

Summer/Fall 2014 • Vol. 25, Nos. 3 & 4 Richard J. Fehring, PhD, RN, FAAN – Marquette University College of Nursing

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## **Natural Family Planning**

# Natural Family Planning Differentiates Women's Perception of the Availability of Reproductive Health Services in Catholic Hospitals

Catholic hospitals and health care systems provide approximately 10% of the health care in the United States. Furthermore, in some smaller communities Catholic hospitals and Catholic health care services are the only health services available. Previous research has shown that Catholic hospitals that follow Catholic Church teachings prevent the use of "standard" (i.e. immoral) reproductive services and that obstetricians and gynecologists view Catholic health systems as preventing the availability of "full" (but often immoral) reproductive services. Researchers theorized that women patients of reproductive age would be surprised and disturbed if they understood that Catholic health care systems are limited in the provision of some types of women's health care services (Guiahi, Sheeder, and Teal 2014). Therefore, these researchers set out to determine if women of reproductive age would expect different reproductive services in a Catholic hospital compared to a secular or non-Catholic hospital. They hypothesized that there would be no difference in the types of reproductive services that potential women patients would expect in a Catholic hospital as opposed to a secular based health system.

The researchers sought volunteer women participants of reproductive age from online lists and a web page advertisement. They randomized volunteer women participants who met their criteria into two groups. Both groups were provided a short vignette that described a new hospital in the Denver, Colorado area in which the respondent is receiving an annual exam. One of the hospitals was named Saint Ignatius and the other Metropolitan Hospital of Denver. There were 236 volunteer participants, and of these volunteers, 115 met the study criteria and were randomized into the "Catholic" hospital group and 121 in the secular hospital group. All participants were provided an online 11 item survey that asked whether they would be able to receive types of reproductive service at the designated hospital or not, -- including methods of contraception, emergency contraception, injectable hormones, IUD, sterilization, Natural Family Planning, and termination of pregnancy (abortion) for a fatal abnormality. There were no differences in the demographics of the two groups. Of interest, most respondents were single, white, and had no religion. The researchers found that there was no difference in expected availability of reproductive services other than Natural Family Planning (NFP), which was expected to be offered at a higher rate for the Catholic hospital.

## **Comments**

The obvious limitation of this study is that the respondents are self-selected and as such can be biased. Although the authors said that the participants represent the characteristics of reproductive age women in Denver, the women were sought through the internet and they were mostly white, single and college graduates. The fact that most did not have a religion is also a trend in the United States but not the norm. Finally, although the women in the secular hospital group less frequently responded that they expected NFP services, there was a large majority of women (86%) in this group who expected to be able to receive NFP services in a secular hospital. It is concerning that women in the survey do not understand that unethical practices would not be offered at a Catholic hospital.

#### Source

M. Guiahi, J. Sheeder, and S. Teal. 2014. Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care. *Contraception* 90: 429-434.

Use of Ovulation Predictor Kits as Adjuncts When Using Fertility Awareness Methods (FAM's): A Pilot Study

Study reviewed by: Mary Schneider, M.S.N., F.N.P.

The use of an inexpensive urinary luteinizing hormone (LH) predictor test that can be used in conjunction with other biological fertility indicators, such as cervical mucus (CM) observations, has the potential of clarifying confusing signs of fertility and even increasing the use of fertility appreciation methods (FAM) in developed countries. Leiva, Burhan, Kyrillos, Fehring, McLaren, Dalzell and Tanguay (2014) conducted a pilot study to see how efficient inexpensive urinary LH test kits were compared to FAM that used CM and/or basal body temperature (BBT) in identifying the post-ovulatory phase of the cycle. The purpose of the study was to determine feasibility of using an inexpensive urinary LH test kit with other biological signs of fertility employed by the FAM of choice to assist in identifying the post-ovulator phase of the menstrual cycle. Once LH was detected the women were asked to continue testing until they had three consecutive days of negative results, at which time the post-ovulatory gold standard test serum progesterone levels were drawn from each participant. If the progesterone level was greater than 10 nmol/L women participants were determined to be in the luteal phase of the cycle.

This pilot study was a two arm crossover block design that enrolled 23 regular cycling Canadian women with a high school education or higher and between the ages of 20 to 48. Women currently using hormonal contraception or trying to become pregnant at the time of recruitment were excluded. Sensitivity of the test kits used detected LH at 20 mIU/ml, a threshold that has been shown to be most accurate and least likely to miss the LH surge (Ecochard, R., Boehringer, H., Rabilloud, M., and Marret, H., 2001).

Women were assigned into either the FAM with LH test kit group or FAM only and after one cycle groups were switched. This technique was chosen to expose each group to both methods in hopes of avoiding learner bias. They began daily urine LH testing from the sixth day of menses through three consecutive days post the last positive LH test. That is, once the woman had a positive LH test she continued to test up to three consecutive negative days after the last positive. Serum progesterone levels were drawn on the third consecutive negative day. Statistical analysis using a McNemar test was used to detect differences between the two arms. Serum progesterone levels provided the markers for the dichotomous variables of "yes" the woman was in the luteal phase or "no" she was not.

## **Comments**

The authors did find statistically significant difference between the two methods. The participants using the LH test kits with FAM correctly identified the postovulatory phase 100% of the time and when FAM alone was used the postovulatory phase was correctly identified 87% of the time. However, to include both FAM methods, i.e., the CM FAM and the CM plus temperature FAM together could potentially skew the results. Although, both FAMs used tertiary signs of fertility (cervical mucus and/or basal body temperature (BBT)) to identify the post ovulatory phase, the addition of temperature may confound the results because it is an objective sign of fertility like the LH test kit. The authors stated they chose women who were having some difficulty identifying the peak day. Thus they were using the rules of the FAM method of their choice. Because there are several FAMs that are CM only or CM plus BBT with different rules of identifying the peak day, it would be helpful if the type of methods within these groups were identified and analyzed separately.

Home urinary monitoring for estrogen, LH and progesterone to identify ovulation and the fertile and infertile phases of the menstrual cycle is an achievable goal. This pilot study is a model for future FAM/Natural Family Planning (NFP) research and another tool for the NFP teacher to place in their toolbox when dealing with women and couples having difficulty with identifying the peak of fertility and the post-ovulatory infertile phase of the menstrual cycle.

#### Sources

Ecochard, R., H. Boehringer, M. Rabilloud, and H. Marret. 2001. **Chronological** aspects of ultrasonic, hormonal, and other indirect indices of ovulation. *BJOG: An International Journal of Obstetrics & Gynaecology* 108 (8): 822-829.

Leiva, R., U. Burhan, E. Kyrillos, R. Fehring, R. McLaren, C. Dalzell, and E. Tanguay. 2014. Use of ovulation predictor kits as adjuncts when using fertility awareness methods (FAMs): a pilot study. *The Journal of the American Board of Family Medicine* 27 (3): 427-429.

#### **Continuous Temperature Monitoring Correlated with Ultrasound**

Daily monitoring of basal body temperature (BBT) is a useful but "fuzzy" gage of fertility for women using that indicator for purposes of avoiding or achieving pregnancy. Use of BBT is of particular concern since the upward shift in body temperature is due to the rise in progesterone post ovulation, hence, the indication of fertility is too late to affect an act of intercourse that would lead to pregnancy; however, newer temperature measuring devices have recently been developed that offer continuous temperature measurement and are thought to be more accurate than a single temperature taken upon rising in the morning. Such a device called the DuoFertility measures continuous temperature and movement by having the woman wear a sensor patch. Researchers recently conducted a study to determine the accuracy of the device by comparing the continuous measure of body temperature with serial ultrasound of the developing follicle, i.e., the gold standard of detecting the day of ovulation (Rollason, Outtrim, and Mathur, 2014).

The researchers obtained eight volunteer women, 18 to 44 years of age, who presented to their clinic for treatment of fertility and who tried to conceive for 12 months or more. These participants were asked to monitor three consecutive menstrual cycles with use of the continuous temperature monitor and with the use of a daily luteninzing hormone (LH) urine tests starting on day eight of their menstrual cycle. When they had a positive LH test they then came to the clinic for transvaginal ultrasound to monitor the dominant follicle and to document the collapse of the follicle. The day of the collapsed follicle was used as the estimated day of ovulation. The participants provided 35 menstrual cycles but only 18 cycles had complete data and were useful for the purpose of the study.

The researchers found that in every cycle that ultrasound detected the day of ovulation the temperature monitor did so as well. The estimated day of ovulation by use of the DuoFertility was 100% plus or minus one day of the ultrasound detected day of ovulation. In 10 of the cycles the temperature monitor detected ovulation on the estimated day of ovulation and in 3 one day after. The researchers realized that as a pilot study it did not have an adequate number of participants nor an adequate number of menstrual cycles of data. They indicated however, that the continuous temperature measurement device might be of benefit for infertile women with regular cycles with infertility problems and is less invasive than ultrasound measures.

## Comments

Many women with infertility have irregular cycles and, as the authors indicated, future studies to test the accuracy and usability of this temperature monitoring device will need to include more participants and participants with irregular cycles. Although continuous measure of body temperature would provide a more accurate measure of temperature it still would be susceptible to body temperature variability that makes use of BBT difficult (i.e., during stress, lack of sleep, exercise, alcohol, infections, etc.). Furthermore, since the DuoFertility BBT shift in body temperature was either on the day of ovulation or the day after, those days most likely are already too late for achieving pregnancy.

## Source

Rollason, J. C. B., J. G. Outtrim, and R. S. Mathur. 2014. A pilot study comparing the **DuoFertility monitor with ultrasound in infertile women**. *International Journal of Women's Health* 6: 657-662.

## Use of Electronic Fertility Monitoring Versus Cervical Mucus Monitoring Results in Less Abstinence and More Frequent Coitus for Couples Using Natural Family Planning

## Study reviewed by Kathleen M. Raviele, M.D, Ob/Gyn, FACOG

Despite modern methods of Natural Family Planning being readily available, there are few couples who use these safe and natural methods. Only 0.1% of women in the U.S. are using a method of Natural Family Planning (NFP). Reasons for the lack of use may include prolonged abstinence, difficulty with observations, difficulty in learning the method and unexpected pregnancies. There is a need for continued research efforts to develop safe, easy methods of NFP to assist couples in living out the teachings of the Catholic Church in the area of family planning.

Fehring and Schneider (2014) conducted an analysis of data from a 12-month prospective comparison study where couples were randomized into an online NFP method that included either the use of an electronic fertility monitor (EHFM) and a fertility algorithm for the beginning of the fertile window in one group and cervical mucus monitoring (CMM) and a fertility algorithm for the beginning of the fertile window in the other group. After six months of use, the fertility algorithm was adjusted for the earliest peak day seen either with the monitor or the mucus. The goal of the study was to compare the estimated time of fertility, and thus days of abstinence, between the two methods, as well as the frequency of intercourse between the two methods.

A total of 197 women were in the EHFM group and 160 women in the CMM group and they were observed over 1,663 menstrual cycles of data. The women were 18 - 42 years of age, with a cycle length of 21 - 42 days, and they were more than three months off hormonal contraceptives as well as more than three months past breastfeeding. There was no demographic difference between the two groups in age, parity, age of male partner or BMI. They learned the method online and were instructed in how to make cervical mucus observations and how to chart with online instructions with a ten-minute video. The online charting for both methods delineated the fertile window in the first six months. This was from day 6 until three full days past the peak day with the mucus for the CMM group and the second peak with the Clearblue Easy Fertility Monitor (i.e., the EHFM used for this study) for the EHFM group. The EHFM detects rising levels of urinary estrone-3-glucuronide (E3G), resulting in a high fertility reading on the monitor, and detects the urinary LH surge with 98.8% accuracy, indicating peak fertility. Mucus observations were simplified as low, high or peak observations and low readings were considered infertile. The participants were asked to chart online daily including the days they had coitus.

In the first six menstrual cycles, with the fixed beginning of the fertile window in both groups starting on day 6, there was no difference between the two groups in the estimated fertile phase. The days of abstinence in the EHFM versus CMM groups were mean (SD) 14.34 (4.04) and 14.19 (3.86) days per cycle, respectively. After the first six cycles, the EHFM group had fewer days of abstinence with 13.25 (2.79) versus 13.68 (2.99) days per cycle in the CMM group (t = 2.07; P = .039). There was significantly more coitus in the EHFM group with 4.22(3.16) versus 4.05 (2.88) (t = 1.17; P = .026) per cycle. The authors expressed the concern that all acts

of intercourse were not being recorded as this was fewer than have been recorded in other studies.

## **Comments**

This study is significant in that it is the first to analyze days of abstinence and frequency of coitus in two simple online programs of NFP, comparing a mucus only program versus an EHFM program. It appears that the EHFM may more confidently identify the fertile window, thus allowing more coitus on days of infertility for those wishing to avoid pregnancy. It is also significant in that it is an analysis of an online program with an online charting system. There are programs that train couples online or have aspects of charting online, but their effectiveness has not been formally studied. Fehring and Schneider (2014) and their fellow researchers have made simple online programs available to anyone in the world, if they have a computer and internet access, making the living out of the Church's teaching on family planning easier to attain.

## Source

Fehring, R. J. and M. Schneider. 2014. **Comparison of abstinence and coital frequency between 2 natural methods of family planning**. *Journal of Midwifery & Women's Health* 59 (5): 528-532.

## **Fertility/Infertility**

## Use of Focused Intercourse During Estimated Fertile Phase Found to Be No Better Than Frequent Random Intercourse on Time to Pregnancy and Fecundability

Research studies have established that there is a window of fertility during the menstrual cycle that includes the day of ovulation and the five preceding days. The six day fertile window is based on the biological knowledge that sperm can live for three to five days in a good (cervical mucus) environment and that the egg following ovulation lives only for 24 hours or less. It therefore makes sense that having intercourse during this fertile window would increase the chance of pregnancy. However, having frequent intercourse (i.e., two to three times a week) might work as well, since some of those frequent acts of intercourse would automatically land on a day of the fertile window. Researchers sought to determine if use of a method of NFP to estimate the fertile window and target intercourse would increase the time to pregnancy and fecundity (Stanford, Smith, and Varner, 2014).

The participants for this study were women: with no known infertility problems; between the age of 18 and 35 years; who had a pregnancy within the past 8 years and not currently breastfeeding; not on any hormonal contraceptives; and who have regular menstrual cycle lengths. Participants were sought through e-mail, web-site, mailings, newspaper advertisement, and person to person contact. The researchers were able to screen 667 potential participants, but of these, 247 were eligible, and of these, 104 declined participation. The remaining 141 were randomized into a group that was taught the Creighton Model System (CrMS) of natural family planning (n = 69) and another group that was asked to have frequent intercourse at least two to

three times per week (n = 71). The CrMS is a cervical mucus only method of natural family planning with a standardized mucus rating and follow-up system. Participants were paid to provide menstrual cycles of data. All participants were provided a blinded electronic hormonal monitor that estimated the fertile window based on urinary measures of estrogen and luteinizing hormone (LH).

Based on menstrual cycles in which couples intended to conceive, the fecundity was 31% in the control (i.e., the frequent intercourse group) and 36% in the CrMS group (p = 0.32). The time to pregnancy for those who conceived was 2.9 cycles in the control group and 3.5 in the CrMS group. The cumulative probabilities of pregnancy for those couples attempting to conceive were 51% and 63% (respectively for the control group and the CrMS group) by menstrual cycle 3, and 88% and 93% (respectively for the control group and the CrMS group) by cycle 7. The researchers concluded that the study found no impact of using the CrMS to focus intercourse during the fertile phase among couples with proven fertility compared with frequent intercourse. The authors suspected that the study might have been under powered statistically.

#### **Comments**

An instruction of the CrMS is to avoid intercourse during the first menstrual cycle of use and although the control group was also asked to avoid intercourse during the first menstrual cycle, it was obvious that more couples in the control group took advantage of the first cycle to achieve pregnancy. The authors felt that this instruction favored the control group and that the control group had a head start on achieving pregnancy. At the end of the first menstrual cycle, the control group fecundatility was 17% (12 out of 71) and the CrMS group was 4% (3 out of 69 (p = 0.02).

#### Source

Stanford, J. B., K. R. Smith, and M.W. Varner. 2014. Impact of instruction in the Creighton Model Fertility Care System on time to pregnancy in couples of proven fecundity: results of a randomized trial. *Paediatric and Perinatal Epidemiology* 28: 391-399.

# Premenstrual Spotting Found to be Predictive of Endometriosis Among Women with Infertility

Endometriosis can be a debilitating disease affecting about 6-10% of reproductive age women and is associated with pelvic pain and infertility. Since endometriosis is a progressive disease, diagnosing and surgically treating it early is important, i.e., before it becomes deeply invasive and infiltrating. Although there is some association of endometriosis with pelvic pain, the most definitive diagnostic procedure is through visual laparoscopy. Although laparoscopy is a fairly safe procedure, there are surgical risks and discomfort. Non-surgical diagnostic indicators would be beneficial for early and non-invasive detection. One potential indicator of early endometriosis is pre-menstrual spotting, i.e., light menstrual bleeding before a frank menses. Researchers sought to determine if premenstrual spotting (of 2 days or more) was predictive of endometriosis among sub-fertile women (Heitmann, Langan, Huang, Chow, Burney, 2014).

The participants for this study were selected from the records of all women who underwent laparoscopy for an infertility assessment – most of whom had pelvic pain – from March 2009 to March 2011 at a tertiary medical center. All participants completed a three page infertility assessment that included questions as to pelvic pain during menses and intercourse, and whether they had spotting before the normal menstrual flow. The researchers only included the symptom if the premenstrual bleeding was two days or more before the onset of menses. They were able to obtain records of 80 women who met their criteria, and of these, 32 reported premenstrual spotting of two days or more. Of the women who reported premenstrual spotting, 89%, or 34 of 38, were diagnosed with endometriosis as compared to only 11 of 42 (26%) in the group of women who did not experience premenstrual spotting (p < .001). They also found that, of the three menstrual symptoms of dysmenorrhea, dyspareunia, or premenstrual spotting, premenstrual spotting was the most predictive, i.e., 81% compared to 76% for dysmenorrhea, and 58% for dyspareunia. A stated limitation of the study was the retrospective design; however, they concluded that if this association of premenstrual spotting and endometriosis is validated in prospective studies that it could be used for the identification of women who would benefit most from laparoscopic evaluation and treatment.

## **Comments**

It should be added that a prospective study that includes prospective charting of the menstrual cycle that includes natural biological markers of fertility and levels of menstrual bleeding, (i.e., charting systems that are commonly found in Natural Family Planning systems), would provide a more accurate assessment of premenstrual spotting. This study also reinforces the benefit of charting the menstrual cycle as a vital sign for women's health.

### Source

Heitmann, R. J., K. I. Langan, R. R. Huang, G. E. Chow, and R. O. Burney. 2014. **Premenstrual spotting of**  $\geq$  2 days is strongly associated with histologically confirmed endometriosis in women with infertility. *American Journal of Obstetrics and Gynecology* 211: 358.e1-6.

## **Pregnancy**

## **Intercourse During Implantation May Lead to Earl Pregnancy Loss**

Theoretically, intercourse during the time of implantation of a human embryo could result in an early miscarriage due to uterine contractions. In order to test this theory, researchers conducted a study to determine whether intercourse around the time of implantation reduced fecundability, i.e., the probability of obtaining a positive pregnancy test (Steiner, Pritchard, Young, and Herring, 2014). This study was a secondary analysis of a data set that was obtained from women attempting to achieve pregnancy between the ages of 30 to 44, had no known fertility problem, and had been trying to achieve pregnancy three months or less. The women

were obtained through advertisement (radio and television), the internet, e-mail, and informational letters. All participants were asked to keep a daily diary of their menstrual cycle, including intercourse, use of luteinizing hormone (LH) testing, and observations of cervical mucus changes. This study included 564 women (or 76% of the total 743 women enrolled into the study) who completed at least one menstrual cycle of data.

The researchers utilized a calendar based calculation to determine the estimated day of ovulation, i.e., 14 days before the following menses was the estimated day of ovulation and days 5-9 following the estimated day of ovulation were the estimated days of embryo implantation. For this study there was 1,332 menstrual cycles, but only 46% had two to three days of intercourse during the fertile window. They discovered that couples who had two or more days of intercourse during the estimated post ovulation implantation window were close to 40% less likely to have a positive pregnancy test compared to those couples who did not have intercourse during the estimated implantation window (fecundability ratio = 0.59; 95% CI, 0.40-0.86). They also noted that the probability of a positive pregnancy test decreased as the frequency of days with intercourse increased during the estimated implantation window. Although the authors concluded that intercourse during the estimated implantation window may reduce the ability to achieve a pregnancy, they did not recommend any change of practice. They did recommend further research.

## **Comments**

An obvious limitation of this study was use of a calendar formula to estimate the day of ovulation and the estimated days of probable implantation. A sub group of 156 participants did use an LH test to estimate fertility, and generated 226 menstrual cycles of data, and found (based on intercourse on days 6-10 after the LH surge) a 26% less likelihood to achieve a positive pregnancy test compared to couples who did not have intercourse during that time period. The decrease in pregnancy rates did not reach statistical significance among this subset of participants. In addition, the frequency of intercourse might have been under reported.

## Source

Steiner, A. Z., D. A. Pritchard, S. L. Young, and A. H. Herring. 2014. **Peri-implantation** intercourse lowers fecundability. *Fertility and Sterility* 102 (1): 178-182.

# **Menstrual Cycle**

## **Cinnamon Supplement Found to Improve Menstrual Cyclicity**

Insulin resistance and the compensatory hyperinsulinemia is a pathological mechanism of polycystic ovary syndrome (PCOS). Insulin sensitizing agents, such as metformin, have been used successfully to treat women with PCOS but often with uncomfortable side effects such as nausea, vomiting, and diarrhea. Cinnamon, a natural supplement, has insulin sensitizing properties and has been used in the treatment of diabetes. Researchers from Columbia University

sought to determine the effect of a cinnamon supplement on menstrual cycle cyclicity and metabolic dysfunction among women with PCOS (Kort and Lobo, 2014).

Participants for this study were recruited by print advertising with the criteria that they were between the ages of 18-38 years and met the Rotterdam criteria for PCOS, (i.e., evidence for hyperandrogenism or ultrasound finding of polycystic ovaries). The researchers were able to recruit and screen 63 women volunteers, of which 45 met the study criteria. Twenty-three of these women were randomized to receive a daily 1500 mg dose of cinnamon (i.e., four 125mg capsules four times a day) and 22 were randomized into the comparison group that received a lookalike placebo pill four times a day. Both the participants and the researchers were blinded as to what group each participant was in. The women participants were recommended to follow an 1800 calorie diet and make daily diary entries. They were also asked to keep track of their menses and have monthly follow-up appointments. The length of the study was six months with the main outcome being menstrual cyclicity measured by menstrual (menses) frequency. Secondary outcomes were insulin resistance and serum androgen levels.

At baseline, there was no difference in age, BMI, insulin resistance, and sex hormone binding globulin. Only 17 of the 45 participants (i.e., 11 in the cinnamon group and 6 in the placebo group) completed all six months of the study. Analysis of the data showed the number of menses/menstrual cycles per month were more frequent in women taking the cinnamon supplement compared with the women taking the placebo (median, 0.75 vs 0.25, P = .0085; Mann Whitney U). Also, there was an improvement of menstrual cyclicity among the women taking the cinnamon supplement (P = .0076, Wilcoxson matched pairs signed rank test) but not with the women taking the placebo (P = .145). There was no difference between the two groups in insulin resistance or serum androgen levels. The main limitation of the study was the large dropout rate of participants and the final small sample size. The researchers were concerned that although there was a significant difference in frequency of menses, there was no physiological change in insulin resistance and androgen levels. Because of the dropout rate and small number of final participants, the researchers felt that this was at the level of a pilot study. They did feel that the preliminary data showed promise as an effective treatment option for women with PCOS.

## **Comments**

The Columbia University researchers realized that they needed better compensation for participants. They felt that recommending women participants to follow an 1800 calorie diet, make daily diary entries, keeping track of their menses, and monthly follow-up appointments contributed to drop out. Instructing the participants in how to chart their menstrual cycles and track natural indicators of fertility through NFP would provide a better understanding of menstrual cycle changes and would enhance the main outcome of the study.

Kort, D. H. and R. A. Lobo. 2014. **Preliminary evidence that cinnamon improves menstrual** cyclicity in women with polycystic ovary syndrome: a randomized controlled trial. *American Journal of Obstetrics & Gynecology* 211: 487.e1-6.

# **Under the Microscope**

## A Brief History of Natural Family Planning

## **Richard J. Fehring**

Many individuals have been intimately involved in the development, research, and promotion of natural family planning (NFP). The names and accomplishments that follow are just a few. This short historical review is intended to help the reader learn more about these individuals and their works. The reader should gain a greater appreciation for NFP and for the work that has been accomplished – often under very difficult conditions and circumstances – in the development of NFP. This review of the history of NFP is not intended to be complete. There are many individuals that have contributed to the development of NFP that are not mentioned in this section.

## Ancient History

The ancient Egyptians are thought to be the first people to record their attempts at birth regulation. In their ancient writings they described a number of substances that were used as vaginal pessaries (barriers), e.g., crocodile dung, honey, and sodium bicarbonate. These substances could have created a hostile environment for human sperm and might have worked as a spermicidal and as a barrier to sperm (Himes, 1936). These practices of course would be considered contraceptive and not a natural method of birth regulation. Throughout recorded history there have been numerous attempts at developing potions and behaviors to control fertility rather than live with and understand it.

Early Greek physicians (5<sup>th</sup> century BC) who were trained in the Hippocratic School speculated on the fertile and "safe" (or non-fertile) time in a woman's monthly cycle. Saoranos (98-138 BC) was one of the most famous Greek physicians who described a "safe" period (Robertson, 1990). These early physicians, however, also prescribed many types of potions and behaviors for the purpose of contraception. There also have been reports and anthropological observations that various indigenous tribes in Africa and Australia intuitively recognized natural signs of fertility, e.g., the natural flow and wetness of cervical fluid at mid cycle (Robertson, 1990). Indigenous women would teach their daughters about natural signs of fertility and pass down fertility knowledge from generation to generation. Tribal women also practiced extended breastfeeding and thus had a built in method of natural child spacing.

Ancient and traditional Jewish laws involved regulation of fertility, purity and generating new life. These practices encouraged God's command through Moses for the Israelites to be fruitful people. For example, in Leviticus 15:19 and 18- Moses state "When a woman has a flow of blood from her body, she shall be in a state of menstrual uncleanness for seven days. Anyone who touches her shall be unclean until evening." "When she becomes clean from her flow, she shall count seven days; after this she becomes clean." This is sometimes called the family law of purity. If a couple waited 7 days after menstruation (which is usually about 3-5 days in length) -

this would bring the couple into the fertile time of the cycle, i.e., from day 10 to 12 in the woman's cycle. The ancient Hebrews had a sense and knowledge of the fertile time.

#### Discoveries Necessary for NFP

A number of biological discoveries were needed in order for modern methods of NFP to be developed. These discoveries included knowledge of the existence of the human sperm and human egg (ovum) and how long they were viable. Determining the fertile and infertile time of a woman's menstrual cycle was also important and how variable this fertile time was from cycle to cycle. And of course discovering natural biological signs and symptoms of fertility and how these biological indicators correlated with events in the menstrual cycle were crucial for the development of NFP.

## Discovery of the Human Sperm

Antoni van Leeuwenhoek (1632-1723) was an early developer of the science of microscopy. He was a cloth merchant by trade but his hobby in the use of the microscope became a scientific pursuit. He visualized hundreds of objects with his early and rather crude magnifying instruments. However, a medical student and friend of van Leeuwenhoek, Johannes Hamm was the first to visualize human sperm in 1677 and to share his findings with Leeuwenhoek. Thus van Leeuwenhoek and Hamm were the first to scientifically describe human sperm. A friend of Leeuwenhoek, Regnier de Graaf (1641–1673), a Dutch physician and anatomist, was the first to visualize the ovarian follicle and deduce the existence of the female ovum. The mature or ripe follicle was later named after him and is now called the Grafian Follicle in medical literature.

After Hamm and Leeuwenhoek discovered the human sperm, there were two schools of thought (both wrong) about human development. Some scientists after visualizing the human sperm thought they saw a complete tiny human being in the head of the sperm and postulated that all that is needed for human growth is the human soil (the womb) from a woman to incubate this life. These sperm theorists were known as "animaculists" or "homunculists." Other scientists called "Ovists" felt that the female was the major contributor to human life and that the egg was the source of human life. There were also scientists who believed in spontaneous generation.

#### Discoveries in the 1800s

It was not until 1826 that Karl Ernst Ritter von Baer (1792-1876; a Prussian-Estonian biologist) reported or confirmed the existence of the mammalian ovum (egg). He thought that sperm were only parasites and hence the name "spermatozoa." Soon after, in 1843, Martin Barry speculated that the entry of sperm into the egg was necessary for human life and in 1875, Oscar Hertwig observed that the sperm actually entered the ovum by studying sea urchins.

A number of physicians and scientists, in the 1800s, reported studies that involved measuring body temperature in relation to events in the woman's menstrual cycle and in particular menstruation. In 1838, Von Fricke correlated (vaginal, axillary auxiliary and uterine)

temperatures with menstruation and determined that menstruation had no influence on body temperature. However, in 1868, William Squire observed that a woman's temperature decreased as menstruation approached. Mary Putnam Jacobi (1842-1906), one of the first modern female physicians, published a paper (1876) on her observations of temperature curves in 6 healthy young women students. None of these scientists, however, connected the temperature shift with the time of ovulation or speculated on the use of this information for family planning.

During the 1800s and early 1900s a number of scientists speculated on the fertile and infertile time (or what was referred to as the "safe period") of the woman's menstrual cycle. A prominent French physician by the name of Felix Pouchet investigated and described the characteristics of mid-cycle cervical mucus and inter-menstrual pain. Pouchet (1845) theorized that conception was possible during menstruation and 1-12 days after. He was one of the first scientists to describe cervical-vaginal mucus – "from the 10<sup>th</sup> to 15<sup>th</sup> day the utero-vaginal mucus which has become thick and whitish begins to get more fluid an abundant" (Noonan, 1986). He did not apply or link this knowledge to the fertile time of the menstrual cycle. He and many other 19<sup>th</sup> century scientists were influenced by their observations of "heat" in animals. Pouchet was better known for his belief in spontaneous generation of life from non-living matter.

In 1883 an influential German gynecologist, Carl C. Capellman, postulated that the first 14 days of a 28-day menstrual cycle were fertile and the second 14 days were sterile except for a few days before menstruation (Dickerson 1927; Noonan 1986). Some theologians and physicians used this knowledge to recommend to couples that there is a time in the menstrual cycle when intercourse could occur without becoming pregnant. His writings on this "safe period" influenced theologians well into the 20<sup>th</sup> century.

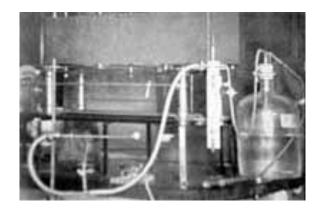
## The 20<sup>th</sup> Century

In the early 1900s reproductive scientists attempted to determine the fertile period of a woman's menstrual cycle by keeping records of intercourse patterns and resultant pregnancies. Some of these studies involved the observation of women who had husbands (or friends) in the military and subsequent marriage records and birth records. When husbands and/or boyfriends would return home during their leave from military service many would have intercourse during that time. These acts of intercourse would be fresh in their minds of their female spouse or partner and provide fairly accurate recall for when intercourse occurred in their menstrual cycle. The scientist could correlate any pregnancy that resulted from an act of intercourse during leave with the recalled day of the menstrual cycle. This recall data resulted in the belief that women are potentially fertile throughout their entire menstrual cycle.

Also in the early 1900s a number of scientific discoveries provided information that could have been applied to the development of natural methods of birth regulation but were largely ignored. Fraenkel in 1903 described how the corpus luteum (i.e., the tissue that results from the luteinized follicle after ovulation) was formed and that ovulation preceded menstruation by about two weeks. A Dutch scientist Theodore Hendrik van de Velde confirmed Mary Jacobi's work by identifying the bi-phasic temperature shift but also correlated this with ovulation. In 1928, he determined that the temperature shift was somehow maintained by the corpus luteum. Kyusaku Ogino from Japan and Herman Knaus from Austria are the two individuals who have been credited with the discovery of the first usable and scientific method of natural birth regulation (Knaus, 1934; Ogino, 1934). They independently (and in very different manners) discovered that ovulation preceded menstruation by about 14 days. Dr. Ogino was the head of gynecology at Takeyama Hospital in Negata, Japan. As a surgical gynecologist, he observed the ovaries of 118 of his patients during abdominal surgery. He was able to determine (based on the size and condition of the follicle or corpus luteum) when ovulation roughly occurred. When he plotted the 118 menstrual cycles and the estimated days of ovulation out on a graph, the days of ovulation were scattered and made no sense. However, when he counted backwards from the last day of the cycle to the estimated day of ovulation, he was able to notice a pattern and realized that ovulation preceded menstruation by about 14 days. He published his results in a Japanese scientific journal in 1923.

At about this time in history scientists speculated (based on their observations of the ovum and sperm) that the life span of the ovum was about 24 hours and that sperm lived about 3-5 days. Knowing this information and the data from his observational research, Dr. Ogino developed a formula known as the Calendar Method for determining the fertile and infertile time of a woman's menstrual cycle.

Dr. Herman Knaus, who was the head of an obstetrics and gynecology clinic at the German University in Prague, used a different approach to estimate the time of ovulation during the menstrual cycle. He injected a pituitary extract into women subjects and then recorded the activity of their uterine muscles. He noticed that before ovulation the pituitary injection would cause uterine contractions but after ovulation it did not. By conducting this research on a day-to-day basis he was able to estimate the time of ovulation (based on the last day of uterine contractions) and (like Dr. Ogino) observed that ovulation preceded menstruation by about 14 days. Knaus's Law actually stated that menstruation would follow ovulation by 14 days. And like Dr. Ogino, he developed a calendar formula for determining the fertile and infertile time of the woman's menstrual cycle and published his findings in a German scientific journal in 1932.



## Figure 1:

This is a photo of Dr. Herman Knaus's lab where he conducted his experiments on pin pointing the day of ovulation. It shows a small balloon type instrument that he inserted into the woman subject's uterus and the tubing that was attached to a pressurized bell jar. In the back is a rotating drum and stylus that recorded uterine contractions. (This photo was taken from an out of print book by Knaus (1934. The picture is past the copyright time period.)

In 1932 a young physician from Chicago (Leo Latz) read a scientific paper by Knaus on his new method of family planning. Latz traveled to Europe to attend a conference on fertility and to study and confer with Dr. Knaus. At that time Dr. Leo Latz was a clinical professor of obstetrics and gynecology from the University of Loyola Chicago. When he came back from Europe, he wrote a small book titled *The Rhythm of Sterility and Fertility in Women* (Latz, 1932). Over 19 editions of the book were published and thousands were distributed throughout the United States. Some authors speculate that the term "rhythm" as applied to NFP came from the title of his book. Dr. Latz also conducted and published an effectiveness study on the use of calendar rhythm for avoiding pregnancy. He reported efficacy based on cases (or numbers of women users) and frequency of intercourse with the number of pregnancies achieved and found 15,924 cases of cohabitation in the sterile time with no pregnancies (Latz and Reiner, 1942).

In 1935, a Catholic parish priest in Germany by the name of Fr. Whilhelm Hillebrand was teaching his married parishioners the Knaus Calendar Method of NFP (Vollman, 1977). A number of the couples he taught became pregnant that did not intend to (i.e., supposedly they only had intercourse during what the Knaus formula indicated was the infertile time). This disturbed Fr. Hillebrand and he sought help from his two physician brothers. One of his brothers was familiar with the early temperature work by Dr. Theodore van de Velde and shared this information with him. Fr. Hillebrand devised a method in which the couple would use basal body temperature (BBT) readings along with the calendar formulas to determine the fertile and infertile time of the menstrual cycle. He is credited as being the first person to develop the use of BBT along with the calendar methods as a natural means of birth regulation. In 1959, Fr. Hillebrand was awarded an honorary doctorate for his work with body temperature as applied to family planning.

There were a number of physician/scientists who researched and developed BBT as a method of Natural Family Planning. Drs. Gerhard Döering from Germany, Rudolf Vollman from Switzerland and subsequently the United States and John Marshall from England are notable for their work on BBT. Vollman developed a charting system where he had women record not only temperature, but also abdominal (ovulation) pain, and changes in cervical mucus. He also studied the lengths and characteristics of the woman's menstrual cycle through the phases of life. Marshall (1968) is credited with conducting the first prospective field trial of the effectiveness of BBT in avoiding pregnancy.

Like Vollman, other physicians began (independently) to combine various biological indicators to aid women in the self-determination of the fertile and infertile times of their menstrual cycles (Vollman, 1977). Edward Keefe from the United States and Josef Röetzer from Austria are considered early developers of the multiple indexed methods or in the United States what are called the Sympto-Thermal (ST) methods (Keefe, 1986; Röetzer, 1977). Keefe asked his women patients to check for temperature, cervical mucus changes and the changes (internally) of the cervix. He is noteworthy for developing the Ovulindex Thermometer - that is specifically used for BBT - the thermometer is calibrated in tenths of a degree and thus more sensitive to detecting small changes in body temperature. Dr. Röetzer is known for developing the "3 higher than the preceding 6" rule of determining the temperature shift. The World Health Organization adapted this rule as the standard means of determining the BBT shift. Dr. Konald Prem was instrumental in helping John and Sheila Kippley in developing the STM system for the Couple to Couple League (Kippley, 1977).

Drs. John and Evelyn Billings (husband and wife) from Australia are considered the developers of the single index model of NFP called the Ovulation Method or sometimes the Billing's Ovulation Method<sup>™</sup> or OM for short (Billings, Westmore, 1980; 2003). In the 1950s, John Billings was asked by the Archbishop of Melbourne to help improve the Rhythm Method. He studied the Calendar Method and BBT but also read some early studies on cervical mucus. Dr. John Billings at first combined BBT with cervical mucus changes. When Evelyn Billings (his wife) became actively involved with the development of the Ovulation Method in the 1960s she realized that women were able to effectively track their fertile and infertile times of the cycle by the changes in cervical mucus alone. James Brown (an endocrinologist) and Dr. Burger helped to validate the method by conducting correlational studies with female reproductive hormones and the peak in cervical mucus. Eric Odeblad, a Swedish physician scientist, meanwhile was conducting research and classifying cervical mucus and helped to provide a scientific foundation for the ovulation method. In 1978, the World Health Organization conducted a 5-country study on the effectiveness of OM in avoiding pregnancy.

The Billings first introduced the Ovulation Method into the United States in 1972. Since then the method has been taught to many people of all educational, cultural, religious and economic backgrounds throughout the world. In the 1990s they introduced the method into mainland China and have been very successful in its use and spread in that country.

There have been a number of variants of the Ovulation Method. Most notable is the Creighton Model system developed by Dr. Thomas Hilgers (an Ob/Gyn), his wife Susan Hilgers and two professional nurses, Diane Daly and Ann Prebil. The system is a standardized form of the Ovulation Method that uses a standardized teaching, charting, follow-up, and pregnancy evaluation system. Dr. Hilgers is also known for his development of what is called NaProTechnology - a system of woman's health care that integrates the use of NFP into medical treatment protocols. Dr. Kathleen Dorrairaj developed what is called the Modified Mucus Method - a simplified form of OM for the indigent population in India.

Some NFP authors also classify the lactational ammenorrhea method (LAM) as a natural method of child spacing. In 1988 experts on breastfeeding and fertility met in Ballagio, Italy and developed a consensus report that if a woman is totally breast-feeding, has no menstrual bleeding, and is within the first 6 months of the birth of her child, then she has a less than 2% chance of pregnancy.

#### 21<sup>st</sup> Century NFP

In 1990, Carl Dejarrsi, one of the developers of the hormonal birth control pill in the United States, predicted in the future women would be able to monitor their own hormones in order to determine the fertile and infertile time of their menstrual cycles. He called this new method "Jet Age" Natural Family Planning. In the late 1990s, Unipath Ltd. (Bedford, England)

introduced two new electronic fertility monitors to help women determine their window of fertility (May 2001). The Persona was developed for women or couples wishing to avoid pregnancy and the Clearplan Easy Fertility Monitor now called the Clearblue Easy Fertility Monitor (CBFM) for couples choosing to achieve a pregnancy.

The Persona is not available in the United States and the CBFM is currently sold and marketed for women and couples who wish to achieve pregnancy and monitor their fertility. The information provided by the Clearblue monitor could be used inversely for avoiding pregnancy. Health professionals and researchers at Marquette University are now incorporating the use of the CBFM with other markers of fertility (i.e., cervical mucus and BBT) as an aid to learning and using NFP. The CBFM is also being used alone along with a simple calendar algorithm for women and couples who want a simple, fast, objective and accurate means to determine the fertile and infertile phases of the menstrual cycle.

#### The Future of NFP

Throughout the history of NFP there have been concurrent technological developments to aid women in self-monitoring their menstrual cycles. Some of these technological aids have been very simple and easy to use such as colored beads, fertility tables, and charting systems. With the advancement of micro-electronics this technology has been applied to basal body temperature and other body signs. Some monitoring devices have never caught on or have been shown to be invalid. The miniature microscope to view salivary ferning is one such device. The ability to simply monitor urinary fertility hormones through devices like the Clearblue Fertility Monitor (Swiss Precision Diagnostics or SPD), GmBH. Geneva, Switzerland) and the Ovarian Monitor is bringing NFP into the 21<sup>st</sup> Century. The Persona fertility monitor (also made by SPD) is the most frequently used method of NFP in Europe.

Where NFP will head into the 21st century nobody knows for sure; however, we do know that NFP teachers, physicians, nurses, and scientists are passionate about the application of NFP to woman's health and chastity education/promotion. These areas will no doubt develop and grow. Obviously technology will continue to impact NFP. The World Wide Web seems to have almost unlimited potential for NFP. Electronic learning both for NFP teachers and users is now a reality over the Internet. Whatever direction NFP takes in the future nobody knows for sure, however, there will always be a need for NFP.

#### Sources

Billings, E. and A. Westmore. 2003. The Billings Method. New York: Ballantine.

Dickinson, R. L. 1927. The "safe period" as a birth control measure. *American Journal of Obstetrics and Gynecology* 14: 718-730.

Hartman, C. G. 1936. Time of Ovulation in Women. Baltimore: The Williams & Wilkins Co.

Himes, N. E. 1963. Medical History of Contraception. New York: Schocken Books.

Keefe, E. 1986. Self-examination of the cervix as a guide in fertility control. *International Review of Natural Family Planning* 10: 322-338.

Kippley, J. 1977. **The couple to couple league, progress through teamwork**. *International Review of Natural Family Planning* 1: 90-92.

Knaus, H. 1934. *Periodic Fertility and Sterility in Woman: A Natural Method of Birth Control*. Vienna: Wilhelm Maudrich Publisher.

Lamm, N. 1977. **Periodic abstinence in the Jewish tradition**. *International Review of Natural Family Planning* 1: 127-135.

Latz, L. 1932. *The Rhythm of Sterility and Fertility in Women*. 2nd ed. Chicago: The Latz Foundation.

Latz, L. and E. Reiner. 1942. Further studies on the sterile and fertile periods in women. *American Journal of Obstetrics and Gynecology* 43: 74-79.

Noonan, J. 1986. Contraception. Massachusetts: Harvard University Press.

Ogino, K. 1934. Conception Period of Women. Harrisburg, PA: Medical Arts Publishing.

Robertson, W. H. 1990. *An Illustrated History of Contraception*. Park Ridge, New Jersey: The Parthenon Publishing Group.

Röetzer, J. 1977. Further evaluation of the sympto-thermal method. *International Review* of Natural Family Planning 1: 139-150.

Uricchio, W. A. and M. K. Williams. Eds. 1972. *Proceedings of A Research Conference on Natural Family Planning*. Washington, DC: The Human Life Foundation.

Vollman, R. 1977. **Brief History of Natural Family Planning**. In: *Natural Family Planning: Introduction to The Method*. Washington, DC: The Human Life Foundation, pp. 1-5.