Natural Family Planning
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In this issue

Natural Family Planning

Persona Enhances Fertility Awareness and Desire for Children

Persona is a hand held electronic fertility monitoring device designed (by Unipath Diagnostics Company) to help the female user avoid pregnancy. The monitor measures urinary metabolites of estrogen (estrone-3-glucuronide) and luteinizing hormone (LH) with the use of urinary assay test sticks. A threshold level of urinary estrogen indicates the beginning of the fertile phase and the detection of the LH surge provides the signal for the beginning of the end of the fertile time. The monitor provides the user with a green signal light to indicate an infertile day, a yellow light to indicate that a test is needed, and a red light to indicate the fertile phase. The fertile phase lasts from 6-10 days. The device was designed for use by women with menstrual cycles in the range of 23-35 days. Persona is not available in the United States. It is readily available in Europe. A device similar to Persona called the Clearplan Easy Fertility monitor (see next article) also made by Unipath is sold in the US as an aid to achieve pregnancy, not to avoid it.

In order to determine the suitability of Persona as a contraceptive device, researchers from the University of Amsterdam surveyed 273 Persona users who called the Unipath help-line service in The Netherlands (Janssen et al., 2000). Of these 273 users, 137 or 51% responded. The respondents were for the most part highly educated and had an above average income for the Netherlands. Most (84%) were either married or in a steady relationship with a man. Sixty-four percent of the respondents were using oral hormonal contraception, about 15% were using condoms and only 4.4% were using some form of Natural Family Planning prior to using Persona. An interesting fact was that 25% of the respondents were using the monitor to become pregnant rather than to avoid it.

The survey showed that the most cited reasons for using Persona were the absence of side effects, and that there was no longer a need to rely on a medical method to avoid pregnancy. Many of the respondents also cited as a benefit of using Persona that it provided insight or information about their menstrual cycles. The most cited disadvantage of the monitor was that it was too expensive (both the monitor and the test strips). About 71% of the couples who used the monitor to avoid pregnancy also used condoms or withdrawal during the fertile phase.

The authors concluded that Persona is a welcome alternative form of NFP for those couples who are open to pregnancy. They assumed that the Persona was not reliable enough to be used as a contraceptive device when the couple had serious reasons for avoiding pregnancy. They also concluded that Persona improved fertility awareness and a desire to have children.

Comments

The study has several limitations. The method of recruiting respondents is flawed. All respondents were self-selected callers to a help-line. Persona users who did not call the help-line were not included in the study. The authors used a 27 item multiple response questionnaire consisting of 7 open-ended questions. Information is not given on the content of the items, questions, or response categories. Furthermore, the authors do not discuss the issue of the questionnaire's validity or reliability. The authors noted that 9 women who were using the Persona as a contraceptive device became pregnant. They concluded from that evidence that the monitor was not very effective for pregnancy avoidance. They presented a Pearl effectiveness rate to avoid pregnancy of 94%. Based on that evidence they state that it is not as effective as hormonal contraception or sterilization. They assumed that all of the pregnancies were not intended.

Of interest is the authors' statement that only 1% of reproductive age women in the Netherlands use NFP as a means to achieve or avoid pregnancy. The respondents in this study were mostly women who previously used oral hormonal contraception. This seems to indicate that a new technological device such as Persona could attract new couples to use NFP. However, there seems to be a lack of understanding of ways to live with abstinence and how to integrate fertility into expressions of human sexuality. The mere monitoring of fertile and infertile days has limitations in that regard. Integrating Persona or similar fertility devices into a method or system of NFP that included help in integrating fertility might solve that problem.

Janssen, C. J. M. and van Lunsen, R. H. W. **Profile and opinions of the female Persona user in The Netherlands.** *The European Journal of Contraception and Reproductive Health Care* 5 (2000): 141-146.

German Researchers Demonstrate Accuracy of the ClearPlan Fertility Monitor

The ClearPlan Fertility Monitor (CPFM) is a hand held home use device similar to Persona except that it is designed to help couples achieve pregnancy rather than to avoid it. Both fertility devices have been developed, produced and marketed through Unipath Limited (Bedford, UK). Like Persona the CPFM measures urinary metabolites of estrogen and LH with the use of a test strip assay method. The device, however, is calibrated to pick up a higher threshold level of estrone-3-glucuronide. It thus gives a shorter window of fertility than Persona. Furthermore, unlike the Persona monitor, ClearPlan does not utilize a colored light feedback system but rather indicates to the user whether she is in a state of “low,” “high” or “peak” fertility. The “peak” fertility icon on the monitor is triggered when a urinary LH surge is detected.

Researchers from the University of Munster, Germany reported the first independent study to determine the accuracy of the CPFM in comparison with serial transvaginal ultrasound and serum hormone measurements among a population of healthy women. (1) The aim of the study was to test the home use performance of the CPFM for predicting ovulation and determining of the potentially fertile period. Fifty-three volunteer women between the ages of 21 and 33 (mean 26 years) with cycle lengths between 21 and 42 days utilized the Clearplan monitor for three consecutive cycles. They also attended a clinic to have their blood sampled for LH and estradiol and follicles examined by the use of transvaginal ultrasound. The day of ovulation was defined as the day when the dominant follicle had disappeared. The 53 volunteers produced 150 usable cycles with a mean cycle length of 28 days (range 24.5 - 34.5).

The results showed that 63.5% of all cycle had up to 7 days warning of ovulation (mode = 6 days). In 91.1% of the cycles ovulation occurred during the 2 days of the CPFM peak day readings and in 97% of the cycles ovulation occurred in the two days of peak fertility or the one following day of high fertility. In most cycles (76.3%) ovulation occurred on the second day of peak fertility. Ovulation never occurred before the two days of the CPFM peak fertility. Based on the knowledge that the highest pregnancy rates occur with intercourse one day before the day of ovulation (2), the authors concluded that if a coupled wished to achieve a pregnancy, the best day for having intercourse is the first day of the Clearplan peak. The authors believe that the monitor has potential as a diagnostic aid for the assessment and treatment of infertility.

Comments

It should be noted that of the 150 cycles recorded by the 53 women volunteers, 14 did not have a monitor detected LH surge along with an ultrasound confirmed ovulation. The CPFM does not detect the LH surge in about 1 out of 10 cycles. This could be due to the fact that the early morning urine test misses an LH surge that occurs in the evening for some women. The monitor, however, will most likely give an indication of “high” fertility on those days. Another important is the results of this study were generated with young healthy women with fairly regular menstrual cycles. Studies would need to determine the usefulness of this monitor with women who have infertility problems.

Since the CPFM provides the user with a mode of 6 days of fertility and in over 60% of cycles, a 7 day warning of ovulation, it would seem this monitor could be used as an adjunct in helping women to avoid pregnancy. This, however, would be an off label use of the monitor. Studies are currently underway to determine the usefulness of the CPFM as an aid to learning NFP (in conjunction with cervical mucus and/or basal body temperature monitoring).

1. Behre, H. M., Kuhlage, J. and Gassner, C. et al. **Prediction of ovulation by urinary hormone measurements with the home use Clearplan Fertility Monitor: comparison**

with transvaginal ultrasound scans and serum hormone measurements. *Human Reproduction* 12 (2000): 2478-2482.

2. Dunson, D. B., Baird, D. D. and Wilcox, C. R. **Day specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation.** *Human Reproduction* 14 (1999): 1835-1839.

Only 22% of Certified Nurse Midwives in the United States Would Offer NFP as an Option for Child Spacing

Since certified nurse midwives (CNMs) practice from a philosophical stance that advocates the use of non-pharmacological approaches to women's health care and promotes practices that integrate the whole person, it might be expected that natural means of child spacing would be utilized, promoted and prescribed. CNMs also believe that a natural process (such as childbirth) should not be medicalized and that women should be attuned to their natural biological signals. These philosophical stances seem to be in alignment with the philosophy behind natural methods of family planning and with breast-feeding.

In order to determine the knowledge and promotion of NFP among practicing CNMs, researchers from Marquette University and the University of Utah surveyed a national random sample of 1,200 CNMs selected from a membership list of the American College of Nurse Midwives (ACNM).(1) Of the 514 CNM respondents (42.8% return rate), 450 (or 87.5%) were currently practicing as CNMs. The average age of the respondents was 46 years (range 26-66 years) and the average number of years of practice was 10 (range .5 to 40.5). The survey mailed to the CNM respondents was a modified form of the 14-item Stanford Brief Physician Opinion Questionnaire on Natural Family Planning.

The CNMs who responded rated methods of NFP as the ninth most frequently used among their clients and the eighth most effective method of family planning among 11 methods listed. The CNMs felt they were on average somewhat prepared to provide NFP for their clients. In fact, 50.2% of the CNM respondents felt prepared enough to provide NFP instruction themselves. However, only 22% would offer NFP as a family planning option. The CNMs ranked the average modern method of NFP (OM and STM) perfect-use effectiveness as 88% and the typical-use effectiveness around 70%. About one fourth of the respondents felt that breast-feeding (the LAM algorithm) was not a reliable form of family planning and 34.8% felt that the efficacy of total breast-feeding to avoid pregnancy extended to 6 months postpartum. Respondents projected that 17.1% of women using LAM would get pregnant unexpectedly in a 6-month time frame.

In comparison with 804 Missouri physicians that were surveyed in a similar study reported by Stanford, Thurman and Lemaire, (2) the CNMs in the current study were somewhat more knowledgeable about the efficacy of NFP and used it more often in their practices. More than 75% of the CNMs versus 41% of the physicians ranked the best possible effectiveness of NFP as greater than 81%. CNMs also more readily recommended the use of NFP for their clients and were more up-to-date in their recommendations then were the Missouri physicians. Sixty three percent of CNMs would mention NFP as an option to select women compared to only 36% of physicians.

The authors speculated that the reason that only 22% of the CNM respondents would recommend NFP is that many of the clients that CNMs work with come from vulnerable groups such as single mothers, adolescents, and those not in stable relationships. Therefore the prerequisites of mutual motivation, understanding and consistent use necessary for use of NFP would not apply. Furthermore, CNMs also felt that NFP was not all that effective and that it took quite a lot of work to teach women about NFP, i.e., it would be hard to fit into a busy practice because of the intensity of teaching. Contraceptive methods such as oral hormonal contraception and hormonal injections are perceived to be more effective and much easier to provide. Finally, many CNMs are not adequately prepared to provide modern NFP services.

Comments

Another reason (not investigated) that the CNMs might not be providing NFP services is that they themselves are most likely not using NFP as their method of family planning. A recent study of female physicians reported that less than 2% of that group used NFP. It would be of interest to do a similar study among CNMs to determine their personal use of methods of family planning.

It would also be of interest to study CNM educational programs to determine how much content is offered on the topic of NFP and in what context. In my work, I have often found CNMs open to NFP. However, their "openness" is often tempered by their belief that they need to provide an array of contraceptive methods to meet the varying needs and wishes of their clients.

1. Fehring, R. J., Hanson, L. and Stanford, J. B. **Nurse-midwives' knowledge and promotion of lactational amenorrhea and other natural family planning methods for child spacing.** *Journal of Midwifery and Women's Health* 46 (Mar/April, 2001): 68-73.

2. Stanford, J. B., Thurman, P. B. and Lemaire, J. S. **Physicians' knowledge and practice regarding natural family planning.** *Obstetrics and Gynecology* 94 (1999): 672-678.

3. Frank, E. **Contraceptive use by female physicians in the United States.** *Obstetrics and Gynecology* 94 (1999): 666-671.

100% Efficacy Reported In Multi-site International Study of LAM

Since the 1988 Bellagio Consensus Conference codified the criteria necessary to have confidence in the natural infertility that is provided through lactation, a number of studies have been conducted to provide these criteria with a stronger scientific base. The criteria established are that if a woman is amenorrheic, is totally or near totally breastfeeding, and is under 6 months postpartum then she has less than a 2% chance of pregnancy within the first 6 months after the birth of her child. The name given to these criteria and the subsequent algorithm is Lactational Amenorrhea Method or LAM. A number of studies have been reported on the efficacy of this breast-feeding infertility algorithm. The most recent was a collaborative effort between the Georgetown University Institute for Reproductive Health and the World Health Organization.(1) In that study, 519 women were followed on a monthly basis over a six month period. The results showed a life table efficacy of avoiding pregnancy of 98.5 (+ 0.07). Furthermore, 62% of the women participants continued the method into the sixth-month postpartum.

The Georgetown University Institute for Reproductive Health coordinated a subsequent study with the collaboration of the United States Agency for International Development and the World Health Organization.(2) They were able to coordinate the effort of 10 different research sites in 8 different countries, including England, Germany, Italy, Sweden, the Philippines, the United States, Mexico, two sites in Nigeria, and Egypt. Unlike the previous study, the participants in this study were only contacted once (at the seventh month of participation) after enrollment. In each of the 9 sites from 10 to 50 volunteer breast-feeding women were recruited for a total of 362 women of which 302 (83.4%) were included in the analysis. The mean age of the 302 participants was 28.2 years, the mean parity 2.8 children, and the mean years of education was 9.8. However, only 6% of the volunteers worked outside the home at 6 months postpartum.

Since there were no reported pregnancies at the 7-month follow-up, the 6-month efficacy of LAM was 100%. This result was based upon 1,705 women-months of use. The probability of continuing LAM through the sixth month postpartum among those still eligible was close to 85%. Furthermore, more than half of the participants completed the 6 months of LAM use. Most of those who stopped LAM (15.4% of the total sample) did so due to the return of menses. Of interest is that 65 to 70% of the women volunteers remained amenorrheic at 7 months. Satisfaction with LAM was also high among the participants with 86.4% reporting being very satisfied and 91.7% indicating that they had no problem with using the method. Another

interesting finding is that close to 72% of the participants chose to use another method after discontinuing LAM and the most frequent method (19.7%) was some form of NFP.

The authors concluded that LAM can be used effectively in a variety of ethnic and cultural settings even with limited counseling. Furthermore, duration of use and satisfaction was high both in industrialized and developing countries. Therefore the results provide further scientific evidence for worldwide acceptance of LAM and indicate that LAM should be offered along with other modern methods of family planning.

Comments

The authors forthrightly point out the limitations of the study: there was a small sample size; participants were self-selected and self-reported; and data was pooled. The most serious limitation, however, was that the volunteers were not representative of the total population of family planning clients. This is demonstrated by the fact that only 6% worked outside the home (in fact none of the volunteers in the U.S. worked outside the home) and almost 20% chose to use NFP after discontinuing LAM.

What is usually not emphasized along with the three main LAM criteria--i.e., totally breastfeeding and within 6 months postpartum--is that there should also be no long intervals between breast-feeding, and that night breast-feeds are important. Variation from these criteria can increase the pregnancy rate. For example, a recent prospective study conducted among 170 urban middle-class Chilean women separated from their infants by work resulted in a 6-month pregnancy rate of 5.2% with the use of LAM.(3) Although the women were monitored on a monthly basis and were taught how to manually express their milk, the pregnancy rate was higher than the pregnancy rate in those women who did not work. Of interest in the Chilean study is that only 28.2% of the study participants met the LAM criteria at 6 months. This is about half the level found in the non-working participants in previous studies on LAM. The authors concluded that women using LAM should be informed that separation from the infant might increase their risk of pregnancy.

1. Peterson, A. E., Perez-Escamilla, R. and Labbok, M. H. et al. **Multicenter study of the lactational amenorrhea method (LAM) III: effectiveness, duration, and satisfaction with reduced client-provider contact.** *Contraception* 62 (2000): 221-230.

2. Labbok, M. H., Hight-Laukaran, V. and Peterson, A. E. et al. **Multicenter study of the Lactational Amenorrhea Method (LAM): I. Efficacy, duration, and implications for clinical applications.** *Contraception* 55 (1999): 327-336.

3. Valdes, V., Labbok, M. H. and Pugin, E. et al. **The efficacy of the lactational amenorrhea method (LAM) among working women.** *Contraception* 62 (2000): 217-219.

Research Briefs

Side of Ovulation Found to be Random among Women with Normal Fertility

Renewed interest in the side of ovulation arose when researchers noticed among infertile women that the dominant follicle in contralateral ovulations are "healthier" than those occurring in the ipsilateral side. Healthier means that the follicular diameter, phase length, and hormones are normal. To determine if this is so, French researchers conducted a study among fertile women to test if ovulation alternates from right to left ovary in successive cycles and whether the site of ovulation affects the next cycle length and/or hormone profile. Eighty healthy women between the ages of 19 and 42 (mean 32.3) from eight centers in Europe were recruited for the study and monitored with ultrasonography and urine hormonal assays to determine the day and side of ovulation. The volunteers yielded 199 cycles of which 104 or 52.3% showed a right-sided ovulation and 61 (51.3%) of the 119 pairs of succeeding cycles showed an alternate side ovulation. The follicular size, phase length or hormonal profile did not differ between ipsilateral and contralateral ovulation in the follicular or luteal phases of the cycles. The authors concluded that in women with normal fertility, the side of ovulation is a rather random event, independent of the side in the previous cycle. They also concluded that the hormonal profile and cycle length are independent of the side of ovulation from the previous cycle.

Comments

This research points out the importance of determining what is a "normal" parameter of the menstrual cycle among "healthy" women with normal fertility. Of interest is that experience in NFP was one of the criteria for participating in the study. Another finding of interest is that the mean follicular phase length was 14.59 days (SD = 0.33) and the mean length of the luteal phase was 13.64 days (SD = 0.25). Based on the standard deviations, there was little variation in either phase of the cycles. There was also little variation in whether the lengths were calculated from ipsilateral or contralateral cycles.

Ecochard, R. and Gougeon, A. **Side of ovulation and cycle characteristics in normally fertile women.** *Human Reproduction* 15 (2000): 752-755.

Study Finds Increased Compliance with Contraceptive Patch

A new system of delivering contraceptive steroids to women that has been researched in the United States and Canada is the contraceptive patch. The contraceptive patch is a transdermal method of delivering 150 mg of norelgestromin and 20 mg of ethinyl estradiol daily to the systemic circulation. A new patch is applied to the buttocks, upper outer arm, lower abdomen or upper torso each week for 3 consecutive weeks with one week off. Data from the 1995 National Survey of Family Growth indicate that the first-year failure of 7.3% to 8.5% with oral contraceptives is due largely to non-compliance. A randomized prospective study was conducted to determine if there was any difference in efficacy, compliance, cycle control and safety between the transdermal patch and oral contraceptive (OC) pills.(1) A total of 1,417 healthy adult women from 45 clinics in the United Sates and Canada were randomly assigned to use either the contraceptive patch (n= 812) or an OC pill (n= 605). Although not statistically significant, the overall and method failure rates (Pearl-Indexes) were numerically lower with the contraceptive patch (1.24 and 0.99, respectively), than with the OCs (2.18 and 1.25 respectively). The mean proportion of the participant's cycles with perfect compliance was 88.2% with the contraceptive patch versus 77.7% with the OC pill ($p < .001$). In the first two cycles of use, there was more break-through bleeding with the patch group and significantly more site reactions, breast discomfort and dysmenorrhea. The authors concluded that although the contraceptive patch is comparable to efficacy and cycle control with OCs, compliance was better with the patch.

Comments

Although compliance was high among the patch group, you would expect this since they were part of a study and had to sign a consent form for participation. I wonder what actual compliance would be with everyday use in a non-study context. The overall incidence of headaches, nausea, and application site reactions was over 20% in the patch group and the incidence of breast discomfort, upper respiratory tract infection, and dysmenorrhea was over 13%. These reactions are not life threatening, but they certainly would contribute to discontinuation and non-compliance.

Audet, A. C., Moreau, M. and Koltun, W. D. et al., **Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs an oral contraceptive.** *Journal of the American Medical Association* 285 (2001): 2347-2354.

Failure Rate of Periodic Abstinence Is Over 36% In First Two Years of Use

Researchers at The Alan Guttmacher Institute (AGI) pooled data from the 1988 and 1995 National Survey of Family Growth to get a better picture of failure rates (i.e., unintended pregnancies) among women using reversible methods of family planning.

The AGI researchers corrected the 1995 survey results for underreporting of abortions by using the data collected on frequency of abortion by the AGI in 1987 and 1994-1995. They determined that in the first year of use 23.5% of women who use periodic abstinence methods of family planning experience an unintended pregnancy, 13.4% in the second year and a combined total of 36.8% in the first two years of use. This compares to 7.0% of women experiencing unintended pregnancies in the first year of use, 4.8% in the second and 11.7% for the combined first two year of use for oral contraceptive (Pill) users. They said periodic abstinence is about the same as withdrawal, which had a 24.1% failure rate in the first year, 12.4% in the second year and 36.4% in the first two years.

Of interest is that the unintended pregnancy rate of cohabiting women (21.2%) is double that of married women (10.0%) in the first year of use for all methods combined. Only 20% of black women using reversible contraceptive are married compared with more than 50% of white and Hispanic women. The authors concluded that "family planning providers should help clients identify methods that they are most likely to use successfully and counsel them on how to be consistent users and to avoid behaviors that contribute to method failure."

Comments

Obviously NFP methods when used by couples trying to avoid pregnancy, work better for those who are married and who have behaviors that demonstrate consistent use and accurate observations of their fertile signs. The periodic abstinence users in this report utilized all methods of NFP including Rhythm, BBT, and the modern methods of NFP. Many of the users who were not married reported the use of Rhythm so as to show that they were responsible in avoiding pregnancy. I personally doubt that these couples were actually using Rhythm. I question that they were familiar with Rhythm instructions. Rhythm to many users means that they abstain on the 14th day of the cycle. The data on periodic abstinence are somewhat skewed.

Ranjit, N., Bankole, A., Darroch, J. E. and Singh, S. **Contraceptive failure in the first two years of use: differences across socioeconomic subgroups.** *Family Planning Perspectives* 33 (2001): 19-27.

Oral Contraceptive Pill Not Popular Option in Japan

In June of 1999, the oral contraceptive pill was legalized for use in Japan. A survey in 1998 revealed that the most common method of contraception among married Japanese women of childbearing age was the condom (78%), followed by Rhythm or BBT (8%), withdrawal (7%) and female sterilization (5%). Of interest was that 17% of unmarried sexually active women used rhythm or BBT. In March of 1999, Japanese and United States researchers conducted an in-person interview among a nationwide probability sample of 1,025 men and women to determine their attitude about the pill. Six hundred thirty (61%) chose to respond. Surprisingly only 12% of the respondents said that they intended to use the pill if it was approved. The most frequently cited negative response was the fear of side effects. More than one third (35%) felt that the pill would undermine sexual morality. About one quarter of the respondents (23-26%) did not realize that the pill does not protect against STDs. The authors' conclusion (and concern) was that condom use will decrease in Japan and that Japanese men and women need to be educated that the pill does not protect against STDs. They also urged Japanese policy makers to encourage dual method use (condom + pill) in Japan.

Comment

As reported in this article, in the year since the pill was legalized in Japan only 1% of women of childbearing age are using the pill. Japanese women seem to be voting on the pill with non-use. The authors stated that the pill should bring greater satisfaction in contraceptive use with men and women. They also said that they believed that the pill will be popular among young unmarried couples and adolescents. (*Is this not another way of saying it will increase immorality? RF*) It will be interesting to see if contraceptive satisfaction increases in Japan, if the STD rate decreases or increases, if condom use drops and if indeed the pill will help to undermine sexual morality. Only time will tell.

Kihara, M. O., Kramer, J. S. and Bain, D. et al. **Knowledge of and attitudes toward the pill: result of a National survey in Japan.** *Family Planning Perspectives* 33 (2001): 123-127.

How Emergency Contraception Works Still In Doubt

Besides delaying or suppressing ovulation, one theoretical mechanism of emergency contraception is that the high doses of female hormones (i.e., 100 mg of ethinyl estradiol and 1 mg of norgestrel given in the Yuzpe regimen) somehow disrupts or toughens the endometrium and inhibits implantation of the developing human embryo. This mechanism of action for many individuals would be considered an early abortion and very problematic. Previous research had indicated some interference of action on the endometrium. To further investigate the effects of emergency contraception and in particular the Yuzpe regimen on endometrial receptivity,

researchers from the University of North Carolina-Chapel Hill followed 19 parous women for two menstrual cycles. In both cycles, the researchers measured multiple markers of uterine receptivity. In the second cycle, the women volunteers took 100 mg of ethinyl estradiol and 1 mg of norgestrel on the day of the urinary luteinizing hormone (LH) surge and a second dose 12 hours later. Based on endometrial biopsy results and serum progesterone levels it appeared that all 19 women ovulated. However, although the researchers found significant differences between the treated cycles and the untreated cycles on five measures of endometrial receptivity, in most of the measures (e.g., endometrial histology or the expression of the beta 3 integrin subunit) there were no significant differences. In other words the researchers found no striking effects on the endometrium that would cause the disruption of implantation.

Comments

However, the researchers did admit that the measurement timing and techniques used in this research might not have detected how the Yuzpe regimen actually affects the endometrial lining. The researchers also speculated that the regimen could work in other ways such as interfering with sperm transport, tubal motility, or the fertilization process. Of interest is that there was a recent report of an ectopic pregnancy in a 26 year old woman who took emergency contraceptive pills 8 hours after being sexually assaulted.(2) The authors of that report recommended that contraceptive providers and package inserts advise women that ectopic pregnancies can occur with emergency pill failure.

1. Raymond, E. G., Lovely, L. P. and Chen-Mok, M. et al. **Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity.** *Human Reproduction* 15 (2000): 2351-2355.

2. Nielsen, C. L. and Miller, L. **Ectopic gestation following emergency contraceptive pill administration.** *Contraception* 62 (2000): 275-276.

Feasibility of Mifepristone as a Once a Month Contraceptive Pill

Mifepristone (also called RU 486) is an anti-progesterone pill developed to cause an early chemical abortion. Researchers from the University of Edinburgh designed a study to determine how effective mifepristone would be to prevent pregnancy if used as a once a month contraceptive pill. The motivation was that previous studies have shown women would be interested in a once a month pill and that women do not like taking a daily steroid pill that might have long term medical consequences. The researchers recruited 32 healthy female volunteers from a family planning clinic and 20 healthy women volunteers who were trying to conceive as a control group. Each woman volunteer was given a Clearplan Easy Fertility Monitor (CPFM) so that she could monitor her cycle for the day of the LH surge and the peak of fertility. The 32

volunteers in the experimental (treatment) group were given 200 mg of mifepristone two days after the LH surge for one to seven menstrual cycles. The 20 volunteers in the control group attempted to achieve a pregnancy by focusing intercourse on the high and peak days of the monitor. (*See the second article in this issue of the CMR for a description of the CPFM*). The treatment group produced 178 cycles for analysis and the control group 50 cycles. The treatment group had 2 documented pregnancies, yielding an effectiveness rate of 95-97% for pregnancy avoidance. The control group had 12 conceptions which yielded a pregnancy rate of 25-32%. The variability of effectiveness rates was due to whether the women volunteers were actually in the early luteal phase when they took the mifespristone pill. The participants experienced few side effects (mostly slight vaginal bleeding) and no disruption of the timing of the subsequent menstrual bleed. The authors concluded that the combination of a home use fertility monitor and a once a month administration of mifespristone is an attractive contraceptive option.

Comments

Please note that the administration of mifespristone in the early luteal phase probably acts as an early chemical abortifacient, not as a contraceptive pill. Mifespristone works by retarding endometrial development and thus would inhibit the implantation of an early human embryo. Of interest is that some of the women in the treatment group found monitoring their cycles too stressful, and found the 6 hour time period in which they had to conduct a simple urine test with the CPFM too restrictive. Many of these women were co-habitating or sexually active outside of marriage.

Hapangama, D. K., Brown, A. and Glasier, A. F. et al. **Feasibility of administering mifepristone as a once a month contraceptive pill.** *Human Reproduction* 16 (2001): 1145-1150.

Under the Microscope

Being A Good Consumer of NFP Research

In order to be good consumers of NFP and NFP related research, NFP teachers should have some understanding of what is quality research. This knowledge will enable the NFP teacher to read and cite good research reports and possibly to use results of research in practice. If poor research is cited, or even guides practice, problems can result. One result of citing poor research is loss of credibility. Utilization of findings from research of questionable quality could result in poor teaching practices, utilization of inaccurate markers of fertility, and/or use of ineffective natural methods of avoiding or achieving pregnancy.

Although there are many valid ways of gaining scientific knowledge, such as through logical thinking, experience, trial and error, and intuition, research methods are recognized by scholars and modern society as the best and most systematic processes for developing a body of knowledge. Furthermore, research that is published in recognized scholarly peer-reviewed journals is one of the best sources of new knowledge on a topic and an important tool for stimulating change. Research articles that are reviewed and abstracted for CMR, for the most part, are taken from peer-reviewed scholarly journals.

Research Basics

There are some broad criteria that NFP teachers can utilize to judge what is good research. These criteria involve knowing some of the basic steps of the research process, determining if they are present, and then judging how well they were followed. There are two broad types of research: basic research and applied research. Basic, or what some call pure research, is research that is conducted to have a deeper understanding of some phenomenon and not for its immediate application. An example of this type of research is the research conducted by Dr. Eric Odeblad and others in classifying types of cervical mucus. Applied research, as the adjective infers, is research conducted to investigate applications in practice. NFP effectiveness studies would be considered applied research because the researchers investigate how effective methods of NFP are in actual practice.

Another broad classification of research is whether it is quantitative or qualitative. Quantitative research reduces and measures discrete variables of interest in order to yield numerical results. Qualitative research, on the other hand, involves investigating phenomena through actual observations, interviews, focus groups and/or open-ended questionnaires and expressing those observations (results) in words or phrases. An example of quantitative research would be to measure in numerical form NFP couples' satisfaction with NFP and display those results in percentages, tables and graphs. In studying the same issue, a qualitative researcher would interview couples about their use and satisfaction with NFP, identify common themes and patterns and express those results in a written narrative. Quantitative research is reductionistic and objective, qualitative research is holistic and subjective.

Quantitative research can be categorized as descriptive, correlational, experimental and quasi-experimental. Descriptive research is for the purpose of quantitatively describing phenomena of interest. An example of descriptive research might be a study that describes satisfaction among NFP couples. Correlational research on the other hand explores how different phenomena relate to one another. For example, a researcher might wish to determine how satisfaction in using a method of NFP correlates with confidence in use of that method. Experimental or quasi-experimental research is used for determining how one variable (the independent) affects (causes a change in) another variable (the dependent variable or variables).

Experimental research is often used to test interventions. It is the only type of research that determines cause and effect with confidence. A method of NFP could be considered an intervention. For example, an experimental research study could be designed to determine how group teaching of NFP affects user satisfaction and confidence. The research question would be, "What are the effects of NFP group teaching on the satisfaction and confidence levels of NFP couples?"

Whether quantitative research might be classified as either experimental or quasi-experimental is based on whether it has or does not have three characteristics: 1) a control group, 2) manipulation of a variable, and 3) randomization. Having all three of these characteristics would make a research study experimental. Lack of either a control group or randomization places it in the quasi-experimental classification. Manipulation means that there is some type of intervention involved (e.g., teaching NFP in a group). A control group means there is a comparative group of participants that will not receive the intervention of interest (or will receive a comparative intervention–like teaching NFP individually). Randomization means that the participants have been randomly selected and distributed into either the intervention or control group (or comparison group). Experimental studies that have all three characteristics of randomization, control group and manipulation are much stronger studies in the sense that you can have more confidence that the intervention caused the desired or predicted change. NFP studies that determine the effectiveness of avoiding pregnancy by comparing one method of NFP with another method or the effectiveness of a one-fertility-indicator method versus a multiple NFP indicator method is a stronger study than one that only determines effectiveness without a comparison group.(1)

Research can also be categorized in a time context. Researchers who collect data that already exists to answer a research question conduct a "retrospective" study. Researchers that propose a study and then collect data from participants conduct a "prospective" study. An example of retrospective research might be a study in which the researcher collected data from old NFP follow-up records to determine levels of satisfaction. A researcher who designed a study to determine satisfaction with a method of NFP and then recruited new NFP couples and measured their satisfaction would be conducting a prospective study. Prospective studies are stronger studies and the data collected from them can be held with greater confidence. Both prospective and retrospective studies provide evidence. Prospective studies are better at doing so.

Another time categorization of research depends on whether data are collected over an extended period or at one time. A study in which data are collected prospectively over an extended period of time is classified as a longitudinal study. For example, if a researcher wanted to determine whether there is a difference in divorce rates among married couples who use NFP versus couples who use oral contraception, the study would be designed to track first time NFP and first time oral contraception users over a 10 to 20 year period. But what if a researcher did

not have the time or money to track couples over a long period of time but still wanted to investigate the same issue? A "cross sectional" longitudinal study could be conducted instead. To do this study a large sample of married couples from NFP centers that have records from the 1970s and early 1980s would be needed. Next, a comparison of that data with a large sample of married couples who attended family planning clinics to obtain oral contraception in the same time period would have to be done. Once large enough samples are obtained from each grouping, an interview (by phone, in person or through mail) of the participants would have to be conducted in order to determine which of the couples divorced and the frequency of doing so. Although the cross sectional longitudinal study has merit, the previously described longitudinal study is considered to be of a higher quality. Researchers have determined that it's design is stronger and therefore the results more accurate.

In the above two examples of possible NFP divorce studies, there are many variables that could explain why couples divorce rather than the variable of interest, that is, using NFP or using oral contraception. Variables that might explain the results (i.e., divorce rates) other than the variable of interest are called "extraneous variables." Extraneous variables in the divorce study can take in: age of the couples, length of marriage, educational levels, income levels, co-habitation before marriage, and religious beliefs and practices, to name just a few. Researchers try to "control" extraneous variables (or eliminate their effect) so that they can be confident that the independent variable of interest (use of NFP versus oral contraception) is the cause of divorce or not. To exercise control over extraneous variables, researchers utilize a number of research methodologies including statistics, research designs, measurement strategies, sampling techniques, and participant selection criteria.

Probably one of the best methods of "control" in eliminating extraneous variables is through research sampling techniques. There are two broad types of sampling techniques, "probability" and "non-probability." Probability sampling involves the use of random selection processes. Non-probability sampling uses non-random selection processes. To use random selection processes the researcher needs to have a sampling frame–or a listing of potential participants or access to potential participants. An example of a sampling frame might be a listing or phone book with all of the certified NFP teachers in the United States. Random selection means that each potential participant (in the pool) for the study has an equal chance of being selected. Random does not mean "haphazard" or "by chance." A random sample is one that best represents the target population as a whole. If researchers wanted to find out (measure) the spiritual well-being (SWB) levels of certified NFP teachers in the United States, they could mail a SWB questionnaire to each certified NFP teacher or they could select a random sample of the U.S. certified NFP teachers. The researcher, however, would need a list of the addresses from a national organization or national certification body. A common way of random selection is through assigning numbers to each of the (potential participants, e.g., NFP teachers listed) and

then using a table of random numbers to select the number desired. A more modern method of probability sampling is through the use of computer-generated random listings.

Non-probability sampling methods do not ensure that each potential participant has a chance of being selected for a given study; nor does it ensure that the sample will be a good representation of the target population as a whole. In the above example of measuring SWB among certified NFP teachers, a researcher could attend a NFP conference where certified teachers are in attendance and ask them to fill out a SWB questionnaire. Or the researcher could log onto an NFP teacher list on the internet and ask for willing NFP teachers to fill out a SWB questionnaire. Both examples are non-probability types of sampling called "convenience sampling." Research studies that use random sampling techniques are stronger studies than those that use sampling by convenience. Many published research studies do not have randomly selected samples--it is difficult to do, and sampling frames often do not exist. A final note about research samples is that they need to be large enough to provide valid results and to allow the statistical tests utilized to be valid. Many research studies do not have large enough samples. Research samples (especially research involving human beings) are often hard to come by. Furthermore, research studies that involve human beings need to go through a human rights review that is conducted by an independent board of review. Human rights for research participation at a minimum involve: informed consent, non-harm to the participant and the right to refuse or no longer participate in a research study. Any coercion of research participants, overtly or subtly is bad research and a violation of human rights.

A final area of research that will be briefly mentioned is that of measurement. As mentioned in the first part of this analysis, quantitative research involves assigning numerical values to phenomena or concepts of interest. In research studies concepts of interest are called variables. Researchers measure these variables directly, if they are concrete concepts, or indirectly, if they are abstract concepts. An example of an abstract concept in NFP research is satisfaction; an example of a concrete concept is progesterone levels. Abstract concepts are usually measured by assigning numerical rankings to indicators of that concept. Whether the variable of interest is concrete or abstract, the way of measuring the variable or the instrument used to measure the variable needs to be valid and reliable. A valid measure is one that measures what it intends to measure and a reliable measure is one that is consistent and accurate in doing so. In research studies, researchers need to use valid and reliable measures of phenomena and to present evidence that they are doing so. An example in NFP research might be if a researcher wished to determine the SWB levels of couples using NFP versus couples using oral contraception to avoid pregnancy. Obviously SWB is an abstract concept and the researcher would need to find a valid and reliable indirect measure of such a phenomenon. Researchers who specialize in developing research measurement tools often spend their entire careers in the development of an accurate measure of a concept or construct. For example, Craig Ellison and Raymond Paloutzian are two psychologists who have developed a paper and pencil instrument

involving 20 items that are ranked on a 1-4 scale to indirectly measure SWB.(3,4) This instrument has gone through development and revisions for the past 20 years. An analogy of the importance of measurement to NFP is that the method of NFP is only as good as the measure or measures of the beginning, peak and end of fertility. How valid and accurate basal body temperature, cervical mucus, cervical checks and assays of female hormones are in determining the fertile time is of importance for past and future NFP research.

Criteria for Evaluating NFP Research

Besides this brief overview of some key elements of good quantitative research, a few broad criteria can be used to evaluate research reports. Probably one of the best ways of knowing what is good research is to read research studies that are published in quality research oriented journals. Reading research, however, is not easy. The style of writing is very compressed, objective, usually written in the third person, and full of research jargon and statistics that can be difficult to understand. The more a person reads research articles the better he or she will become in discerning what is good research.

Good research studies are usually published in scholarly research journals or in specialty clinical journals that have research sections. Scholarly research journals that publish scientific studies are for the most part "peer reviewed." This means that the research article has been critiqued by a panel of 2-3 volunteer research experts who decide based on their evaluation whether the article is of worth to be published. Scholarly research articles are usually not invited by the editor of a journal but rather are submitted for peer review and revision. The best scientific research journals reject over 90% of the articles submitted for review.

Not all peer reviewed scientific journals are of the same quality and prestige. In the community of medical scholars, one of the top scholarly journals that is recognized world wide is the *New England Journal of Medicine*. In the area of fertility (in which NFP and NFP related studies might be published) the top journals are *Human Reproduction and Fertility and Sterility*. Lancet, the *British Medical Journal* and the *Journal of Obstetrics and Gynecology* are also recognized as top line medical journals. The journals *Contraception and Advances in Contraception* are good second level journals that publish NFP and NFP related research articles. Depending on the specialty area and the profession (e.g., psychology, nursing, etc) or the scientific field (e.g., biochemistry) there are many other scholarly journals too numerous to mention in this short article.

When peer reviewers for scholarly research journals receive an article to critique from the editor of a given journal they do not know who the authors are. They conduct what is called a blind review. When presented with an article they are asked to provide a careful, critical

appraisal of the strengths and limitations of the study. Reviewers are commonly asked to critique the following aspects of a study (3):

1. **Significance.** Is the research problem addressed significantly? Can the study make an important contribution to the field or topic?

2. **Theoretical/Background Studies.** Are the theoretical underpinnings sound? Is an adequate review of past research studies on the topic presented? Are the studies recent and are they primary sources? Did they establish a need for the research?

3. **Methodology.** Are the research methods appropriate? Are the results presented clearly? Are the findings believable?

4. **Interpretive.** Did the researcher properly interpret data and develop reasonable conclusions? Discuss limitations? Are the conclusions beyond the scope of the study?

5. **Ethical.** Were the rights of the study participants protected? Was the research reviewed by an internal board of review?

6. **Stylistic.** Is the report clearly written, objective and well organized?

Conclusion

Research is not easy to do. It takes a great deal of knowledge, skill, time, access to participants and money. The most significant research is typically conducted by a research team that includes statisticians and clinicians. It also involves multiple sites and large amounts of funding (e.g., 1 million dollars is considered little funding for comprehensive research). Grants from either the federal government (through the National Institutes of Health) or large philanthropic foundations are often the only avenues for such funding. There is precious little research on NFP being conducted in the United States and only a few qualified researchers interested in NFP. Those who are conducting NFP research are often doing so with little resources and funding.

The above notes provide an explanation of some key research methods, concepts and terminology. This will help NFP teachers to understand research and be better judges of what is sound research. *CMR* is designed to be a source of brief research reports and only provides a secondary synopsis through the perspective of this author. I encourage readers of *CMR* to find and read the original articles and to evaluate them with some of the above criteria in mind. Further issues of *CMR* will provide an overview of other research methodologies of interest.

1. Lamprecht, V. and Trussell, J. **Natural family planning effectiveness: evaluating published reports.** *Advances in Contraception* 13 (1997): 155-165.

2. Ellison, C. W., **Spiritual well-being: conceptualization and measurement.** *Journal of Psychology and Theology* 11 (1983): 330-340.

3. Bufford, R. K., Paloutzian, R. F. and Ellison, C. W. **Norms for the spiritual well-being scale.** *Journal of Psychology and Theology* 19 (1991): 56-70.

4. Polit, D. F., Beck, C. T. and Hungler, B. P. **Reading research reports.** Chapter in *Essentials of Nursing Research.* Philadephia: Lippincott.

For Your Information

Understanding Scientific Research – Definitions

Basic Research/Pure Research
Basic, or pure research, is conducted in order to gain a deeper understanding of some phenomenon. It is not interested in the immediate application of the phenomenon.
Example; classification of types of cervical mucus.

Applied
Investigation of the application of a phenomenon.
Example; NFP effectiveness studies.

Quantitative
Research which reduces and measures discrete variables of interest in order to yield numerical results. It can be categorized as descriptive, correlational, experimental and quasi-experimental.

Qualitative
Research that involves investigating phenomena through actual observations, interviews, focus groups and/or open-ended questionnaires and expressing those observations (results) in words or phrases.

Correlational
Research that explores how different phenomena relate to one another.

Experimental/Quasi-experimental
Research which determines how one variable (the independent) affects (causes a change in) another variable (the dependent variable or variables).

Longitudinal
Research in which data are collected prospectively over an extended period of time.

Sampling Techniques

Probability and Random

Involves the use of random selection processes. Random selection means that each potential participant (in the pool) for the study has an equal chance of being selected. Random does not mean "haphazard" or "by chance." A random sample is one that best represents the target population as a whole.

Non-probability and Non-random

Non-probability sampling uses non-random selection processes. Non-probability sampling methods do not ensure that each potential participant has a chance of being selected for a given study; nor does it ensure that the sample will be a good representation of the target population as a whole.

Breaking News: Federal Government Publishes Study on Condoms and STD Prevention

Breaking news is the publishing of the Federal Government's study on condom effectiveness. The results are published in the 49 page report, "Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention."

Former Rep. Tom Coburn of Oklahoma, requested that the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the U.S.Agency for International Development (USAID) organize a workshop on condom effectiveness and STD prevention. The workshop, held in June 2000, included twenty-eight expert panel members who analyzed more than 138 peer-reviewed, published studies on the properties and user patterns of the male latex condom during heterosexual intercourse.

The panel studied condom effectiveness in preventing the eight most prevalent STDs: HIV, gonorrhea, chlamydia, syphilis, chancroid, trichomoniasis, genital herpes, and human papillomavirus (HPV). Their findings present a conflicted picture--the condom can protect against HIV transmission but not from most other STDs.

According to them, the "good news" for HIV prevention is that there is an 85 percent decrease in risk of HIV transmission among consistent condom users versus non-users. With regard to the other STDs reviewed, existing studies were found insufficient to accurately assess effectiveness. For human papillomavirus (HPV), the panel found there was no evidence that condom use reduced the risk of HPV infection.

The workshop summary, "Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention," is available on the Web at http://www.niaid.nih.gov/dmid/stds/condomreport.pdf