

Natural Family Planning

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Richard J. Fehring, DNSc, RN, Marquette University College of Nursing

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Reviews and Analysis

Richard Fehring, DNSc, RN

Study shows that greater than 37% of Missouri women have interest in using NFP

Although only 1-2% of women in the United States use natural methods of family planning to achieve or avoid pregnancy, a recent study showed that many more might have an interest in using natural methods in the future.(1) A family practice physician and clinical researcher from the University of Utah, Dr. Joseph Stanford and a family nurse practitioner, Janis C. Lemaire, along with research assistant, Poppy Thurman, attempted to determine if the low use of Natural Family Planning (NFP) methods (to achieve or avoid pregnancy) was due to a lack of available information, a lack of interest, or other factors. This current study was a follow-up to prior research in which they had found that 43% of female patients in a family medicine clinic were interested in learning more about NFP.(2) In order to obtain more general results than those obtained in the pilot study, they randomly selected 1500 women, aged 18-50 from the Missouri drivers license renewal records and mailed them a questionnaire.

Seven-hundred-forty seven questionnaires (49.8%) were returned. Of these, 484 (33.3% of total) were from women who were still potentially fertile with only 2.8% currently using some form of NFP; however, 22.5% of these same women indicated that they would be likely or very likely to use NFP in the future to avoid pregnancy and 37.4% of these said that they would likely or very likely use NFP to achieve a pregnancy.

The results also indicated that past use of any type of NFP method to avoid or achieve pregnancy was associated with interest in future use of modern methods of NFP. The authors concluded that many women who are not currently using NFP indicated that they are interested in doing so either to achieve or avoid pregnancy. An implication of the results of this study for NFP teachers is that there are probably many women/couples in the United States who are not using NFP, but who are interested in doing so. If provided with information in a positive way, these women may well choose natural methods. As the authors point out, other factors are likely to impact a decision to learn NFP, including the availability of accurate information, availability of qualified NFP teachers, support of health care providers, and the support and participation of the male partner.

Although the results of this study are based on a large random sample of Missouri women, the authors indicate that the sample is probably biased toward more educated and more affluent women. Further research is needed to determine if interest in modern methods of NFP is lower or greater in other categories of women and men, for example, less affluent populations and minority groups.

1. Stanford, J. B., Lemaire, J. C. and Thurman, P. B., **Women's interest in natural family planning**, *Journal of Family Practice* 46 (January 1998): 65-71.

2. Stanford, J. B., Lemaire, J. C. and Fox, A., **Interest in natural family planning among female family practice patients**, *Family Practice Research Journal* 14 (1994): 237-249.

Knowledge of fertility is low among women who attend a fertility clinic

Common sense would seem to dictate that if couples have an infertility problem and have been trying to achieve pregnancy for over two years, that they would understand clearly how to determine the optimal time of fertility. At a minimum one would expect that their primary care provider would assess their depth of knowledge and help them obtain any information they might lack. Investigators at an infertility clinic in Auckland, New Zealand observed in their practice that couples often have a poor understanding of their fertility even though they have been trying to conceive for over two years and have been assessed by at least one other medical practitioner. In order to validate their observations, the New Zealand investigators conducted a study in which they hypothesized that less than 50% of menstruating women, with a history of at least two years of infertility, have an adequate understanding about the fertile time of their menstrual cycle.(1) The investigators defined fertility awareness as knowledge of the peri-ovulatory endocrine process and the natural physiological markers associated with it: i.e., changes in cervical mucus and the post-ovulatory shift in basal body temperature.

In order to test their hypothesis, the investigators administered a 16 item questionnaire designed to determine level of knowledge about the fertile time (and the optimal time to have intercourse in order to get pregnant) to 90 women that attended the New Zealand National Women's Fertility clinic over a three month period. The questionnaires were graded (on a scale of 0-6, with a higher score indicating more knowledge of fertility) by two independent NFP teachers. A score of 4 or more was determined to be the cut-off for having adequate knowledge of fertility.

Of the 90 women who responded to the questionnaire, 80 were ovulatory and thus had changes in cervical mucus and BBT. Of these 80 respondents, only 26% had a score of 4 or greater. Therefore, the investigators' hypothesis that less than 50% of subjects have an adequate understanding of their 'fertile time' was supported. Other interesting findings were that 80% of those respondents who had used NFP in the past had a score of 4 or greater and 80% of all the respondents indicated interest in attending a NFP clinic. The investigators felt that it was important for the primary care practitioner to establish if couples having difficulty in achieving pregnancy understand ovulation and the optimal time to have intercourse.

The investigators also implied that providing infertile couples with information about fertility awareness will be an empowering experience in an often dis-empowering experience of infertility, and that knowledge of the fertile time will be more cost effective and will aid in the accurate timing of infertility tests. The authors recommended incorporating NFP trained professional nurses in tertiary infertility clinics to rectify the lack of knowledge of fertility awareness.

1. Blake, D., Smith, D. and Bargiacchi, A. et al., **Fertility awareness in women attending a fertility clinic**, *Australian/New Zealand Journal of Obstetric and Gynecology* 37 (1997): 350-352.

A string of pearls and hibernating sperm: the integrative functions of the various types of cervical mucus.

Dr. Eric Odeblad, Emeritus Professor in the Department of Medical Biophysics at the University of Umea, Umea, Sweden, has been studying the physical, chemical and biological properties of cervical mucus since the 1950s. His paper, "Cervical Mucus and Their Functions," published in the January 1997 issue of the *Journal of the Irish Colleges of Physicians and Surgeons* and which received the American Academy of Natural Family Planning Annual Research Paper Award (see announcement in the Sum/Fall '98 issue of the *NFP Forum*) is a review of his research observations on cervical mucus, his research techniques and a description of the latest microscopic classifications and functions of cervical mucus.(1)

Although Dr. Odeblad utilized complex technological methods in studying cervical mucus (such as Nuclear Magnetic Resonance Imaging-NMRI) much of his work involved simple microscopic examination of cervical mucus. To obtain cervical mucus for microscopic examination he used either the delicate aspiration of mucus from single crypts along the endocervical canal, the bulk removal of cervical mucus with forceps or plastic tubes, and more recently, the use of specially designed cotton swabs.

Odeblad originally classified two main types of cervical mucus obtained from single crypts, the G type, that reacted to the stimulation of progesterone and the E type, that reacted to estrogen stimulation. He later divided the classification of the E type into L-type (which referred to the loaf shaped rods that was observed using NMRI) and the S-type (which refers to string shaped rods) or for sperm conveying mucus. He also noticed in further studies with microscopy, that there was another type of mucus that had a crystallization pattern different than the L and S types. This type of mucus he labeled P type since it had its maximum amount on the days of peak fertility.

The descriptions of the integrated functioning of the various types of cervical mucus that Odeblad provides in his paper is fascinating. Although the G type of mucus is stimulated by progesterone, it is present in the cervical canal in all phases of the menstrual cycle, except during the fertile period and menstruation. Most NFP practitioners know that the G mucus is a natural barrier to sperm, but many do not know that the G mucus is probably also a protective barrier to other foreign bodies (e.g., bacteria) since it contains various types of infection fighting cells and substances.

Unlike the G type mucus, the L mucus is secreted during the entire fertile period, and when L mucus fills a crypt it looks like a tiny droplet or "pearl." During the fertile period there

are 30 or more of these “pearls” (L-mucus crypt units) in the cervical canal. These “pearls” of L mucus serve as a system to filter out defective sperm and as a support structure for the string like S mucus (hence the “string of pearls”).

The S mucus also serves as a transport system for sperm. Some sperm enter into the S mucus at the opening of the cervix and find their way to the uterine cavity. Most sperm however, travel to an S crypt where they lose or reduce their movement and seem to 'hibernate' for an average of about 20 hours. In the meantime the P mucus works on liquefying any mucus that is blocking sperm from entering into the S crypts. Dr. Odeblad believes that there is some type of neural factor that is involved with sperm immobilization. In any case, sperm eventually leave the crypts, regain their mobility and find their way to the uterine cavity. Finally, Odeblad also indicated that a certain type of P mucus also plays a role in immunological processes in the cervix. This, he says “remains to be investigated.” Let us hope (and God willing) that Dr. Odeblad and others are able to continue this needed work in understanding the integrated functions of cervical mucus and the applications these functions have on fertility.

1. Odeblad, E., **Cervical mucus and their functions**, *Journal of the Irish Colleges of Physicians and Surgeons* 26 (January 1997): 27-32.

The Need for Improved Studies of NFP Effectiveness

Joseph B. Stanford MD, MSPH, CNFPMC

Although dozens of NFP effectiveness studies have been published, there are still significant deficits in the methods and reports of many studies. A concise review of what constitutes a good NFP study has been recently provided by Lamprecht and Trussell.³ They list seven questions which provided a good basis for evaluating the methodological quality of an NFP study: 1) Is the study a survey or a clinical trial? Clinical trials, particularly prospective ones, make for a stronger study. 2) What NFP method is being tested? Unfortunately, many surveys (such as the National Survey of Family Growth) lump all NFP methods (including self-taught methods of questionable efficacy) into the single category of “rhythm.” 3) How was the method taught? In NFP effectiveness, the quality of the teaching is at least as important as the method itself. The teaching needs to be described or referenced in such a way that a different investigator could replicate the study. 4) What are the characteristics of the study participants? Characteristics such as age, education, coital frequency, and reproductive status (e.g. breastfeeding, discontinuing birth control pills) affect both pregnancy rates and generalizability. 5) How are pregnancy rates calculated? It is more meaningful to divide cycles (or months) of use by how the method was actually used—for example, by whether intercourse occurred during the fertile phase or not—and then calculate pregnancy rates in those groups of cycles. To date, few NFP studies have done this. One that has is the German study reviewed above.¹ This type of analysis will result in pregnancy rates that are slightly higher than have been reported in the past--and this is true both for NFP and for artificial contraception. 6) What rates or probabilities are reported? Most NFP studies of the past have used Pearl Rates, but more recent studies have used Life Table Probabilities, which are

more accurate. Gross Life Table Probabilities are more accurate than Net Life Table Probabilities (and are usually noticeably higher as well), but to date few NFP studies and few contraceptive studies have reported Gross Probabilities. A discussion of the differences between these methods goes far beyond the scope of this review.

NFP and “Intentional” Pregnancy

The final question proposed by Lamprecht and Trussell to evaluate NFP studies is 7) How are pregnancies classified? The authors note that “NFP is the only method of family planning that can be used to achieve as well as to prevent pregnancy.” They then propose that all pregnancies that occur during use of NFP be classified as “intentional” or “unintentional” based on a prospective declaration by the couple as to their desire for pregnancy. They further propose that pregnancy rates for “typical use” and “perfect use” be based only on “unintentional” pregnancies, to allow for comparison to contraceptive studies. While I agree with this question, I must differ on the answer. I believe that this conceptual framework is inadequate to fully understand NFP, to describe its use, or even to adequately advise couples considering NFP about what to expect when they use it. Couples need to know what is the “best possible” effectiveness of an NFP method if they use it conscientiously and consistently to avoid pregnancy. Since the effectiveness of NFP is highly dependent on how it is taught, it is very important that a couple choosing to use a NFP method know what contribution user error or teacher error might make to a pregnancy rate when they are conscientiously and consistently using that NFP method to avoid pregnancy. Thus, “teaching-related pregnancies” are of high clinical relevance to couples. Couples also need to know that the probability of pregnancy from genital contact during the fertile time is high. It would be valuable for them to know precisely how high depending on the specific circumstances (e.g., the probability of pregnancy from intercourse on peak day vs. intercourse on the third day post peak). This would allow for them to consider whatever probability of pregnancy is comfortable for their own particular situation, and would be part of the spectrum of allowing for the use of NFP to achieve pregnancy.

I also question whether the use of an “intentional/unintentional” pregnancy framework allows for accurate comparison between an NFP study and a study of an artificial contraceptive method. Since motivations to avoid pregnancy are complex and will vary widely among individuals, an approach which dichotomizes pregnancy intention based solely on face value statements is unlikely to lead to results which are truly comparable between two different study populations, even though each study may report an “unplanned pregnancy rate.” Thus, I believe that NFP studies should report all pregnancies, including “planned” pregnancies, in order to provide a complete and clear picture of the spectrum of use of NFP. I also believe that the development and validation of more sophisticated measures that can describe a spectrum of user intention (including measures which can be compared to users of artificial contraceptives) should be a high priority for NFP research.

With the above as background, it is with mixed feelings that I review a recent paper which attempts to summarize the effectiveness of NFP.⁴ On the one hand, this paper fills an important gap in the gynecologic literature by providing a good review of the various methods of NFP and

their underlying physiology, and a thorough overview of some of the major NFP effectiveness studies. It concludes that “NFP involves reliable and affordable contraceptive methods if used perfectly, i.e. following the rules [sic]...” Unfortunately, this paper also perpetuates some significant errors. The review recommends that NFP effectiveness studies employ a teaching phase for couples before they enter the effectiveness phase of a study. This is an idea which should be discarded. What couple wants to hear, “if you make it through the teaching phase, then your effectiveness will be...?” The statements on statistical methods are confusing at best, omit a number of important issues, and include significantly incorrect statements (such as stating that the modified Pearl Rate is 13 months when it is actually 13 cycles). There is a long, and in my opinion, misleading section on the question of aged gametes which underestimates the value of a recent large epidemiologic study on this issue which found no significant effect overall of aged gametes (from intercourse on the “fringes” of the fertile time).⁵ The concept of intendedness is distorted and confused by repeatedly referring to “unintended” pregnancies as “unwanted” pregnancies. Finally, there is no discussion of the use of NFP to achieve pregnancy, its value in infertility, or its potential contribution to gynecology and women’s health issues. So while this review represents a step forward, we still have a long ways to go to get accurate and balanced information on NFP into the medical literature.

1. Frank-Herrmann, P., Freundl, G., Gnoth, C. et al., **Natural family planning with and without barrier method use in the fertile phase: efficacy in relation to sexual behavior: a German prospective long-term study**, *Advances in Contraception* 13 (1997): 179-189.
2. Trussell, J. and Grummer-Strawn, L., **Further analysis of contraceptive failure of the ovulation method**, *American Journal of Obstetrics and Gynecology* 165 (1991): 2054-2059.
3. Lamprecht, V. and Trussell, J., **Natural family planning effectiveness: evaluating published reports**, *Advances in Contraception* 13 (1997): 155-165.
4. Guida, M., Tommaselli, G., Pellicano, M., Palomba, S. and Nappi, C., **An overview of the effectiveness of natural family planning**, *Gynecology/Endocrinology* 11 (1997): 203-19.
5. Gray, R. H., Simpson, J. L., Kambic, R. T. et al., **Timing of conception and the risk of spontaneous abortion among pregnancies during use of natural family planning**, *American Journal of Obstetrics and Gynecology* 172 (1994): 1567-72. (See also Kambic and Stanford’s discussion in NFP Forum, Summer/Fall 1998).

Under the Microscope

Menopause: Disease or Normal Life Passage?

Richard Fehring, DNSc, R.N.

Approximately 20 million women of the “baby boom” era will experience the transition to menopause over the next 10 years. This will undoubtedly foster an increased interest in understanding the phenomenon of menopause. Likewise, it may also increase the production of books, medicines, and other products related to this topic. Recognizing our limitations as teachers of NFP, nonetheless, we must become wise consumers of both the research conducted to help understand menopause as well as the therapies and products designed to treat and prevent perimenopausal symptoms.

Two recent studies, one from the Netherlands and the other from the United Kingdom, contribute to an understanding of the factors that predict when natural menopause will occur.(1,2) Conducted through Utrecht University, the Netherlands study tested the hypothesis (called the Frisch hypothesis) that there is an inverse relationship between the age of menarche and the age of natural menopause (as opposed to surgical menopause). The investigators questioned a cohort of 3,756 Dutch women on the age they experienced menarche and menopause as well as on a number of lifestyle factors. They found that there was no relationship between the age of menarche and the age of menopause, i.e., early menarche was not related to late menopause or vice versa. They did find, however, that oral contraceptive (OC) use and parity tended to postpone menopause. Presumably, both OC use and pregnancy helps to prevent oocyte depletion.

The United Kingdom study, conducted through the University of York, questioned a random sample of 2,399 women aged 45 to 54 on their current menstrual status and the age their mother sustained menopause. The researchers found that women with premature (<40 years) and early menopause (<45 years) reported significantly lower maternal menopausal ages than women with normal menopausal ages. They concluded that the data seems to support a strong relationship (and therefore a genetic link) between mother-daughter menopausal ages.

One aspect of menopause is that many women who go through the sustained sensation of menstruation do not experience symptoms that need treatment nor do they end up with severe osteoporosis or heart disease in later life. Those who have severe experiences with some of the symptoms associated with the perimenopausal and menopausal period in life (e.g., hot flashes, night sweats, mood alterations, depression, dyspareunia, insomnia, vaginal dryness, dry skin, urinary complaints and decreased or increased libido, to name just a few) and/or who are at high risk for osteoporosis or heart disease need to seek professional medical care. They may also be advised by a physician to undertake hormone replacement therapy. The majority of women might choose to augment medical care with life style changes and what is referred to as complementary and alternative medicine (CAM). Women who use or have used NFP might be interested in CAM. Complementary therapies are often noninvasive, simple to use, inexpensive, reversible, and without side effects.

Three recent articles review the literature on CAMs and herbal therapies for perimenopausal and menopausal complaints.(3, 4, 5) One article (3) reviewed over 41,000 clinical studies obtained from the National Library of Medicine (NLM). Another article provides a pharmaceutical review of the research (or rather lack of research) on herbal therapies (5). The third article is a review of traditional and non-traditional therapies for “hot flashes” (5). All three of these reviews concur that there were only a small number of high-quality published research on CAM for perimenopausal and menopausal complaints. The majority of articles were anecdotal and lacking in randomized clinical trials. Others had insufficient numbers of subjects, no randomization, and poor descriptions of intervention/therapy.

Six articles had enough scientific merit to be included in the NLM review (3). Of those six, three reported on the effects of soy products on “hot flush” frequency, vaginal cytology and FSH levels. Only one study reported a significant decrease in hot flushes among menopausal women after being on soy flour for a six week period (6). Another one of the six articles reports of a randomized trial study that showed a decrease in nighttime flushes after the menopausal women were on vitamin E supplemented primrose oil for 6 months (7). The herbal treatment pharmaceutical review article mentioned that there were no FDA approved herbal therapies for perimenopausal and menopausal complaints.

Of interest is that women from other countries and cultures don't necessarily experience menopausal symptoms or experience them as severe as American women. Notably, Japanese women exhibited far fewer symptoms than American women. One article observed that the traditional Japanese diet of high-vegetable, low-meat, low-saturated fat, is high in phytoestrogens. Phytoestrogens are thought to be anticarcinogenic substances that are found in such foods as legumes, bean sprouts, wheat, sunflower seeds and especially in soybeans (5). Two other articles recommend the use of soy products and primrose oil with Vitamin E supplements for the treatment of hot flushes. Also recommended is cultivating an awareness of events that trigger menopausal symptoms (e.g., stress, anxiety, caffeine, spices, hot drinks and hot temperatures) and trying to avoid or eliminate them. Finally, exercise and relaxation exercises are encouraged. Evidence suggests that women who exercise on a regular basis experience fewer hot flashes.

I would recommend two books written for consumers: Susan Love's *Hormone Book* and *What Your Doctor May Not Tell You about Menopause* by John R. Lee, MD. (8, 9) These books give a good lay explanation of the perimenopausal process. The books are well documented and don't medicalize menopause. The authors realize that some women will experience severe symptoms and others will be at high risk for osteoporosis and heart disease. Of particular interest in Dr. Lee's book is that he believes, and provides plenty of evidence, that perimenopausal symptoms are not due to low levels of estrogen (since the body still manufactures estrogens in fat and other cells) but really a lack of progesterone. His argument that women on estrogen replacements might have symptoms of too much estrogen is convincing. He also favors the use of progesterone (if needed) to help treat perimenopausal symptoms and to re-establish the estrogen-progesterone balance. Both authors opt for alternative therapies and life-style changes to treat most of the symptoms of menopause.

Based on the literature that I have reviewed, I have come to the conclusion that the best approach for living through the perimenopausal transition for most women is to adopt a healthy lifestyle. This is not too surprising, since menopause is not a disease. It is a real biological change which is normal and natural in women. As with fertility and pro-creation, it is important to avoid thinking that menopause is a negative thing. The medical profession has too often slipped into treating women's bodies as being defective or having a problem. Menopause requires health care professionals to understand it and work with it. Addressing specific health issues per patient is only logical and a sign of good medicine. Women who experience severe perimenopausal and menopausal complaints and who are at risk for heart disease or osteoporosis, need to seek medical advice.

Meanwhile, lifestyle changes such as eating a balanced low-fat diet with plenty of fresh vegetables and fruits (including some soy protein and vitamin supplements), exercising, and taking time for relaxation and reflection should be implemented. Making a commitment to these few basic changes in one's lifestyle will benefit most woman.

1. Van Noord, P. A., Dubas, J. S. and Dorland, M. et al., **Age at natural menopause in a population-based screening cohort: the role of menarche, fecundity, and lifestyle factors**, *Fertility and Sterility* 68 (July 1997): 95-102.
2. Torgerson, D. L., Thomas, R. E. and Reid, D. M., **Mothers and daughters menopausal ages: is there a link?** *European Journal of Obstetrics and Gynecology* 74 (1997): 63-66.
3. Chez, R. A. and Jones, W. B., **Complementary and alternative medicine. Part II: Clinical studies in gynecology**, *Obstetrical and Gynecological Survey* 52 (1997): 709-716.
4. Isreal, D. and Youngkin, E. Q., **Herbal therapies for perimenopausal and menopausal complaints**, *Pharmacotherapy* 17 (1997): 970-984.
5. Shaw, C. R., **The perimeopausal hot flash: epidemiology, physiology, and treatment**. *The Nurse Practitioner* 22 (March 1997): 55-66.
6. Murkies, A. L., Lombard, C., Strauss, B. J. G. et al., **Dietary flour supplementation decreases postmenopausal hot flashes: effect of soy and wheat**, *Maturitas* 212 (1995): 189-195.
7. Chenoy, R., Hussain, S., Tayob, Y. et al., **Effect of oral gamolenic acid from evening primrose oil on menopausal flushing**, *British Medical Journal* 308 (1994): 501-503.
8. Love, S. M. and Lindsey, K., *Dr. Susan Love's Hormone Book*, (New York: Random House, 1997).
9. Lee, J. R. and Hopkins, V., *What Your Doctor May Not Tell You About Menopause*, (New York: Time Warner Books, 1996).

Research Briefs

Lorna Cvetkovich, MD, FACOG

May, K., **Monitoring reproductive hormones to detect the fertile period: development of persona—the first home use system**, *Advances in Contraception* 13 (1997): 139-141.

This report introduced a method of NFP based on the detection of Estrone-3-gluconuride (E-3-G), and LH in the urine. The concept of a home test to monitor reproductive hormones was originally raised because of work originally done by the WHO task force in Human Reproduction. Persona is the first product to realize this concept and was first marketed in the UK in September 1996. The system united two technological advances: the development of one step immunoassays and advances in microelectronics which allowed the development of an intelligent hand held monitor capable of reading, storing, and using the information on the hormone changes. Clinical trials have been completed and are being prepared for publication. Practically this means the woman will test her urine 16 times in the first cycle and 8 times thereafter. When the monitor detects rising E-3-G levels, it changes the fertility status from “green” to “red.” When LH is detected, the monitor marks this as “O” for ovulation and uses that information to mark the end of the fertile phase. The author states that since natural methods have many qualities desired by women in a contraceptive, Persona may make natural methods more acceptable in increasing their reliability. (Persona and similar devices may indeed be useful for those few with very difficult or irregular cycles or who have very serious reasons to avoid a pregnancy, but for the great majority of users who should experience a 99% use-effectiveness, they will be unnecessary. LC)

Hirata, J. D. et al., **Does dong quai have estrogenic effects in postmenopausal women? A double-blind, placebo-controlled trial**, *Fertility and Sterility* 68 (December 1997): 981-986.

Since many women are now looking for alternatives to estrogen replacement for menopausal symptoms and since dong quai has been touted as a natural remedy, these authors wanted to evaluate its possible estrogenic effects on vaginal cells and the endometrium in 71 postmenopausal women in a prospective randomized study. Each woman took either dong quai or placebo for 14 weeks. Endometrial thickness as measured by transvaginal ultrasound and vaginal cytology were evaluated as markers for estrogen effect. Menopausal symptoms were evaluated by a Kupperman Index and hot flash diary. Results showed no difference in endometrial thickness, vaginal maturation index, menopausal symptoms, or hot flashes in women who took the supplement versus placebo. Thus in this well designed study, dong quai was no more helpful than placebo in relieving menopausal symptoms and produced no estrogenic responses in the vaginal epithelium or endometrium. This study not only demonstrates just how significant a placebo effect can be, but also provides valuable information about a commonly used supplement.

Gentile, G. P. et al., **Is there any evidence for a post-tubal sterilization syndrome?** *Fertility and Sterility* 69 (February 1998): 179-185.

Tubal sterilization is the most common form of contraception in the world, with an estimated 10 million women aged 15-44 using it in 1988 in this country. Thus any effect this procedure might have on their subsequent gynecologic health could constitute a significant health problem. Clinically many women are seen for menstrual problems usually abnormal or heavy bleeding or pain which they ascribe or date to their sterilization. The first report of abnormal bleeding after sterilization appeared in 1951 by Williams. Since then many studies have been done looking at risk of hysterectomy after sterilization, subjective changes in menstrual symptoms after sterilization, as well as objective measures of menstrual changes. This article analyzed all these types of studies in an effort to answer this question.

With regard to risk of hysterectomy after tubal sterilization: in studies with a control group all showed an increased risk of hysterectomy but the greatest risk occurred in those who had undergone sterilization at an earlier age (i.e., before age 29). The author stated that this was possibly due to an increased demand for surgery since once childbearing is considered to be over, women were less likely to tolerate menstrual disorders and may self-select for hysterectomy in that those who accept surgery for contraception, are more likely to accept surgery for gynecologic complaints.

Looking at the question of change in menstrual symptoms after sterilization, most studies which controlled for prior oral contraceptive use found no significant changes in menstrual symptoms. Controlling for age, prior menstrual disturbances, and oral contraceptive use is very important because each has a significant influence on the incidence of menstrual disturbances as well as the woman's perception of menstrual problems.

Lastly, many investigators have looked at objective measures of menstrual function after sterilization such as endometrial biopsy, hormonal analysis, and measured blood loss. One study evaluated menstrual blood loss 6 to 12 months after surgery and found no increase in menstrual bleeding in this time frame. Of three studies which looked at endometrial biopsies, two showed normal endometria, and the third showed evidence of a luteal phase defect associated with sterilization. In several studies there was evidence for lower mid-luteal phase E2, P, or LH levels but in studies in which the women served as their own controls, no significant or persistent changes in hormone levels were seen.

Gentile summarized by commenting that the only consistency in the articles reviewed was their inconsistency. Overall however, prospective studies that took important factors into consideration typically found small and insignificant changes. Thus, in the end there appeared to be no clear cut evidence for the existence of post-tubal sterilization syndrome. And if it does exist, it probably does so in a very small minority of women: those at highest risk being very young at the time of sterilization and having a prior history of menstrual dysfunction.

Readers' Rounds

Dear Readers,

In launching this new format our goal was to make current medical research on NFP and related information more “user friendly” and generate lively discussion among readers. That’s exactly what happened! We received compliments on both the format and content. We also received several commentaries on the research as reported. Due to space constraints, only one letter is published here. It touches on a hotly debated issue in the NFP community: “Should NFP research be done according to the definitions for research which the family planning world accepts?”

Theresa Notare

Dear Editors:

The recent issue of *Current Medical Research* (Winter/Spring 1998), contains a review of a paper (Bitto 1997) written by my colleagues and me and based upon research conducted here at Johns Hopkins. This review contains serious errors which, as one of the authors of the paper and scientists responsible for the research, I am obliged to correct.

The reviewer states, “I (Fehring) would have been more comfortable with the results if a power analysis had been conducted ...” The answer to Dr. Fehring is that power and sample size analysis was completed before we began to collect data. This is required for any epidemiological study. Let me explain.

Power and sample size calculations are the second steps taken when designing a clinical epidemiological study. The first step in any study is to clarify the research questions to be answered by the study. The second step is to ask the question, “How many patients, users, charts, women, men, couples, etc. do we need to have in the study to answer the research question with a high degree of assurance that our answers will be correct?” In other words if we say there is a significant difference, or that there is not a significant difference, how certain are we of our answers. Power and sample size calculations provide the expected levels of certainty of the study, even before we begin to collect data.

Bitto (1997) is based on the NFP pregnancy outcome study which has been reviewed extensively elsewhere (Kambic 1989, Gray 1995, Simpson 1994-1995). This study began in 1987 and data analysis work was completed in 1987; it was funded by the United States Agency for International Development (USAID) through the Georgetown University Institute for Reproductive Health (IRH). As I showed above, proper planning of any research study includes power and sample size analysis. Funding agencies will not consider research proposals lacking power and sample size calculations. Our original proposal suggested, and the study followed, a prospective study design with outcome variables of spontaneous abortion, birth defects, and low

birth weight. We included sample size estimates for four risk levels and three levels of difference for each outcome and estimated samples based on 95% confidence limits and 80% power. For example, if the spontaneous abortion rate was estimated as either 10%, 15%, and 20% in a population, we calculated sample sizes needed to show an increased risk of 2, 3, and 4, in spontaneous abortion for NFP users. Assuming an average frequency of spontaneous abortion of 15%, a sample with 35 pregnancies in the control and in the exposure group would detect a 3 fold increased risk among NFP users, if it existed. At study closure with 868 pregnancies registered, the sample sizes allowed us to estimate an increased risk for spontaneous abortion of about 1.5 if it existed. The numbers were sufficient for similar risk assessment for the birth defect and low birth weight analysis. In 1996 at the DDP meeting in Florida, and in 1997 at the American Academy meeting in Utah, I presented the results of this study which showed that there was no extra risk of spontaneous abortions to NFP users. This is good news for NFP users as it had long been hypothesized that there could be problems with NFP pregnancies because of aging gametes. But that is another story.

Bitto (1997) is a secondary analysis of a subset of the data with the comparison groups stratified by planned and unplanned pregnancy rather than highly fertile and less fertile times of the cycle. Prior to analysis Dr. Bitto prepared similar estimates for several risk. Given her sample sizes (367 in the planned and 333 in the unplanned), her study had a power of 60% to find a doubling and a power of 98% to recognize a threefold increase in low birth weight among the unplanned; that would be about 20 to 30 low birthweight babies in the unplanned. However the study found that the proportion of low birthweight babies in the unplanned was actually lower than in the planned. The power was certainly there to find a difference, if a difference existed.

I recommend that in the future the same standards of review be applied to all articles reviewed in *Current Medical Research (CMR)*. I note that in a review of another paper in the same issue of CMR (Fehring 1996), the reviewer overlooked the apparent lack of a power analysis in the original paper. Fehring (1996) found, “no significant difference between the length of the fertile period ... as determined by the CUE and the CrM.” This study has 21 cycles in each sample and found a mean difference in length of fertile period of 0.29 days between CUE and CrM. The power of the study, based on data given in the paper is 20%. This means that there is only a one in five chance of seeing a difference if one exists between CUE and CrM. To detect a difference if one exists, given the study data and a power of 80%, requires a sample size of approximately 360 charts. Furthermore, the paper does not appear to address the issue of non-independence of data collected from the same woman. In this study, eleven women submitted two charts each. This means that we can expect half of the sample, the second charts from each, to resemble the first charts. The result is less variance in the samples and a need for even larger sample sizes to answer statistical questions.

Let me move to a slanderous allegation. The reviewer says of Bitto (1997), “The biggest concern that I have about this study is that it operates under an overt contraceptive framework.” This is a serious charge from an NFP perspective especially as it is made in a publication of the NFP office of the United States Bishops’ Conference. In my opinion this charge is not to be taken lightly. I do not know on what basis the reviewer is able to make this statement. What evidence

does Dr. Fehring present to make his case? For the ten years of the study I was the data co-ordinator at Johns Hopkins; I am not aware of Dr. Fehring participating in any aspects of the study during that time and I wonder how he has come to his conclusions. Dr. Fehring had no firsthand knowledge of how NFP was taught in the collaborating centers. Let me briefly review three of them. Dr. Patricio Mena is the Chairman of Obstetrics and Gynecology in the Medical School at the Pontifical University of Chile. Dr. Mena is an international NFP leader of high repute and he would be quite concerned to think that someone had termed his program “contraceptive”. Dr. Michele Barbato is the Director of the Camen NFP group in Milan Italy. Dr. Barbato and his colleagues including dedicated NFP physicians, teachers and supporters would also be puzzled if the term “contraceptive” was applied to their excellent Sympto-Thermal program. Wilma Stevenson, at the time of the study, was the director of NFP for the Archdiocese of Washington. Ms. Stevenson labored in the NFP vineyards for over 30 years and would be angered and hurt by this unjust dart. It is an affront to these and other NFP leaders who adhere to *Humanae vitae* to say that the project, “operates under an overt contraceptive framework.” If one is able to call the collaborating centers of the project “contraceptive” than any NFP program anywhere is contraceptive in nature.

Let me put it another way; say someone in a far-off land, never having visited the USA, reads a short review and decides that an NFP program in Milwaukee operates, “under a contraceptive framework.” This reviewer then publishes his impression in an authoritative Roman Catholic newsletter. Would the Milwaukee program think that was a fair evaluation of their program? Would the Milwaukee program think that a retraction was in order?

Dr. Bitto was a PhD student at Johns Hopkins who began analysis of the data after the project itself was underway and did not participate in the NFP teaching or data collection.

The reviewer, Dr. Fehring, has concerns with the definitions of planned and unplanned pregnancy used in the study. He admits that he is not convinced by “the woman herself, the NFP teacher, and independent chart reviews.” There is no one else to ask. These issues were examined over the ten years of the study by NFP expert investigators in Italy, Columbia, Chile, Peru and the USA; all independent chart reviewers. In addition to the principal investigators named above, reviewers included Dr. Claude Lanctot, Founding Director of the International Federation for Family Life Promotion. Dr. Lanctot worked worldwide promoting NFP for over 35 years and was author and collaborator on numerous NFP studies. Another was Dr. Mary Martin. Dr. Martin, a nursing PhD, worked with the Human Life Foundation and the Diocesan Development Program for NFP (DDP) as an expert in program evaluation and quality assurance. She contributed greatly to the DDP national standards. I was also one of the chart reviewers. My wife and I were taught NFP by the Billings in 1972 and have worked in NFP practically full time since 1972. We personally have taught NFP to over 2,000 couples. I have published a number of original papers on NFP effectiveness. If the Dr. Fehring distrusts the NFP interpretation and evaluation completed by these and other NFP experts, who would he trust?

These categories of planned and unplanned pregnancy, as used in Dr. Bitto's paper, are based on research in the sociology of family size and birth spacing. If one thinks differently about

these categories, the usual approach is to describe your theory, collect data, and observe how well the data fit the theory. Dr. Fehring prefers to illustrate his ideas with analogies that confuse motivation, intention, and behavior. His theory suggests that couples who want to avoid having another pregnancy, but behave as if they want a pregnancy and have intercourse during the fertile time, want to have a pregnancy. If I jay walk, do I want to get hit by a car? Following Dr. Fehring's system I guess I do. In any case analogies are a poor substitute for science.

To study the question of pregnancies in NFP users, one could begin with the Health Belief Model or with psychological decision making models dealing with incomplete knowledge or unsure preferences (Coombs 1970). These approaches could help us deal with the differences in motivation, intention, behavior, belief, and other factors involved in these complex issues. Such studies would add to the knowledge of unplanned pregnancy among users of NFP and contribute to making NFP use more effective.

Let me close with a few more general comments. Natural Family Planning has been built upon scientific work of dedicated individuals throughout the world. If we began to name those who have contributed to it we would have a very long list that would include names such as Ogino, Knaus, Vollman, Hartman, Odeblad and others whose efforts tell us why NFP works.

Epidemiological and social sciences make similar contributions to NFP knowledge. But the work of those that *Humanae Vitae* addresses as “scientists, who can considerably advance the welfare of marriage and the family... if by pooling their efforts they labor to explain more thoroughly the various conditions favoring a proper regulation of births” will only make these contributions if the scientific works and writings are correctly interpreted and accurately reported to NFP teachers and NFP advocates. I urge the DDP to provide accurate reporting, clear writing, and to maintain the highest standard in reporting of science.

Finally allow me make a few suggestions to ensure the quality of *CMR*. First, following from my discussion of sample size and power, similar standards of review should be applied to all articles reviewed. Second, opinions and issues of controversy must be substantiated. To use a charged word such as “contraceptive” in the DDP newsletter is a serious matter and can harm the reputations of credible individuals and programs. Third, analogies are not a good substitute for hard analysis and clear writing. I hope they can be avoided in future reviews. Fourth, reviewers' personal opinions should be placed at the end of the review so that readers are able to distinguish what the paper reported from the opinions of the reviewer. I note that Dr. Hanna Klaus, the previous editor, to her credit was careful to distinguish her personal observations from those in the paper she was reviewing.

Sincerely,

*Robert T. Kambic, MSH
Research Associate, Department of Population Dynamics
Manager, Leadership Program in Population and Reproductive Health
The Johns Hopkins School of Public Health*

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Response by Dr. Fehring:

If I have offended or slandered anybody, I sincerely apologize. There was no intent on my part to slander any author or program. In retrospective, I should have explained myself more clearly. By “contraceptive framework” I was referring to two things: the primary focus of family planning research which typically upholds “pregnancy avoidance” as the important fact to study (that is my difficulty with most of the scientific research in this area of study). I believe that it is a limiting modus operandi and certainly one that does not fairly represent NFP. And second, the wording in the research itself indicated that the definitions and conceptualization of the Bitto et al., study was contraceptive. The authors stated that clients “were using NFP for contraception.” This sounds like NFP was being used as “just another method of contraception.” However, I did not say, nor do I mean that the NFP service programs where the subjects were obtained are contraceptive in philosophy. They are not. Again, I am sorry if my words were misleading and thereby offended anyone.

With regard to the scientific quality of my analysis: Kambic's point on power analysis is well taken. My research on the CUE fertility monitor which I cited in CMR did not involve power analysis and violated a basic assumption of inferential statistics in that the data was not independent. My study was only a small pilot and was included because it had relevance to the Moreno, et al (1997) study (See Winter/Spring Issue of CMR for review) that also investigated the CUE fertility monitor. I am glad that the Bitto et al. study included a power analysis. However, the article failed to mention a power analysis, and I can only judge the article on the merits of what was presented. I again reiterate that I believe in the non-significant results of the Bitto et al. study that showed no significant difference in the pregnancy outcomes between NFP users who have a wanted or unwanted pregnancy.

I continue to have a problem with the definition and resulting measurement of unwanted pregnancy. The article stated that a pregnancy was considered planned or unplanned by asking the pregnant NFP client, whose response was then validated by the NFP instructor and an independent reviewer. Validation was based on a review of the chart to see that the “pattern of intercourse” was consistent with the client's and instructor's statements. The investigator's definition of planned pregnancy was “that the woman stated that her intention had been to become pregnant and the chart showed that intercourse had taken place during her fertile time.” Their definition of unplanned pregnancy was “that the woman and her partner had not wanted a pregnancy and were using natural family planning for contraception.”

The point that I made was that the two definitions are not consistent. The definition of planned pregnancy only included the woman. The definition of unplanned included the woman and her partner. The definition of planned pregnancy mentioned “intention of having intercourse during the fertile period,” the definition of unplanned did not mention “intent” or patterns of intercourse. I questioned what would be the pattern of intercourse for an unplanned pregnancy.

If a couple is held to their intentions when trying to get pregnant, why should they not also be held to their intentions when they are not trying to get pregnant? If a couple knowingly has intercourse on a fertile day, but did not intent to get pregnant, then the couple's behavior is not following their intentions, i.e., they are exhibiting an “achieving pregnancy” behavior and poor planning. Would Kambic jay walk when traffic is coming? If the intent is to cross the street without getting hit by a car or truck (i.e., crossing safely) then crossing while traffic is coming is a violation of that act (and of the law -at least in Milwaukee).

Finally, I agree with Kambic, that he and fellow researchers (Gray and Simpson) at Johns Hopkins have provided good news for NFP users (and providers) in conducting research on pregnancy outcomes and providing evidence that the NFP/aging gamete theory is false. I look forward to further NFP research coming from that institution.

Richard J. Fehring, DNSc, R.N.

For Your Information

Couple to Couple League Holds Its First Physicians' Seminar

A seminar for physicians was held June 5-7, 1998 in Cincinnati, Ohio, by the Couple to Couple League (CCL). For several years many physicians had expressed the need for a short but intense workshop which would allow them to become acquainted with NFP and the teachings of the Church which underlie it's use. The seminar was directed to physicians who either already have established an “NFP only” practice or were wanting to do so. Twenty-five physicians from all parts of the country attended.

Lectures included the history of NFP, Sympto-Thermal methodology, common signs of fertility and infertility, ecological breastfeeding, as well as training volunteer teaching couples. A special feature of the seminar addressed common gynecological problems that could be identified with the aid of an NFP chart. Examples of long and short cycles, continuous mucus, short luteal phases, anovulatory cycles, and unusual bleeding were discussed. Stress was placed on the evaluation of a patient's nutritional status, height/weight ratio, stress, and environment, as well as disease conditions such as ovarian cysts and pituitary tumors. Suggestions for dealing with a continuous mucus cycle included evaluation and treatment for an ectropion, vitamin B6, vitamin A, optivite, and making sure that the patient's bedroom is void of all light.

An important witness was provided by Dr. Paul Hayes who described his practice in Lincoln, Nebraska. Holy Family Medical Specialists is comprised of Dr. Hayes (an Ob/GYN), and three family practitioners all of whom fully understand and support the Ethical and Religious Directives for Catholic Hospitals. Their practice is approved and supported by Bishop Fabian Bruskowitz and is provided ongoing spiritual and ethical formation and direction by the diocesan vice-chancellor, Msgr. Vasha. The goal of the practice is to provide excellent and comprehensive

medical care in an atmosphere which supports the whole person physically and spiritually, and does so in faithfulness to the teachings of the Catholic Church. All care related to obstetrics, gynecology, and reproductive medicine is centered around the patient's NFP chart. In addition, the entire nursing staff have an in depth knowledge of NFP. This practice is an inspiration for all physicians who are trying to establish "NFP only" practices.

The seminar was a welcome addition to the discussion on how physicians can practice according to the teachings of the Church. The seminar underscored the importance of doctors establishing a harmony between their spiritual and professional lives. It also helped doctors to consider how to incorporate NFP into their practices so that they can offer their patients something that is truly wholesome and holy. Gratitude is therefore offered to John and Sheila Kippley and to the staff of CCL for organizing the seminar.

Lorna Cvetkovich, MD, FACOG