

HUMAN FERTILITY—WHERE FAITH AND SCIENCE MEET

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SCIENCE POSTERS

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Multi-country data on Lactational Amenorrhea Method (LAM) knowledge and practice, counseling received during routine health contacts, and challenges to implementation

Justine A. Kavle, PhD, MPH, CPH, Rebecka Lundgren, MPH, and Victoria Jennings, PhD

Poor birth spacing contributes to a significant proportion of maternal, neonatal and child mortality and morbidity. Lactational Amenorrhea Method (LAM) supports optimal breastfeeding (BF) practices in the initial 6 months postpartum and contributes to healthy timing and spacing of pregnancies. Yet, providers are often poorly equipped to offer LAM. Evidence is needed on LAM messages during routine health contacts and the extent to which women are aware of and use LAM.

We examined scale-up of LAM in Mali, India and Rwanda in January-August 2009. We conducted household surveys, health facility assessments and health facility and community-based provider interviews to provide a baseline measure of LAM counseling, LAM knowledge/ attitudes/ practice, and infant feeding practices in project areas. Although most Malian and less than half of Indian women receive exclusive BF messages, few received information on LAM. Only 30% of Malian women and virtually no Indian women ever heard of LAM. Accordingly, very few women report use of LAM in Mali and India. Early introduction of foods, late initiation of BF and low exclusive BF rates present challenges for implementing LAM in India. In Mali, breastfeeding practices were more favorable.

Emphasis on LAM in the context of child survival and maternal health messages is needed during routine health contacts. These data point to the need to promote exclusive BF and to teach amenorrheic BF women to use Natural Family Planning upon approaching 6 months post partum to maximize resources for both maternal and child health.

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Meeting clients' needs for family planning without hormones: opportunities for introducing SDM/CycleBeads

Katherine S. Lavoie, MPH, Myriam Hernandez-Jennings, MA, Renee Marshall, MA, and Rebecka Lundgren, MPH

Despite their efficacy and safety, availability and use of fertility-awareness based family planning methods (FAM) are low in U.S. Title X clinics. The Standard Days Method® (SDM) is a simple yet effective FAM that can be taught in a short time. Introducing SDM into clinic programming represents a feasible way to mainstream FAM and expand client choice by providing an alternative to hormonal methods.

SDM is appropriate for women who get their periods every 26 to 32 days and is used with a color-coded visual tool called CycleBeads®. A study is being conducted to develop and test a process to introduce SDM in four clinics in California and Massachusetts. The process pioneers the World Health Organization's Strategic Approach for family planning method introduction in a U.S.-based project and calls for the integration strategy to be developed through a participatory process focusing on client needs and quality services.

This paper presents the results of the needs assessment phase that assesses the demand for SDM and identifies opportunities and obstacles for SDM introduction. Methods included community focus groups to assess potential demand for SDM; provider interviews to assess knowledge, attitudes and practices with regard to FAM and SDM; and a site assessment to identify operational and logistical considerations to adding SDM to services.

Results suggest that SDM appeals to potential clients who desire a non-hormonal family planning method, and providers are amenable to offering it. The results from the needs assessment will be used to tailor the integration strategy to each clinic's setting.

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First year experience with NFP instruction as a marriage requirement in the Diocese of Covington, KY

Michael D. Manhart, PhD

Beginning in January 2009, the Diocese of Covington required a complete course of NFP instruction as part of its Catholic marriage preparation program. In the first year of this requirement, Couple to Couple League teachers instructed 262 student couples in a total of 21 class series; a five fold increase compared to the previous 3 year average. Based on published diocesan records, this represents approximately 54% of the annual weddings in the diocese. A cohort (n=219) of this student population had demographic information available for review.

Not unexpected, the vast majority of student couples were engaged (n=209, 94%) with some married (n=13, 6%). When asked reasons for attending, only 25% indicated a reason other than “required for marriage.” Consistent with historical trends in the diocese, 65% of engaged couples are both Catholic. Of the engaged couples, 35% are cohabitating (based on identical address for man and woman), 54.2% are currently using hormonal birth control (HBC), 22.6% formerly used HBC (with most discontinuations within the last 12 months), and 23.6 % claimed to have never used a form of HBC. Those couples attending class solely due to the marriage requirement were significantly more likely to be current users of HBC than those attending for reasons other than required for marriage (55% vs. 38% respectively p=0.011).

In conclusion, couples being married in Covington do not appear to differ markedly from national averages for young adults when examining HBC use and cohabitation rates although those seeking NFP instruction for reasons beyond a marriage requirement are less likely to be current users of HBC.

Michael D. Manhart, PhD, Couple to Couple League

A profile of NFP students using a home study course

Michael D. Manhart PhD and Karen B. Manhart BS

All charts from students in Couple to Couple League's Home Study course seeking assistance from a single expert reviewer (Karen B. Manhart) were collected over a 12 month period (July 2008-June 2009). In total, 98 women (mean age= 27.8 yrs) submitted 251 charts over this period; 59 were engaged, 32 married, 5 were postpartum (all married).

Forty-eight women reported taking the course as a requirement for marriage. Engaged women taking the course as a requirement ($n=42$) began charting on average 3.2 months prior to their planned wedding date (range 0-9 months) whereas engaged women taking the course voluntarily ($n=17$) began just 1.4 months (range 0-8 mos.) prior to their wedding ($p<0.002$). On average, women submitted 2.7 charts during the training (range 1-8); there was no difference in the number of charts per woman between those taking voluntarily versus those required to take the course. Women who continued taking Hormonal Birth Control (HBC) during the course ($n=13$) submitted significantly fewer charts (mean=1.3, range 1-3, $p=0.001$). Loss to follow-up (defined as < 3 charts reviewed and no response at 4 & 6 months follow-up) was comparable in those taking the course as a requirement (20/48, 42%) and those voluntarily enrolling (11/45, 24%) ($p=0.08$).

Overall, 58% of the charts were classified as normal by the expert reviewer; those recently discontinuing HBC ($n=24$) had a similar incidence of normal charts. The remaining charts fell into one of several classes of abnormality with no one type dominating. A weak or irregular mucus pattern was infrequent overall but significantly more common in those recently stopping HBC compared to those with no recent history of HBC (11.5% vs. 1.8% respectively, $p=0.002$).

Michael D. Manhart PhD and Karen B. Manhart BS, Couple to Couple League

An algorithm for identifying and treating three groups of PCOS Patients

Mary W. Martin, MD, FACOG

Polycystic ovarian syndrome (PCOS) is the most common reproductive endocrinopathy of women. Medical literature cites insulin resistance as the etiology underlying the polycystic ovary, yet admits there are patients who do not respond to insulin-reducing or sensitizing therapies.

Recent research conducted by Vigil identifies three distinct groups of PCOS patients: the insulin-resistant, the non-insulin resistant, and an intermediate group.¹ Discriminating between these three groups is clinically challenging: standard lab testing does not identify the subtle differences in insulin sensitivity or hyperprolactinemia which underlie hyperandrogenism, the unifying feature and cause of PCOS.

The purpose of this study is to clinically evaluate an algorithm to identify and treat the 3 groups of PCO patients, utilizing the Billings Ovulation Method (BOM) chart, standard lab tests and transvaginal ultrasound. The study population is a private-practice obstetric/gynecologic/infertility patient group of 30. The desired clinical outcome is the correction of ovulation defects, as evidenced by Peak as defined by BOM, or a positive pregnancy test. Study drugs included Metformin, Decadron, or both.

Since May of 2009, more than twelve pregnancies have occurred in Decadron patients who had been previously treated unsuccessfully with Metformin. One pregnancy occurred on dual therapy group, nine patients developed ovulatory cycles, and nine patients are currently in the treatment algorithm. The algorithm represents a valid method of identifying and treating PCOS using a Natural Family Planning method.

1. Vigil P., Contreras P., Alvarado J.L., Godoy A., Salgado A.M., Cortés M.E. "Evidence of subpopulations with different levels of insulin resistance in women with polycystic ovary syndrome." *Human Reproduction*. 2007 Nov;22(11):2974-80.

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Characteristics of the menstrual cycle after discontinuation of oral contraceptives

Claudia L. Nassaralla, PhD, MD; Joseph B. Stanford, MD, MSPH; K. Diane Daly, RN, CFCE; Mary Schneider, MSN, RN; Karen C. Schliep, MSPH; and Richard J. Fehring, PhD, RN

Menstrual cycle function may continue to be altered after discontinuation of oral contraceptives (OC). Few studies have been published on the effects of recent OC use on menstrual cycle parameters.

The purpose of this retrospective matched cohort is to assess biomarkers of the menstrual cycle after discontinuation of OC. The population studied included 140 women from three clinical sites in the United States: Atlanta, Georgia; Milwaukee, Wisconsin and St Louis, Missouri.

Among a sample of women who daily recorded observations of menstrual cycle biomarkers, 70 women who had recently discontinued OC were randomly matched by age and parity with 70 women who had not used OC for at least one year. Outcomes investigated included overall cycle length, length of the luteal phase, estimated day of ovulation, duration of menstrual flow, menstrual flow score (menstrual intensity) and mucus score (mucus quality). Differences between recent OC users and controls were assessed using random effects modeling.

The results demonstrate that recent OC users had significantly lower scores for mucus quality and intensity of menstrual flow for up to 6 cycles. Additionally, OC users had longer cycle lengths for up to 6 cycles (difference=3.50 days, $p<0.05$), a later estimated day of ovulation for up to 6 cycles (3.78 days, $p<0.05$) and decreased duration of menstrual flow for up to 2 cycles (difference= -0.48 days, $p<0.05$).

The authors conclude that menstrual cycle biomarkers are altered for at least 6 cycles after discontinuation of OC, this may help explain the temporary decrease in fecundity associated with recent OC use.

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(presenter: Joseph Stanford, MD, MSPH)*

Natural Family Planning Archive: A valuable new resource for researchers

Christopher H. Owen, PhD

This poster describes the foundation of a promising new NFP archive which provides an important new source of information for researchers. The archive encompasses the collections of seven major American NFP scientists and organizational leaders, including the papers of Lawrence J. Kane (Human Life Foundation), Kay Ek (BOMA), Mary Shivanandan (John Paul II Institute), Konald A. Prem (University of Minnesota), Robert Kambic (USAID and WHO), Claude Lanctot (International Federation for Family Life Promotion and SERENA), Hanna Klaus (TeenSTAR), Thomasina Bjorkman (George Mason University). These seven men and women, recognized widely for their contributions to the development of NFP, have brought together their personal libraries, correspondence and research notes to build the Natural Family Planning Archive of the Canizaro Library at Ave Maria University (Florida). The archives contains key publications in NFP history including basic works by Latz, Hartman, Rötzer, and also includes complete series of important relevant journals such as *Child and Family* and the *International Review of Natural Family Planning*.

The purpose of the project is to make interested researchers aware of this resource and how they can use it. To do so, the poster will demonstrate how Lawrence J. Kane put the collection together, detail what resources it includes, show where it is located and how it may be accessed. After delving into the origins and contents of the archive, the poster will explain how the collection will help researchers both to understand the growth of NFP science and to place NFP into its proper social and historical context.

Christopher H. Owen, PhD, Northeastern State University

Identifying the peak day of fertility: peri-conceptual exposure assessment

Christina Porucznik, PhD, MSPH, Karen Schliep, MSPH, and Joseph Stanford, MD, MSPH

Early intrauterine exposures may have both short- and long-term consequences on human growth and development. Monitoring should begin near the time of conception. Prospectively determining ovulation dates would allow for targeted exposure assessment during the relevant developmental windows.

The purpose of this study is to demonstrate the acceptability, accuracy and actual use of cervical secretion observation or cervical secretion observation combined with basal body temperature readings for identifying the estimated day of ovulation.

The population examined included women (n=100) between the ages of 18 and 44 who are not currently pregnant nor using hormonal contraception are being recruited using referrals from other reproductive studies, flyers, word-of-mouth and social media.

Women who consent to participate: 1) completed baseline exposure questionnaire securely online; 2) read a 3-page educational brochure; and 3) were asked to record their fertility signs and complete a 1-page exposure questionnaire for up to 6 months or pregnancy. The women were informed that they could choose to monitor cervical mucus alone or cervical mucus combined with basal body temperature.

The results demonstrate that of the 37 currently enrolled women, 97% correctly estimated day of ovulation at least once. On average, it took women 1.23 cycles (range 1-2) to correctly estimating day of ovulation. Women preferred to measure cervical secretions alone (65.4%), compared to monitoring cervical secretions along with basal body temperature.

The authors conclude that the preliminary results indicate that most women who receive little compensation can properly identify their estimated day of ovulation but require phone and/or email follow-up.

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Trends in family planning and NFP use among U.S. Hispanic women: 1995-2002

Dana Rodriguez, MSN, PNP

Hispanics are the largest and the fastest growing minority population in the United States. Many Hispanics follow the Catholic faith, which only allows the use of Natural Family Planning (NFP) for avoiding pregnancy. Past studies have shown that religiosity affects sexual behaviors among the U.S. Hispanic population.

The purpose of this study was to describe the trends in family planning among U.S. Hispanic women between the age of 15-44, with particular interest in type and importance of religion and the use of NFP.

The method of the study was to review the data sets of the 2,702 Hispanic (Latina) women in the 1995 and the 1,589 Latinas in the 2002 National Survey of Family Growth. The current religious status and importance of religion were used to describe NFP use.

Results included: In 1995 only 0.1% of Hispanics were using NFP. That figure increased to 0.3% in 2002, as compared to 0.2% in all US women at both time periods. However, in both time periods, female sterilization (19-21%) followed by the pill (13.0-13.6%) were the top two family planning methods utilized. In 2002, 3.5% of Catholic Latinas ever used NFP and 3.3% who viewed religion as important but only 0.3% of Catholic Latinas and 0.5% who viewed religion as very important were currently using NFP.

It was concluded that although there is a slight increase in use of NFP among Latinas, faith and the importance of religion has little influence in family planning choice.

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The TwoDay Method: a quick start approach

Irit Sinai, PhD

The TwoDay Method is a fertility awareness method of family planning based on the identification of the presence or absence of cervical secretions (of any type). An efficacy study demonstrated that the method is efficacious. Participants in the study were counseled in method use during the first week of their menstrual cycle, before the onset of secretions. However requiring women to wait until the onset of secretions before they can begin using a method presents an obstacle to access.

An Operations Research study was conducted in Peru to assess if women who are counseled in TwoDay Method use later in the cycle, can use it as successfully. Some 161 women were admitted to the study, and were followed for up to seven months of method use. Only a third were in their first week of the cycle at the time of method counseling. Participants were counseled in TwoDay method use regardless of their cycle-day, and started using the method immediately.

Results demonstrate that the time in the cycle in which users are counseled in method use does not influence correct use of the method. In addition, simulated client visits show that day of the cycle client is on does not affect the quality of counseling. We conclude that the TwoDay Method is an effective and acceptable fertility awareness-based method of family planning that can be taught to users at any time in their menstrual cycle.

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Estimating the probability of a live birth with natural procreative technology

Joseph B. Stanford, MD, MSPH, Karen C. Schliep, MSPH, Tracey A. Parnell, MD, and Philip C. Boyle, MB

Infertility is a common problem, affecting approximately one in every 7 couples in their reproductive lifetime. Treatments for infertility include assisted reproductive technology, which carries potential risks for both the woman and her baby. Natural procreative technology (NPT) is an alternative approach that is less invasive and has fewer adverse perinatal outcomes.

The authors sought to devise a prediction model using logistic regression to calculate the chance of a live birth within 2 years for couples treated for infertility with NPT.

Included in the analyses were 1,072 Irish couples who had been trying for at least a year to conceive before initiating NPT treatment between 1998 and 2002.

The main outcome was live birth predictors included women's characteristics, reproductive history, and physiological parameters identified by NPT evaluation. Model selection was done manually based on iterative results and physiologic considerations. From the final model, a prediction equation was generated for the probability of a live birth.

The results include: woman's age, length of time trying to conceive, prior pregnancies and live births, prior ART attempts, the presence of an abnormality of semen analysis, decreased production of cervical mucus, suboptimal levels of estrogen and progesterone and laparoscopic intervention were significant independent predictors of the probability of live birth.

The authors conclude that the prediction model is consistent with prognostic factors identified for other infertility treatments and also includes factors uniquely identified by the NPT evaluation. It requires validation studies and may prove useful for clinical counseling.

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The fertile and infertile phases of the menstrual cycle are signaled by cervical-vaginal fluid die swell functions

Jian Wang, PhD, Stephen J. Usala, MD, PhD, Faye O'Brien-Usala, DC, William C. Biggs, MD, FACE, Mark W. Vaughn, PhD, and Gregory B. McKenna, PhD

Natural Family Planning is a method of fertility awareness based in part on detection of the fertile and infertile phases of the menstrual cycle through self-observation of cervical-vaginal secretions.

Cervical-vaginal fluid (CVF) contains cervical mucus, a hydrogel that undergoes cyclic changes in viscoelasticity. We constructed a die swell device to study the viscoelastic properties and establish material functions of CVF samples that women obtain by self-aspiration. Two women for a total of 8 cycles provided day-specific CVF, urine and blood samples. Day-specific CVF samples were indexed to the day of ovulation (day 0) defined as the day of the luteinizing hormone peak. These samples were analyzed by extrusion through the die swell device and measurement of the subsequent flowgrams. Die swell ratio (B) was measured as the ratio, (maximum diameter of fluid swell after extrusion)/(inner die diameter), and die swell position (DisMax) was measured as the start position of maximum swell from the die orifice. These 2 rheological material functions, B and DisMax, were found to reliably correlate with the fertile and infertile phases of the cycle. This novel die swell device and methodology enables detection of viscoelasticity and therefore the presence of cervical mucus in CVF. Furthermore, it provides rheological measurements of cervical-vaginal secretions that correlate with the fertile and infertile phases of the menstrual cycle. The die swell device and methodology may serve as an aid for Natural Family Planning. Algorithms based on B and DisMax measurements to monitor real-time fertility will be discussed.

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Calendar rules for the Marquette Model II

Paul J. Yong, MD, PhD and Richard J. Fehring, PhD, RN

The Marquette Model II combines the Clearblue monitor with calendar rules for NFP; however, these rules require validation.

At the Marquette Institute for Natural Family Planning, the study designed seeks to develop evidence-based calendar rules. The population examined is a retrospective sample of women using Clearblue for 3 consecutive cycles prior to the current cycle (130 women). The method employed is statistical analysis of cycle data.

Results include the following:

Rule 1: For the first 3 cycles, if the fertile window (FW) is defined as starting on *Day 5*, then 0.8% of women (1/130) had a FW that began prior to this cut-off.

Rule 2: For the current cycle, if the start of FW is defined as the earliest day of ovulation from the previous 3 cycles *minus 9 days* (with a minimum of *Day 5*), then 0.8% of women (1/130) had a FW that began prior to this cut-off.

Rule 3: For the current cycle, if the end of the FW is defined as the latest day of ovulation from the previous 3 cycles *plus 4 days*, then 0.8% of women (1/130) had a FW ending after this cut-off.

The preliminary conclusions of the findings demonstrate that conservative calendar rules are:

Rule 1: For the first 3 cycles, fertility begins on *Day 5*;

Rule 2: For subsequent cycles, fertility begins on the earliest day of ovulation from the previous 3 cycles *minus 9 days* (minimum *Day 5*);

Rule 3: If the monitor misses the LH surge, then the estimated day of ovulation is the latest day of ovulation from the previous 3 cycles *plus 4 days*.

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