluded that based on the low level of knowledge of NFP and fertility that nurse practitioners need to discuss with their clients fertility awareness and believe that this knowledge is essential for assisting women to reach their reproductive goals.

Comments The authors also presented three cases of women who potentially could use NFP services, of which only one was provided NFP services and then, unfortunately, with back up use of condoms. These three cases were as follows. Case one was Lucinda (24-years-old) and her partner who previously used condoms and now is planning pregnancy within 12–18 months. She was offered NFP with backup condoms. Case two involved Maria who was 25-years-old with two young children and only saw her husband from Mexico 5–6 times a year. She was placed on an intrauterine device in order to have a “forget-able” method of family planning. The third woman (Natelie) was on and off birth control pills due to irregular cycles. She was 44-years-old and her partner 45 and was provided advice to seek tubal ligation. Of interest is that NFP would be a viable method for all three of these cases. The third woman, Natelie, probably has extremely low fertility (less than 2% chance of pregnancy) and since she had irregular menstrual cycles, at this stage of her life, pregnancy is most likely impossible. Furthermore, it is common for the woman to be

sterilized rather than the man even though it is a more extensive procedure for her. All of these cases illustrate distrust for NFP by the health professional providing family planning services and by the couples (many in non-marital relationships) seeking family planning services.

Source

Witt, J., K. McEvers, and P. J. Kelly. 2013. Knowledge and experiences of low-income patients with natural family planning. *The Journal of Nurse Practitioners* 9: 99–104.

Breastfeeding

Go to:

Review of the Marquette Breastfeeding Study

Reviewed for CMR by Rebecca Peck

There are few natural family planning (NFP) studies which examine the applicability of an NFP method during the breastfeeding and weaning stages of the postpartum period. NFP instructors have long known that this period can be especially challenging due to the woman's unclear cervical mucus and temperature signs (Kennedy et al. 1995; Labbok et al. 1991). Some methods of NFP (during breastfeeding) overestimate the actual days of fertility and lead to long stretches of confusing mucus patterns and required abstinence. Moreover, the basal body temperature shift will not be a helpful sign until after ovulation occurs, thereby limiting its usefulness during this period (Zinaman and Stevenson 1991). The Lactational Amenorrhea Method (exclusive breastfeeding during the first 6 months postpartum) is a highly effective way to avoid pregnancy but women still need help in identifying their fertile period during the weaning period (Tommaselli et al. 2000). Typical efficacy rates of NFP studies during this period, therefore, are usually lower due to these challenges (Zinaman and Stevenson 1991; Labbok et al. 1991). Recently, for example, a Breastfeeding Bridge Method developed for users of the Standard-Days Method of NFP, reported 16 unintended pregnancies per 100 women over 6 months of use (Sinai and Cachan 2012).

A successful Marquette breastfeeding protocol was developed by Bouchard, Fehring, and Schneider (2013) for breastfeeding women who utilize a hand-held urinary hormonal monitor in conjunction with an internet-based charting system. The breastfeeding protocol creates artificial cycles of 20 days during the postpartum amenorrheic period, whereby women test urinary estrone 3 gluconorate (E3G) and luteinizing hormone (LH) from days 6–26 on the monitor, i.e., the 20 days that the monitor will ask for a test strip and read it. If, during a 20-day interval, no LH surge has been detected, the monitor is retriggered to start a new 20-day interval. This method accurately signifies the onset of approaching fertility, which is known by increasing number of “highs” (which indicates the rise of urinary E3G from baseline), proceeding to an eventual “peak” (known by an increase of urinary LH), followed by ovulation and eventual resumption of the menses. Once the menses resumes, the monitor is used the traditional way, with urinary hormonal testing beginning on day 6. Online instruction, charting, and users forum were available for study participants (see, http://nfp.marquette.edu/).

The efficacy of a new postpartum transition protocol for avoiding pregnancy was a prospective, 12-month, longitudinal cohort study in which 198 postpartum women aged 20–45 years were taught the above protocol for avoiding pregnancy with either online or in-person instruction. 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. There were 8 unintended pregnancies per 100 women at 12 months postpartum. With correct use, there were 2 unintended pregnancies per 100 women at 12 months. The authors concluded that the online postpartum protocol may effectively assist a select group of women in avoiding pregnancy during the transition to regular menstrual cycles.

Comments The authors acknowledge that their participants were largely white, married, and Catholic which limits the generalizability of their study to the general population. Moreover, the cost of the monitor and testing strips may be perceived as too high by some. Finally, the lack of a control group is a real concern of this study as well as of the other existing NFP research pertaining to the postpartum period. However, the typical use efficacy rates found in this study are encouraging and among the lowest found in the existing postpartum NFP research. Randomized controlled trials will be needed to effectively compare the different methods.

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Menstrual Cycle

Go to:

Timed Intercourse Found Not Stressful for Women Seeking Pregnancy

European (i.e., National Institute for Health and Clinical Excellence) evidence-based guidelines for sub-fertile couples seeking pregnancy is to have intercourse every 2–3 days. The guidelines also counsel against focusing intercourse during the fertile window based on indicators of fertility because it is thought to be too stressful. At the same time, the guidelines provide no evidence for this recommendation. Researchers therefore sought to determine if timing intercourse based on self-observed indicators of fertility was stressful for couples seeking pregnancy.

The study was a prospective randomized controlled trial in which volunteer couples from the United Kingdom were randomized into either a group who were provided a digital urinary ovulation predictor kit based on detecting a rise from baseline in urine luteinizing hormone (LH) or a group of women who were advised to have frequent intercourse (every 2–3 days) and not use any self-observation fertility indicators. Of the 210 UK volunteer women/couples 115 were randomized into the digital LH kit group and 95 into the frequent intercourse group. Both groups of women were administered (at baseline and at the end of the study) two paper and pencil psychological subjective measures of stress, i.e., the perceived stress scale (PSS) and the positive and negative affect schedule (PANAS). They were also provided with a measure of health status with a short form health survey (SF-12). All participants collected their first morning urine samples to measure cortisol levels as a biological measure of stress. The digital LH kits were designed to measure the rise from baseline urinary LH. The women receiving these kits were asked to have intercourse on the positive test days. The control women received the digital LH test kits after completion of the study as compensation. The study data were collected over two complete menstrual cycles.

The researchers found that there were no differences in subjective perceived stress with the PSS and the PANAS and the biological measure of cortisol at all measurement time points. Although pregnancy rates were not the main question of the study, they did find 43 percent of the women in the digital LH group achieved pregnancy and 30 percent in the control group. The odds of achieving pregnancy with the digital LH test kit and timed intercourse was 59 percent greater compared to the control group. The researchers concluded that there were no differences in stress with women using timed intercourse compared with women using frequent intercourse to achieve pregnancy, nor was the pregnancy rate negatively affected by use of focused intercourse during the estimate fertile window.

Comments This is good news for couples who use fertility awareness based methods or natural family planning (NFP) to achieve pregnancy, in that couples using these methods are asked to focus intercourse on the estimated fertile window to achieve pregnancy. However, this study was based on use of an objective test for urinary LH that provided a very clear indicator of pending ovulation. Randomized comparisons of different natural indicators of fertility (i.e., cervical mucus versus urinary LH testing) would need to be conducted to further understand the dynamics of achieving pregnancy with traditional indicators of fertility used with NFP methods.

Source

Tiplady, S., G. Jones, M. Campbell, S. Johnson, and W. Ledger. 2012. Home ovulation tests and stress in women trying to conceive: A randomized controlled trial. *Human Reproduction* 28:138–51.

Variability of the LH Surge among Women with Regular Menstrual Cycles

Recent studies have shown that there is considerable variability among the phases of the menstrual cycle (e.g., day of ovulation and the follicular and luteal phases) and with hormonal measures (i.e., luteal phase progesterone levels and the luteinizing hormone, LH, surge) (Alliende 2002; Park et al. 2007; Cole, Ladner, and Byrn 2009). These recent studies did not investigate the variability of the LH surge configuration, amplitude, and duration in relation to the phases of the menstrual cycle and the estimated day of ovulation. Due to this gap, researchers sought to determine the relationship between the variants of the LH surge with the profiles of other reproductive hormones and the estimated day of ovulation (Direito et al. 2013).

This was a secondary analysis of prospectively collected data collected from healthy menstruating women between the ages of 18–45 from natural family planning centers in five European countries in the mid-1990s. The researchers studied 107 women who had regular menstrual cycles from 24–34 days in length. These women were asked to record and chart on a daily basis their basal

body temperature and changes in cervical mucus characteristics and to collect a first morning void urine sample. The urine samples were measured for LH, follicle stimulating hormone (FSH), esgrone-3-glucuronide (E3G), and pregnanedil-3α-glucuronide (PDG) with immunoassay techniques. The participants also underwent serial transvaginal ultrasounds every other day until a follicle was detected at least 16 mm in size, and then every day until evidence of the day of ovulation (US_DO). The researchers obtained 283 menstrual cycles of usable data.

The researchers discovered a variation in LH amplitudes, duration, and configuration; i.e., short, medium, double, and prolonged LH surges. They also described LH surges with single peaks, plateaus, double peaks, and multiple peaks. Prolonged LH surges were associated with longer cycle lengths, longer follicular, and luteal phases, with lower E3G, PDG, and LH levels on the third day of the cycles and higher LH and FSH levels during the luteal phase of the cycle. The women with LH surges with multiple peaks had smaller follicle sizes and significantly lower LH levels before rupture. The researchers concluded that multiple LH peaks might be a symptom of follicular insufficiency and a prolonged LH surge of luteal insufficiency. Both conditions might affect the probability of conception but further studies are needed to provide evidence with regard to pregnancies and birth outcomes.

Comments Limitations, as discussed by the authors, were that the participants were rather homogeneous with a mean basal metabolism index quite low compared to the European norm. They also eliminated any participants who were runners, breastfeeding, and those less than three months postpartum i.e., women who would have greater menstrual cycle variations due to those conditions. From a clinical and natural family planning perspective, a diversity of LH surges should be expected even among regularly cycling women. This is of particular importance for women who use urinary LH test kits to time intercourse or to estimate fertility for avoiding pregnancy.

Sources

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Under the Microscope

Go to:

Systematic Reviews on the Effectiveness of Natural Family Planning Methods

Basing clinical decisions on best possible evidence and high-quality research findings is an important topic in medicine and health care. This is because much of healthcare practice lacks a strong evidence base and many healthcare providers fail to integrate the best and latest research into practice. There have been a number of movements in health care and medicine that have been developed to promote the use of the best research findings in clinical practice. One of the best and most useful has been the development of systematic (also called integrative) research reviews (Mulrow 1994; Higgins and Green 2011).

Systematic research reviews are summaries of past research in which the reviewer (or reviewers) extract, analyze, and integrate findings from peer reviewed scientific studies and produce conclusions that can aid practice. Systematic reviews are based on a wide and exhaustive search of existing studies. These reviews have prescribed criteria, steps and methods in how to report the findings. The general steps include selecting a topic or issue that is important to practice, conducting an exhaustive search of the existing evidence, establishing criteria for selecting the best evidence, making a table of the studies in the review, analyzing the evidence, and providing a summary and conclusion.

The research studies selected for the reviews are also ranked according to level of evidence—i.e., from the most convincing to the least credible studies or evidence. The evidence is then provided a grade from A to F, e.g., strong scientific evidence = A, good scientific evidence = B, mixed or conflicting evidence = C, strong negative evidence = D, and lack of evidence = F.

An example of a simple evidence hierarchy is as follows:

Levels of evidence (from strongest to weakest):

- Systematic review of controlled comparison studies
- Randomized controlled studies
- Non-randomized comparison studies
- Quasi-experimental studies
- Non-experimental studies

- Program evaluations, quality improvement projects, case reports
- Opinions of respected experts and authoritative professional committees.

Another movement in health care and medicine is the call for comparative effectiveness research (CER) that involves providing evidence for treatments, methods or approaches for managing major health concerns and conditions. The purpose of CER is to identify what works best for which patients under what circumstances and is patient focused. The Institute of Medicine (IOM) has delineated the 100 most significant areas that need better research and comparative evidence for treating or managing health problems (IOM 2009). In the top 25 list of the IOM's CER is the effort to compare the effectiveness of innovative strategies for preventing unintended pregnancies. Which method of NFP works best for which couples (for achieving or avoiding pregnancy) and under what circumstances is of interest to those health providers who provide or refer for a moral (and integrative) approach to family planning.

Natural Family Planning and Evidence-Based Reviews

Two review articles on NFP methods were recently published that used some form of assessing, grading, and ranking research evidence for the effectiveness of major NFP methods provided in the United States. The first review study reviewed observational trials and provided a list of the data sources from which the studies were obtained (Smole and Robinson 2012). The authors ranked the Creighton Model (a mucus only based method) as the most effective and the Standard-Days Method, a fixed day calendar method, as the least effective. The authors graded the evidence for perfect use of six major NFP methods as a “B” and the evidence for the Creighton Model and the Sympto-Thermal Method as being the most effective NFP methods as “B.” Table 1 displays perfect and typical use pregnancy rates for major U.S. NFP methods as developed by the authors of this review.

Table 1

Effectiveness of Modern Natural Family Planning Methods

The second review article was developed by a group of individuals that represented several modern fertility awareness-based methods (FABM) of family planning (i.e., Creighton Model, Sympto-Thermal, Standard-Days Method, and the Two-Day simplified mucus method). This review used a strength of recommendation taxonomy (SORT) that was developed by experts in NFP and based on the recommendations of Lamprecht and Trussell (1997). The SORT criteria were developed for prospective cohort effectiveness studies, since the authors felt, that for pragmatic reasons, FABM methods do not lend themselves to randomized controlled trials (RCTs). The SORT criteria were further categorized or ranked as being (a) critical criteria, (b) important criteria, and (c) useful criteria. Critical criteria could receive a potential score from 0 to 4, important criteria a score from 0 to 2, and useful criteria 0 to 1. The maximum score that a study or method could receive is 56.

The critical criteria are as follows:

- Prospective study design;
- Involved only sexually active women participants;
- Large enough sample size to address the effectiveness question;
- Efficacy calculations began with the start of method use;
- Involved at least a one year follow-up;
- Statistical analysis involved either life table or survival analysis;
- All pregnancies were included;
- Intention to avoid (or achieve) pregnancy was determined prospectively (and ideally at the beginning of each menstrual cycle);
- Typical use analysis included all pregnancies and all cycles/months of use;
- Correct use analysis included only those cycles in which the method was used consistently and correctly;
- The study was reviewed for human rights compliance by an institutional review board.

The important criteria are:

- Users/participants obtained from multiple centers and multiple countries;
- Included a diverse population;
- Recorded all sexual behavior (e.g., intercourse, abstinence, withdrawal, and use of barriers).

Useful criteria are:

- Participant demographic profiles were presented and motivation was measured;
- Coital frequency was monitored.

The authors were able to obtain 29 peer-reviewed studies that were published since 1980. It is not clear what criteria was used to reject or include the studies, but the authors indicate that one robust "level one" cohort study was included for all of the modern FABM. The two highest scored studies (with a score of 56) were the efficacy studies of the Standard-Days Method and the Two-Day simplified mucus method developed through the Institute of Reproductive Health at Georgetown University. Four European sympto-thermal studies received a score of 55, one Marquette Model study received a score of 54, two Billings Ovulation Method studies received a score of 52, and two Creighton Model studies received a score of 43. The authors mentioned that it was difficult to determine the effectiveness of the Creighton Model studies due to the unique method of interpreting unintended pregnancies. For example, with the Creighton Model of NFP, if a couple knows they are in the estimated fertile phase and have intercourse it is classified as an achieving related pregnancy, even if the intention was to avoid pregnancy. The standard method of classifying an unintended pregnancy is based on the couple's intention. Therefore, most efficacy studies of NFP methods classify a couple who take a chance and have intercourse during the estimated fertile phase as an unintended pregnancy. The authors point out that the reviewed studies involved 8,200 women participants with over 107,000 cycles of use. Based on the 29 studies and NFP methods reviewed, the overall correct-use effectiveness was from 0.4–5.0 per 100 women years. Except for the European Sympto-Thermal studies (which had a typical use rate of 1–2 unintended pregnancies per 100 women years) the overall typical use ranged from 10 to 14 unintended pregnancies per 100 women years.

Comments The authors of both of these review articles on NFP effectiveness studies should be commended for their efforts as there are few systematic reviews on NFP other than the Cochrane review of older (1980s) RCTs of NFP methods (Grimes et al. 2012). It is also commendable that they provided some ranking and grading of the research studies included in their reviews. However, even with the use of their stated criteria for reviews there is some bias in the interpretation, as evidenced by the high ranking of the Creighton Model NFP in one study and the low ranking in the other. Future systematic reviews of NFP effectiveness studies might be best conducted by researchers and health professionals that are not tied to one of the NFP methods.

As a NFP researcher and developer, I obviously have a bias toward the Marquette Method, and given that fact I do have some concerns with the two reviews. First of all, I disagree with the reviewers of the Manhart et al. (2013) study that categorizes NFP as a sub-set of FABM. Natural family planning methods were developed before FABM. FABM accept the use of barriers during the estimated fertile time and hence are not considered a moral or true natural method of family planning. I understand the reason for using the term FABM as being more acceptable for those who have no problem with the use of contraception. But FABM came out of the long development and history of NFP methods not the other way around.

I also disagree that RCTs or CER studies of NFP methods are not practical or cannot be conducted. In fact they are needed so that health professionals can best decide which NFP methods work best for which couples and in what circumstances. I found it remarkable that the cohort comparison of the Marquette Method with the Creighton Model study was not even mentioned (Fehring et al. 2009). Furthermore, RCTs of NFP studies, although very difficult to conduct, are possible and desired—as testified by Dr. Thomas Bouchard in the current issue of *Current Medical Research*.

Other issues of concern are that many of the studies reviewed were not conducted in the United States and the findings might not relate to women and couples in the United States. Many of the U.S. studies primarily include only middle to upper class white educated Catholic participants, i.e., they lack diversity. Furthermore, most of the studies reviewed included women with only regular length menstrual cycles. At a given time, many women in a population will have irregular length menstrual cycles due to being postpartum, breastfeeding, peri-menopausal, or have irregular menstrual cycles as a result of health problems. Finally, some of the best prospective efficacy studies were not included in the reviews like the World Health Organization (1981) five country study of the ovulation method of NFP.

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Biography

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