

## **Fertility Report: September, 2007 – Prepared by Richard J. Fehring, PhD, RN**

### **Study Finds 7.7% Failure Rate among French Fertility Awareness Users**

French researchers recently conducted a retrospective population based study to determine method-specific contraceptive failure rates among women participants in a French National database (1). A stimulus for the study was the concern that 1 of 3 pregnancies among French women is unintended and of these 65% occur while on some form of contraception. The data base was from the population-based cohort 2000 Cocon Study. This study involved a representative sample of 1689 women aged 18-44 years who were randomly selected to answer a series of questions on their life time contraceptive and reproductive history -- from first intercourse to the date of the interview. The sample was over represented by women who had an abortion or an unintended pregnancy. Life table survival analysis (Kaplan-Meier) was used for data analysis.

The researchers discovered that the lowest first year failure rate of 1.1% was among IUD users, followed by a 2.4% failure rate among oral hormonal contraceptive pill users, then the male condom at 3.3%, 7.7% among fertility-awareness users, 10.1% among withdrawal users, and 21.7% among those using spermicides. They also found a 24 month failure rate of 4.3% among IUD users, 3.6% among pill users, 7.8% with condom users, and 18.8% among fertility awareness users. The researchers mentioned that in comparison to United States (US) retrospective population-based contraceptive efficacy studies the contraceptive failure rates among French women are in the same order of effectiveness but significantly lower than those among US women. They did mention a number of possible reasons and limitations in the study, including underreporting of abortion and the fact that the US data analysis includes all pregnancies regardless of intention. Furthermore, the French data set could be limited by recall bias and lack of data on sexual activity. The researchers concluded that comparative contraceptive failure rates between French and US women suggest differences in contraceptive practices. They recommended further study of contraceptive failure rates and practices among different populations.

Comments: The “unintended” label given by the researchers to pregnancies was rather liberal in that it included: a) not being planned at all, b) being planned later, and c) did not remember if she had planned to become pregnant at that time. The types of fertility awareness methods listed in the study included 31.6% using “periodic abstinence” and 68.4% “safe period by temperature or Ogino.” This is confusing in that it is not clear what they mean by “periodic abstinence” other than maybe this was a self determined guess by the woman when she was fertile or not. Furthermore, it is surprising that there was not an inclusion of more modern fertility awareness methods, such as the ovulation method and or the sympto-thermal methods. I wonder whether this retrospective cohort population of women contraceptive users was representative of the entire female reproductive population, i.e., the authors did not attempt to insure or provide evidence for this.

1. Moreau C, Trussell J, Rodriguez G, Bajos N, Bouyer J. **Contraceptive failure in France: results from a population-based survey.** *Human Reproduction*, 2007;22:2422-2427.

### **Method Discontinuation due to Dissatisfaction Found to be Low among Fertility Awareness Users Compared to Users of Hormonal Contraceptives**

As mentioned in the previous review, unintended pregnancies are a major health problem -- not only in France, but the United States (US) as well -- with 50% of all pregnancies in the US unintended. Many of these unintended pregnancies are due to discontinuation of contraceptive methods, and in turn, discontinuation is often due to dissatisfaction with use of these methods. Researchers from the Office of Population Research at Princeton University, therefore, sought to determine the reasons for and percentage of discontinuations among US women using reversible methods of contraception (1). Reasons for discontinuation were sought for only those who were dissatisfied with their method of contraception.

The Princeton researchers utilized the Cycle 6 (2002) data set from the National Survey of Family Growth (NSFG) that involved 7643 women between 15-44 years of age. The NSFG is a periodic national population-based survey of US women selected through probability statistical methods to obtain representative samples. The women are interviewed in person about their contraceptive and reproductive history with an average of 85 minutes per interview. The NSFG has an 80% response rate. Of the 7643 women, 6724 used a reversible method of contraception sometime during their reproductive life span. Of these women, 33% used fewer than 3 different reversible methods during their lifetime and 50% used 3-4 different methods, and the remaining 17% used more than 4 methods.

The researchers found that women users of the cervical cap and diaphragm had the highest (un-weighted) percentage (51.6%) of discontinuation due to dissatisfaction, with users of the sponge in second place at 47.6%. Users of long acting contraceptives, i.e., Depo-Provera and Norplant had a 42% discontinuation rate due to dissatisfaction and users of oral contraceptives were associated with a 29% risk of discontinuation. However, users of fertility awareness methods had only a 14.6% discontinuation risk. The lowest rate of discontinuation (11%) was among users of the male condom. Among the users of the pill, Norplant and Depo-Provera, the most frequent reason for discontinuation was side effects, menstrual cycle disorders, and method failure. The most frequent reasons that women users of the male condom provided for discontinuation were partner unsatisfied, decreased sexual pleasure, and messy to use. The authors suggested better contraceptive counseling might help improve dissatisfaction and discontinuation. However, the counseling should be based on a better understanding on why women discontinue contraceptive methods.

Comments: I would say no matter how you package, market the product, and counsel women on why they should not discontinue, if the method causes discomforting side

effects, menstrual cycle disorders, are messy to use, and interfere with sexual pleasure you will still have high rates of discontinuation. The “ever use” percentage of fertility awareness users listed in this study was 17.9%, compared with 84.5% ever users of the pill and 57.5% users of withdrawal. Fertility awareness was not defined, but probably included self devised calendar methods and the more modern mucus and temperature based methods. It would be of benefit to better know why users of fertility awareness methods discontinue.

1. Moreau C, Cleland K, Trussell J. **Contraceptive discontinuation attributed to method dissatisfaction in the United States.** *Contraception*, 2007, Article In Press.

### **Method Failure Most Frequent Reason for Discontinuing Periodic Abstinence Methods among Brazilian Women**

Researchers utilized a 1996 population-based data set of 12,612 Brazilian women between the ages of 15-49 (selected through a 2-stage random selection method) to analyze reasons for contraceptive dissatisfaction (1). The data set contains variables on contraceptive use and discontinuation ascertained through retrospective survey methods. The researchers were interested in reasons for discontinuation of reversible methods of contraception. The researchers stated a concern about the high rate of unintended pregnancy in that country. Furthermore, unintended pregnancy tended to occur during the time period of discontinuing and switching to another method of contraception. Greater than 50% of the women in Brazil use sterilization (either female 49% or male 3%) as a method of family planning. Only 4% of Brazilian women list periodic abstinence as a method of family planning.

The researcher found that “method failure” was the most frequent reason (17%) why women discontinue periodic abstinence methods in Brazil. The most frequent reason given for abandoning use of the pill (11.8%) and injectable hormones (27.4%) was because of side effects and health. The most frequent reason for discontinuing the condom (5.1%) was method failure. The researchers calculated a 12 month cumulative failure rate for the various contraceptive methods and found a 22.7% failure for traditional methods (that included periodic abstinence and withdrawal), a 6.5% failure rate for the pill, and 9.1% for the condom. However, the abandonment rate for the pill was 13.4% and for injectable contraception 17%, whereas for the traditional methods only 3.7%. The highest continuation rate was found among pill users at 64%, followed by condom users at 46%, and then traditional methods at 44%. There was a greater rate of abandonment, switching, and failure rates among the less educated, younger, and less educated women. The researchers felt there was a need for increased access to a greater range of contraceptive methods.

Comments: Since the fertility rate (2.1) among the more wealthy and educated Brazilian women is much lower than among the poor and less educated and since the failure rates are also lower among the more educated, maybe the Brazilian government would do better to concentrate its efforts on better education and economic opportunities for the

poor. Maybe more efforts need to take place to increase access to a greater variety of choices of modern fertility awareness based methods – especially for the poor that cannot afford the pill or injectables.

1. Leite IC, Gupta N. **Assessing regional differences in contraceptive discontinuation, failure and switching in Brazil.** *Reproductive Health*, 2007;4:6. (BioMed Central)

### **Men with Excess Body Weight are at Increased Risk for Infertility**

Researchers from the National Institute of Environmental Health Sciences (NIEHS) recently investigated the influence of male obesity on infertility (1). Obesity in the United States (and worldwide) is increasing and is a risk related to many health problems. There have been few population based studies to determine the influence of body mass and infertility among males, so too, there are no studies that examined coital frequency as a confounding factor. Therefore, NIEHS scientists conducted a study to determine the influence of being overweight i.e., having a basal metabolism index (BMI) of 25 or over, in association with infertility that included frequency of intercourse around the time of conception.

This study was retrospective and population-based, utilizing data from the ongoing Norwegian Mother and Child Cohort Study (MoBa). The MoBa study aims to enroll 100,000 pregnant women from 52 hospitals and birthing centers throughout Norway. Available to the NIEHS researchers were 45,132 women participants, of which 26,303 met the study criteria and included the women's report of the man's height and weight. Of these women, 12 percent (3113) were infertile. A BMI of > 25, calculated from the man's height and weight, was considered overweight, and a BMI > 30 was defined as obese.

The researchers found that infertility was significantly related to the men's BMI, with overweight men having a 19% increase in infertility (OR = 1.19: 95% CI = 1.03–1.37) and obese men having a 36% increase incidence of infertility (OR = 1.36: 95% CI = 1.12–1.62). When the Odds Ratios were adjusted for coital frequency, there was not much of a change in results with an OR of 1.20 for overweight men and an OR of 1.36 for obese men. The results did not change as well when adjusted for age and parity of the woman. The researchers speculated that the increase in infertility among obese men was due to a decrease in reproductive hormone levels and a decrease in sperm production. They also speculated whether weight loss would improve their chances of conception.

Comments: Fertility awareness and NFP teachers working with couples who wish to achieve a pregnancy should assess the BMI levels of both the woman and her male partner. If either has a BMI over 25, weight loss might be recommended. I wonder if targeted intercourse during peak fertility as determined by fertility monitoring methods would obtain the same results as found in this study?

1. Nguyen RHN, Wilcox AJ, Skjaervben R, Baird DD. **Men's body mass index and infertility.** *Human Reproduction*, 2007;22:2488-2493.

### **Oral Hormonal Contraceptive use Increases Estrogen Receptors in Vulvar Vestibular Mucosa**

Swedish researchers sought to determine the effects of combined oral contraceptive (COC) use on the sex steroidal receptors in vulvar vestibular mucosa in healthy women (1). The background reason for conducting this study was that this area of research has few studies and these same researchers recently found morphological changes in vulvar vestibular mucosa during COC use. Furthermore, the Swedish researchers believe that there is some connection between COC use and vestibular pain during intercourse.

The researchers recruited 45 healthy sexually active subjects of which 20 (mean age 23.7) were on COCs for a minimum of one year (actual use ranged from 2-15 years) and 25 control women (mean age 25.6 years) who used non-hormonal means of contraception. A vestibular punch biopsy was obtained on the 7-11th day after the beginning of the menstrual cycle in all subjects. Serum samples for estradiol and progesterone levels were drawn to determine the phases of the menstrual cycle. Tissue from the punch biopsies were subjected to immunohistochemistry analysis for sex steroid receptors. Five of the control women were determined not to have ovulated during the test cycle and were not included in the analysis.

The researchers found that there were significantly more beta type estrogen receptors in the vulvar vestibular tissue of the COC users compared to the controls ( $p < 0.024$ ). They also found a greater abundance of progesterone receptors in the vulvar tissue during the follicular phase than in the luteal phase ( $p < 0.01$ ) among the non-COC users. They did not find any significant differences in the abundance of progesterone, androgen, or glucocorticoid receptors between the two groups. However, the researchers did point out that a limitation was in the small number of participants in each group. They concluded that the results indicated a hormonal influence on the steroid receptor expression by ethinyl estradiol as well as by progestins. They believe that the hormones in the COCs not only effect the expression of the estrogen receptors but the morphology of the vestibular mucosa as well.

Comments: The Swedish researchers indicated that the clinical implication for the findings was unknown. However, they have proposed that COCs make the vestibular tissue more sensitive and a possible reason why COC users report more sexual pain compared to non-users. I wonder if the increase in estrogen receptors also occurs in the cervical endometrial tissue and is one reason why there is an increase of cervical mucus found in post COC users who switch to use a mucus based method of fertility awareness?

1. Johannesson U, Sahlin L, Masironi B, Rylander E, Bohm-Starke N. **Steroid receptor expression in the vulvar vestibular mucosa – effects of oral contraceptives and menstrual cycle.** *Contraception*, 2007: Article in Press.