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Recommended Citation

Fehring, Richard, "The Present State of NFP Science, the Challenges we Face" (2006). *College of Nursing Faculty Research and Publications*. 114.

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THE PRESENT STATE OF NFP SCIENCE

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In response to the observations of Dr. Leiva, I would say that it is always time for good efficacy studies on methods of natural family planning (NFP). I concur with him that there is a need for randomized controlled trials (RCTs) of NFP methods. This need was pointed out in two published reviews on the lack of RCTs with NFP methods in helping couples to avoid pregnancy¹ and in a letter in a recent issue of the journal *Human Reproduction*, which addressed the lack of evidence for the use of NFP methods to help couples to achieve pregnancy.² RCTs are important, since they are considered the gold standard for scientific evidence in medicine, for which we should strive. However, there are some positive and negative aspects to this issue that I would add to the concerns expressed by Dr. Leiva.

The Negative Aspects

First, I will address the negative aspects. To conduct quality NFP efficacy studies in academic centers requires qualified scientists to carry out the studies; multiple qualified personnel to gather and track data, maintain compliance, and develop and teach the various methods of NFP at multiple sites; scientists with the ability to analyze and interpret the data; completion of the National Institutes of

Health Human Participant Protections Education program by all scientists and data collectors involved in the project; institutional review board approval for the project at the academic center and at the various data collection sites; advertising for participants; screening of participants; incentives for participants; and financial support.

To conduct a study to compare one method of NFP with another method of family planning (in order to show differences in pregnancy rates) would require a minimum of about two hundred fifty couples in each group (that is one thousand participants when you count the male and female contributors). Another requirement for scientific credibility is to have ethnic and racial diversity within the participant group, and to design the NFP systems to address that diversity (for example, through translation into different languages).

It takes from six months to one year to develop such a research proposal, gather a credible research team, and have it approved by an institution before it is submitted for review and funding. To conduct a quality study like this would cost from one to two million dollars. I recently developed a research team (with two medical consultants, a psychologist, six health professionals as coordinators at six data collection sites, and a biostatistician) and developed a federal research proposal for an RCT NFP efficacy study. My proposal was submitted to the National Institutes of Health (NIH) and was reviewed, but not funded point all of this out because this is what is required at a minimum for such a study. Usually, to be considered for NIH funding, you need first to conduct a pilot study and have data that shows that your intervention (i.e., the NFP method) is effective and worth funding for a larger RCT study. If an RCT study were to be funded, it would take from four to five years to conduct and complete it, and another year before a paper would be published. There are not many academic centers or qualified researchers in North America (or the world) that have the interest to carry out such a study. I can count the U. S. and European academic centers conducting NFP studies on one hand.

I would also point out that NFP is not one method. There are a considerable number of methods of NFP, including several varieties of calendar-based methods, ovulation (mucus-only) methods, "multiple indexed methods" that utilize multiple natural indicators of fertility (including some or all of the following: monitoring of basal body temperature, cervical mucus, and other biological signs, and various calendar algorithms) , and electronic hormonal monitoring methods.

The proposal that I developed compared hormonal monitoring utilizing an electronic fertility monitor with a method that monitored only cervical mucus. However, what the medical and scientific community is really interested in is a randomized comparison of NFP methods with traditional contraceptive methods (e.g., the male condom or oral hormonal contraceptive pill). As Dr. Leiva alludes this would be required from an RCT scientific perspective, but immoral from a Catholic health perspective. I could not carry out such a study. I believe that RCTs of various NFP methods would be a benefit to NFP providers and users, specifically, to help them to discern the most effective natural methods. However, I am not sure how this could be accomplished with one well-designed RCT of NFP methods, as Dr. Leiva suggests.

The Positive Aspects

There are numerous positive aspects to this issue. Although there are few RCTs of NFP methods, some very credible efficacy studies of NFP methods have been conducted in academic centers in the past few years. The criteria that Dr. Leiva references from the Lamprecht and Trussell article were actually presented to a conference hosted by the Georgetown University Institute for Reproductive Health (IRH).³ Those criteria were essentially applied in two recently published efficacy studies conducted by the IRH, one with a very simple calendar-based method utilizing beads to help couples track their fertility, and the other applying a very simple algorithm to tracking cervical mucus.⁴ These studies were carried out in several developing countries at multiple sites. Both studies achieved very credible correct use pregnancy rates (i.e., approximately 3 to 5 percent) and typical-use pregnancy rates that were comparable to rates usually seen with condom use (i.e., approximately 12 to 14 percent). European researchers at the University of Düsseldorf also have reported very good efficacy rates with a double-check multiple indexed method of NFP (that is, using multiple indicators to check fertility, both at the beginning and at the end of the fertile phase).⁵ I would be confident in presenting the findings of these studies to physicians and other health professionals.

It should also be noted that the efficacy rates from other methods of family planning (e.g., the cervical cap, female and male condoms, and spermicides) are often extrapolated from six-month clinical trials (paid for by the manufacturers). There are no pharmaceutical companies that are paying for clinical trials (much less RCTs) of NFP methods. Furthermore, although RCTs are the gold standard for providing evidence to determine efficacy of medical interventions, evidence from well-designed non-comparison efficacy studies of NFP methods should not be discounted.

However, there are many problems with existing clinical efficacy studies of NFP methods. One of the biggest studies of the ovulation method, conducted by a World Health Organization task force, found the total unintended pregnancy rate to be 22.3-i.e., under study conditions, 22.3% of one hundred couples using the method will become pregnant over a twelve-month period while not intending to do so.⁶ This is with women in this study who had been screened to have regular cycles. However, NFP advocates would point out that around fifteen of those 22.3 couples knowingly had intercourse on a fertile day.⁷ If the method says you are fertile and you have intercourse, should you really be surprised when you achieve a pregnancy? NFP advocates will also point out that NFP methods are different from contraceptive methods, in that with NFP methods you are learning how to live with and understand your fertility, not trying to block, suppress, or destroy it. One could argue that RCTs which compare NFP methods with methods of contraception are actually comparing apples with oranges.

It should be noted that modern NFP methods are often complex to learn and require ten to twelve days of abstinence or more per cycle of use (even though the fertile phase is only six days). This difficulty in use and the required time of abstinence contribute to the pregnancy rate in a positive and negative way; i.e., very low correct-use pregnancy rates (2-3 percent) but very high typical-use (12-25 percent) and often high discontinuation rates (51 percent in one year of use).⁸ Also, medical professionals for the most part will not look at the philosophical and anthropological differences between NFP and methods of contraception when assessing efficacy rates.

This is important, since medical professionals are often the gate-keepers and promoters of family planning methods, and without secure methods of family planning, will be reluctant to prescribe them or use them.⁹ Relatively few couples in the United States use modern methods of NFP (only about 120,000), and most women by far receive family planning services from health professionals.¹⁰ Only 0.2 percent of women (including Catholic women) between the ages of fifteen and forty-four years use modern methods of NFP as their primary method of family planning. This rate of use has not changed considerably since the 1980s.¹¹

Credible Studies Needed

In summary, I agree with Dr. Leiva that there is a need for good RCTs that compare methods of NFP. It is a great idea that academic and clinical NFP researchers should gather to discuss, plan, and cooperate in producing rigorous and scientifically credible NFP studies. The prime purpose is to help our patients and couples have a secure scientific base to discern what NFP methods are best for them in order to meet their family planning needs.

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Notes

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- ³V. Lamprecht and J. Trussell, "Natural Family Planning Effectiveness: Evaluating Published Reports," *Advances in Contraception* 13.2-3 June-September 1997): 155-165.
- ⁴Marcos Arevalo, Victoria Jennings, and Irit Sinai, "Efficacy of a New Method of Family Planning: The Standard Days Method," *Contraception* 65.5 (May 2002): 333-338; Marcos Arevalo et al., "Efficacy of the New TwoDay Method of Family Planning," *Fertility and Sterility* 82.4 (October 2004): 885--892.
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- ⁶World Health Organization, "A Prospective Multicentre Trial of the Ovulation Method of Natural Family Planning: II. The Effectiveness Phase," *Fertility and Sterility* 36.5 (November 1981): 596.
- ⁷*Ibid.*
- ⁸J. Trussell, "Contraceptive Failure in the United States," *Contraception* 70.2 (August 2001): 89-90.

- ⁹J. B. Stanford, P. B. Thurman, and J.C. Lemaire, "Physicians' Knowledge and Practices regarding Nat'l Family Planning," *Obstetrics & Gynecology* 94.5, pt. 1 (November 1999): 672-678; R.). Fehring, L. Hanson, and J. B. Stanford, "Nurse-Midwives' Knowledge and Promotion of Lactational Amenorrhea and Other Natural Family Planning Methods for Child Spacing," *Journal of Midwifery & Women's Health* 46.2 (March-April 2001): 68-73.
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