

Natural Family Planning  
**CMR**  
Current Medical Research

**SPECIAL EDITION**  
**Research in Natural Family Planning**  
**1998-2003, A Review of Studies**

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*For more than five years (1998-2003), I have critiqued published peer reviewed research for Current Medical Research (CMR) on the topic of Natural Family Planning (NFP) and related subjects. Nearly 100 articles have been critiqued and many more have been commented on in CMR.*

*The following is a brief review of the best NFP studies in the past five years that were published in the CMR. They are grouped under the seven headings listed below. A short review of these studies is provided. Additional recommendations are offered for research and NFP practice.*

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## Accuracy of Biological Markers of Fertility

The three best studies on the accuracy of biological markers of fertility that have been reviewed for CMR in the past 5 years are all from European research groups and include the use of serial ultrasound of the follicles to pinpoint the actual day of ovulation as a reference marker.<sup>1,2,3</sup> The biological markers that were evaluated were all self-observed observations that are used in current systems of NFP, i.e., cervical mucus changes, basal body temperature (BBT), and urinary luteinizing hormone (LH).

The first study reviewed was by an Italian research group that correlated the estimated day of ovulation (by serial ultrasound of the follicles) with a urinary (LH) test, the peak in cervical mucus, the basal body temperature shift (BBT), salivary ferning, and salivary Beta-Glucuronidase levels.<sup>1</sup> The participants were 48 healthy women between the ages of 21 and 42 who generated a total of 148 menstrual cycles. The Italian researchers found that the most accurate self-observed measure was urinary LH, followed by the peak in cervical mucus and then BBT. Salivary ferning and Beta-glucuronidase were not accurate. According to the researchers, self-observed cervical mucus and BBT overestimated the day of ovulation and prolonged the time for abstinence.

The second study was conducted by a French group of scientists that developed a data set from 107 normally cycling women (aged 19 to 45) who produced 326 cycles of data that included daily measurements of urinary LH, self-observation of BBT, self-observation of cervical mucus, and transvaginal ultrasound examination of the ovaries.<sup>2</sup> The researchers found that the urinary LH estimated day of ovulation was (on average) an equivalent of the ultrasound determined day of ovulation. They estimated that the cervical mucus peak was fairly accurate (plus or minus 1 day of the estimated day of ovulation) in 70% of the cycles and that BBT was not a good estimator of the day of ovulation.

The third study was conducted by German researchers who reported the first independent investigation to determine the accuracy of the Clearplan Easy Fertility Monitor (CPEFM) in comparison with serial transvaginal ultrasound and serum hormone measurements among a population of healthy women.<sup>3</sup> The aim of the study was to test the home use performance of the CPEFM for the prediction of ovulation and the estimation of the potentially fertile period. The Clearplan monitor measures a threshold level of urinary metabolites of estrogen and LH. Fifty-three volunteer women between the ages of 21-33 (mean 26 years) with cycle lengths between 21 and 42 days utilized the Clearplan monitor for three consecutive cycles. They also attended a clinic to have their blood sampled for LH and estradiol and follicles examined by the use of transvaginal ultrasonography. The day of ovulation was defined as the day when the dominant follicle had disappeared. The 53 volunteers produced 150 usable cycles with a mean cycle length of 28 days (range 24.5 - 34.5).

The results showed that 63.5% of all cycles had up to 7 days warning of ovulation (mode = 6 days). In 91.1% of the cycles ovulation occurred during the 2 days of the CPEFM peak day readings and in 97% of the cycles ovulation occurred in the two days of peak fertility or the one

following day of high fertility. In most cycles (76.3%) ovulation occurred on the second day of peak fertility. Ovulation never occurred before the two days of the CPFM peak fertility.

It should be noted that of the 150 cycles recorded by the 53 women volunteers, 14 did not have a monitor detected LH surge along with an ultrasound confirmed ovulation. The CPFM does not detect the LH surge in about 1 out of 10 cycles. This could be due to the fact that the early morning urine test misses an LH surge that occurs in the evening for some women. The monitor, however, will most likely give an indication of “high” fertility on those days. Another important consideration is the results of this study were generated with young healthy women with fairly regular menstrual cycles.

The next two studies were conducted to determine the accuracy of two electronic fertility devices, the CUE fertility monitor (based on electrical resistance) and the Cyclotest.<sup>4,5</sup> The CUE 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 Cyclotest is a very precise electronic thermometer that has a built in algorithm that follows the rules of the temperature method of natural family planning (NFP).

Researchers from Baylor College of Medicine compared the CUE method with the Ovulation Method (OM) in defining the fertile time of the menstrual cycle.<sup>4</sup> In this study, ten experienced users of the OM monitored their cervical mucus, urinary LH and basal body temperature on a daily basis for two menstrual cycles. In addition they were also monitored by pelvic ultrasound from day 9 of their cycle until follicular collapse was observed. The Texas study had 42 usable cycles of data and the researchers found a strong significant linear correlation between the peak in CUE salivary readings and the LH surge ( $r = 0.82$ ,  $p < 0.001$ ). The researchers also found a very strong correlation between the vaginal electrical resistance rise and the day of follicular collapse ( $r = 0.98$ ,  $p < 0.001$ ). Furthermore, they reported that the vaginal electrical resistance rise occurred 100% of the time within one day of the follicle collapse whereas, the peak in mucus occurred only 69% of the time within one day of follicle collapse. What these results essentially mean is that the CUE markers of predicting and confirming ovulation are accurate when compared with other standardized methods of determining the fertile period. The Baylor researchers concluded that a more precise beginning and end of the fertile phase were found with the CUE than with OM and with fewer days of required abstinence.

A group of researchers from the Academic Teaching Hospital of the University of Dusseldorf, Germany tested the efficacy of the Cyclotest 2 Plus by comparing the fertile time in a woman's cycle as detected by the Cyclotest 2 Plus with the fertile time determined by the Sympto-Thermal Method (STM) of NFP.<sup>5</sup> Two hundred seven women used the device for 13 cycles which yielded 4,430 cycles of comparison. In 120 women (58%) the beginning of the fertile time (FA) was on the same day for both methods, in 57 women (27.5%) there was a difference of 1-3 days, in 3 women the FA was four days later with the Cyclotest 2 Plus. The computer/thermometer detected the beginning of the fertile time 6 days later than the STM in

only one woman. The authors considered this to be “risky.” The end of the fertile time (FE) as detected by the Cyclotest 2 Plus, was on the same day as the STM with 127 women (61.4%), the FE was 1-2 days earlier than the STM day with 4 women, and with only 1 woman did the device show the FE 3 days earlier than the STM day. From this data the researchers predicted that the device would detect a “wrong” FE in about 1 in 200 women and have a “dangerous” reduction in the fertile time in 2 out of 207 woman cycles. The authors concluded that the Cyclotest 2 Plus has a medium degree of reliability when used to avoid pregnancy and that there is a need for further studies to determine the actual efficacy of the device.

Two fertility devices have been researched that have not been found to be accurate in determining the fertile time. The first device called the Rovumeter is a small inexpensive plastic syringe like device that could be used to accurately measure cervical and vaginal fluid volume (CVF) in the home setting. In 1997, Flynn, Collins, and Roystons, et al. published a multi-center prospective study that was designed to determine how effective the Rovumeter was in defining the fertile period.<sup>6</sup> The study was conducted with 72 women volunteers from 3 NFP centers; 23 women from a center in Birmingham, England, 24 women from Milan, Spain, and 25 from Santiago, Chile. The women volunteers collected daily early morning urine samples and daily CVF samples beginning with the day after menses over three menstrual cycles. Laboratory immunoassays were conducted on the urine samples to determine the peak in luteinizing hormone (LH). The LH was used as the primary marker to define what they called the minimal period of potential fertility (PPF). The PPF was defined “as the day of the LH peak minus 3 to day plus 2 inclusive.” Based on this definition they discovered that the Rovumeter method only covered the PPF in 50% of cycles and that only 21% of the women volunteers had a consistent test result over three consecutive cycles. They concluded that the type of CVF (e.g., consistency and characteristics) is probably more important in determining fertility rather than the total CVF volume.

The second fertility device is a miniature microscope that is designed to view a dried sample of saliva on a small slide to determine if there is a ferning pattern or not. Theoretically if ferning is present the woman is fertile, if ferning is not present, the woman is in the infertile phase of her menstrual cycle. There are numerous miniature microscope fertility devices on the market and some have obtained the Food and Drug Administration approval as fertility devices. Researchers from the Department of Obstetrics and Gynecology from the University Hospital in the Netherlands recently studied the accuracy of salivary ferning as detected through the use of a miniature microscope and a regular light microscope.<sup>7</sup> The subjects for this study were 36 women with regular menstrual cycles. The day of ovulation was determined through the use of serial ultrasound of the ovaries, serum luteinizing hormone or the shift in basal body temperature. The researchers also compared salivary samples of estradiol levels with serum estradiol levels and asked 10 post-menopausal women and 10 men to perform salivary ferning tests as two comparison groups.

They found that there was a strong correlation between salivary estradiol and serum estradiol levels but did not find a significant correlation between salivary estradiol levels and ferning patterns. They also found a positive ferning pattern in 8 of the 10 menopausal women and all of the men. They concluded that the use of salivary ferning is an unreliable test for predicting fertility and discouraged the use of miniature microscopes as fertility monitors. The

results of this research study are similar to the study by the Italian researchers (that also analyzed the effectiveness of salivary ferning) and had the same conclusion in that salivary ferning (as measured by miniature microscope monitors) is not accurate for use in NFP.<sup>1</sup>

## **Analysis**

The overall analysis of this section of the review is that based on the best studies that utilized serial ultrasound to view and measure the growing follicle and observe the day of collapse as the estimated day of ovulation, the most accurate self test of ovulation is the use of test strips or monitors that measure the urinary metabolites of the LH surge. The studies on the electronic monitors show that the BBT/calendar based monitor and the CUE electrical resistance monitor both have some potential for use in NFP. The CUE monitored vaginal electrical resistance rise actually showed a very strong correlation with the estimated day of ovulation by serial ultrasound, but the CUE monitor is an invasive device. The Rovumeter (cervical vaginal fluid volume syringe) and the miniature microscopes to view salivary ferning were not found to be accurate and are not recommended for use in NFP.

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## **Effectiveness Studies on Methods of NFP**

There have been seven effectiveness studies reviewed in the CMR over the past five years. These studies include the five center meta-analysis of the Creighton Model (CrM) System of NFP, the single center Houston study of the CrM, a European study on the double and single check STM systems, two studies on two different standard day calendar methods that use bead systems for tracking the cycles, and two effectiveness studies on electronic fertility monitors, i.e., the Baby/Lady Comp electronic BBT monitor and the Persona monitor that measures urinary metabolites of estrogen and LH.

## **Creighton Model Ovulation Method**

The Creighton Model (CrM) is a standardized educational system of the Ovulation Method (OM) that was developed by Dr. Thomas Hilgers, MD and others during the mid to late 1970s and early 1980s. A prospective study on the effectiveness of the Creighton Model (CrM) system of the Ovulation Method (OM) to avoid pregnancy was conducted at five centers (Omaha, St. Louis, Wichita, Houston, and Milwaukee) in the United States.<sup>8</sup> The combined results of these five effectiveness studies were analyzed and reported by Thomas Hilgers, MD, Director of the Pope Paul VI Institute for the Study of Human Reproduction and Joseph Stanford, MD from the Department of Family and Preventive Medicine at the University of Utah, Salt Lake City. The five studies represented a total of 1,876 couples and 17,130.0 couple months of use. The results were analyzed using life table analysis. Method effectiveness (or perfect use) of the CrM to avoid pregnancy was 99.6 at the 12th ordinal month and 99.5 at the 18th ordinal month. Use effectiveness (or typical use) rates to avoid pregnancy were 96.8 and 96.4 at the 12th and 18th ordinal months. Howard and Stanford reported an effectiveness study of the Houston subset of the CrM that was published a year after the Hilgers and Stanford meta-

analysis of the CrM.<sup>9</sup> The Houston study utilized 701 couples using the CrM who had a total of 17.12 pregnancies per 100 couples over a 12 month period. Of these pregnancies, only 0.14 were method related, 1.43 were unresolved pregnancies, 2.72 were a result of user or teacher error and 12.84 were a result of couples having genital contact on a day of known fertility. The authors utilized life table analysis to examine “probability of pregnancy” rather than “failure of the method” as a way to be more objective in their analysis.

### **Sympto-Thermal Methods**

The European Natural Family Planning Study Groups reported a large prospective efficacy study that compared two versions of the Sympto-Thermal (ST) Method of Natural Family Planning.<sup>10</sup> One ST method called the Double Check Method, involves use of a calendar day formula and the observation of cervical mucus to determine the beginning of the fertile period. Two biological markers are used to determine the end of the fertile phase (i.e., the peak in cervical mucus and temperature changes). The other ST method, called the Single Check Method, uses one biological indicator (cervical mucus) to determine the beginning of the fertile period and one indicator (temperature) to determine the end of the fertile period. This efficacy study involved 10 European countries and 15 NFP centers that generated data for the study during the time period of 1989 through 1995.

The Double Check Method involved the analysis of 16,865 cycles of exposure generated by 1,046 women between the ages of 19 and 45; and the Single Check Method involved 214 women in the same age range and 1,495 cycles of exposure. At the end of 12 cycles of use, the Double Check Method had 34 unintended pregnancies for a rate of 2.6%, a drop-out rate of 3.9% and a lost-to-follow-up rate of 3.1%. The Single Check Method experienced 13 unintended pregnancies for a rate of 8.5%, a drop out rate of 3.0%, and a lost-to-follow-up rate of 23.4%.

The lower unintended pregnancy rates in the Double Check group was surprising to the European researchers in that women in the Single Check group were older, more experienced in the use of NFP, already had on average two children, and were in stable relationships (i.e., 98% were married). The researchers speculated that one of the reasons that there were lower pregnancy rates in the Double Check group was that this method required more pre-ovulatory days of fertility and thus reduced the risk of getting pregnant through long sperm survival.

### **Standard Day Calendar Methods**

The “fixed-day” (also called the Necklace Method or Standard Day Method) of NFP involves use of a “blanket rule” type of Calendar-Rhythm along with a bead system to keep track of the days of the menstrual cycle. For example, one fixed day method developed and tested at Georgetown University and by the United States Center for Disease Control and Prevention, is for a woman to consider herself fertile from days 9 through 19 of her menstrual cycle. In order to see how useful this method might be, researchers from the Population Council in New York and Guatemala evaluated the “regularity” of the menstrual cycles among 303 Guatemalan women of whom 96% were Mayan.<sup>11</sup> The 303 Guatemalan/Mayan women yielded 880 cycles of useful data. Regularity was defined as having a cycle length in the range of 26 to 32 days for three

consecutive cycles. Cycle lengths out of this range would not be effective in the use of a “fixed-day” calendar system.

Of the 808 cycles, 76% fell within the cycle length range of 26 to 32 days. More than half (54%) of the women participants did not have 3 consecutive regular cycles. The researchers estimated that from 11 to 28% of the cycles would have days within the 9-19 blanket which could be considered fertile days. The apparent irregularity of the Mayan women’s menstrual cycles seem to be influenced by the younger age and high incidence of breast-feeding among this population of women. The researchers essentially found that the 9-19 method would not work with a sizable portion of the Mayan women.

A follow-up effectiveness study of the “fixed-day” bead method of Calendar Rhythm was tested among 301 couples (women between the ages of 18-39 years) living in the Guatemalan highlands.<sup>12</sup> A team of one supervisor and three instructors at 5 centers taught the method. Instructors visited each couple and completed follow-up forms after the first three cycles and every three months until the end of the 12 -month study period. Suspected pregnancies were confirmed by pregnancy tests. After 12 months of use, 32 couples were pregnant giving an 11% pregnancy rate. However, only 34% of these couples were sure that they did not have sexual relations during the fertile period. At 1, 3, and 12 months, 100% of the women reported satisfaction with the method. Only 5 of the men reported being dissatisfied due to the periodic abstinence.

Researchers from the Georgetown University Institute for Reproductive Health (IRH) recently reported on a multi-site effectiveness study of what they call the Standard Day Method (SDM) of family planning.<sup>13</sup> The SDM is essentially a modified form of Calendar Rhythm that has a “fixed” number of days of fertility for each cycle – i.e., day 8 to 19. The method is intended for women who have regular cycles between 26 and 32 days in length.

The SDM was prospectively tested for its effectiveness in helping couples avoid pregnancy among 478 women from 5 different sites in three developing countries (the Philippines, Peru, and Guatemala). The participants were between 18-39 years old, had menstrual cycles between 26-32 days in length, and were willing to avoid intercourse for 12 consecutive days each cycle. Each study site had 5-10 trained health workers who instructed the participants in the SDM and who contacted them monthly for the length of the study. Participants were also asked to keep a calendar to record the beginning and end of their cycles, acts of intercourse, and any method other than SDM used to avoid pregnancy (e.g., condoms or withdrawal).

The SDM uses a colored bead necklace system (called CycleBeads) that indicate the beginning (a red bead) of the cycle, followed by 6 brown beads of infertility, then 12 days of fixed fertility (white beads) and then 13 more days of infertility (with brown beads). The CycleBead system also has a dark brown bead for day 27 that indicates to the user that if they start their menses before that date they should contact their “provider.” If they reach the last bead (day 32) and still have not started their menses they were also asked to contact their provider. The marker beads helped the user to know whether they fell into the 26-32 day cycle length to which this CycleBead system applies. The rules for the CycleBead system are simple, i.e., “on

brown bead days you can have intercourse with very low probability of pregnancy”, and “on white bead days you can get pregnant. Avoid unprotected intercourse to prevent a pregnancy.”

The 478 participants had a mean age of 29.4 years, most (90%) had at least a primary level education, 98.9% had children (mean 2.5), and almost 80% were Catholic. One third of the women were breast-feeding on admission to the study, but had at least three menstrual cycles since the last birth. Of the 478 women who entered the study, 46% completed 13 cycles of use. Most (28%) of the women who discontinued did so because they had 2 cycles out of the 26-32 day range.

The 478 women generated 4,035 cycles of data of which 92% had correct method use (i.e., no intercourse on the white bead fertile days of 8-19), 5% of the cycles had intercourse with condoms or withdrawal during the fertile phase, and 3% had intercourse during the fertile phase. Only 43 of the 478 women became pregnant with use of the CycleBead system. Of these 43, 15 conceived when having intercourse outside of the “method defined” fertile phase. Most (65%) of the pregnancies occurred in cycles in which the participant reported intercourse during the 8-19 day fertile phase. Using life table analysis the Georgetown University researchers were able to calculate a 1- year pregnancy rate of 4.8 (95%; CI 2.33-7.11) with perfect use and a pregnancy rate of 12.0 (88%; CI 8.74-15.33) with typical use of the method (that involved all cycles and all pregnancies).

The authors concluded that this study demonstrated that the SDM with use of the CycleBead system was an effective method of family planning that is comparable to the male condom and significantly better than other barrier methods. They also concluded that this method is acceptable to couples in a wide range of settings and would be a valuable addition to reproductive health providers and other community services programs.

### **Electronic Fertility Monitors**

The Babycomp/Ladycomp (LC/BC) is a fertility monitor that electronically records basal body temperature and Calendar Rhythm and identifies for the user the infertile and fertile days of the menstrual cycle. The Babycomp version of the monitor is targeted for women who are trying to conceive and the Ladycomp for those women who are trying to avoid a pregnancy. The monitor does not show the degree of temperature but rather a green, red or yellow light. The green light means infertility, the red light fertility and a yellow light that indicates unsure or probable fertility. The LC/BC is similar to two other electronic fertility monitors now on the market, i.e., the Bioself 2000 and the Cyclotest. Data from these monitors can be interfaced with a personal computer and displayed as fertility charts.

The German researchers from the Women’s Clinic (Frauenklinik) at the University of Dusseldorf were able to obtain the names of 648 women from Germany and Switzerland who purchased and used the LC/BC.<sup>14</sup> These women were sent questionnaires on whether they were using these electronic devices to achieve or avoid pregnancy and whether the light on the day they had intercourse was green, red or yellow. Of these 648 women, 597 used the device for contraceptive purposes (i.e., to avoid pregnancy) over a grand total of 10,275 months. Thirty-three of these women had an unintended pregnancy. Using life-table analysis, the researchers

determined that there was a 5.3% unintended pregnancy rate after one year, 6.8% after two years of use and 8.3% after 3 years. The average length of the fertile period that the monitor identified was 14.3 days. Ninety percent of the LC/BC users would recommend the monitor for their friends. Twenty-one of the 33 users with an unintended pregnancy would also do so.

Researchers from Germany, Ireland, and the United Kingdom collaborated on the first European study to determine the effectiveness of a personal hormone monitoring device to help women to delay pregnancy.<sup>15</sup> The personal hormone device was developed by Unipath Ltd. (Bedford, England) and was a prototype of the Persona (R) fertility monitor now marketed in Europe. The data collected in this three country study helped to refine the algorithms used for the current Persona hormone fertility monitor. The hormone monitor that was used in the collaborative European study consisted of a hand held electronic device and disposable test strips designed to detect urinary luteinizing hormone (LH) and a urinary metabolite of estrogen, i.e., oestrone-3-gluconeride (EG) 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 researchers recruited 710 volunteer women (median age 30 years, with regular menstrual cycles) through press advertisements from the general population of England, Germany and Ireland to use the fertility monitor (without training) for the purpose of avoiding pregnancy. The volunteer subjects also recorded all acts of intercourse and their interpretation of the monitor's status on a daily basis. At completion of the study, there were 67 method related pregnancies (i.e., a pregnancy resulted from having intercourse on a "green light" day), 92 user related pregnancies (intercourse on "red light" days,) and 3 unsure pregnancies, from 7209 cycles of use. A 13 cycle life table analysis yielded a method pregnancy rate of 12.1 percent. After changing the algorithm to a more conservative formula the method related pregnancy rate dropped to 6.2 percent. The revised algorithm is what is currently used in the Persona (R). The authors calculated the method effectiveness based on the new algorithm for the Persona as 93.8 percent and concluded that personal hormone monitoring is simple to use and of value for women trying to avoid pregnancy.

Study	Method/Type	No. of Subjects/Cycles	One Year Pregnancy Rate	
			Perfect	Imperfect/Typical
Hilgers (8)	OM/CrM	1,876/17,130	0.50*	3.2*
Howard (9)	OM/CrM	701/5,630	0.14	17.12**
European (10)	STM/2XCheck	1,046/16,865		2.6
European (10)	STM/1XCheck	214/1,495		8.5
Burkhart (12)	Fixed Day 9-19	303/808		11.00**
Arevalo (13)	Standard Day 8-19	478/4,035	4.8	12.00**
Fruendl (14)	BBT/LadyComp	597/10,275		5.30**
Bonnar (15)	Urine LH/Persona	710/7,209		12.1/6.2***

\* reported in study as method (99.5) and use effectiveness (96.8) per 100 couple-

	years
**	pregnancy rates that include all pregnancies and all cycles
***	pregnancy rates before/and after an algorithm change

## Analysis

Comparison of studies to determine the effectiveness of methods of NFP to avoid or achieve pregnancy is difficult due to the different methods of NFP, the different population studied, the methods used to interpret pregnancies, the length of the study, whether the study was prospective or retrospective, whether the participants were formally enrolled and expressed consent to either avoid or achieve over a specified period of time, the frequency of intercourse among the users, the age and education of the users, the various reproductive categories represented, the teaching methods and preparation of the NFP providers, biases of the researchers and whether there were any comparison groups (to name some obvious variables that could affect pregnancy rates). Of the above studies probably one of the best was the European study that compared the single versus double check system between two groups of users.<sup>10</sup> The Georgetown study of the SDM method was also very well thought out and provided rigorous criteria for entrance and monthly follow-up.<sup>13</sup> The German study of the electronic BBT system was retrospective and self recall and thus produced the least reliable results. The Persona monitor study was with the use of a prototype of the fertility monitor and needs to be replicated with the new algorithm. The CrM studies were multi-site and had a large number of participants but there were no comparison groups.<sup>8</sup> The couples utilizing the CrM are well educated, white, Catholic couples. Furthermore, the interpretation of the pregnancy outcomes are biased toward being classified as achieving related rather than user failure. The Houston subset of the CrM as interpreted by Howard and Stanford with the (net) typical use pregnancy rate of 16.98 and the (gross) pregnancy rate of 18.72 are most likely closer to reality.<sup>9</sup>

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## Probabilities of Fecundity

A number of studies on the day specific probabilities of pregnancy during the menstrual cycle have come out of the research efforts of scientists from the National Institute of Environmental Health Sciences. Much of this research was stimulated by a study reported in the 1995 issue of the New England Journal of Medicine which verified that there are only 6 days in a woman's menstrual cycle that are potentially fertile, i.e., the day of ovulation and the 5 preceding days.<sup>16</sup> These 6 days are known as the "fertile window." The probability of pregnancy if a couple has intercourse on the first day of that window is around 10% and increases to a peak of about 40% during the two days before ovulation.

Researchers from the National Institute of Environmental Health Sciences conducted a prospective study to estimate the probability of that 6-day fertile window occurring on a given day of the menstrual cycle.<sup>17</sup> The study participants were 221 healthy women between the ages of 25 and 35 who collected their first morning urine on a daily basis and recorded the days in

which intercourse and menstrual bleeding occurred. The estimated day of ovulation was determined by the ratios of urinary metabolites of estrogen and progesterone. There were 696 cycles with an estimated day of ovulation that were included in the analysis. The cycle lengths ranged from 19 to 60 days.

What the researchers found was that ovulation occurred as early as the 8th day and as late as the 60th day of the menstrual cycle. They also found that even among women with regular cycles, the post-ovulatory period was highly variable, ranging from 7 to 19 days. They estimated that approximately 2% of women were in their fertile window by the fourth day of their cycle and 17% by the seventh day. By days 12 and 13 of the cycle over half of the women were in their fertile window. There was a 1-6% probability that women were in their fertile time on the day their next menses was expected. The authors concluded that the timing of the fertile window is highly variable even among women who have regular menstrual cycles. More than 70% of women are in their fertile window before day 10 and after day 17 of their menstrual cycle. They also concluded that there are few days in the menstrual cycle during which some women are not potentially fertile.

Researchers from the National Institute of Environmental Health Sciences also determined that the highest day of fecundity is the day before ovulation.<sup>18</sup> They determined this by re-analyzing two existing data sets that provided information on the estimated day of ovulation based either on the last day of hypothermia (i.e., the shift of basal body temperature/BBT) or on urinary reproductive hormone metabolites. The BBT data were taken from charts collected by Barrett and Marshall from British couples who used BBT during the 1950s and 1960s. The urinary steroid based estimate of ovulation was taken from charts of couples from North Carolina who were attempting to become pregnant in the early 1980s. Both the English couples and the North Carolina couples recorded their acts of intercourse and subsequent pregnancies. The English study yielded usable data from 241 women and 2,192 menstrual cycles, the North Carolina study yielded usable data from 221 women and 674 menstrual cycles.

Both sets of “error corrected” data found the fertile interval to begin 5 days prior to ovulation and ending on the day of ovulation. Both sets of data also indicated that the maximum probability of pregnancy (i.e., estimated day of peak fecundability) occurs with intercourse one day prior to the estimated day of ovulation.

David Dunson, PhD, a bio-statistician from the National Institute of Environmental Health Sciences (NIEHS), Professor Bernardo Colombo from the Department of Statistical Science at the University of Padua, Italy and Donna Baird (a colleague from NIEHS) utilized a statistical model to estimate the effects of male and female age on natural fertility and the length of the fertile window.<sup>19</sup> These researchers determined probabilities of pregnancy associated with intercourse on specific days relative to ovulation and compared them across the following age groups; 19-26, 27-29; 30-34 and 35-39 years. Data for the analysis was obtained from a large European multinational study that enrolled 782 women between the ages of 18 and 40 who kept records of their daily BBT, acts of intercourse and menstrual bleeding. Study results were based upon 2539 cycles of data from 647 participants that had at least 1 day of intercourse during a generous 10-day estimate of the fertile window (i.e., 7 days prior to and 2 days after the

estimated day of ovulation). Ovulation was estimated as the first day of the temperature shift. There were 433 detected pregnancies that occurred in the 2539 cycles.

The data showed that there was a 6-day window of fertility in which there was a 5% chance or more that intercourse would result in pregnancy. This 6-day window of fertility that included the day of ovulation and the 5 days before, was the same for the youngest three age categories and one day shorter for the 35-39 age category. The shortened fertile window for the older age category was not statistically significant. Dunson, Columbo and Baird also found that the day specific probabilities of pregnancy in the 6-day fertile window decreased with age. There was a close to 50% decrease in fertility among women in their late 30s compared to women in their early 20s. The researchers also found a decreased fertility among men. When they adjusted for the woman's age, the men in the 40 plus age range had significantly reduced fertility. The authors concluded that fertility for women begins to decline in the late 20s and that the decrease accelerates by the late 30s. Men's fertility is less affected by age, but does show a significant decline by the late 30s.

Researchers from the University of Padua, Italy and the National Institute of Environmental Health Statistics collaborated on a project with Georgetown University researchers to determine the relationship between cervical-vaginal secretions and fecundability.<sup>20</sup> The hypothesis tested was "that the presence of secretions is predictive of not only impending ovulation, but also of the day-specific pregnancy probabilities within the fertile interval defined relative to ovulation." (p.2278) The researchers utilized existing NFP charts that had recordings of cervical mucus, basal body temperature and the incidence of coitus. These NFP data charts were obtained from 782 women from 7 European centers that were part of a prospective daily fecundability study from 1992-1996.

The estimated day of ovulation for the study was based on the BBT shift - i.e., the first day of the BBT rise was considered the day of ovulation. The fertile window was eleven days - defined as the eight days before and two days after the estimated day of ovulation. Out of 7,288 cycles, approximately 80% (5,860) had interpretable BBT shifts and of these cycles, 2,832 cycles had coitus charted in the estimated 11-day fertile window. The researchers used Bayesian statistics and fertility modeling to analyze the results.

The researchers also determined the probabilities for pregnancy during the fertile window and found that the highest days of fecundity were the 5 days before the estimated day of ovulation and the day of ovulation. The two days before the estimated day of ovulation had the highest probability of fertility. Furthermore, in the 5 days before the estimated day of ovulation the probability of pregnancy decreased nearly 50% when there were no cervical-vaginal secretions on those days. They also concluded that this was the first study to provide evidence that cervical-vaginal secretions are associated with higher fecundity within the fertile window.

Researchers at Johns Hopkins University (Baltimore) and Georgetown University (Washington, DC) hypothesized that women who have planned pregnancies would have better pregnancy outcomes than those women with unplanned pregnancies.<sup>21</sup> They hypothesized this based on the assumption (and on previous published research) that women with planned pregnancies would adopt better health behaviors during pregnancy (eg., early prenatal care, less

smoking and alcohol use) than those with unplanned pregnancies. Pregnancy outcomes were defined as rates of spontaneous abortion, low birth weight, and pre-term birth.

Their hypothesis was tested through a subcomponent of an international, multi center, prospective cohort study of women using NFP, the objective of which was to determine if an association exists between pregnancy planning status and eventual pregnancy outcome. The study included 373 unplanned pregnancies and 367 planned pregnancies which occurred from women who were taught NFP at 5 centers worldwide (two centers in Santiago, Chile, and one each in Bogota, Columbia; Milan, Italy; and Washington, D.C.) from January 1987 to September, 1990. Multiple methods of NFP were used including, Ovulation Method, Basal Body Temperature and Sympto-Thermal.

The results did not support the hypothesis. The researchers found that there were no significant differences in adverse pregnancy outcomes between the two groups of women, i.e., there were no associations between adverse pregnancy outcomes and pregnancy intention. Overall both groups of women had healthy behaviors in that most women did not smoke (92.7%) did not use alcohol (88.8%) and had similar numbers of prenatal visits. Although both groups of women had good health behaviors, the researchers speculated that this might have been offset by poorer reproductive histories found among the planners.

In order to determine if sex ratio was related to the timing of intercourse in relation to the day of ovulation, the estimated length of the follicular phase of the conception cycle, or by the planned or unplanned status of the pregnancies, researchers at Johns Hopkins, Georgetown and Baylor Universities conducted a prospective study of all women who became pregnant from 1987 to 1994 while using NFP as taught in five centers located in Chile, Colombia, Italy and the United States.<sup>22</sup> There were 947 singleton births during that time period, of which 477 were boys and 470 were girls. This yielded a sex ratio of 101.5 males per 100 females, which was not significantly different from the expected ratio of 105 males to 100 females as found in previous studies. The researchers also observed no association between the timing of intercourse and the sex ratio or evidence to show that intercourse around the time of ovulation results in a predominance of females. Nor did they find any consistent association between follicular phase length or planning status of the pregnancy and the sex ratio. They concluded that manipulating the time of intercourse in relation to the estimated day of ovulation or the length of the follicular phase couldn't be used to pre-select the sex of the baby.

## **Analysis**

The studies in this section (primarily from researchers at the National Institutes of Environmental Health Sciences) have confirmed that there is essentially a 6-day interval of fertility ending with the day of ovulation. They also have shown that the most fertile day is the day before ovulation and that the timing of the 6 day interval varies across menstrual cycles. Furthermore, the probabilities of pregnancy during this 6 day interval decreases after the age of 35 among women and is also affected by the man's age. The probability of pregnancy decreases (by about 50%) during this 6 day window when cervical mucus is not observed. Finally, two studies from researchers at Johns Hopkins University have shown that there is no difference is

pregnancy outcomes whether the pregnancy was wanted or not by users of NFP and that the timing of intercourse during the menstrual cycle does not affect the gender of the baby.

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## Breastfeeding

In 1988, world experts on breast-feeding met in Bellagio, Italy and (after a review of the available research) concluded that there is less than a 2% pregnancy rate within the first 6 months of lactational amenorrhea if women are fully or nearly fully breast-feeding. In the last five years there have been a number of studies that have re-confirmed the lactational amenorrhea method (LAM) protocol.

A large prospective multinational study supported by the World Health Organization (WHO) was conducted to determine the relationship between breast-feeding practices and lactational amenorrhea and to test the Bellagio consensus.<sup>23</sup> A total of 4,118 women who were breast-feeding were enrolled in this study from 5 developing and 2 developed countries. The women participants monitored their breast-feeding episodes, supplementary feedings and vaginal bleeding episodes. Of the 3,422 women who completed this study, 46 became pregnant while breast-feeding and not using some form of contraception. The cumulative pregnancy rate for all the women who were still breast-feeding and amenorrheic at 6 months was 0.8% and at 12 months 4.4%. The differences in pregnancy rates between full breast-feeding and partially breast-feeding women was not statistically significant at either the 6 or 12 month time period. The WHO task force concluded that the lactational amenorrhea method is a viable method for post-partum family planning.

An interesting facet of this study was how the WHO task force defined or confirmed the participant's first "true" menses. They used what they called the "HRP rule" (Human Reproductive Program). The HRP algorithm defines menses as bleeding which lasts at least 2 days and requires the use of sanitary protection for at least one day. This must be confirmed by a second bleeding episode within the next 21-70 days. In a related study the WHO task force described the length of lochia in these same breast-feeding women participants and found the median duration to be 27 days (range, 22-34 days).<sup>24</sup>

Researchers from the Georgetown University Institute for Reproductive Health (IRH) and WHO conducted a study to further test the LAM protocol.<sup>25</sup> In that study, 519 women were followed on a monthly basis over a six month period. The results showed a life table efficacy of avoiding pregnancy of 98.5 (+ 0.07). Furthermore, 62% of the women participants continued the method into the sixth-month postpartum. The Georgetown University IRH research group also collaborated with the United States Agency for International Development and the WHO in a subsequent study to test the LAM protocol at 10 different research sites in 8 different countries, including England, Germany, Italy, Sweden, the Philippines, the United States, Mexico, two sites in Nigeria, and Egypt.<sup>26</sup> Unlike the previous study, the participants in this study were only contacted once (at the seventh month of participation) after enrollment. In each of the 9 sites from 10 to 50 volunteer breast-feeding women were recruited for a total of 362 women of which

302 (83.4%) were included in the analysis. The mean age of the 302 participants was 28.2 years, the mean parity 2.8 children, and the mean years of education was 9.8. Only 6% of the breastfeeding volunteers worked outside the home at 6 months postpartum.

Since there were no reported pregnancies at the 7-month follow-up, the 6-month efficacy of LAM was 100%. This result was based upon 1,705 women-months of use. The probability of continuing LAM through the sixth month postpartum among those still eligible was close to 85%. Furthermore, more than half of the participants completed the 6 months of LAM use. Most of those who stopped LAM (15.4% of the total sample) did so due to the return of menses. Of interest is that 65 to 70% of the women volunteers remained amenorrheic at 7 months. Satisfaction with LAM was also high among the participants with 86.4% reporting being very satisfied and 91.7% indicating that they had no problem with using the method. Another interesting finding is that close to 72% of the participants chose to use another method after discontinuing LAM and the most frequent method (19.7%) was some form of NFP.

The authors concluded that LAM can be used effectively in a variety of ethnic and cultural settings even with limited counseling. Furthermore, duration of use and satisfaction was high both in industrialized and developing countries. Therefore the results provide further scientific evidence for worldwide acceptance of LAM and indicate that LAM should be offered along with other modern methods of family planning.

What is usually not emphasized along with the three main LAM criteria i.e., amenorrheic, totally breastfeeding and within 6 months postpartum--is that there should also be no long intervals between breast-feeding, and that night breast-feeds are important. Variation from these criteria can increase the pregnancy rate. For example, a recent prospective study conducted among 170 urban middle-class Chilean women separated from their infants by work resulted in a 6-month pregnancy rate of 5.2% with the use of LAM.<sup>27</sup> Although the women were monitored on a monthly basis and were taught how to manually express their milk, the pregnancy rate was higher than the pregnancy rate in those women who did not work. Of interest in the Chilean study is that only 28.2% of the study participants met the LAM criteria at 6 months. This is about half the level found in the non-working participants in previous studies on LAM. The authors concluded that women using LAM should be informed that separation from the infant might increase their risk of pregnancy.

Researchers in the Department of Nutrition and the Program In International Nutrition at the University of California-Davis conducted a study with breast-feeding Honduran women to test whether the duration of lactational amenorrhea would be shorter in women who began feeding solid foods at 16 weeks and breast-fed at will than in those women who breast-fed exclusively for six months duration and in those women who introduced solid foods at 16 weeks post partum but maintained the frequency of breast-feeding.<sup>28</sup> Women who participated in the study were from two public hospitals in San Pedro, Honduras. At 16 weeks postpartum those women who met the criteria for the study and who were still exclusively breast feeding were randomly distributed into one of three groups; 1) full breast feeding (FBF), 2) solid foods and breast feeding as desired (SF), and 3) solid foods but maintaining the same frequency of breast feeding (SF-M).

The results showed that the proportion of women who were amenorrheic at 6 months was 64.5% in the SF group, 80.0% in the FBF group, and 85.6% in the SF-M group. The most significant determinant of LA was time spent breast-feeding. However, the SF-M group women had difficulty in maintaining the level of breast-feeding due to the child being satiated with solid foods. The researchers concluded that there is a significant effect on LA at 6 months when solid foods are introduced at 16 weeks but that this is moderated in mothers that maintain breast feeding frequency.

In a final study, a NFP research group from the University of Naples followed 40 breast-feeding women participants (aged 23-40 years) from the birth of their child through the first cycle after return of menses.<sup>29</sup> All of the women recorded their daily basal body temperature (BBT), cervical mucus changes, and salivary ferning patterns as well as duration, frequency, and interval of breast-feeding. Serial transvaginal ultrasound was performed on the woman during the first cycle after the return of menses to estimate the day of ovulation. They found that in 8 of the 40 breast-feeding women the return of menses preceded weaning and in the remaining 32, menses followed weaning. Eighty-two percent of the first cycles following the resumption of menses were ovulatory.

The authors stated that this study was conducted “above all” to evaluate by means of BBT, cervical mucus changes, and salivary ferning patterns, the protective effect of breast-feeding with the return of ovarian activity. They found that the 8 women participants who menstruated before weaning had no temperature rise or an inadequate thermal shift in the first cycle. Of the 32 women who experienced menses after weaning, 12 had thermal shifts before menses, 16 had inadequate thermal shifts before menses, and 4 had no thermal shift. Not one of the 40 women had level three ferning (on a scale of 0= no ferning; 1= some; 2=more; and 3= full ferning), only one women had level 2 ferning and 15 had level 1 ferning. Twenty-four of the women experienced no ferning patterns before menses. Eight of the women failed to record cervical mucus changes, 12 had cervical mucus constantly present, 6 had cervical mucus present greater than 20 days, and 14 had fertile mucus for 7-10 days. The authors concluded that cervical mucus characteristics were not reliable in indicating the return of postpartum fertility. They based this on the fact that cervical mucus identified fertility with only 14 of the 40 women. They concluded that complete breast-feeding associated with lactational amenorrhea maybe considered an appropriate method to control fertility.

**Table Two: LAM Effectiveness Studies**

Study	Number of Women	% amenorrhic	Pregnancy Rate	
			6 months	12 months
WHO <sup>23</sup>	3,422	83.0	0.8	4.4
Labbok <sup>25</sup>	302	84.6	0.0	
Peterson <sup>26</sup>	519	62.0	1.5	
Valdes <sup>27</sup>	170	28.2	5.2*	
Dewey <sup>28</sup> Honduran	-Solid Food/Full BF	85.6		
	-Full Breast Feeding	80.0		

	-Solid Food/BF at	64.5		
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\* = Worked outside of home and pumped breasts

## Analysis

Since 1988 there have been several studies conducted with women from over 10 countries that have confirmed the LAM protocol. In fact the studies show that LAM when followed properly might be more effective than 98%, and be robust to some changes (such as the introduction of solid foods) as long as the woman continues the frequency and length of breastfeeding. Furthermore the suppression of ovulation seems to extend up to a year with an increased pregnancy rate of only 5%. However, in the United States the portion of childbearing women who had ever breastfed is only around 50%. Whereas in Japan and in developing countries more than 90% of childbearing women breastfeed their infants. At this time, it might be unrealistic for women in today's modern society to return to childbearing and breast-feeding patterns that were characteristic a century ago.

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## Research on the Psychological Aspects of Practicing NFP

There has been relatively little published research over the past 5 years on the psychological aspects of practicing NFP. Probably one of the best studies is the study conducted by the Marquette University College of Nursing researchers that will be reviewed for the next issue of CMR.<sup>30</sup> However, a German study that compared NFP with other methods of family planning was of great interest in that the participants were randomly selected and the study was comparative. Other studies, on psychological issues related to NFP, such as compliance, user satisfaction, and user interest were reviewed in past issues of CMR.

Bjorn J. Oddens, MD, PhD, a researcher from the International Health Foundation in Geneva, Switzerland, surveyed German women on the physical and psychological effects of current and past use of five common methods of family planning: oral contraceptives, intrauterine devices, condoms, natural family planning and sterilization.<sup>31</sup> The survey was conducted by randomly selecting addresses throughout the Western states of Germany. These addresses were visited in person by a fieldworker to administer a women's health questionnaire. Of the 2,499 households visited there was a response rate of 58.7% or 1,466 women respondents. Of these respondents, 1,303 had past or current use of oral contraceptives, 996 had used condoms, 428 NFP, 342 intrauterine devices (IUD), and 139 were sterilized.

The women's health questionnaire was designed to address experiences and satisfaction with current and past use of family planning in terms of the client's concern about unwanted pregnancy, health risks, ease of use and overall effects on sex life. By "satisfaction," the author meant the emotional response (e.g., anxiousness, depression, cheerfulness, relaxation, etc.) of clients to the methods. The effects on sexuality referred to how each method influenced the overall sex life of the client (e.g., frequency of intercourse, spontaneity, libido, pleasure, etc.).

The results indicated that satisfaction was highest (92%) among “ever” users of sterilization, followed by 68% of oral contraceptive users, 59% of IUD users, 43% of NFP users and 30% among condom users. The highest percent of negative moods (various moods were measured, e.g., anxiety, restlessness, depression) was among ever users of NFP (30% felt more anxious when using NFP), followed by condom users (23%) and then users of oral contraception (16%). Oral contraceptive (53.7%), IUD (54.6%), and sterilization (57.4%) users broadly felt that their methods of family planning had a more positive effect on their sex life, while condoms users often felt a negative effect (20.4%). The author concluded that the use of oral contraception and sterilization had the least negative impact on physical and psychological functioning than the other three methods studied.

Still and all, NFP scored as good or better in 5 of the 12 indicators in the Oddens study. Women currently using some form of NFP had fewer health concerns, were less irritable, less depressed, had high levels of sexual pleasure and a higher sex drive than with other methods of contraception (See Table 3).

**Table Three: Satisfaction with Current use of NFP in Comparison with Current Users of Contraception and Sterilization (in percentages)**

<b>Questionnaire Item</b>	<b>Pill (N=522)</b>	<b>Steril (N=136)</b>	<b>NFP (N=76)</b>
Very Concerned about pregnancy	2.7	1.9	13.6
Concern about health risks	71.0	37.2	0.0*
Easy to use	91.9	86.9	38.3
Satisfied	82.9	92.1	71.6
More tense	5.5	6.5	21.5
More irritable	13.0	7.2	5.1*
More anxious	1.9	1.4	19.0
More depressed	10.3	5.0	3.8*
High frequency of intercourse	23.3	28.1	7.6
More spontaneity	38.8	37.4	11.4
More pleasure	25.0	28.8	27.8
Sex drive increased	8.4	19.0	21.5*

\*Indicates item in which NFP users scored the best.

Without denying the negative indications about NFP raised by the Oddens survey, it is not unfair to point out that the questions asked in that survey were more adapted to the dynamics of contraception than those of NFP. For example, there were no questions on whether the method

of family planning increased understanding of fertility, self-control, communication, trust, intimacy, or relationship with God. Theoretically one would expect NFP to do better than contraception on these indicators because of its dynamics of living with one's fertility rather than avoiding it. However, research would be needed to verify whether this is so.

Oddens also collaborated with another researcher to determine satisfaction of use of NFP among German women.<sup>32</sup> Knowing what factors influence "satisfaction of use" with methods of birth control and NFP is important. Satisfaction influences both compliance and continuation of use. Of the 1,466 women surveyed in the original Oddens study, 428 had used NFP sometime in the past. Of these women, 181 were satisfied with use of NFP and 139 were not. Of the dissatisfied users 70% had concerns about becoming pregnant, 76% felt that NFP was not easy to use, 64% experienced negative moods from use of NFP, and 50% felt that NFP had a negative effect on their sexual life. The factors that contributed the most to dissatisfaction of use among all users of NFP were concerns about pregnancy (i.e., becoming pregnant and not intending to), and ease of use (i.e., NFP was not easy to use). The authors recommended that providers of NFP should address pregnancy concerns and ease of use among women users of NFP.

Several studies have been conducted on the acceptance and satisfaction of use with the new electronic fertility monitors developed by Unipath, i.e., the Persona monitor that is designed to help women avoid pregnancy and the Clearplan Easy Fertility Monitor to help women/couples to achieve pregnancy.

In order to determine the suitability of Persona as a contraceptive device, researchers from the University of Amsterdam surveyed 273 Persona users who called the Unipath help-line service in The Netherlands.<sup>33</sup> Of these 273 users, 137 or 51% responded. The respondents were for the most part highly educated and had an above average income for the Netherlands. Most (84%) were either married or in a steady relationship with a man. Sixty-four percent of the respondents were using oral hormonal contraception, about 15% were using condoms and only 4.4% were using some form of Natural Family Planning prior to using Persona. An interesting fact was that 25% of the respondents were using the monitor to become pregnant rather than to avoid it.

The survey showed that the most cited reasons for using Persona were the absence of side effects, and that there was no longer a need to rely on a medical method to avoid pregnancy. Many of the respondents also cited as a benefit of using Persona that it provided insight or information about their menstrual cycles. The most cited disadvantage of the monitor was that it was too expensive (both the monitor and the test strips). About 71% of the couples who used the monitor to avoid pregnancy also used condoms or withdrawal during the fertile phase. The authors concluded that Persona is a welcome alternative form of NFP for those couples who are open to pregnancy. They assumed that the Persona was not reliable enough to be used as a contraceptive device when the couple had serious reasons for avoiding pregnancy. They also concluded that Persona improved fertility awareness and a desire to have children.

Besides effectiveness and safety of a method of family planning, another important outcome measure is whether the method is acceptable to the woman or couple user. Long-term use is (in a sense) the ultimate measure of success of a method of family planning and of NFP. A

method of NFP might be extremely effective in helping couples achieve or avoid pregnancy but if few couples use it then a question to be asked is whether the given method is acceptable. Besides long-term use other measures of acceptability include ease of use and whether the method can involve both partners.

Larry Severy, PhD, (Department of Psychology, University of Florida, Gainesville) recently assessed the acceptability of two hand held fertility devices among couple users in England and the United States, i.e., the Persona and the ClearPlan Easy Fertility Monitor (CPEFM).<sup>34</sup> The acceptability of the Persona was assessed through in-depth interviews and questionnaires provided to 721 Persona users in the UK. The qualitative data showed that women users readily accepted the device, it had a positive effect on their relationship with their partner, and it provided important information about their cycles and reproductive health. The UK users also recorded their evaluation on the ease of use of the Persona monitor on 5 functional tasks (i.e., pressing the start button, remembering to view the monitor on a daily basis, using the test strips, understanding the results and understanding the test booklets) on a 10 point scale with 1 being the most difficult and 10 being the easiest. All of the 5 functions were rated at least 7 or above by the UK Persona users.

Another 220 US women users of the Persona recorded their acceptability and ease of use of the fertility device on a 7-point scale with 1 being the least acceptable (and most difficult to use) and 7 the most acceptable (and the easiest to use). The 220 women users were between the ages of 18 and 35, were in monogamous relationships, sexually active, were not intending to have a child in the next year and used the device for at least 6 months. The mean ratings of the ease of use was above 6 and the mean acceptability score was close to 6.

The investigator concluded that the Persona fertility monitor is highly acceptable to volunteer couples and that the data suggests that the monitor has a positive effect on the woman's reproductive functioning, her health and the couples' relationship.

Severy and colleagues also reported on the acceptability of the use of the Persona in a longitudinal study of 608 English women users.<sup>35</sup> The 680 participants were recruited through press advertising. They had to be willing to avoid pregnancy for at least 15 months and to be accepting of an unplanned pregnancy. The participants were between the ages of 18-45 years, had menstrual cycles between 23 and 35 days in length, were sexually active, had not used hormonal contraception for at least three menstrual cycles and had experienced at least three menstrual cycles after a pregnancy. The women were provided the Persona monitors without training and were asked to use them for 1 year.

Acceptability was conceptualized for this study as perception of accuracy and trust. Accuracy was measured on a 1-7 scale with 1 = *inaccurate* and 7 = *accurate*. Perception of accuracy was asked of both the green light (infertile) and the red light (fertile) days that were provided by the home monitors. Trust in the monitor was evaluated with a 101 point scale with 0 = *no trust* and 100 = *complete trust*. The researchers also assessed contextual measures, i.e., women's education, number of children, and length of relationship as predictors of acceptability. Acceptability data were collected at the end of menstrual cycle 1, 3, 6, and 13. At cycle 1, there were 680 women participants, at cycle 3, 603 participants, at cycle 6, 480 participants, and by

cycle 13, only 250 participants who provided data.

### **Acceptability-perceived accuracy**

The mean perceived accuracy of the red (fertile) and green (infertile) light days ranged from 5.25 to 6.30 on a 7-point scale. On average the mean perceived accuracy was consistently higher for the green days than the red days. Based on paired t-test analysis, the participants perceived the accuracy of the red light days to be significantly higher at cycle 6 ( $M = 5.64$ ) than at cycle 1 ( $M = 5.29$ ) ( $t = 3.71, p < 0.005$ ) and the accuracy of the green light days to be marginally statistically higher at cycle 6 ( $M = 6.09$ ) than at cycle 1 ( $M = 5.95$ ) ( $t = 1.82, p = 0.07$ ). Therefore, perceived accuracy in home monitoring with the Persona monitor increased over time.

### **Acceptability – perceived trust**

Overall trust in the Persona monitor was high. The mean trust scores ranged from 87.35 to 94.23 on a scale of 0-100. The mean trust scores also significantly increased from cycle 1 ( $M = 87.35$ ) to cycle 6 ( $M = 91.74$ ) ( $t = 6.17, p < 0.005$ ). Therefore, trust in the use of the Persona for avoiding pregnancy also increased over time.

### **Acceptability – contextual variables**

Based on regression analysis, the researchers determined that the number of years in relationship, the number of children, and the education level of the participants influenced trust over time. Those participants who lived with their partners longer reported significantly higher trust than those who lived with their partners for shorter periods ( $t = 2.21, p < 0.03$ ). Those who had less education developed more trust in the monitor over time than those who had more education ( $t = -1.98, p < 0.05$ ) and the more children the participants had the more they developed trust in the monitor ( $t = 1.94, p = 0.05$ ). In addition, the less educated participants rated the monitor more accurate than the more educated and those in longer relationship rated the monitor more accurate than those in shorter relationships. Another finding was that women who did not have children or did not want any children and those women with an already large family (i.e., 4 or more children) were the least likely to be positive about the monitor or to report an increase in acceptability.

The authors concluded that the participants, in terms of initial acceptability of the Persona monitor, were very positive and that acceptability (i.e., perceived accuracy and trust) became more positive over time. Those women in stable unions, less education, and 1-3 children rated the use of the monitor more positively and their ratings of acceptability increased over time. The authors speculated that those in new relationships were still in the discovery mode and in the process of reassuring themselves that the relationships will last.

### **Analysis**

Overall the two best studies under this section were the Oddens study of German women users of contraception and the Severy longitudinal study of the acceptance of the Persona

monitor. There are few studies that determine the psychological effects of various methods of family planning and especially in comparison with various methods. The fact that the Oddens study not only compared the psychological aspects of various methods of contraception and NFP, but also randomly selected a large group of participants across Germany, it thus provided a good representative sample of German women. There are also few studies that measure psychological aspects of practicing NFP across time. The Severy study on the acceptance and use of the Persona monitor did so and provides an example of how other methods of NFP could be studied through using similar methodologies. The good news for NFP teachers and users is that the practice of NFP has many positive psychological benefits.

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### Lifestyle Factors and Fertility Health

Although the following studies do not directly involve NFP, they are important because they involve lifestyle and fertility health. NFP teachers need to be aware of lifestyle factors that can either improve or decrease fertility based on research. The following studies are not comprehensive but represent those studies that have been reviewed in the CMR over the past five years.

#### **Alcohol and Fertility**

There were three studies that investigated the effect of alcohol consumption on fertility. Alcohol is known to decrease steroid hormone concentrations, inhibit ovulation and decrease sperm transport in the fallopian tubes. Researchers from the Department of Growth and Reproduction at the National University Hospital in Copenhagen, Denmark conducted a study to determine the effect of alcohol consumption on the probability of conception.<sup>36</sup> They recruited couples who had no known fertility problems and who were trying to conceive for the first time from members of a national trade union that represented office workers, nurses, metal workers, and day care workers. They obtained a total of 430 couples who reported after each menstrual cycle their daily and weekly consumption of smoking, caffeine and alcohol until they became pregnant or for six menstrual cycles. After six cycles of reporting, 65% (179) of the women with a weekly intake of 5 or fewer drinks conceived and 55% (75) of the women with a higher intake conceived. They also found a decrease in fecundity (after adjusting for a number of variables) in women with 5 or fewer drinks per week compared to women with no alcohol consumption. The authors concluded that even moderate alcohol consumption (5 or fewer drinks) is associated with a decreased fecundability but that their findings need further corroboration.

Meanwhile, researchers from the Institute of Pharmacological Research and the University of Milan, Italy examined the relationship between alcohol intake and difficulties in conceiving among 1769 women who gave birth on randomly selected days at the largest obstetric hospital in Milan.<sup>37</sup> All of the subjects had a previous history of having difficulty in conceiving. After interviewing these women, they found that 135 women had difficulty in conceiving while 1634 had no difficulty in conceiving. When comparing the two groups they found no relation between alcohol drinking and difficulty of conceiving. Of the two above studies, the Denmark one is the strongest. The Milan study was retrospective (recall information) and the subjects were

selected from women from one setting who had difficulty in conceiving and then successfully gave birth. The findings of the study, however, agree with the results of previous studies on the relation of alcohol and conception. Like the Milan study those studies were retrospective, and had small and biased samples. The Denmark study was prospective, subjects were selected from a national population pool and data was collected on a cycle to cycle basis. There was some bias in the sample in that they all were trying to conceive and some might have some difficulty in conceiving or suspected infertility, i.e., only 65% became pregnant in a 6 month period. The study could have been enhanced if the subjects were charting their cycles on a daily basis, were knowledgeable about the optimal time of fertility and recorded the frequency and timing of intercourse.

Danish researchers conducted one of the largest studies on the relationship between alcohol consumption and fertility.<sup>38</sup> They surveyed 39,612 women on their alcohol consumption and waiting time to get pregnant. All of these women were within their first 24 weeks of pregnancy. What they discovered was that moderate and high consumption of alcohol was not associated with longer waiting times to pregnancy. The only group of women alcohol drinkers that had a significantly longer waiting time to pregnancy were those who drank on average more than 14 alcoholic drinks per week and had previous pregnancies. In fact women who had a low consistent alcohol intake of 1-2 drinks per week had a shorter waiting time period than those who were non-drinkers. The authors speculated that moderate amounts of alcohol may have a positive effect on the female reproductive system, especially by the way of stress reduction. Although the authors did not find a prolonged waiting time to pregnancy among moderate alcohol drinkers, they did find a longer waiting time among smokers, overweight women and older women.

### **Caffeine and Fertility**

There were two studies (reviewed) that investigated the effect of caffeine on fertility. One study reported in the *New England Journal of Medicine* indicated that the blood levels of paraxanthine, a metabolite of caffeine, was higher in women who had spontaneous abortions than in women who gave birth to live infants.<sup>39</sup> Researchers from the Division of Epidemiology, Statistics, and Preventive Research from the National Institute of Child Health and Human Development and from the Center of Human Toxicology at the University of Utah, measured serum paraxanthine in 591 women who had spontaneous abortions and in 2,558 matched women from the same clinic who gave birth to live infants. They found that only very high serum paraxanthine concentrations (an equivalent of more than 5 cups of coffee per day) were associated with spontaneous abortion. They concluded that a moderate intake of caffeine should not increase the risk of spontaneous abortion.

The strength of this study is that the researchers used an actual biological marker of caffeine rather than recall of caffeine intake from a woman's own report. A weakness is that the researchers only used one serum measurement of the caffeine metabolite during the entire pregnancy. A follow-up critique of the study in the same issue of the journal stated that moderate intake of caffeine should not be assumed to be safe for pregnant women.<sup>40</sup> The critique cites a meta-analysis of the published research on caffeine and spontaneous abortion that suggests women who consume only one to two cups of coffee per day have an increased risk for spontaneous abortion and low birth weight infants. The critique also cited the 1981 Food and

Drug Administration recommendation that pregnant women avoid caffeine containing foods and drugs.

A research team from Sweden and the US conducted another study on the effects of caffeine and found that the equivalent of 1-3 cups of American coffee increased the risk of miscarriage by 30% and 3-5 cups raised the risk by 40%.<sup>41</sup> The study involved 562 Swedish women who had miscarriages at between 6-12 weeks of pregnancy. These women were matched with 953 who did not have spontaneous abortion. The director of the study (Dr. Sven Cnattingius) recommended that pregnant women limit their caffeine intake to about 2 American cups per day. A typical American cup of coffee has about 100 milligrams of coffee as compared to a Swedish cup, which has about 180 milligrams. A critique of the results is that the study might be biased towards including women with unhealthy fetuses. Women who have healthy fetuses usually experience more morning sickness and have a tendency of not drinking strong aroma beverages like coffee.

### **Stress and Fertility**

Stress is part of the modern lifestyle especially among women who try to balance careers and families. One study was reviewed that investigated the effects of stress on the menstrual cycle. A study conducted by members of the Reproductive Epidemiology Section of the Department of Health in Emeryville, CA, indicated that women who experience high job stress are twice as likely as women in low stress jobs to have short menstrual cycles.<sup>42</sup> Job stress was defined as work positions that require high demands and low control. Of the 276 healthy women who participated in the study, 61 were determined to have high job stress. All of the participants collected daily urine samples for an average of 5 cycles. Urinary metabolites of estrogen and progesterone were measured in order to estimate the day of ovulation and to detect anovulatory cycles. Although the 61 job stress women experienced twice the rate of short cycles, they did not experience an increased risk for anovulation, unusual bleeding, or cycle irregularity. The decrease in cycle length was accounted for by a decrease in the length of the follicular phase. The researchers theorized that the stress related short cycle length could be from the inhibition of luteinizing hormone secretion by the increase in corticotropin-releasing hormone or glucocorticoids, i.e., stress released hormones that affect the hypothalamic-pituitary-adrenal axis.

### **Male Fertility and Driving a Car**

One study was reported on a lifestyle factor that affects male fertility.<sup>43</sup> Past studies have shown that men who drive cars for prolonged periods of time (e.g., taxi drivers) have lower sperm counts, sperm motility, and a higher level of sperm morphology than men in other occupational groups. The theory is that the cause of the low sperm quality in male car drivers is due to higher scrotal temperature levels produced while in prolonged sitting positions. To test this theory, Italian researchers recorded the scrotal temperatures of 9 male volunteers every two minutes while walking for 40 minutes and subsequently while driving for 160 minutes. They found that the scrotal temperatures increased significantly (1.7-2.2 degrees C) after 2 hours of driving from the temperatures recorded while walking. The researchers concluded that the link between driving time and scrotal temperatures indicate a potential lifestyle risk for male infertility.

## **Lifestyle Factors and Menstrual Cycle Variability**

Researchers from the epidemiology branch of the National Institute of Environmental Health Sciences, the University of Michigan School of Public Health, and the National Cancer Institute recently completed one of the largest ever studies on menstrual function among adult women.<sup>44</sup> Three thousand nine hundred forty one women participants were selected from the (1994-96) Agriculture Health Study. They met the criteria of: being between the ages of 21-40; not currently taking oral contraceptives; and not currently breastfeeding or pregnant. The study sample was primarily white (98%) rural women (farm wives) from Iowa (78%) and North Carolina. The purpose of the study was to describe medical and lifestyle factors that might be associated with menstrual cycle characteristics. The rationale behind the study was that menstrual cycle patterns or characteristics might be indicative of certain health problems. Menstrual cycle characteristics, lifestyle and medical factors were measured by use of a self-recall questionnaire developed by the researchers.

The cross sectional data revealed that 9.7% of the sample experienced short cycles, 3.2% experienced long cycles, and 5% irregular cycles. Some of the key study results were as follows:

- Body fat, measured by body mass index (BMI) was strongly associated with long and irregular cycles. The odds of having a long cycle were 5 times higher among women with BMI's of 35 or more.
- Experiencing menarche before age 12 was moderately associated with an increased chance of short and irregular cycles.
- Experiencing menarche after 15 was associated with almost 3 times the chance of having long and irregular cycles.
- Smoking a pack or more of cigarettes per day increased the risk (odds ratio) of short and irregular cycles by more than 3 fold.
- Long, irregular, and cycles with inter-menstrual bleeding were associated with increased odds of infertility.
- Long and irregular cycles were associated with increased odds for fetal loss.

Although the sample size for this study was large, the authors admit that the sample was primarily white women living on farms and that the sample might differ from women in the general population. They also speculated that they might have underestimated the prevalence of long and irregular cycles, because women often take oral contraceptives for that purpose and these women were eliminated from the study. Furthermore, they did not identify women who recently stopped breastfeeding, discontinued oral contraceptives, and ended a pregnancy. All of these women would have more irregularity in their cycles. The authors concluded that menstrual cycle patterns are often influenced by lifestyle and environmental factors and that menstrual cycles that are disturbed by these factors might precipitate other reproductive disorders.

## **Menstrual Cycle Variability**

Since 1976 Harvard researchers have been monitoring the health behaviors of a large cohort of female professional nurses. The original purpose of the 1976 study was to determine

the long-range health effects of using oral hormonal contraception. In 1989 another cohort of 116,671 nurses was recruited for a longitudinal study (called the Nurse Health Study II) in order to prospectively study a wide array of health outcomes. On a biannual basis these nurses complete a detailed health questionnaire that includes questions about the length and regularity of their menstrual cycles. In order to determine if menstrual cycle length and regularity is predictive of future type 2 diabetes researchers from Boston's Brigham and Women's Hospital and Harvard University analyzed 507 documented cases of diabetes that were diagnosed among the original Nurse Health Study II participants.<sup>45</sup> The investigators found that women with a usual cycle length of 40 days or more (or who had cycles that were too irregular to estimate) had a significantly increased risk for type 2 diabetes compared with women who had normal menstrual cycle lengths (of 26-31 days). They also found that the risk for diabetes was further increased among women who were overweight. The authors suggested that women with long and irregular menstrual cycles consider lifestyle approaches to decrease the risk of ovarian cancer through weight control and exercise. A limitation of this study was that cycle characteristics were retrospectively self-reported. Some women might have classified their cycles as normal length while being treated with oral contraceptives. Over classification as normal, however, would bias the results towards not finding long cycles being a risk.

A final study for this section of the review demonstrated that even among women with regular menstrual cycles there could be considerable variability from cycle to cycle in hormonal levels.<sup>46</sup> Researchers at the University of Chile Center for Natural Family Planning (Santiago, Chile) conducted a prospective case series study of 25 women in order to evaluate hormone profiles of normal menstrual cycles. All 25 were experienced NFP users (i.e., they monitored cervical-vaginal fluid and basal body temperature), aged 24-37 years (mean age 30 years), had regular menstrual cycles of 25 to 35 days in length in the previous 6 cycles, and had not used any hormonal contraception in the previous 6 cycles. They collected early morning urine samples each day of the cycle for 3 or more cycles and generated 78 complete cycles of data. The early morning urine samples were analyzed for estrone glucuronide, LH, and pregnanediol glucuronide through noncompetitive radio-immunoassay methods.

The 78 cycles in the data set had a mean length of 28 days (range 23-35 days), with a follicular phase mean length of 16 days (range 11-24 days), and a mean luteal phase length of 13 days (range 10-17 days). Although the 78 cycles produced a classic mean hormonal value curve for the 3 hormones measured, only 23% of the cycles in the data set presented hormonal profiles similar to that classic curve. In 69% of cycles, the estrone glucuronide curve was similar to the mean curve and in 44% of the cycles the LH curve was similar to the mean curve. The estrone and LH peaks were not always easy to determine, some lasted more than one day or fluctuated with double or small peaks. The researchers found pre-peak estrone glucuronide surges, and pre and post-peak LH surges. The pregnanediol glucuronide, however, increased more clearly and in only 6% of the cycles did the pregnanediol fluctuate by more than one day.

The authors concluded that normal menstrual cycle hormonal profiles often differ from the classic mean hormonal curves. They also suggested that the addition of adding pregnanediol glucuronide would make ovulation detection kits based on urinary estrone and LH more reliable.

This study had some limitations in that there was no concurrent verification of the estimated day of ovulation through serial sonographic measurement of the developing follicle. Nor did the researchers validate the urinary hormone levels with blood levels. The urinary measures, with home collection, freezing, thawing, dilutions and timing could have resulted in some of the variability in the findings. The results do show that even with healthy women, with regular menstrual cycles, there can be a lot of hormonal variability between cycles. This means that one cycle of hormonal data does not predict what the next cycle will look like.

## **Analysis**

Lifestyle can have a profound effect on male and female fertility and on the dynamics of the menstrual cycle. The studies on fertility health reviewed in this section indicate that alcohol in moderation can have a good effect on fertility and caffeine in moderation probably does not have much of an effect. Lifestyle factors that involve heating the scrotal area in a man can effect sperm viability. Obesity, smoking and underweight can have profound effects on the menstrual cycle.

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## **Miscellaneous Studies on NFP**

The final section of this review includes two studies on health professionals' views about NFP methods, a study on interest in NFP among women patients, two studies on new or proposed methods of NFP, and a study on how calendar rhythm is used in different countries of the world.

## **Interest, Use and Knowledge of NFP**

Of the two studies published on health professionals' views of NFP, one was conducted with physicians and the other with certified nurse midwives. Researchers at the University of Missouri-Columbia conducted a study to determine physicians' knowledge and practices of modern methods of NFP.<sup>47</sup> Researchers assumed that modern methods of NFP are important for medical practice in order to help women and couples avoid or achieve pregnancy. A one-page questionnaire on knowledge and practice of NFP was mailed to 840 randomly selected physicians in Missouri. While 69% of the 547 respondents saw women for reproductive needs, only 46% mentioned NFP to at least some women when discussing family planning issues. When women patients asked for information about NFP, the majority described basal body temperature (54%) or calendar rhythm (45%). Most physicians recommend BBT (71%) or calendar timed intercourse (64%) for women who had infertility problems. Only 36% recommended cervical mucus observations. They found that 79% of physicians in Missouri estimated the best possible effectiveness of natural family planning for avoiding pregnancy to be less than 91%. Sixty-five percent of those surveyed ranked the actual effectiveness of NFP to be 70% or less. The estimated effectiveness of NFP and information provided on modern methods of NFP was highest among physicians that had NFP instructors in their area. From this study, it seems that the availability of NFP instructors is a key factor in facilitating physicians knowledge and regard for modern NFP.

In order to determine the knowledge and promotion of NFP among practicing CNMs, researchers from Marquette University and the University of Utah surveyed a national random sample of 1,200 CNMs selected from a membership list of the American College of Nurse Midwives (ACNM).<sup>48</sup> Of the 514 CNM respondents (42.8% return rate), 450 (or 87.5%) were currently practicing as CNMs. The average age of the respondents was 46 years (range 26-66 years) and the average number of years of practice was 10 (range .5 to 40.5). The survey mailed to the CNM respondents was a modified form of the questionnaire utilized by Dr. Stanford with the Missouri physicians.

The CNMs who responded rated methods of NFP as the ninth most frequently used among their clients and the eighth most effective (among 11) method of family planning. The CNMs felt they were on average somewhat prepared to provide NFP for their clients. In fact, 50.2% of the CNM respondents felt prepared enough to provide NFP instruction themselves. However, only 22% would offer NFP as a family planning option. The CNMs ranked the average modern method of NFP (OM and STM) perfect-use effectiveness as 88% and the typical-use effectiveness around 70%. About one fourth of the respondents thought that breast-feeding (the LAM algorithm) was not a reliable form of family planning and 34.8% thought that the efficacy of total breast-feeding to avoid pregnancy extended to 6 months postpartum. Respondents projected that 17.1% of women using LAM would get pregnant unexpectedly in a 6-month time frame.

In comparison, 804 Missouri physicians who were surveyed by Stanford in the current study were somewhat more knowledgeable about the efficacy of NFP and used it more often in their practices. More than 75% of the CNMs versus 41% of the physicians ranked the best possible effectiveness of NFP as greater than 81%. CNMs also more readily recommended the use of NFP for their clients and were more up-to-date in their recommendations than were the Missouri physicians. Sixty three percent of CNMs would mention NFP as an option to select women compared to only 36% of physicians.

The authors speculated that the reason that only 22% of the CNM respondents would recommend NFP is that many of the clients that CNMs work with come from vulnerable groups such as single mothers, adolescents, and those not in stable relationships. Therefore the prerequisites of mutual motivation, understanding and consistent use necessary for use of NFP would not apply. Furthermore, CNMs also thought that NFP was not all that effective and that it took quite a lot of work to teach women about NFP, i.e., it would be hard to fit into a busy practice because of the intensity of teaching.

Dr. Stanford and colleagues were also involved with a study to determine interest in NFP when health professionals presented NFP in a positive way to women patients.<sup>49</sup> Stanford, Lemaire, and Thurman attempted to determine if the low use of Natural Family Planning (NFP) methods (to achieve or avoid pregnancy) was due to a lack of available information, a lack of interest, or other factors. This study was a follow-up to prior research in which they had found that 43% of female patients in a family medicine clinic were interested in learning more about NFP. In order to obtain more general results than those obtained in the pilot study, they randomly selected 1500 women, aged 18-50 from the Missouri drivers license renewal records and mailed them a questionnaire.

Seven hundred forty-seven questionnaires (49.8%) were returned. Of these, 484 (33.3% of total) were from women who were still potentially fertile with only 2.8% currently using some form of NFP; however, 22.5% of these same women indicated that they would be likely or very likely to use NFP in the future to avoid pregnancy and 37.4% of these said that they would likely or very likely use NFP to achieve a pregnancy.

The results also indicated that past use of any type of NFP method to avoid or achieve pregnancy was associated with interest in future use of modern methods of NFP. The authors concluded that many women who are not currently using NFP indicated that they are interested in doing so either to achieve or avoid pregnancy. An implication of the results of this study for NFP teachers is that there are probably many women/couples in the US who are not using NFP, but who are interested in doing so. If provided with information in a positive way, these women may well choose natural methods.

### *Two Unique Methods of NFP*

#### **The Frank-Dunlap Method**

One of the challenges of using Basal Body Temperature (BBT) for Natural Family Planning is the determination of the post-temperature shift phase (and presumably post-ovulation phase) of the cycle. All of the current methods of interpreting the BBT shift are retrospective in that the “rules” call for at least three temperatures after the suspected shift. A more objective and prospective means of determining the post shift (luteal) phase of BBT might help those who use BBT as a natural biological marker of infertility.

One way of determining if the post shift luteal phase of a woman’s menstrual cycle has taken place is by comparing her basal body temperature with a comparable basal body temperature reading that does not undergo a shift in temperature, i.e., the male partner’s BBT. Two researchers from Emory University demonstrated in a case study that exogenous factors that affect temperature can be controlled by comparing the BBT of a woman’s male partner with her BBT recordings. They hypothesized that most exogenous factors that happen to body temperature with the woman would also happen to the man - except of course the shift due to ovulation.

To determine if this pattern of pre-ovulatory similarities had merit, researchers from Emory University recruited a sample of 12 couples and had them monitor their BBT for 2-3 cycles.<sup>50</sup> The investigators wanted to determine if the male partner could serve as a control for the exogenous changes (other than ovulation) in the female’s BBT. The females of the 12 (co-habiting) couples were between the ages of 21 to 43, had not been pregnant for at least 6 months and were not using any hormonal form of birth control for the past 6 months. The women had to be in a stable relationship with the male partner, sleep together, sleep at approximately the same time, follow similar work patterns, and not be apart for more than two days a month. The female participants also monitored their urinary LH with an ovulation predictor kit. The researchers estimated the day after the LH surge to be the day of ovulation.

A total of 41 cycles of data were collected of which 5 were non-ovulatory. The data showed that the temperatures of the pre-ovulatory phase had a highly significant co-variance and the postovulatory temperatures had a significant difference. The size of the mean temperature gap in the post-ovulatory phase between the men and women (pairs) was at least 0.3 degrees Fahrenheit higher than the pre-ovulatory mean temperature difference.

The researchers concluded that the recording of the male's BBT may improve the objectivity, interpretation and accuracy of the female's BBT. They also concluded that the size of the couple's temperature gap could be used to determine the transition from the pre to post-ovulatory phase. The researchers then proposed the Frank-Dunlap BBT method of determining if the women's cycle has begun its infertile luteal phase. The Frank-Dunlap method requires that the couple record their temperatures for a few cycles. They then calculate the magnitude of their unique temperature gap that indicates when the luteal phase has begun. In subsequent cycles when this gap is reached they would consider themselves in the infertile phase.

Although the Frank-Dunlap method of determining the infertile phase with the use of BBT monitoring might be more objective than the traditional retrospective methods (e.g., 3 high over the previous 6 lows) there needs to be a much larger study to determine the accuracy and effectiveness of this method to avoid pregnancy. However, the Frank-Dunlap method does represent fresh and innovative thinking about the use of BBT and determining the phase shift in a more objective prospective manner.

### **The TwoDay Method**

In 1999, researchers from the Georgetown University IRH utilized data from the 5-Country World Health Organization (WHO) study of the Ovulation Method (OM) to determine the theoretical effectiveness of what they call the TwoDay Algorithm. This algorithm was developed as a simple means to determine the fertile and infertile days of the woman's menstrual cycle utilizing external cervical mucus observations. The Algorithm essentially states that two days of no cervical-vaginal secretions i.e., "yesterday and today" are needed in order to be in an infertile state. A replication of this study by the Georgetown University researchers was conducted with a different data set of OM charts than from the WHO study.<sup>51</sup>

The WHO study data set included only the first day that women noticed cervical-vaginal secretions and the Peak Day. Although the 725 women in the WHO study charted daily observation of cervical mucus this data was not available to the Georgetown researchers and thus they were unable to determine how many "false positives" occurred outside of the fertile phase of the cycle. The Georgetown University researchers, however, were able to obtain OM data charts from Italy in which 282 women (average age of 27 years) contributed 2,707 cycles of data that included daily observations of vaginal-cervical secretions.

In order to determine the theoretical effectiveness of the TwoDay Algorithm the IRH researchers calculated the fertile phase to be a generous 8 days before the Peak Day of cervical mucus and the three days after the Peak Day. They based their days of fertility on the relative accuracy of the Peak Day in determining the day of ovulation (i.e., the Peak Day of cervical mucus falls plus or minus two days of the day of ovulation 95% of the time) and on the

probabilities of pregnancy during the 6 day fertile window as determined by Wilcox et al in a 1995 study.<sup>16</sup>

The study showed that with retrospective application of the TwoDay Algorithm on the Italian OM charts, the probability of pregnancy on the Peak Day of cervical mucus and the two days before and after were zero or near zero (i.e., a probabilities in the range of 0 -0.006). The two highest days of probability of pregnancy were days 4 (0.024) and 5 (0.020) before the Peak Day. The probabilities of pregnancy within the period of 8 days before and 3 days after the Peak Day of cervical mucus were very similar to the probabilities that they found with the WHO study data. However, with the Italian OM data charts they were able to determine that, from Peak Day plus 4 days through Peak Day plus 14 days, 15-30% of the days studied had false positives (i.e., the TwoDay Algorithm would indicate days as fertile when in truth they were not fertile). The pre-Peak Days from day 9-12 had 6-19% false positives.

Based on the researcher's calculations of the Italian OM charts the average number of fertile days using the TwoDay Algorithm is 11 days versus 10 days if they followed the OM rules. However, the researchers concluded that this one-day difference is not significant. The investigators found the TwoDay Algorithm to be theoretically effective and a promising (and simple to use and teach) method of family planning.

The Georgetown researchers mention in their article that one of the deficits of the TwoDay Algorithm is that it does not teach women how to differentiate vaginal-cervical secretions as do the OM and other mucus only methods. Because of this the TwoDay method has a significant amount of false positives, i.e., secretions that are interpreted as fertile that are in actuality not fertile. With the OM method these days might be interpreted as a basic infertile pattern of unchanging mucus.

### **Calendar Rhythm Method**

A multi-country focus group study was conducted recently to determine how couples actually use calendar methods, how they determine the fertile phase of the menstrual cycle, what behaviors they use during the fertile phase, and whether they are satisfied with natural methods of birth regulation.<sup>53</sup> The study was located in four countries (Hungary, Peru, the Philippines, and Sri Lanka) where a relatively high percentage of couples use natural methods of family planning. Each focus group consisted of 6-12 persons and a moderator familiar with group qualitative research techniques and experience in leading group discussions. The participants were men and women who avoided "unprotected" intercourse during certain days of the cycle to avoid pregnancy, were in stable relationships, were between the ages of 18-45, and belonged to similar socioeconomic and cultural groups. The focus groups were conducted in community centers and lasted about 2 1/2 hours. The following is a summarization of the qualitative results.

#### *Sources of Information about the Natural Methods*

The men in the focus groups obtained information about natural methods from their wives or partners, friends, and older family members. The women obtained information from books, newspapers, health posts, friends and older family members.

### *Factors related to the identification of the fertile period*

The participants in Peru, the Philippines, and Sri Lanka primarily used the calendar method, while those in Hungary used a mixture of natural methods including calendar, temperature, cervical self-examination and the Billings Ovulation Method. Participants in Peru and the Philippines did not apply the instructions for the Calendar Method consistently and the women in the Philippines often had a poor understanding of their menstrual cycle. For example one Philippine woman stated “A woman is fertile during the menstruation period. After menses she is no longer fertile.” Only 26% of the ever users of the Calendar Method in the Philippines were able to correctly identify the fertile phase of the menstrual cycle.

### *The use of abstinence and alternatives during the fertile period*

Most participants from each country reported the use of abstinence some time during the menstrual cycle to avoid pregnancy. However, participants in Peru, the Philippines and Sri Lanka reported the use of withdrawal, and those in Hungary and Peru commonly used condoms during the fertile time. Participants also reported the use of genital contact and “alternative sex” practices during the fertile period.

### *Perceptions of other contraceptives*

All participants in all four countries reported that modern methods of contraception were available to them. Participants in all four countries also felt that oral contraceptives and the IUDs were unhealthy and dangerous to use or have some unacceptable side effects. Expense was viewed as a barrier to use of modern contraceptives in Hungary and Sri Lanka.

### *Acceptability of Calendar Methods*

Participants in the Philippines and Sri Lanka, liked the calendar methods and found them effective, while those in Peru and Hungary disliked the natural methods because of their unreliability. Participants in every center felt that the methods were difficult to learn, understand and use. They also disliked coping with abstinence. However, they did appreciate the fact that the natural methods cost little, were safe and did not have negative side effects. Participants in three centers also felt that the autonomy of use and self-sufficiency were positive characteristics of the natural methods.

### *Suggested Ways to Improve Calendar Methods*

In Hungary the participants called for the development of more reliable methods, in Sri Lanka participants were enthused about participation in NFP programs because they previously only had access to programs for modern contraceptive methods. In Peru, participants suggested the use of schoolteachers for promoting and teaching the use of the natural methods and in the Philippine participants asked for more counseling on alternative methods to be used during the fertile phase. All participants called for increased public knowledge, awareness and better public

communication about calendar methods. They felt that credible persons in the mass media would be helpful. Credible and comprehensive counseling and support was also recommended.

The authors indicated that the participants in this study cannot be assumed to be representative of the population of Calendar Method users. However, the qualitative focus group approach does give a depth to the participant's responses and provides insights into their use of the methods. The authors also mentioned that many of the participants did not know how to use the Calendar Method and that the method could be more effective if the participants were taught how to use it and were given a better understanding of their menstrual cycles. Greater participation of the male in the use of the natural methods would also increase cooperation between the partners and efficiency of use. Helping couples to cope with abstinence during the fertile period—coping methods that involve non-genital and non-contraceptive means in synch with Catholic sexual ethics—is also a need.

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### SUMMARY

In the world of professional health care, basing practice on research evidence is necessary for quality health care services. The goal is to have practice guidelines and practice protocols that are evidence based. The same standards should also apply to providing NFP services. However, all research evidence is not equal and different organizations rate or grade the levels of evidence differently. For example the federal government has a grading system (see National Guideline Clearinghouse at [www.guideline.gov/](http://www.guideline.gov/) and the Agency for Healthcare Research and Quality - AHRQ) that grades levels of evidence (from 1 to 5 with 1 indicating the highest rating) and the strength and consistency of evidence (from A to D with A being the best). The evidence that reaches a Level 1 would be from a meta-analysis of multiple quality studies. Level 2 is evidence generated from experimental studies. Level 3 is evidence from well-designed quasi-experimental studies, Level 4 is evidence from well-designed non-experimental studies and finally Level 5 is from case reports and clinical examples. The highest strength of evidence “A” is from meta-analysis of quality studies or from consistent evidence from Level 2-4 studies. The “B” graded strength of evidence is from consistent findings from Level 2-4 studies, a “C” strength from inconsistent findings from Level 2-4 studies, and “D” strength means little or no evidence or Level 5 type studies only.

Based on the guidelines I would rate most of the LAM studies as Level 4 – in that they are well designed studies and the strength of evidence either an A or B in that there is consistency in the findings, i.e., when the LAM protocol is followed there is a consistency in the findings of a pregnancy rate below 2 percent. The LAM protocol also has been repeated with different populations in different countries. I would grade the Standard Day Method effectiveness studies as being Level 4 in that they are well-designed non-experimental studies and the strength of evidence to a tentative “B” in that there are two studies with consistent findings but the consistency of evidence is still being determined, in that the researchers from the Georgetown University IRH are repeating the study in different countries among different populations of women/couples.

I would also rate the evidence that the self-determination of urinary LH surge correlates very closely to the day of ovulation as Level 4 in that the studies conducted are well designed and use the gold standard of estimating the day of ovulation as the criterion to judge the LH surge. I would rate the strength of evidence as “B” in that there is also a consistency to the evidence. The other studies that have good consistency are those that estimate the probability of fecundity, in that the six-day interval of fertility seems to be consistent (even with imperfect markers of fertility).

Overall, the number and quality of studies in NFP and related areas are impressive in that there are a relatively few qualified scientists conducting studies in this area and the resources to do so are also limited. Research in the area of NFP is important for users and teachers of NFP. Good research will help guide NFP protocols and help provide quality NFP services. Good NFP research will also help us have a better understanding of human fertility, what constitutes good fertility health, and how the practice of NFP influences human relationships. Good NFP research will also help the NFP teaching community to identify practices and beliefs that need to be either changed or discarded. Change, however, is often hard but necessary for growth and life.

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## REFERENCES

### Accuracy of Biological Markers of Fertility

1. Guida, M., Tommaselli, G. and Palumba, S. et al. **Efficacy of Methods for Determining Ovulation In a Natural Family Planning Program.** *Fertility and Sterility* 72 (November, 1999): 900-904.
2. Ecochard, R. Boehringer, H., Rabilloud, M. and Marret, H. **Chronological aspects of ultrasonic, hormonal, and other indirect indices of ovulation.** *British Journal of Obstetrics and Gynecology* 108 (2001): 822-829.
3. Behre, H. M., Kuhlage, J. and Gassner, C. et al. **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* 12 (2000): 2478-2482.
4. Moreno, J. E., Khan-Dawood, F. S. and Goldsieber, J. **Natural Family Planning: Suitability of the CUE(TM) Method for Defining the Time of Ovulation.** *Contraception* 55 (April, 1997): 233-237.
5. Freundl, G., Frank-Herman, P. and Bremme, M. **Results of an efficacy-finding study (EFS) with the computer-thermometer Cyclotest 2 plus containing 207 cycles.** *Advances in Contraception* 14 (1998): 201-207.

6. Flynn, A. M., Collins, W. P. and Royston, P. et al. **Volumetric self-sampling of cervicovaginal fluid to determine potential fertility: a multicentre pre-effectiveness study of the Rovumeter.** *Human Reproduction* 12 (August, 1997): 1826-1831.
7. Braat, D. D., Smeen, J. and Manger, A. P. et al. **Saliva test as ovulation predictor.** *Lancet* 352 (October 17, 1998): 1283-84.

### Effectiveness of NFP Methods

8. Hilgers, T. and Stanford, J. **Creighton model naproeducation technology for avoiding pregnancy - use effectiveness.** *The Journal of Reproductive Medicine* 43 (1998): 495-502.
9. Howard, M. P. and Stanford, J. B. **Pregnancy probabilities during use of the Creighton Model FertilityCare™ system.** *Archives of Family Medicine* 8 (September/October, 1999): 391-402.
10. The European Natural Family Planning Study Groups. **European Multicenter Study of Natural Family Planning (1989-1995): Efficacy and Drop-out.** *Advances in Contraception* 15 (1999): 69-83.
11. Burkhardt, M. C., de Mazarigos, L. and Salazar, S. et al. **Incidence of Irregular Cycles Among Mayan Women Who Reported Having Regular cycles: Implications for Fertility Awareness Methods.** *Contraception* 59 (1999): 271-275.
12. Burkhardt, M. C., de Mazariegos, L., Salazar, S. and Lamprecht, V. M. **Effectiveness of a Standard-Rule method of Calendar Rhythm among Mayan couples in Guatemala.** *International Family Planning Perspectives* 26 (August, 2000): 131-136.
13. Arevalo, M., Jennings, V. and Sinai, I. **Efficacy of a new method of family planning: the Standard Day Method.** *Contraception* 65 (2002): 333-338.
14. Fruendl, G., Frank-Hermann, P. and Godehardt, E. et al. **Retrospective clinical trial of contraceptive effectiveness of the electronic fertility indicator Ladycomp/Babycomp.** *Advances in Contraception* 14 (1998): 97-108.
15. Bonnar, J., Flynn, A. and Fruendl, G. et al. **Personal hormone monitoring for contraception.** *The British Journal of Family Planning* 24 (1999): 128-134.

### Day Specific Probabilities of Fecundity

16. Wilcox, A. J., Weinberg, C. R. and Baird, D. D. **Timing of sexual intercourse in relation to ovulation.** *New England Journal of Medicine* 333 (1995): 1417-1521.
17. Wilcox, A. J., Dunson, D. and Baird, D. D. **The timing of the “fertile window” in the menstrual cycle: day specific estimates from a prospective study.** *British Medical Journal* 321 (November, 2000): 1259-1262.

18. Dunson, D. B., Baird, D. D. and Wilcox, A. J. et al. **Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation.** *Human Reproduction* 14 (July, 1999): 1835-1839.
19. Dunson, D. B., Colombo, B. and Baird, D. D. **Changes with age in the level and duration of fertility in the menstrual cycle.** *Human Reproduction* 17 (2002): 1399-1403.
20. Dunson, D. B., Sinai, I. and Colombo, B. **The relationship between cervical secretions and the daily probabilities of pregnancy: effectiveness of the TwoDay Algorithm.** *Human Reproduction* 16 (2001): 2278-2282.
21. Bitto, A., Gray, R. H. and Simpson, J. L. et al. **Adverse Outcomes of Planned and Unplanned Pregnancies among Users of Natural Family Planning: A Prospective Study.** *American Journal of Public Health* 87 (March, 1997): 338-343.
22. Gray, R., Simpson, J. and Bitto, A. et al. **Sex ratio associated with timing of insemination and length of the follicular phase in planned and unplanned pregnancies during use of natural family planning.** *Human Reproduction* 13 (1998): 1397-1400.

### Breastfeeding

23. World Health Organization Task Force. **The World Health Organization multinational study of breast-feeding and lactational amenorrhea. III. Pregnancy during breast-feeding.** *Fertility and Sterility* 72 (September, 1999): 431-39.
24. World Health Organization Task Force. **The World Health Organization multinational study of breast-feeding and lactational amenorrhea. IV. Postpartum bleeding and lochia in breast-feeding women.** *Fertility and Sterility* 72 (September, 1999): 441-47.
25. Labbok, M. H., Hight-Laukaran, V., and Peterson, A. E. et al. **Multicenter study of the Lactational Amenorrhea Method (LAM): I. Efficacy, duration, and implications for clinical applications.** *Contraception* 55 (1999): 327-336.
26. Peterson, A. E., Perez-Escamilla, R. and Labbok, M. H. et al. **Multicenter study of the lactational amenorrhea method (LAM) III: effectiveness, duration, and satisfaction with reduced client-provider contact.** *Contraception* 62 (2000): 221-230.
27. Valdes, V., Labbok, M. H. and Pugin, E. et al. **The efficacy of the lactational amenorrhea method (LAM) among working women.** *Contraception* 62 (2000): 217-219.
28. Dewey, K. G., Cohen, R. J. and Rivera, L.R. et al. **Effects of age at introduction of complementary foods to breast-fed infants on duration of lactational amenorrhea in Honduran women.** *American Journal of Clinical Nutrition* 65 (May, 1997): 1403-9.

29. Tomaselli, G. A., Guida, M. and Palomba, S. et al. **Using complete breast-feeding and lactational amenorrhea as birth spacing methods.** *Contraception* 61 (April, 2000): 253-257.

### Psychological Aspects of Practicing NFP

30. VandeVusse, L., Hanson, L. and Fehring, R.J. et al. **Couples' views of the effects of natural family planning on marital dynamics.** *Journal of Nursing Scholarship* 35 (2003): 171-176.
31. Oddens, B. J. **Women's satisfaction with birth control: a population survey of physical and psychological effects of oral contraceptives, intrauterine devices, condoms, natural family planning, and sterilization among 1466 women.** *Contraception* 59 (1999): 277-286.
32. den Tonkelaar, I. and Oddens, B. J. **Factors influencing women's satisfaction with birth control methods.** *The European Journal of Contraception and Reproductive Health Care* 6 (2001): 153-158.
33. Janssen, C. J. M. and van Lunsen, R. H. W. **Profile and opinions of the female Persona user in The Netherlands.** *The European Journal of Contraception and Reproductive Health Care* 5 (2000): 141-146.
34. Severy, L. J. **Acceptability of home monitoring as an aid to conception.** *The Journal of International Medical Research* 29 (2001, Suppl 1): 28A-34A.
35. Severy, L. H., Klein, C. T. and McNulty, J. **Acceptability of personal hormone monitoring for contraception: longitudinal and contextual variables.** *The Journal of Social Psychology* 142 (2002): 87-96.

### Lifestyle Factors and Fertility Health

36. Jensen, T. K., Hjollund, N. H. and Henriksen, T. B. et al. **Does moderate alcohol consumption affect fertility? Follow up study among couples planning first pregnancy.** *British Medical Journal* 317 (August, 1998): 505-510.
37. Parazzini, F., Chatenoud, L. and Di Cintio, E. et al. **Alcohol consumption is not related to fertility in Italian women.** *British Journal of Medicine* 318 (February, 1999): 397.
38. Juhl, M., Anderson, A. M., Gronbaek, M. and Olsen, J. **Moderate alcohol consumption and waiting time to pregnancy.** *Human Reproduction* 16 (2002): 2705-2709.
39. Klebanoff, M. A., Levine, R. J. and DerSimonian, R. et al. **Maternal serum paraxanthine, a caffeine metabolite, and the risk of spontaneous abortion.** *The New England Journal of Medicine* 341 (November, 25, 1999): 1639-44.
40. Eskenazi, B. **Caffeine - filtering the facts.** *The New England Journal of Medicine* 341 (November, 25, 1999): 1688-89.

41. Cnattingius, S., Signorello, L. B. and Anneren, G. **Caffeine intake and the risk of first-trimester spontaneous abortion.** *New England Journal of Medicine* 343 (December, 2000): 1839-1845.
42. Fenster, L., Waller, K. and Chen, J. et al. **Psychological stress in the workplace and menstrual function.** *American Journal of Epidemiology* 149 (1999): 127-134.
43. Bujan, L., Daudin, M. and Charlet, J. P. et al. **Increase in Scrotal Temperature In Car Divers.** *Human Reproduction* 15 (2000): 1355-1357.
44. Rowland, A. S., Baird, D. D. and Long, S. et al. **Influence of medical conditions and lifestyle factors on the menstrual cycle.** *Epidemiology* 13 (2002): 668-674.
45. Solomon, C. G., Hu, F. B., Dunaif, A. et al. **Long or highly irregular menstrual cycles as a marker for risk of type 2 diabetes mellitus.** *Journal of the American Medical Association* 286 (2001): 2421-2426.
46. Allende, M. E. **Mean versus individual hormonal profiles in the menstrual cycle.** *Fertility and Sterility* 78 (July, 2002): 90-95.

#### Miscellaneous Studies on NFP

47. Stanford, J. B., Thurman, P. B. and Lemaire, J. C. **Physicians' knowledge and practices regarding natural family planning.** *Obstetrics and Gynecology* 94 (November, 1999): 672-678.
48. Fehring, R. J., Hanson, L. and Stanford, J. B. **Nurse-midwives' knowledge and promotion of lactational amenorrhea and other natural family planning methods for child spacing.** *Journal of Midwifery and Women's Health* 46 (Mar/April, 2001): 68-73.
49. Stanford, J. B., Lemaire, J. C. and Thurman, P. B. **Women's interest in natural family planning.** *The Journal of Family Practice* 46 (1998): 65-71.
50. Dunlop, A. L., Allen, A. D. and Frank, E. **Involving the male partner for interpreting the basal body temperature graph.** *Obstetrics and Gynecology* 98 (2001): 133-138.
51. Sinai, I., Jennings, V. and Arevalo, M. **The TwoDay Algorithm: A new algorithm to identify the fertile time of the menstrual cycle.** *Contraception* 60 (1999): 65-70.
52. Jennings, V. and Sinai, I. **Further analysis of the theoretical effectiveness of the TwoDay method of family planning.** *Contraception* 64 (2001): 149-153.
53. Research Group on Methods for the Natural Regulation of Fertility. **Periodic abstinence and calendar method use in Hungary, Peru, the Philippines, and Sri Lanka.** *Contraception* 64 (2001): 209-215.