

Natural Family Planning

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*A New Chapter:*

With this issue we begin a new chapter in the life of *Current Medical Research*. Doctors Lorna Cvetkovich, M.D., FACOG and Richard Fehring, DNSc, R.N. have consented to replace Hanna Klaus, M.D., Director of the NFP Center of Washington, DC, as editors of *Current Medical Research*. As many of you know, Dr. Klaus' work in training teachers in the Teen STAR curriculum has increased over the years. Dr. Klaus decided to limit some of her extracurricular activities after her co-worker Sr. Ursula Fagan became ill and had to leave the NFP Center of Washington, DC.

As we look forward to working with doctors Cvetkovich and Fehring we are also grateful to Dr. Klaus for her enormous contribution over the years in keeping the NFP diocesan community up to date on the trends of medical research.

*About the Editors:*

**Lorna Cvetkovich, M.D., FACOG**, practices medicine in Wichita, KS. Dr. Cvetkovich began her career in medicine at the University of Kansas where she specialized in Obstetrics and Gynecology. After completing her internship at St. Luke's Hospital in Kansas City, MO, she accepted a Fellowship in Reproductive Medicine and NFP at the Pope Paul VI Institute for the Study of Human Reproduction in Omaha, NE. In addition to the numerous professional associations which she belongs to, Dr. Cvetkovich is also a member of the Catholic Medical Association and is listed in the *NFP-Only Physicians Directory*.

**Richard J. Fehring, DNSc, RN** is an Associate Professor of Nursing and the Director of the Marquette University Natural Family Planning Institute. He received his bachelors in biology and nursing from Marquette University and his masters and doctorate in nursing science from The Catholic University of American, Washington, DC. He completed the Pope Paul VI Institute's NFP practitioner and educator program and is certified as a NFP practitioner and educator through the American Academy of Natural Family Planning (AANFP). In 1991 he received the American Academy's Outstanding NFP Practitioner Award. Dr. Fehring is also a current member of the National Advisory Board to the National Conference of Catholic Bishops

for Natural Family Planning and a member of the Billings Ovulation Method Association (BOMA) - USA.

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## **Natural Family Planning**

### **No Increased Risk of Adverse Pregnancy Outcomes Was Observed among Women Who Experienced an Unplanned Pregnancy While Using Natural Family Planning**

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.(1) They hypothesized this based on the notion (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. Their definition of a planned pregnancy was “that the women stated that her intention had been to become pregnant and the chart showed that intercourse had taken place during her fertile period” and their definition of unplanned pregnancy was “that the woman said that she and her partner had not wanted a pregnancy and were using natural family planning for contraception”. Based on these definitions 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, DC) from January 1987 to September, 1990. Multiple methods of NFP were used including, Ovulation, 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.

One reason that the researchers did not find a differences in pregnancy outcomes between the two groups might be that they did not have a large enough sample to detect differences. Past studies that have found differences in pregnancy outcomes have had samples in the thousands. This is because most pregnancies do not have adverse outcomes and in order to accumulate an adequate number you need large samples. For example, in the current study there were only 10

low birth weight live births in the unplanned group and 14 in the planned group and 25 preterm births in the unplanned group and 19 in the planned group. If the samples were bigger would these trends become significant? I (Fehring) would have been more comfortable with the results if a power analysis would have been conducted (based on previous studies) to determine adequate sample size. Although the researchers of this article might have committed what researchers call a Type II Error (i.e., failing to reject the Null Hypothesis that there is no difference in the pregnancy outcomes when there is an actual difference) I tend to agree with the results and conclusions of the authors. I suspect that women and couples who use NFP are conscious of their health and healthy behaviors and use NFP for that reason.

A concern I have with the study are the researchers assumptions and definitions of planned (intended) and unplanned (unintended) pregnancies. Although they state that pregnancy intention was unambiguous and confirmed by a number of sources, eg., the women herself, the NFP teacher, and independent chart reviews, I am not that convinced. As stated in their report, independent reviewers analyzed the charts for patterns of intercourse that was consistent with the client's and instructor's statements about pregnancy intention. For a planned pregnancy intercourse patterns are clear, i.e., they occur during the woman's fertile period. But what about an unplanned pregnancy? What pattern of intercourse do you look for? I would say it is a clear unintended pregnancy if there is a pattern of intercourse outside of the defined times of fertility and the couple got pregnant, but what if there is a pattern of intercourse during the fertile time? What if there were acts of intercourse during the Peak day of cervical mucus or during the temperature rise? Is that an unplanned or unintended pregnancy? If so, then the NFP teacher did a poor job in instructing on what happens when you have intercourse on fertile days and/or the couples behaviors are not consistent with their intentions. Maybe, rather than "unintended" or "unplanned," the pregnancies were a result of being non-compliant or that the couples were lacking self-control. Another interesting aside about the researcher's definition of planned and unplanned pregnancy is why with a planned pregnancy it only involves the woman's decision and with an unplanned pregnancy it involves the woman and her partner? Why is it only the woman's choice in one and the couple's in the other? This does not seem consistent.

The biggest concern that I have about this study is that it operates under an overt contraceptive framework. The reason that the researchers have to hold to their definition of unplanned pregnancy is that they dissociate the possibility of pregnancy from the act of intercourse. To make my point clear I offer this analogy: if the researchers of this article did not want to or intend to travel to Washington, DC but boarded an Amtrak train that travels from Baltimore to Washington, DC and did so only with the intention to have a drink and conversation on the dining car, when they arrived at Union Station in Washington, DC would they be surprised and say that they did not plan on going there? I think not. I think that they know that riding in a dining car in a train traveling to Washington, DC includes more than just having a drink and a pleasurable ride, i.e., they would not dissociate the trip with the pleasure of having a drink on the trip. Or a more reproductive analogy, if a farmer did not want his field planted with

corn would he or she plow the fields and plant corn seed in the Spring? If the farmer did not want corn he or she would act accordingly to his or her intention and not plant the corn.

NFP is not contraception, and as such it entails knowledge of fertile and infertile times of a women cycle and along with this knowledge an assumed responsibility to act according to one's intentions. If a couple is truly using NFP to avoid pregnancy and know when they are fertile or not, then if they do not want to get pregnant they must also act accordingly and not use fertile times to have intercourse. Catholic based NFP research (and that is Catholic with a large and small c) must be honest with the conjugal act, not dissociate its unitive and procreative intent and include the total meaning of the act in any definition.(RJF)

1. 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.

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## **Breastfeeding**

### **Researchers Recommend Avoiding Use of Pacifiers**

Did you know that maternity leave in Sweden is for more than a year? Because of this extended time of government supported leave, mothers in Sweden are more likely to breastfeed their infants than mothers in the United States and are a good population for breastfeeding studies. A physician-nurse research team from Sweden studied a group of 82 healthy breast-feeding mother infant pairs over a 4 month period. They hypothesized that incorrect sucking technique and pacifier use were factors contributing to breastfeeding failure.

What they found was that 96% (22/23) of infants discharged from the hospital with a correct sucking technique and with no pacifier use were still breastfeeding at 4 months, whereas, if pacifiers were used, the rate of breastfeeding was only 59% (20/34). One of the mothers in the non-pacifier correct sucking technique group had a breast operation and could not breastfeed for two weeks. In the non-pacifier group of infants who were discharged with an incorrect sucking technique, 82% (9/11) were still breastfeeding at 4 months, whereas, only one mother in the pacifier incorrect sucking technique group (7%, 1/14) was breastfeeding at 4 months. The combination of pacifier use and incorrect sucking technique led to early weaning. The authors recommend that the use of pacifiers should be avoided or restricted to promote successful breastfeeding.

(Since breastfeeding is healthy for both the infant and the mother and since breastfeeding extends the period of infertility after birth of a child, I would recommend that NFP teachers

discourage the use of pacifiers and artificial nipples among their couples and encourage the use of breastfeeding. This is also a recommendation of WHO/UNICEF Baby Friendly Hospital Initiative and a standard of international practice - Ed/RJF).(2)

1. Lennart, R. and Alade, M. O. **Breast-feeding and the Use of Pacifiers.** *Birth* (June, 1997):116- 120.
2. *Protecting, Promoting and Supporting Breast-feeding: The Special Role of Maternity Services.* A joint WHO/UNICEF statement. Geneva: World Health Organization, 1989.

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### **Maintaining Breast-feeding Frequency Important for Duration of Lactational Amenorrhea**

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 (LA) 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. 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. This group had to have continued encouragement from the researchers to continue to breast feed at the level they did at 16 weeks. This was reflected in the results that showed time spent breast-feeding negatively associated with the infant's energy intake from solid foods. The researchers concluded that there is a significant effect of introducing solid foods at 16 weeks on LA at 6 months but that this is moderated in mothers that maintain breast feeding frequency.(RJF)

1. 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.
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## **Adolescent Sexuality**

### **Prevalence of Herpes Up 30% While Sex Education Programs Continue to Fail**

The lead article of the October 16, 1997 issue of the *New England Journal of Medicine* reported that the prevalence of HSV-2 (Herpes) infection has increased by 30% since the late 1970s.(1) The biggest increase in HSV-2 seroprevalence was in white teenagers. Herpes can now be detected in one out of every five persons in the United States over the age of 12, which corresponds to approximately 45 million people being infected with HSV-2. The scary part of this news is that Herpes is often transmitted silently (i.e., the person infected or the person transmitting herpes may not recognize any symptoms), HSV-2 can and often produces genital ulcers that facilitate the transmission of HIV, condoms have limited effectiveness in protecting against the transmission of HSV-2 even when used properly (HSV-2 lesions occur on areas of the body not covered by condoms), at this time there is no cure for herpes, and herpes can be transmitted during vaginal delivery to the baby and cause a severe systematic disease.

In order to decrease the rates of sexually transmitted diseases (STDs) and pregnancy among the adolescent population in this country (and Canada) numerous sex education programs have been developed and tested. Most of the programs are contraceptive based (i.e., encourage the use of contraceptives) and most fail. In the past 6 months four articles were published that described sex education and/or cognitive/behavioral programs that were designed to either decrease the incidence of pregnancy, decrease rates of sexual intercourse, prevent repeat pregnancy and/or increase contraceptive use.(2,3,4,5)

The McMaster Teen Program (MTP) was tested on 7th and 8th graders in the Hamilton, Ontario school system in a prospective randomized control trial study.(2) The MTP is a cognitive-behavioral program that includes information on male and female reproduction, teaching strategies to develop responsible relationships, communication skills, and decision-making skills related to sexual activity. The program is taught in small (6-8 persons) coeducational groups through 10 one hour sessions with trained tutors. The control group was made up of students who received the traditional board of education sexual education program. There were 2,309 students who enrolled in the experimental MTP program and 1,666 students in the control program. The results showed that there were no difference between the groups in male and female time to first sexual activity and time to first pregnancy but there was a significant increase of males using birth control in the MTP group as compared to the controls.

A similar study was conducted with 10,600 7th and 8th graders in the California school system.(3) The Postponing Sexual Involvement (PSI) is a non-contraceptive based program designed to delay the onset of sexual intercourse. The PSI consists of 5 sessions that are delivered in classroom or small groups settings and includes information on the risks of sexual involvement and strategies to resist social and peer pressures to be sexually active. Although the

PSI is not contraceptive based, the PSI was implemented in addition to the traditional sex and contraceptive based program that was already in the school system. Furthermore, some of the leaders who implemented the PSI program did not agree with the non-contraceptive approach of the PSI. Like the Canadian study, the PSI was tested with a prospective randomized control group trial. Randomization was implemented either at the classroom, school or community based agency level. There were 4,289 youths in the control group that received traditional sex education programs and 3,538 youth that also received the PSI program. Data was collected before the PSI program began, and at 3 and 17 months after implementation. At 17 months there were no differences in sexual behavior between the two groups, i.e., students in both groups were equally likely to have become sexually active.

In Denver Colorado, an incentive based program to prevent repeat pregnancy among 286 primiparous girls younger than 18 years was tested through a randomized control trial design.(4) The program was called the Dollar-a-Day program because it entailed providing a dollar a day to the participants for a two year period as an incentive to not get pregnant. The program also included career planning and promoting the consistent use of contraceptives. The 286 participants were recruited from the University Hospital and The Children's Hospital in Denver and randomly placed into either a control group with no intervention, a monetary incentive only group, a peer support only group and a peer-support and monetary incentive combined group. At 6 months, 12 months, 18 months, and 24 months the incident of second pregnancy did not differ among the four groups, i.e., the intervention did not prevent repeat pregnancies even with the availability of and promotion of long acting contraceptive agents.

A final study reported the effectiveness of a pregnancy prevention program that was implemented through school-based clinics in four New York city junior high schools.(5) The program was essentially a case management program that included group and individual education and counseling, referrals for contraception, and risk-identification for sexual activity and other healthy behaviors (like alcohol use). The educational component included knowledge, behavior and decision-making about sexual activity, abstinence and contraception as an option. The design to test the program was a within group pre-test post-test. There were no control group comparisons or randomization. Because of lack of a control group and randomization there is very little confidence that you can place in the results, i.e., there could be many explanations for the findings other than the effects of the program. Given that, the researchers claimed a 34% decrease in pregnancy rates among teenagers younger than 15 years over a four year period of the program. However, I would not place much weight in those results.

The actual published report of this study is poorly presented from a research perspective. Documentation to establish reliability and validity of pregnancy incidence was weak. The pregnancy rates were determined by reviewing clinical records, referrals, and picking up symptoms of pregnancy in the clinics. The researchers felt that they tracked most of the pregnancies because "conversations with students and staff indicated that students were likely to



come to the clinic if they were pregnant.” From a research standpoint this is not very rigorous or valid method to document incidence of pregnancy. Another poor aspect in the reporting of the study is that you cannot tell how many students actually participated in the study. They did not provide raw numbers - only percentages. However, reviewing the data table was enlightening in that in 1992-93 (33%) of the participants in the program claimed they had sex (as compared to 7% that did not), in 1993-94 (42%) of the participants had sex (as compared to 8% who did not use the program) and in 1994-95 (48%) claimed they were sexually active (as compared to 8% who did not use the program). In other words, sexual activity among the participants increased from 33% to 48% in the first three years of the program. I don't think that this concerned the researchers of this study as long as the students were using contraception. The study was poorly designed, poorly presented and the results showed that sexually activity increased. How this study got published in a peer review journal is beyond me, other than that this journal has a definite contraceptive bent.(RJF)

1. Fleming, D. T, McQuillan, G. M., and Johnson, R. E., et al., **Herpes Simplex Virus Type 2 In the United States, 1976 to 1994.** *The New England Journal of Medicine* 337 (October 16, 1997):1105-1111.
2. Mitchell-DiCenso, A., Thomas, B. H., and Devlin, M. C. et al., **Evaluation of an Educational Program to Prevent Adolescent Pregnancy.** *Health Education and Behavior* 24 (June, 1997): 300-312.
3. Kirby, D. K., Korpl, M., and Barth, R., et al., **The Impact of the Postponing Sexual Involvement Curriculum Among Youths in California.** *Family Planning Perspective* 29 (May/June, 1997):100-108.
4. Stevens-Simon, C., Dolgan, J. I., and Kelly, L., et al., **The Effect of Monetary Incentives and Peer Support Groups on Repeat Adolescent Pregnancies.** *Journal of the American Medical Association.* 277 (March 26, 1997):977-982.
5. Tiezzi, L., Lipshutz, J., and Wroblewski, N., et al., **Pregnancy Prevention Among Urban Adolescents Younger than 15: Results of the 'In Your Face' Program.** *Family Planning Perspectives* 29 (July/August, 1997):173-176.

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### **Large National Study Confirms that Prayer, Religion and Parental Disapproval of Contraception Delays Sexual Activity among Adolescents**

The September 10, 1997 issue of the *Journal of the American Medical Association* reported the results of a large National study on adolescent health.(1) The objective of the study was to identify risk and protective factors as they relate to adolescent health and morbidity in the domains of emotional health, violence, substance use, and sexuality. The participants in the study were 12,118 adolescents in grades 7 - 12 that were recruited from 80 high schools randomly selected from the 26,666 high schools in the United States. Of particular interest are the findings

as they relate to sexual behaviors and pregnancy. Results were reported according to family context, school context, and individual characteristics.

The significant family factors that were associated with delaying sexual activity were parental-family connectedness, parental disapproval of their children being sexually active and disapproval of them using contraceptives. School factors associated with delaying sexual activity were connectedness to school, attending parochial school and attending a school with high attendance levels. Taking a pledge to remain a virgin was a very significant individual factor that was related to delaying sexual activity along with ascribing importance to religion and prayer. A sobering statistic was that 17% of 7th and 8th graders and almost half (49.3%) of 9th through 12th graders reported having experienced sexual intercourse.

Parental disapproval of adolescent children using contraception and sharing activities with parents were family factors protective against pregnancy. There were no protective school factors that delayed pregnancy but delaying sexual activity and viewing pregnancy as a negative consequence and using contraception at first and/or most recent act of intercourse were protective individual factors. Of the female participants who indicated that they were sexually active 19.8% (369/1860) reported having ever been pregnant.(RJF)

1. Resnick, M. D., Bearman, P. S., and Blum R. W., et al., **Protecting Adolescents From Harm - Findings From the National Longitudinal Study on Adolescent Health.** *Journal of the American Medical Association* 278 (September 10, 1997): 823-832.

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## **Abstracts**

*By Lorna Cvetkovich, M.D., FACOG*

Rapkin, Andrea J. et.al., **Progesterone Metabolite Allopregnanolone in Women with PMS.** *Fertility and Sterility* 90 (Nov. 97): 709-714.

Since the etiology of PMS remains a mystery despite much research, a metabolite of Progesterone (P4), allopregnanolone was evaluated for its possible role in this widespread and often difficult to treat syndrome. 35 women with prospectively documented PMS were compared with 36 controls. Serum P4 and allopregnanolone levels were measured on day 5 and 12 after ovulation as determined by LH detection kits. They indeed found that allopregnanolone levels were significantly lower on day 26 in the PMS group than in controls. Allopregnanolone is known to be anxiolytic and thus its lack could lead to irritability, depression, and anxiety - some of the common symptoms of PMS. If this finding is born out by further study, it could explain why Xanax (a tranquilizer) and Prozac (a serotonin reuptake inhibitor) are effective in PMS as well as why total P4 levels have not been found to be different in women with and without PMS.

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Rosenberg, L., et.al., **Modern Oral Contraceptives and Cardiovascular Disease.** *American Journal Obstetrics and Gynecology* 177 (Sept. 1997): 707-714.

Epidemiological studies established that 1st generation OCs (>50 mcg or more of Estrogen) increased the risk of thromboembolism, stroke, and heart attacks in young women. Subsequent formulations with < 50 mcg E2 and new progestins (levonorgestrel - second generation, and gestodene and norgestimate - third generation) have been developed to reduce those risks. Evidence on the cardiovascular safety of second and third generation OCs has emerged only recently. A “pill scare” was noted after a recommendation by the British Committee on Safety of Medicines that OCs containing desogesterel or gestodene be used by women who could not tolerate other formulations. The studies indicating a double rate of thromboembolism with those compounds have just now been published. Since third generation OCs have captured 15% of the market, and the remaining 85% are second generation, the data are important. The article reviewed evidence on the safety of low estrogen second and third generation OCs. The studies reviewed included the WHO Collaborative Study, the Transnational Study, the General Practice Research Database, and the Meditel Studies. Overall the combined data suggested that use of second and third generation OCs is associated with a smaller increase in the incidence of thromboembolism than earlier formulations. With regard to myocardial infarction, there was a smaller increase in risk with second and third generation OCs as well. And finally, the recent studies of stroke indicate little or no increase in risk with newer formulations among women with no risk factors. They concluded that modern combined OCs are safer than earlier formulations with respect to cardiovascular disease. Probably the results can be interpreted also to indicate what has always been thought...that the major side effects and complications due to OCs are Estrogen related and the progestational agents are not implicated in the cardiovascular (particularly thromboembolic) risk. One still wonders given the effectiveness (and lack of risk) of NFP methods why doctors would prescribe OCs with such risks at all.

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Fauchin, Renato, et.al., **Transvaginal Administration of Progesterone.** *Obstetrics and Gynecology* 90 (September. 1997) 396-401.

Achieving an adequate progestational effect is important in several areas of Ob/Gyn...support of an early pregnancy in women with luteal phase defect and secretory transformation of the endometrium in women who are on estrogen replacement to name a few. The current study was done to analyze the endometrial effect of varying Progesterone (P4) levels using a new form of P4 (Crinone; P4 in a sustained release, vaginal gel) while keeping estrogen levels within the menstrual cycle range. All subjects had premature ovarian failure or ovarian dysgenesis and thus no active ovarian tissue. All received transdermal estrogen in a scheduled dosage. In addition they received either 45 (N=14), 90 (N=13), or 180 mg (N=13) of

progesterone gel (Crinone) on days 15 to 27 of their cycles. Weekly FSH, LH, Estrone, Estradiol, and Progesterone levels were obtained. An endometrial biopsy was performed on either day 20 or 24. Endometrial dating was done according to Noyes et.al. In all groups, secretory transformation of the endometrium in the glands (by day 20) and stroma (day 24) was seen as well as a normal distribution of estrogen and progesterone receptors. This effect was noted despite low plasma levels of progesterone and varying but normal menstrual levels of E2. These results suggest that during the luteal phase, progesterone alone controls secretory transformation as long as adequate estrogen priming has been achieved in the follicular phase. It also suggests a direct transit into the uterus or “first uterine pass” effect. This form of natural Progesterone may eventually have wide usage giving its superior effect on the endometrium and reduced systemic levels. (LC)

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Porcu, et.al., **Birth of a healthy female after intracytoplasmic sperm injection of cryopreserved human oocytes.** *Fertility and Sterility* 68 (October, 1997): 724-726.

This is the report that made headlines for the use of not one but two “assisted reproductive technologies” in the “production” of a live birth. In the past embryos were frozen for use in subsequent cycles because they survived the freeze/thaw process better than oocytes, but of course this brought along with it many attendant ethical dilemmas which the investigators in this report thought would not be present if only the oocytes were frozen. In this case, a woman scheduled for IVF underwent ovarian hyperstimulation but when the time came for the husband to produce a semen sample, he was unable. Because 12 oocytes had been harvested, and now could not be utilized, they were frozen using a slow step wise process that would allow them to remain viable after rapid thawing. Several months later, the oocytes were thawed, and inseminated using intracytoplasmic sperm injection (ICSI), which had been shown to produce a higher rate of fertilization in such cycles. After thawing, 4 of the 12 oocytes survived. After ICSI, two fertilized, but only one cleaved, resulting in one normal 4-celled embryo which was transferred on the second day. A BHCG was positive on day 15, and a normal female infant was born at 38 weeks gestation by cesarean section. {Whether it is frozen oocytes or embryos being used, the fact remains that the *child* was conceived outside the loving act of the parents which is an injustice to the child. Too, the technology opens the door to permutations such that the child might have no relationship to the parents..coming out of neither the emotional and spiritual (unitive), nor the biological/genetic connection (procreative) between the parents. Ed.}

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Oyesanya, O.A., et.al., **Concordance of Predicted Time of Ovulation in Natural cycles with Endometrial Development Comparison Between Serial Ultrasonography and LH Assays: Implications for Protocols for the Development of Alternative Contraceptive Strategies.** *Fertility and Sterility, ASRM Abstracts*, (Oct. 18-22, 1997).

The presenter began by stating “The knowledge of the precise timing of ovulation in relation to endometrial development in natural cycles is of paramount importance in the management of infertile women at primary, secondary and tertiary levels and for the development of strategies of fertility control.” They compared ovulation predication in natural cycles using serial Ultrasound (U/S) (to determine follicular rupture), and serial LH levels (in conjunction with confirmatory endometrial biopsies) in 60 regularly cycling women of proven fertility. The concordance index was not significantly different between U/S and LH surge. At the end of the presentation, the comment was made that ultrasound was a very reliable predictor of ovulation but somewhat expensive. We know that the Peak Day as determined by natural family planning methods is as accurate as either follicular rupture or LH surge and is much less expensive than either.

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Vercellini, Paolo, et.al., **Menstrual Characteristics in Women With and Without Endometriosis.** *Obstetrics and Gynecology* 90 (August 1997): 264-267.

Here the authors wanted to assess menstrual blood loss and other menstrual characteristics prospectively in women with and without endometriosis. 315 premenopausal women undergoing laparoscopy for various reasons were asked to evaluate their blood loss by the Higman blood loss assessment chart, cycle length, and flow duration. They also graded their dysmenorrhea with a 100 mm visual analog and verbal rating scale. The median pictorial blood loss score was 110 (range 66-156) in women with endometriosis (N=163) and 84 (range 56-129) in women without endometriosis (N=152). This finding was statistically significant. Menstrual flow duration was slightly longer in women with endometriosis (mean difference 0.33d). Dysmenorrhea was significantly higher in the endometriosis than the nonendometriosis group. There was, not surprisingly, a significant correlation between dysmenorrhea and blood loss assessment scores for both groups. It has long been theorized that endometriosis results from tubal regurgitation and implantation of the regurgitated endometrium. Thus a correlation between prolonged and heavy flow might be expected to be associated with endometriosis. Whether the longer heavier and more painful menses are related to endometriosis as cause or effect however could not be determined without a more objective measurement of blood loss, establishment of the relationship of transtubal to transcervical flow, and a way to determine whether exposure precedes outcome or vice-versa. Nevertheless, this is an interesting study and seems to lend some evidence in the direction of a very old theory.

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Barnhardt, K. T., et.al., **The Effect of DHEA replacement in the Endocrine and Lipid profiles of Perimenopausal woman.** *Fertility and Sterility, ASRM Abstract* (Oct. 18-22, 1997).

This was an oral presentation from the 1997 ASRM Scientific Session which reported on a randomized, double blinded, placebo controlled two parallel arm trial of 30 healthy perimenopausal women ages 45-55 to investigate the impact of DHEA replacement on their endocrine and lipid profiles. Daily supplementation of 50 mg. of DHEA was used in the study group. Among others, cholesterol, HDL, LDL, Serum DHEAS, Estradiol, Testosterone, and Cortisol levels were evaluated after 1,2, and 3 months of supplementation. The results showed significant elevation in DHEAS and Testosterone levels at the 1,2, and 3 month evaluation when compared to placebo. However, these levels were not elevated above “normal”. There were no statistically significant differences in the lipid levels between the study and placebo groups although there was a trend toward a decrease in Cholesterol and HDL levels in the study group. Because many women are asking about DHEAS and taking it sometimes in large quantities, it is important for those involved in women's health care as NFP providers to know what supplements are being taken and to have some idea of what the medical literature is saying with respect to these supplements. This study seems to show elevations of the androgens DHEAS and Testosterone when women took DHEA. This is of concern because of the many metabolic effects of these androgens not to mention the potential for virilizing side effects and menstrual irregularities.

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## Under the Microscope

### “Fertility Monitors”

#### **Cue™ fertility monitor compares well with modern methods of natural family planning in determining the fertile period.**

Two studies comparing the CUE™ fertility monitor with modern methods of natural family planning (NFP) were recently published.(1,2) The CUE fertility monitor is a hand held device that is designed to measure salivary and vaginal electrical resistance. 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.

This author (Fehring) published a study in the October 1996 issue of the *Journal of the American Academy of Nurse Practitioners*, in which the CUE method was compared with the Creighton Model (CrM) Ovulation method in determining the fertile period. Eleven female users of the CrM ovulation method measured their salivary and vaginal electrical resistance with the CUE, observed their cervical mucus as taught by the CrM, and measured their urine for luteinizing hormone (LH) with the OvuQuick test kit on a daily basis for two menstrual cycles. A

similar study by Drs. Moreno and Khan-Dawood from the University of Texas, Health Science Center and Dr. Goldzieher from The Baylor College of Medicine was published in the April, 1997 issue of *Contraception*. The Moreno study compared the CUE method with the Ovulation Method (OM) in defining the fertile time of the menstrual cycle. 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 Moreno et al., study had 42 usable cycles of data and the Fehring study had 21.

Both studies found strong significant linear correlations between the peak in CUE salivary readings and the LH surge ( $r = 0.82$ ,  $p < 0.001$  for Moreno and  $r = 0.79$ ,  $p < 0.001$  for Fehring). The Fehring study found a strong linear association between the vaginal electrical resistance nadir readings and the LH surge ( $r = 0.84$ ,  $p < 0.001$ ), whereas the Moreno et al., study found a very strong correlation between the vaginal electrical resistance rise and the day of follicular collapse ( $r = 0.98$ ,  $p < 0.001$ ). Furthermore, Moreno et al. 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.

Fehring found no significant difference between the length of the fertile period (or days of required abstinence if the method is used to avoid pregnancy) as determined by the CUE and the CrM. The CUE fertile period ranged from 5 to 10 days with an average of 6.7 days, and the fertile period of the CrM ranged from 4 to 9 days with an average of 6.5 days. Moreno et al. did find a significant difference between the length of the CUE determined fertile period and the OM length. They found the CUE provided a range of 6-13 days of defined fertility with an average of 9 days and the OM a range of 6-16 days with an average of 11 days. The differences between the two studies might be due to the different methods of NFP utilized (i.e., the CrM versus the OM), variants in observed mucus cycles, smaller number of subjects in the Fehring study, and slightly different definitions for the fertile phases.

Of interest is that Moreno et al. defined the theoretical fertile period as beginning at least three days before ovulation and until one day after (i.e., a five day theoretical fertile period). Based on this theoretical definition, they determined the actual fertile period in 39 of the 42 cycles in which follicular collapse was observed. The actual day of ovulation was defined as the day of follicle collapse preceded by an LH surge. Using these criteria, they determined that the OM method defined the beginning or end of fertility in four cycles incorrectly and that the CUE method defined the beginning and end of the fertile period correctly in every cycle. Therefore, Moreno, et al. concluded that a more precise beginning and end of the fertile phase was found

with the CUE than with OM and with fewer days of required abstinence. Both Fehring and Moreno et al. concluded that the CUE method has potential for use in NFP.

What Moreno, et al, however, failed to take into consideration is the role that cervical mucus plays in the fertile period. Cervical mucus serves as a medium for the viability of sperm, so at least theoretically, even though the OM fertile period began or ended within the 5 days of defined fertility, if the couple was using the method to avoid pregnancy they would not become pregnant because the sperm could not survive and if they were trying to achieve pregnancy, it would not serve any purpose to have had intercourse on a dry day within the defined period of fertility other than to strengthen conjugal relations. No report was mentioned in Moreno's or Fehring's study of the satisfaction of use of the CUE monitor. Since it is an invasive device, it might not appeal to many women. There is also potential for spread of infection if the vaginal probe is not kept clean or shared among women.

I commented in my 1996 study that further research needs to take place with the CUE method. At that time, I mentioned the need to conduct a study that used pelvic ultrasound to track follicular collapse. This has now been done by Moreno et al. I also recommended use-effectiveness studies comparing the simultaneous use of a modern method of NFP and the CUE method. This I still recommend. However, from a clinical practice perspective I would not hesitate to recommend the simultaneous use of the CUE with OM, CrM, or S-T with motivated couples, especially if they are having difficulty in determining their fertile period and/or have a lack of confidence in other markers of fertility.(RJF)

1. Fehring, R. **A Comparison of the Ovulation Method With the CUE Ovulation Predictor in Determining the Fertile Period.** *Journal of the American Academy of Nurse Practitioners* 8 (October, 1996):461-466.
2. 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.

### **Rovumeter™ Not Accurate in Defining Fertile Period**

In 1983, Usala and Schumacher reported on the development of a small inexpensive plastic syringe like device that could be used to accurately measure cervical and vaginal fluid volume (CVF) in the home setting.(1) Since CVF changes during the menstrual cycle, the developers thought that this device could be used to determine the fertile period of a woman's menstrual cycle, i.e., the volume of CVF would increase during the follicular phase and peak around the time of ovulation and then drop off and diminish. In 1988, Dr. Anna Flynn\* and colleagues reported on a study in which they tested the Rovumeter with 25 women.(2,3) In this study, the researchers were able to compare the daily Rovumeter collection of CVF with the day of maximum follicular development determined through serial ultrasound. Although the



beginning of the fertile period as defined by the Rovumeter varied from cycle to cycle, the peak in CVF correlated closely with the day of maximum follicular development. The results were encouraging and Flynn et al., recommended further studies.

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.(4) 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 (eg., consistency and characteristics) is probably more important in determining fertility rather than the total CVF volume. They did recommend that the Rovumeter might have potential use in conjunction with other methods of NFP and for sub-fertile couples who are trying to determine the days of maximum fertility.(RJF)

1. Ursala, J. S., and Schumacher, G. F. D. **Volumetric self-sampling of cervicovaginal fluid: a new approach to ovulation timing.** *Fertility and Sterility* 39 (1983):304-309.
2. Flynn, A. M., McCarthy, N, and Docker, M. F. et al., **The temporal relationship between vaginal fluid volumes obtained with the Rovumeter vaginal aspirator and the fertile phase of the cycle.** *Human Reproduction* 3(1988):201-205.
3. Flynn, A. M., Docker, M. F., and McCarthy, N. et al., **Detection of the fertile phase from changes in cervical-vaginal fluid volume.** *International Journal of Fertility* 1 (Supplement, 1988):17-23.
4. 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.

\* Dr. Anna M. Flynn, M.D. (Natural Family Planning Unit, Birmingham Maternity Hospital and Queen Elizabeth Medical Center) a long time researcher and promoter of NFP in the UK passed away this past year.

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## Resources

NFP teachers need to be aware of the latest research regarding human sexuality, fertility/infertility, contraception, and sexually transmitted diseases. Especially with the majority of their clients coming for NFP instruction after a range of contraceptive use, it is important for the NFP teacher to be familiar with the possible effects of the various forms of contraception on the menstrual cycle. Journals treating current research on these subjects have been and continue to be, grossly expensive or hard to retrieve unless one has access to a medical or university library. With the coming of the home computer and the internet however, even the poorly funded NFP program can have access to such information and keep their teachers up to date. The following are web sites where such information can be retrieved:

Med-Line.

The United Nations publishes numbers and population information:

- For current world population figures check: [www.undp.org/popin/wtrends/agespec.htm](http://www.undp.org/popin/wtrends/agespec.htm)
- For the latest information on rates and trends: [www.undp.org/popin/wtrends/wpgrow.htm](http://www.undp.org/popin/wtrends/wpgrow.htm)

If you have a computer but are not on the internet, you can take advantage of two free services which the World Health Organization (WHO) offers. The first is their newsletter *Progress in Human Reproduction Research*, an easy to read publication which summarizes the studies reported on. The second is the *WHO Reproductive Health Library* (RHL), a series of computer disks which contain current medical information on reproductive health. Please note that both of these resources are tailored to developing countries in general and family planning clinicians in particular. Contact: WHO, 1211 Geneva 27, Switzerland. Please designate which (or both), resource(s) you want to receive.

News from the Billings Ovulation Method Association- USA (BOMA):

Erik Odeblad, MD, PhD, of Sweden sent his latest research called Cell-to-Cell Communication. He has given *BOMA* first rights to publish in *BOMA News* and the diocese of St. Cloud's newsletter, *NFP Quarterly*. Although both newsletters will contain his article, *BOMA News* will have the information in its entirety. Sue Ek (diocese of St. Cloud) reports that Dr. Odeblad noted the text presents the ideas of cell-to-cell communication.

*BOMA News* is available for members only - an annual membership is \$25.00, per individual or \$50.00 per organization. Besides receiving the newsletter, members receive quarterly issues of the Drs. Billings newsletter from Australia - "Bulletin of the Ovulation Method Research and Reference Centre of Australia." Members also receive an annual directory of Billings instructors in the U.S. Contact: BOMA-USA, 316 North 7th Ave.,

St. Cloud, MN 56303-3631; 320-252-2100 or 1-888-637-6371; FAX: 320-252-2877; E-mail: [nfpstc@cloudnet.com](mailto:nfpstc@cloudnet.com)