Natural Family Planning
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Natural Family Planning

United States Physicians Underestimate Effectiveness of Natural Family Planning

A recent study conducted by researchers at the University of Missouri-Columbia, found that 79% of physicians in Missouri estimated the best possible effectiveness of natural family planning for avoiding pregnancy to be less than 91%. Sixty-five percent of those surveyed ranked the actual effectiveness of NFP to be 70% or less.[1] The purpose of the study was to determine physicians' knowledge and practices of modern methods of NFP. The researchers assumed that modern methods of NFP are important for medical practice in order to help women and couples avoid or achieve pregnancy.

A one page questionnaire on knowledge and practice of NFP was created by the researchers and mailed to 840 randomly selected physicians in Missouri. While 69% of the 547 respondents saw women for reproductive needs, only 46% mentioned NFP to at least some women when discussing family planning issues. When women patients asked for information about NFP, the majority described basal body temperature (54%) or calendar rhythm (45%). Most physicians recommend BBT (71%) or calendar timed intercourse (64%) for women who had infertility problems. Only 36% recommended cervical mucus observations. The estimated effectiveness of NFP and information provided on modern methods of NFP was highest among physicians that had NFP instructors in their area.

Comments

Among the physicians from Missouri, the low level of recommending modern methods of NFP was similar to previous studies conducted on physicians in Germany and Italy.[2,3] Standford, Thurman and Lemaire suspect that the low estimation of the effectiveness of NFP in their study was due to anecdotal reports of NFP/rhythm “failures” by colleagues, patients or as cited in the medical literature. Physicians have a tendency to prescribe family planning methods that are used by peers, that can simply be medically prescribed and that are reported positively in the medical literature. Most physicians in the United States have learned very little about modern NFP in medical school or the literature and when they do it is often of a negative nature.[4] From this study, it seems that the availability of NFP instructors is a key factor in facilitating physicians knowledge and regard for modern NFP. A study similar to this would be of interest among other health providers that recommend or prescribe family planning methods, such as Certified Nurse Midwives and Family Planning Nurse Practitioners.

1. Stanford, J. B., Thurman, P. B. and Lemaire, J. C. **Physicians' knowledge and practices regarding natural family planning.** *Obstetrics and Gynecology* 94 (November, 1999): 672-678.

2. Doring, G., Baur, S. and Frank-Herrman, P. et al. **Results of a physician survey on the status of knowledge and attitude to natural family planning in West Germany 1988.** *Geburtshilfe Frauenheilkd* 50 (1990): 43-8.

3. Girotto, S., Del Zotti, F. and Baruchello, M. et al. **The behavior of Italian family physicians regarding the health problems of women and, in particular, family planning (both contraception and NFP).** *Advances in Contraception* 13 (June/September, 1997): 283-93.

4. Fehring, R. **Physician and nurses' knowledge and use of natural family planning.** *The Linacre Quarterly* 62 (November, 1995): 22-28.

Peak of Fertility Determined to be the Day before Ovulation: Assessment of Cervical Mucus Recommended for Couples Who Want Either to Avoid or Facilitate Conception

Researchers from the National Institute of Environmental Health Sciences in North Carolina re-analyzed two existing data sets that provided information on the estimated day of ovulation based either on the last day of hypothermia (i.e., the shift of basal body temperature/BBT) or on urinary reproductive hormone metabolites.[1] The BBT data were taken from charts collected by Barrett and Marshall from British couples who used BBT during the 1950s and 1960s. The urinary steroid based estimate of ovulation was taken from charts of couples from North Carolina who were attempting to become pregnant in the early 1980s.[2,3] The North Carolina couples collected daily morning urine specimens that were then analyzed for rapid decline in the ratio of estrogen to progesterone that accompanies luteinization of the ovarian follicle. Both the English couples and the North Carolina couples recorded their acts of intercourse and subsequent pregnancies. The English study yielded usable data from 241 women and 2,192 menstrual cycles, the North Carolina study yielded usable data from 221 women and 674 menstrual cycles.

The authors stated that both the last day of hypothermia and the urinary luteinizing hormone (LH) peak are on average close to the day of ovulation, but that there will be measurement error with both biological markers. They therefore entered the data into a statistical formula that corrects for errors in estimating the day of ovulation and then re-analyzed the data sets to determine the probability of pregnancy on a given day of the menstrual cycle. They determined that the urinary hormone based indicator had less error in determining the day of

ovulation than BBT. They found that 60% of the urinary hormone estimated days of ovulation were correct compared with only 43% of the BBT-estimated days. Both sets of "error corrected" data found the fertile interval to begin 5 days prior to ovulation and ending on the day of ovulation. Both sets of data also indicated that the maximum probability of pregnancy (i.e., estimated day of peak fecundability) occurs with intercourse one day prior to the estimated day of ovulation. This model of fecundability provides couples with an estimated 6 day window of fertility.

Comments

This study's results find that the peak of fecundity is the day before ovulation. This differs from the 1998 Wilcox, et al., study which demonstrated that the peak day of fecundity was the day of ovulation. The researchers explained that the difference between the two studies might be due to the Wilcox et al study including early pregnancy losses in its data and the current study only using clinically verified pregnancies. They believe that intercourse on the day of ovulation might result in fertilization with an aged ovum and thus have a higher incidence of pregnancy loss.[5]

The authors concluded that since the two highest days of conception rates are on the two days before ovulation, biological markers that provide couples with information to have intercourse 2-3 days before ovulation are important for couples trying to achieve pregnancy. They indicated that the BBT shift comes too late and that the urinary LH surge offers only a short one day warning of pending ovulation. Changes in cervical mucus on the other hand is an earlier and more useful biological maker. The evidence provided by these researchers continues to add to the scientific foundations of modern methods of Natural Family Planning.

1. Dunson, D. B., Baird, D. D. and Wilcox, A. J. et al. **Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation.** *Human Reproduction* 14 (July, 1999): 1835-1839.

2. Barrett, J. C. and Marshall, J. **The risk of conception on different days of the menstrual cycle.** *Population Studies* 23 (1969): 455-461.

3. Wilcox, A. J., Weinberg, C. R. and O'Connor, J. F. et al. **Incidence of early loss of pregnancy.** *New England Journal of Medicine* 319 (1988): 189-194.

4. Wilcox, A. J., Weinberg, C. R. and Baird, D. D. **Timing of sexual intercourse in relation to ovulation.** *New England Journal of Medicine* 333 (1995): 1417-1521.

5. Wilcox, A. J., Weinberg, C. R. and Baird, D. D. **Post-ovulatory ageing of the human oocyte and embryo failure.** *Human Reproduction* 13 (1998): 394-397.

Two Day Algorithm Proposed as Alternative to Ovulation Method

Teaching modern methods of natural family planning (i.e., the Ovulation Method and the Sympto-Thermal Methods) can be labor intensive both for NFP teachers and clients. The complexity of and the time that it takes to teach modern methods of NFP can also make it difficult to reach large numbers of users, illiterate couples or couples with a variety of ethnic backgrounds. The intensity of teaching NFP can lead to teacher burnout, dropout and frustration. Any means to help simplify NFP methods for teachers and users would be welcome.

Researchers at the Georgetown University Institute for Reproductive Health have developed a simple Two Day algorithm that can be applied to methods of NFP that rely on observing changes in cervical mucus.1 The two day algorithm for a woman is as follows: two consecutive days without any cervical mucus (either sensations or visual appearance) equals infertile days. To test this algorithm, the Georgetown researchers applied it retrospectively to NFP records obtained from the World Health Organization five country study of the Ovulation Method and from three NFP service programs. The WHO study yielded 7,592 cycles of data and the three NFP centers 183 cycles. The algorithm was applied to a conservative estimate window of fertility running eight days before the Peak day and continuing through three days after peak.

The researchers found that in the pre peak phase, the 2 day algorithm identified the exact days of fertility as in the Ovulation Method. In the post peak phase, the algorithm determined that the first two days after peak were fertile in 54.6% of cycles and in the third day post-peak 11.3% of the cycles were considered fertile. By five days post peak, 94.4% of the cycles were infertile. Although the two day method identified some days as fertile that were not, overall the algorithm identified the infertile phase well. The two day algorithm would have required the users to abstain an average of 9 days (if avoiding pregnancy) compared with 9.7 days if they were using the Ovulation Method.

The Georgetown researchers concluded that the two day algorithm appears to be a promising new and simplified approach to NFP. They felt that it could be used as an alternative approach to the Ovulation Method especially for individuals who have no access to OM or who want a more simplified method.

Comments

As was pointed out in the article, there might be some situations in which application of the two day algorithm would be difficult. Any method that is based on changing characteristics of cervical mucus has some difficulty in application when the given women has a continuous or

confusing mucus pattern. The Ovulation Method and other variants (e.g., the Creighton Model System) relies on mucus patterns and the differentiation of types of cervical mucus characteristics (sensations or observations) to do this. The two day method is based only on the presence or absence of mucus and thus would have difficulty in such situations. The developers, teachers and users of the Ovulation Method might also argue that OM is already simple and is based on the daily observations of sensations at the vulva. The two day algorithm needs further research on its efficacy and acceptability to users and providers.

1. Sinai, I., Jennings, V. and Arvalo, M. **The two day algorithm: A new algorithm to identify the fertile time of the menstrual cycle.** *Contraception* 60 (1999): 65-70.

Necklace Method of NFP Tested Among Mayan Women

The Necklace method of NFP involves use of a "blanket rule" type of calendar-rhythm along with a beaded necklace that is used to keep track of the days of the menstrual cycle. For example, one blanket rule method developed and tested at Georgetown University and by the United States Center for Disease Control and Prevention, is for a woman to consider herself fertile from days 9 through 19 of her menstrual cycle. Obviously in order for this to be effective, the population of women using the blanket rule need to have fairly regular cycles. In order to see how useful this method might be, researchers from the Population Council in New York and Guatemala evaluated the "regularity" of the menstrual cycles among 303 Guatemalan women of whom 96% were Mayan.[1] The 303 Guatemalan/Mayan women yielded 880 cycles of useful data. Regularity was defined as having a cycle length in the range of 26 to 32 days for three consecutive cycles.

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

Comments

The actual number of "regular" cycles among the Maya women were less than that appearing in the results. The researchers excluded 146 women volunteers from the study for various reasons, e.g., 33 stated they had irregular cycles, 39 did not feel that they could abstain for 11 days, 27 had signs of pregnancy and 13 had been using hormonal contraception in the last

3 months. Although newly formulated rhythm formulas are easy to teach, there is no evidence that they would be any more effective in practice than the Ogino/Knaus formulas; i.e., they fail in reality to not be useful to many women because of the variability of the women's menstrual cycle.

1. Burkhart, M. C., de Mazarigos, L and Salazar, S et al. **Incidence of Irregular Cycles Among Mayan Women Who Reported Having Regular cycles: Implications for Fertility Awareness Methods.** *Contraception* 59 (1999): 271-275.

Work Stress Associated with Short Menstrual Cycles

A study conducted by members of the Reproductive Epidemiology Section of the Department of Health in Emeryville, CA, indicated that women who experience high job stress are twice as likely as women in low stress jobs to have short menstrual cycles.[1] Job stress was defined as work positions that require high demands and low control. Of the 276 healthy women who participated in the study, 61 were determined to have high job stress. All of the participants collected daily urine samples for an average of 5 cycles. Urinary metabolites of estrogen and progesterone were measured in order to estimate the day of ovulation and to detect anovulatory cycles. Although the 61 job stress women experienced twice the rate of short cycles, they did not experience an increased risk for anovulation, unusual bleeding, or cycle irregularity. The decrease in cycle length was accounted for by a decrease in the length of the follicular phase.

Comments

Of interest is that of the 6,481 women who were successfully screened for the study, 83.2% were ineligible for the study, the majority because they were either on oral contraception or sterilized. The researchers theorized that the stress related short cycle length could be from the inhibition of luteinizing hormone secretion by the increase in corticotropin-releasing hormone or glucocorticoids, i.e., stress released hormones that affect the hypothalamic-pituitary-adrenal axis.

1. Fenster, L., Waller, K. and Chen, J. et al. **Psychological stress in the workplace and menstrual function.** *American Journal of Epidemiology* 149 (1999): 127-134.

Pregnancy and Breastfeeding

Creighton Model System Study Confirms Most Pregnancies Result from Genital Contact during Fertile Time

A study recently reported in the *Archives of Family Medicine* determined that among 701 couples from the Houston area who were taught the Creighton Model System there was a total of 17.12 pregnancies per 100 couples over a 12 month period. Of these pregnancies, only 0.14 pregnancies were method related, 1.43 were unresolved pregnancies, 2.72 were a result of user or teacher error and 12.84 were a result of couples having genital contact on a day of known fertility.[1] The authors utilized life table analysis to examine "probability of pregnancy" rather than "failure of the method" as a way to be more objective in their analysis. They also determined that pregnancy probabilities in the use of the CrM system was similar among reproductive subgroups, including those women discontinuing hormonal contraception, breast-feeding and with long cycles. The authors concluded that the pregnancy probabilities with use of the CrM system compares favorably with other methods of family planning.

Comments

This study is unique in that the authors did not attempt to catagorize pregnancies as "planned/unplanned," or "wanted/not wanted." These terms, Joseph Stanford, M.D., has shown, have different meanings to different people in different situations.[2,3] The 12.84 pregnancies that were reported as achieving related in this study includes those couples who consciously tried to get pregnant with the CrM system but also those who were not trying to get pregnant but knew that they were having genital contact on a fertile day. The authors postulated that the most relevant statistics for users of the CrM system are the probabilities of becoming pregnant when they consistently use the CrM to avoid pregnancy and limit their genital contact to infertile days. A critique of this CrM study (and past studies) is the results reflect essentially a young, white, middle class, educated user population. Further studies need to determine how the CrM system fairs with low-income, less educated, and ethnically diverse populations. In addition, controversy continues to surround the researchers' definition of "achieving related" pregnancy.

1. Howard, M. P. and Stanford, J. B. **Pregnancy probabilities during use of the Creighton model fertility care system.** *Archives of Family Medicine* 8 (September/October, 1999): 391-402.

2. Trussell, J., Vaughan, B. and Stanford, J. B. **Are all contraceptive failures unintended pregnancies? Evidence from the 1995 National Survey of Family Growth.** *Family Planning Perspectives* 31 (September/October, 1999): 246-47:260.

3. Fischer, R. C., Stanford, J. B. and Jameson, P. et al., **Exploring the concepts of intended, planned, and wanted pregnancy.** *The Journal of Family Practice* 48 (February, 1999): 117-122.

Moderate Consumption of Caffeine Unlikely to Increase Risk of Spontaneous Abortion

A recent study reported in the New England Journal of Medicine indicated that the blood levels of paraxanthine, a metabolite of caffeine, was higher in women who had spontaneous abortions than in women who gave birth to live infants.[1] Researchers from the Division of Epidemiology, Statistics, and Preventive Research from the National Institute of Child Health and Human Development and from the Center of Human Toxicology at the University of Utah, measured serum paraxanthine in 591 women who had spontaneous abortions and in 2,558 matched women from the same clinic who gave birth to live infants. They found that only very high serum paraxanthine concentrations (an equivalent of more than 5 cups of coffee per day) were associated with spontaneous abortion. They concluded that a moderate intake of caffeine should not increase the risk of spontaneous abortion.

Comments

The strength of this study is that the researchers used an actual biological marker of caffeine rather than recall of caffeine intake from a woman's own report. A weakness is that the researchers only used one serum measurement of the caffeine metabolite during the entire pregnancy. A follow-up critique of the study in the same issue of the journal stated that moderate intake of caffeine should not be assumed to be safe for pregnant women.[2] The critique cites a meta-analysis of the published research on caffeine and spontaneous abortion that suggests women who consume only one to two cups of coffee per day have an increased risk for spontaneous abortion and low birth weight infants. The critique also cited the 1981 Food and Drug Administration recommendation that pregnant women avoid caffeine containing foods and drugs.

1. Klebanoff, M. A., Levine, R. J. and DerSimonian, R. et al.. **Maternal serum paraxanthine, a caffeine metabolite, and the risk of spontaneous abortion.** *The New England Journal of Medicine.* 341 (November, 25, 1999): 1639-44.

2. Eskenazi, B. **Caffeine - filtering the facts.** *The New England Journal of Medicine* 341 (November, 25, 1999): 1688-89.

World Health Organization Study Confirms Bellagio Consensus

In 1988, world experts on breast-feeding met in Bellagio, Italy and (after a review of the available research) concluded that there is less than a 2% pregnancy rate within the first 6 months of lactational amenorrhea if women are fully or nearly fully breast-feeding. A large prospective multinational study supported by the World Health Organization was conducted to determine the relationship between breast-feeding practices and lactational amenorrhea and to test the Bellagio consensus.[1] A total of 4,118 women who were breast-feeding were enrolled in this prospective WHO study from 5 developing and 2 developed countries. These women monitored their breast-feeding episodes, supplementary feedings and vaginal bleeding episodes. Of the 3,422 women who completed this study, 46 became pregnant while breast-feeding and not using some form of contraception. The cumulative pregnancy rate for all the women who were still breast-feeding and amenorrheic at 6 months was 0.8% and at 12 months 4.4%. The differences in pregnancy rates between full breast-feeding and partially breast-feeding women was not statistically significant at either the 6 or 12 month time period. The WHO task force concluded that the lactational amenorrhea method is a viable method for post-partum family planning.

Comments

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

1. World Health Organization Task Force. **The World Health Organization multinational study of breast-feeding and lactational amenorrhea. III. Pregnancy during breast-feeding.** *Fertility and Sterility* 72 (September, 1999): 431-39.

2. World Health Organization Task Force. **The World Health Organization multinational study of breast-feeding and lactational amenorrhea. IV. Postpartum bleeding and lochia in breast-feeding women.** *Fertility and Sterility* 72 (September, 1999): 441-47.

Contraception

Oral Contraception Preferred Method of Family Planning Among Female Physicians in the United States

To test the assumption that personal contraceptive use among female physicians could influence their prescribing practices, Erica Frank, MD, from the Emory University School of Medicine, utilized data from the Women Physicians Health Study and compared this data with the 1990 National Survey of Family Growth.[1] The Women Physician' Health Study involved a national stratified random sample of female medical doctors (ages 30-44) from the United States in 1993-1994 and had a total of 4,501 female physician respondents. Dr. Frank, however, only utilized those physician respondents who were at risk of becoming pregnant (i.e., 1,625 physicians). The 1990 National Survey of Family Growth consisted of 5,686 women (ages 15-44) who were telephone interviewed by members of the National Center for Health Statistics of the Centers for Disease Control and Prevention.

Dr. Frank found that, in general, female physicians were more likely to use some form of contraception (72.9% of the physicians) than women in general (59.3% for general population). This held true even when the female physicians were compared with women who had a higher socioeconomic background. She also found that the female physicians were more likely to use intrauterine devices, diaphragms, or condoms and less likely to use female or male sterilization when compared with women in general. The most frequently used method of contraception among the physicians was oral contraception (27.0%), followed by the condom (20.4%), and the diaphragm (17.8%) . Only 11.7% of the physicians reported being sterilized compared with 29.5% of the general population. However, the percentage of sterilization among the older physicians (aged 40-44) jumped to more than double (25.5%) but still was only half of the general population of the same age (52.0%). The author concluded that female physicians' contraceptive practices were different than the general population.

Comments

Although the physicians' contraceptive patterns were different than the general population, their use of NFP (listed as rhythm) was not. The physicians' percentage use of rhythm was 2.9% and the general population was 2.7%. Of interest is that about 5% of the Catholic female physicians (n= 325) used NFP (rhythm) while 27% listed the use of oral contraceptives as their preferred method of family planning.

1. Frank, E. **Contraceptive use by female physicians in the United States.** *Obstetrics and Gynecology* 94 (November, 1999): 666-71.

Family Planning and User Satisfaction

Bjorn J. Oddens, M.D., Ph.D., a researcher from the International Health Foundation in Geneva, Switzerland, recently surveyed German women on the physical and psychological effects of current and past use of five common methods of family planning: oral contraceptives, intrauterine devices, condoms, natural family planning and sterilization.[1] The survey was conducted through a technique called random-walk sampling. Addresses were randomly selected throughout the Western states of the Federal Republic of Germany. These addresses were then visited in person by a fieldworker to administer what they called a women's health questionnaire. Of the 2,499 households visited there was a response rate of 58.7% or 1,466 women respondents. Of these respondents, 1,303 had past or current use of oral contraceptives, 996 had used condoms, 428 NFP, 342 intrauterine devices (IUD), and 139 were sterilized.

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

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

Comments

The results of this study as reported are misleading. A careful examination of the study yields two areas of weaknesses: a discrepancy between the study's discussion and that of data reported in tables; and the design of the survey questions themselves.

A careful examination of the data presented in the table of the published report compares NFP favorably to and sometimes much better than, the other methods, yet the published discussion said otherwise. For example, the discussion stated that the highest rates of negative mood changes and lowest rates of satisfaction were reported with regard to the "less reliable methods," i.e., condoms and NFP. Yet, data in the table showed 100% of current users of NFP reported that they never had a concern about health risks, whereas, 71.4% of the current users of oral contraception had health concerns. Only 3.8% of current users of NFP reported feeling more depressed and 5.1% feeling more irritable, whereas, 10.3% of the users of oral contraception felt more depressed and 13% more irritable. Ten percent of the current users of NFP felt more cheerful as compared to 8% of users of oral contraception. Sexual satisfaction indicators among the users of NFP compared well to the users of oral contraception. Although the users of NFP felt they had a 31% lower frequency of intercourse and 39% less spontaneity, 28% felt that sex was more pleasurable and 22% felt it increased their sex drive (i.e., libido). Only 8.4% of users of oral contraception felt an increase in their sex drive. In other words, users of NFP had less frequent use of intercourse, but when they did it was stimulated by a heightened libido and was more pleasurable. The author clearly overlooked these important indicators or played them down in his interpretation.

Finally, the questions of the study were too narrowly focused. Other important questions about the dynamics of use and satisfaction could have been asked: "did the individual method of family planning help to increase or decrease the user's understanding of his/her fertility?"; "did couple communication increase or decrease?"; "did self-control increase or decrease?"; "how did the method effect the user's spiritual well-being?" NFP, as the only holistic form of family planning represented in the study, requires wider questions in order to reveal how its users perceive it. People knowledgeable of NFP science and use understand that NFP users would fair better in their responses to these questions as compared to users of artificial methods.

1. Oddens, B. J. **Women's satisfaction with birth control: a population survey of physical and psychological effects of oral contraceptives, intrauterine devices, condoms, natural family planning, and sterilization among 1466 women.** *Contraception* 59 (1999): 277-286.

Once-A-Month Post Implantation Pill Considered Unacceptable by Most Women

Since a once a month hormonal contraceptive pill (e.g., mifeprestone) is now feasible, researchers from the United Kingdom surveyed 1,818 women who attended family planning clinics (in Shanghai, Hong Kong, Cape Town or Edinburgh) to determine the acceptability of

such a pill.[1] A two thirds majority of all the women respondents indicated that they liked the idea of taking a pill once-a-month for contraceptive purposes. However, most preferred a pill that worked by inhibiting ovulation. Over half of the women from all four centers would consider a pill that worked post-implantation unacceptable.

Comments

Of interest is that such a pill taken once a month for contraceptive purposes would probably need to be taken at a precise time in the cycle. The authors of this study suggest that women could use some type of urine test to detect ovulation, such as current home urinary luteinizing hormone ovulation detection kits or the Persona monitor developed by Unipath. Therefore, this once-a-month pill is essentially a fertility awareness early hormonal abortion technique. The anti-estrogenic pill works by either inhibiting ovulation, preventing implantation or dislodging an already implanted embryo.

1. Glasier, A. F., Smith, K. B. and Cheng, L. et al. **An international study on the acceptability of a once-a-month pill.** *Human Reproduction* 14 (December, 1999): 3018-3022.

Research Briefs

Risser, W. L., Gefler, L. R. and Barratt, M. S. et al. **Weight change in adolescents who used hormonal contraception.** *Journal of Adolescent Health* 24 (June, 1999): 433-6.

A study was conducted to compare weight gain over a one year period between 86 adolescents who were taking oral contraceptives (OC) and 44 adolescents who were using the injectable depo-medroxyprogesterone acetate (DMPA). The adolescent participants were attending a Planned Parenthood teen clinic and ranged in age from 13 - 19 years. After one year (70%) of adolescents who were on OCs and 56% of the users of DMPA either lost weight or gained less than 5% of their baseline weight. However, 25% of the adolescents who were using DMPA gained more than 10% of their baseline weight. *(Weight gain is just one of the reasons that adolescents are not compliant to the use of hormonal contraception. RJF)*

Fu, H., Darroch, J. E., Haas, T. and Ranjit, N. **Contraceptive failure rates: new estimates from the 1995 National Survey of Family Growth.** *Family Planning Perspectives* 31 (March/April, 1999): 56-63.

Data from the 1995 National Survey of Family Growth (NSFG) and the 1994-1995 Abortion Patient Survey (APS) were analyzed to determine contraceptive failure rates during the first year of use among all United States women. The results were corrected due to the under reporting of induced abortion among the women in the NSFG. The lowest failure rate after a one year period was 2-3% among users of implants and injectables, followed by users of the pill (8%), the diaphragm and cervical cap (12%), the male condom (14%), periodic abstinence (21%), withdrawal (24%) and spermicides (26%). Failure rates were highest among cohabitating and other unmarried women. *(Please note: I do not consider pregnancy a "failure." Periodic abstinence users included those women who were using modern methods of NFP. However, the majority of periodic abstinence users were so-called users of rhythm, i.e., there is an over reporting of the use of rhythm. The reasons that there is an over reporting of rhythm is that women who get pregnant using no method of contraception have a tendency to report that they used rhythm to show that they were being responsible. RJF)*

Stevens-Simon, C., Kelly, L. and Singer, D. **Preventing repeat adolescent pregnancies with early adoption of the contraceptive implant.** *Family Planning Perspectives* 31 (Mar-Apr, 1999): 88-93.

In order to determine if the use of implants would lower the unintended pregnancy rates among unmarried adolescent mothers, 171 adolescent mothers who began using an implant within 6 months of delivery were compared with 138 adolescent mothers who used nothing or another method of contraception. After the first year post-partum, only 1% of the implant users were pregnant as compared to the 20% of the mothers who used nothing or another method. After a two year period, 12% of the implant users became pregnant as compared to 46% of the non-implant using mothers. However, after one year post-partum 7% of the of the implant users had their implant removed and after two years 37% discontinued use. *(I would like to see the addition of a comparison group of adolescent mothers who are taught to understand and respect their fertility. For some reason hormonal implants are intuitively and naturally not attractive to many young women. RJF.)*

Colli, E., Tong, D., Penhallegon, R. and Parazzini, F. **Reasons for contraceptive discontinuation in women 20-39 years old in New Zealand.** *Contraception* 59 April, 1999): 227-31.

Researchers in New Zealand followed 2,469 users of oral contraception (OC), 2,072 users of the intrauterine device (IUD) and 1,721 users of the injectable depo-medroxyprogesterone acetate (DMPA) over a 5 year period in order to determine the medical

and non-medical reasons for discontinuation. After only a 2 year period, 42% had discontinued OC, 44% discontinued the IUD, and 48% discontinued use of DMPA. The most frequent non-medical reasons for discontinuation were desire to conceive, patient preference, no longer needing contraception and sterilization. Intermenstrual bleeding and menorrhagia were the most frequent medical reasons given for discontinuation among users of OC and DMPA, pelvic pain and infection were the most frequent reasons given among users of the IUD. *(The high discontinuation rate of contraceptive methods is similar in other developed countries including the US. RJF)*

Yusuf, F. and Siedlecky, S. **Contraceptive use in Australia: evidence from the 1995 National Health Survey.** *Australian and New Zealand Journal of Obstetrics and Gynaecology* 39 (February, 1999): 58-62.

Australia, as in the United States, has periodic national health surveys to determine contraceptive patterns and other health practices among the general population. The 1995 Australian National Health Survey showed that more than 44% of Australian women between the ages of 18-49 use some form of contraception. The two most common methods of contraception are oral hormonal contraception (60%) and the condom (27%). The IUD and natural methods accounted for less than 5% each. The most frequent reason for women over 35 not using contraception was sterilization. For those women younger than 35, trying to get pregnant or not sexually active were the most frequent reason. *(Unlike the 1995 Australian survey of contraceptive use, the United States 1995 National Survey of Family Growth counts sterilization as a method of contraception and includes women from age 15-45. Otherwise there is not too much difference in contraceptive patterns between the two countries. RJF)*

Zibners, A., Cromer, B. A. and Hayes, J. **Comparison of continuation rates for hormonal contraception.** *Journal of Pediatric and Adolescent Gynecology* 12 (May, 1999): 90-94.

Non-compliance with contraception and other health and non- health behaviors is common among adolescents. Researchers in the department of pediatrics at the Ohio State University, Children's Hospital conducted a retrospective chart review to determine continuation rates for hormonal contraception. The participants were 64% black, 34% white and had an average age of 15.5 years. After a one year period, the continuation rate for contraceptive implants was 82%, for depo-medroxyprogesterone acetate (DMPA) 45% and for oral contraception (OC) 12%. When uninterrupted hormonal contraceptive use was included, (i.e., un-interrupted switching to another hormonal method was included) the rates were 96% implants, 83% DMPA, and 49% OC. *(A retrospective chart audit is not the most reliable*

research method to follow compliance across time. Nevertheless, contraceptive hormonal compliance does not seem to be very high unless the hormones are surgically imbedded under the skin!)

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Trussell, J., Rodriguez, G. and Elerston, C. **New estimates of the effectiveness of the Yuzpe regimen of emergency contraception.** *Contraception* 57 (June, 1998): 363-9.

Well known contraceptive researchers from the Office of Population Research at Princeton University analyzed the data from 7 studies and 5 different data sets to provide new estimates of the effectiveness of the Yuzpe emergency contraceptive regimen to prevent pregnancy. The Yuzpe regimen is the use of the emergency contraceptive pill or what is commonly referred to as the post-coital pill. Their estimates of conception probabilities by cycle day ranged from a low of 44.2% to a high of 88.7%. From this they determined that the emergency contraceptive pill reduced the risk of pregnancy by at least 75%. They made this estimate based on the assumption that "treatment failures" included women who were already pregnant and women who became pregnant after treatment. *(Pregnancy for these researchers is defined as implantation; therefore, many of the "treatment successes" probably include early abortion of the early human embryo. RJF)*

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Liyng, Z. and Bilian, X. **Preliminary analysis of a multi center clinical trial using Multiload Cu 375SL for emergency contraception.** *Advances in Contraception* 14 (December, 1998): 161-70.

The purpose of this study was to determine the effectiveness of and side effects of the use of Multiload Cu 375SL (a type of IUD) as emergency contraception. 515 Chinese women who requested emergency contraception had the IUD inserted within 5 days of unprotected intercourse. The majority (80.5%) of the women were parous and most of the nulliparous women had previous abortions. The efficacy rate of preventing pregnancy was 92.4%. There were no cases of pelvic infection; however, pain and bleeding were common complaints. The authors concluded that insertion of an IUD within 5 days after unprotected intercourse provides an alternative emergency contraceptive method. *(Again, some of the "effectiveness" of this method of emergency contraception is most likely due to preventing implantation rather than preventing conception. Hopefully this method will not catch on in the United States. IUDs are not now a popular method of contraception among American women. RJF)*

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Virjo, I., Kirkkola, A. L. and Isokoski, M. et al. **Contraceptive methods: knowledge sources rated by women and men.** *Contraception* 59 (April, 1999): 257-63.

Determining the source of information that men and women use to understand and make decisions about family planning methods is important for both contraceptive and natural family planning providers. The purpose of this study was to determine the relative importance of various information sources for contraception. Three hundred ninety three women and 395 men were randomly drawn from the Finnish population and asked to estimate the amount of knowledge about contraception they obtained from various sources. The response rates were 56% for women and 45% for men. The three most important sources of information on contraceptive methods for the women respondents were literature, physicians, and women's journals. For the male respondents, literature and the spouse or partner were the most important sources of information. Younger women and men alike received more information from the school nurse and teacher than did older respondents. *(Natural family planning teachers need to be aware of information sources for family planning in their communities and adapt their marketing strategies accordingly. RJF)*

Affandi, B., Korver, T. and Geurts, T.B. et al. **A pilot efficacy study with a single-rod contraceptive implant (Implanon) in 200 Indonesian women treated for < or = 4 years.** *Contraception* 59 (March, 1999): 167-74.

The purpose of this study was to determine the contraceptive efficacy, safety and acceptability with the single-rod implant called Implanon (68 mg etonogestrel) among 200 sexually active Indonesian women with proven fertility. After (4 years of use) and 658.4 women years of exposure, no pregnancies were reported, giving a Pearl Index of 0.0. There were no discontinuations of the implant due to irregular bleeding episodes. The incidence of irregular bleeding and amenorrhea experienced by subjects (7% - 12%) occurred during the first two years of use. There were 3 adverse reactions (2 headaches and 1 case of dyspnea) that resulted in discontinuation. There was only one difficult implant removal that was reported. The authors concluded that single rod implants are reliable, safe, and acceptable method of contraception. *(Whether we will have single rod hormonal implants in the United States remains to be seen. RJF)*

Woodsong, C. and Koo, H. P. **Two good reasons: women's and men's perspectives on dual contraceptive use.** *Social Science and Medicine* 49 (September, 1999): 567-80.

The high rates of unintended pregnancy, sexually transmitted diseases and the heterosexual transmission of HIV in the United States has magnified the concern for promoting the use of two forms of contraception (hormonal and barrier) among sexually active individuals. This longitudinal focus group study was conducted with African-American men and women to determine their attitudes on the use of dual contraception. There was high consensus among both the men and women that condoms should always be used along with another method of contraception. However, the researchers reported that beliefs did not follow actual practice. Although the focus group participants knew intellectually that they should be using condoms for protection (along with another method of contraception) they do not because the use of condoms might signal sexual infidelity and resultant conflict with the partner. The authors concluded that these people are caught in a bind, i.e., distrust in a relationship increases the need for dual methods but using condoms decreases the chance of achieving trust in a relationship. *(I think that the focus groups are right in that use of condoms does decrease the lack of trust in a relationship. I wonder if it occurred to them, and the researchers, that a better way to build trust in a relationship and to decrease the risk of pregnancy and sexually transmitted disease at the same time is through learning to live as sexual men and women in a non-genital way, i.e., to be chaste, faithful and loving. RJF)*

Under the Microscope

The Effectiveness of Natural Family Planning
Robert T. Kambic, MSH

The following is a short summary of a paper presented at a meeting of the Italian NFP Centers Confederation at the Institute for Statistics and Operations Research at the University of Verona in 1997. The entire paper is online at http://popctr.jhsph.edu/publications/wp/papers/wp9907/abstract.html.

Introduction

Why should Catholics give attention and resources to the questions of pregnancy rates in NFP when the Church holds no other method of birth spacing acceptable? Why bother with research and measurement; isn't it enough to know that the Church has spoken? Let us examine these questions. NFP providers have a responsibility to provide accurate information about pregnancy rates and the public has a right to useful accurate information. Professional ethics and public rights and responsibilities are also issues the Church holds dear.

Who is the public interested in the effectiveness of NFP methods? First of all, the couples who use the method. Without interventions to space births, women could have over ten children; today, couples have smaller families. Couples have the right to know the pregnancy rate in order to help make informed decisions about using the method. They also have the right to know if one NFP method is more effective than another. Others include physicians and direct providers of primary and reproductive health care who have a skeptical view of NFP. Scientific evidence of NFP effectiveness overcomes misgivings of health care professionals. Finally, birth rates are vital indicators for government economic and social welfare planning and effectiveness of birth spacing methods is directly linked to birth rates.

NFP providers have a deep interest in the pregnancy rates of the methods they champion. Providers are the NFP experts. They should be able to speak knowledgeably about the methods and they must be able to present information about pregnancy rates supported in the biomedical literature.

The scientific methodology used to evaluate NFP effectiveness is also used to evaluate other birth spacing methods such as the contraceptive pill, condoms, sterilization, etc. This makes cross method comparisons easy in terms of pregnancy and drop out rates, the two numbers we cite when speaking about effectiveness.

There are three ways commonly used to measure unplanned pregnancy in NFP. The first measures the percentage of women using the method who become pregnant. The second is the Pearl rate, measuring the number of pregnancies per 100 women years of use; and finally, the life table giving the number of pregnancies at 12 months per 100 women beginning the study. Let us look at these ways of measuring unplanned pregnancy.

The percentage of women who become pregnant while using a method is used in surveys which compare birth spacing methods in populations. For example, a survey that compares the pill with Norplant can give us some indication of the relative numbers of women in the survey population that became pregnant using those methods. But, this number tells us nothing about how long the women used the method before becoming pregnant. In the midst of a study, as time passes, more and more women who began the study not pregnant become pregnant. The numbers used to demonstrate this process are called rates.

The Pearl rate has a serious error. The longer the observation time of the study, the lower will be the Pearl rate, appearing as if the total number of women pregnant becomes less over time, exactly the opposite of what actually happens. This error makes the Pearl rate an inappropriate measure of the effectiveness of birth spacing. The correct measure of the effectiveness of birth spacing methods is the life table. The life table calculates the percentage of users becoming pregnant in a way that increases over time. Of course, women may drop out of a study for reasons other than unplanned pregnancy. They may stop using NFP, move away,

become ill, or have a planned pregnancy. Life tables can account for all dropouts, and provide accurate pregnancy rates.

There are three ways to conduct studies of NFP: the population survey, the prospective (clinical) study, and the retrospective or historical study. In the population survey, a sample of the general population is asked about their use of birth spacing methods. To conduct a prospective study we study the records of and interview NFP users rather than interviewing a sample of the general population. In the strict sense, NFP effectiveness studies cannot be prospective clinical trials because in a clinical trial there is both a treatment group and a control group where persons in both groups are studied over the same time period. NFP effectiveness studies fall into the category of observational studies where there is only an observed group which is self selected, that is the NFP users, and there is no comparison group. In a concurrent study, data is collected as the women use the method. In a historical study, the investigator examines the clinical records of the users at a later date.

Problems and sources of error in studies

Scientific data that can help people, that can answer questions, is difficult to collect, analyze, and interpret. There are many sources of error that can produce inaccurate and incorrect study results. These problems are not unique to NFP.

First, the category of "Lost to follow up" (LFU) is a major concern in studies. "Lost to follow up" occurs when we do not know what happened to a woman who began the study. Did she stop using the method? Is she pregnant? We either must find and interview her, or classify her as lost to follow up. If many users are LFU, the results of the study can be questioned. What if they all had a pregnancy or stopped the method because they were unhappy with it? We just don't know.

Another issue is called the "generalizability" of the study. If we survey women age 40 to 50 and find a low pregnancy rate can we say the same for women age 20 to 30? Obviously, the answer is no. If a study is done in Italy, will the conclusions be true for the rest of Europe, for Africa, for North America? Our study group may be so selective, that only women with similar characteristics will have similar experience. In particular because users in NFP studies are self selected, NFP studies may report good results because couples disposed to use NFP will be less likely to drop out or to become pregnant than couples who are neutral about NFP.

Surveys and retrospective studies interview people about events that took place in the past, but time plays tricks with memory. Subjects may not remember, or they may have selective memory where they remember only certain things. If a woman has an unplanned pregnancy and we interview her about it at a later time, she may try to rationalize it. Inaccurate, incorrect, and selective memory are all elements of recall bias.

Another source of error occurs when scientists and directors of studies have a hypothesis or idea which leads them to expect certain behavior, or a certain result; they may even impose their views on the study and may neglect observations or results which do not fit their hypothesis. This is called observer bias. Observer bias is the reason for "blind" or "masked" studies. In testing drugs to control cancer, for example, the users are randomly given either a placebo or the drug. Neither the patient nor the investigator knows who is taking which of the two treatments. Both groups will be treated equally. Random assignment to a group using NFP or a group not using NFP would be difficult, and is unethical. Obviously masking is not possible because users and investigators will know who is using which methods.

Concurrent studies are also subject to observer bias. For example, an over zealous investigator might provide too much attention or follow up and pressure users and as a result users might either drop out of the study or have fewer pregnancies. The number and timing of follow up visits of the client to the clinic has been shown to be related to NFP effectiveness.

Observer bias can be introduced in other places in the study, such as in the structure of the questions to be asked. To NFP advocates the following terms are all quite different: rhythm, calendar method, periodic abstinence, counting days, safe period, BBT, Ovulation Method, Billings, Basal Temperature, and Sympto-Thermal. An investigator who is not familiar with NFP may think all of these terms are equivalent and treat them as such. An NFP advocate would question the validity of a study which treated these terms interchangeably.

NFP studies have their own particular problems that may cause results to differ from study to study. When does a study begin and end? Does it begin when the woman says she will use NFP, when she charts her first day, her first month, or her third month? Some studies have permitted a learning and an effectiveness phase which begin some time after the woman begins to chart. What if she used NFP before the study begins? Should she be included? Trussell recommends that women be interviewed three months after the study closure date to ensure that all pregnancies occurring during study dates be included because a woman may unknowingly be in the early stages of pregnancy on the last day of the study.

The objective of an NFP effectiveness study can be stated very clearly; we answer the question, "Of those women entering the study, how many have become pregnant after 12 months of use?" Study entry criteria should allow only women intending to avoid pregnancy to begin the study. We observe these women to an end point: pregnancy, discontinuation, or study closure. Women can leave the study at any time in order to discontinue or to become pregnant. We therefore assume that any woman who remains in the study wants to avoid pregnancy. All we ask is that they notify the study before they attempt to become pregnant and we drop them from the study of women avoiding conception. We classify an unplanned pregnancy as a pregnancy occurring to a woman in the study. This rule avoids several problems.

The first problem is user ambivalence. A woman may be ambivalent about pregnancy, and decide, once she is pregnant, that she planned the pregnancy. She may be embarrassed that she either did not understand or did not follow the rules because of the circumstances of that particular day. The second problem is investigator bias in classification of pregnancies where pregnancies are discounted by the scientist leading to lower pregnancy rates.

In another approach, Hilgers argues that conceptions occurring from intercourse during identified infertile days are the only ones that can be classified as unplanned and conceptions from intercourse during fertile days are achieving-related. Hilgers' definition of unplanned pregnancies results in almost no unplanned pregnancies, and pregnancy rates which use this definition of unplanned pregnancy cannot be compared with rates using the standard definition above.

In the past, NFP studies compared “user failure rates” with “method failure rates.” User failures were pregnancies resulting from intercourse in the fertile time and method failures from intercourse in the infertile time. The calculation of these rates was erroneous (similar to the Pearl rate). Trussel and Grummer-Strawn demonstrated correctly calculated rates called perfect and imperfect use, rather than user and method failure. The overall unplanned pregnancy rate is not changed by the new terms and we are able to use data from older studies reported as total unplanned pregnancy rates.

What are the criteria for a well-designed NFP study? One must be aware of bias and sources of variance and to try to control for them. The study should have a clear objective, valid definitions, a clear beginning and end date, well-defined endpoints, and life table rates. The NFP methods should be standardized throughout the study period although they can differ from center to center. Pregnancies should be analyzed by at least two objective observers, especially when calculating perfect and imperfect rates.

Pregnancy Rates

Let us first examine calendar rhythm because it is a natural method and it can be useful to women who understand how to apply it. There are only five useful reports on calendar rhythm, and using these studies I estimate a 12 month pregnancy rate of 15.0+ 4.0. That is, after one year of correct calendar rhythm use, about 15 women will become pregnant who didn't plan to do so. It may be that calendar rhythm is in the same range of effectiveness as modern NFP. The projected rhythm pregnancy rates, 15.0 are within the range of modern NFP methods shown here below. The advantages of the Calendar Rhythm include those of other Natural Methods. It is low cost. After an initial learning time, a woman can use it without the need to purchase supplies or to return for medical follow up. It has no medical contraindications. It can be taught by para-professionals releasing medical personnel for other tasks. Additionally, Calendar Rhythm may have some unexplored advantages. There is no need to chart temperature or mucus daily. A

woman simply keeps track of her cycle on a calendar and uses safe days for intercourse. It is essential that women wishing to use calendar rhythm do have records of the cycle length of their six previous cycles and preferably the previous twelve. Of course, any woman with irregular cycles is not a candidate for this method. This includes women with a previous cycle variation of more than seven days in the prior six cycles.

Let us turn to modern NFP methods. Table 1 shows the results of analysis of 38 NFP studies published since 1974. There is a significant difference ($p<.02$) in the pregnancy rates of the ST (10.2+2.5) and OM (16.0+3.3) but the discontinuation rates are virtually identical, ST (37.2+18.1) and OM (38.7+9.2). Users' age is also similar between ST (27.3+.5) and OM (28.8+1.8).

Based on the criteria above, I have chosen two best NFP studies. The Rice (1981) study is a sympto-thermal study of experienced users and the WHO OM (1981) study is of new users with a learning and an effectiveness phase. The life table rates in the Rice study vary from 3.3 in Canada to 15.6 in Colombia with an overall mean of 8.2. The WHO study rates range from 17.7 in Ireland to 33.2 in El Salvador with an overall mean of 22.3. In so far as best use, in the European collaborative study the life table pregnancy rate is reported by Frank-Herrmann (1997) as 2.9 which is one of the lowest life table pregnancy rates ever reported and is close to the perfect use rate (3.1) for the WHO OM study reported by Trussel and Grummer-Strawn . Figure 1 graphically represents comparisons of the 38 studies with that of the best studies and best use..

Life table rates examined by year over the past 25 years show a significant decrease in more recent years. This trend is due to several factors: we are getting better at NFP and getting better at NFP studies. The rules of NFP have been clarified, teaching is standardized, and teachers are better trained. We understand the necessity of following up for proper education and use of the method. Furthermore we now understand how to conduct an NFP observational study. There is more selection of users, and we allow women to change their intention from avoiding to planning and to leave the study.

Using two separate approaches to examine the data, by multivariate analysis of life table rates, and by choosing the “best” NFP studies, ST shows itself to have lower unplanned pregnancy rates than the OM. This is probably because of the increased abstinence of ST methods whereby there is a cross check to identify fertility and using the most conservative of signs.

How effective is NFP? It is not as effective as the pill, sterilization, or implants which have pregnancy rates less than three. It is as effective as the barrier methods of birth spacing, the condom, foam and diaphragm which have average pregnancy rates between ten and twenty. We know that in any group of couples using NFP to space pregnancy, there are those who will take chances and have intercourse in the fertile time. There are also couples who have a low

conception threshold, or high fertility, and will be more likely to become pregnant. The pregnancy rate of any group of NFP user couples will depend on the proportions of risk takers and high fertility couples in the cohort. We also know from the studies of Trussell and others that if the NFP rules are followed, if couples are perfect users, the probability of pregnancy is quite low, less than 5%. Couples who follow the rules for abstaining when signs of fertility are apparent, can use NFP with confidence that they will not become pregnant.

Table 1. NFP studies from 1974 to the present, life table unplanned pregnancy and discontinuation rates and age of the user by ST or OM method.
NS = not significant

	Sympto-Thermal	Ovulation	
	N=15	N=23	p
Unplanned Pregnancy	10.2	16.0	<.02
Discontinuation	37.2	38.7	NS
Mean Age of User	27.3	28.8	NS

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