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# **Advances in Contraception**

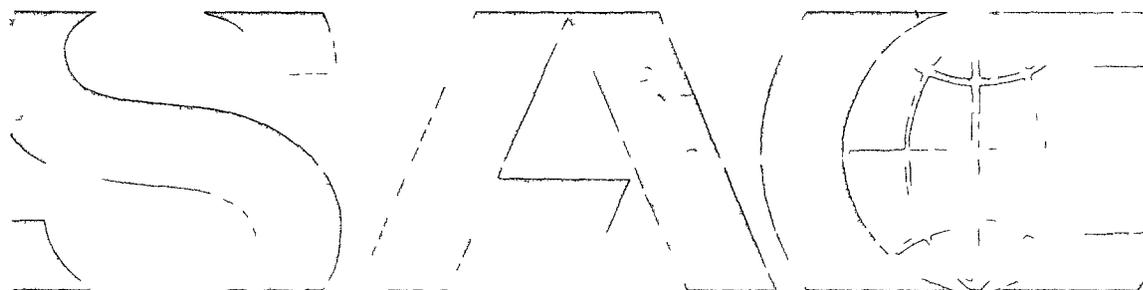
The Official Journal of the Society for  
the Advancement of Contraception

**NATURAL FAMILY PLANNING AND  
REPRODUCTIVE HEALTH AWARENESS**  
**Expanding options and improving health**

April 2-5, 1997

Leavey Conference Center, Georgetown University

*Guest Editors* Max Elstein, Victoria H Jennings,  
John T Queenan, Jeffrey Spieler



**Kluwer Academic Publishers**

# Advances in Contraception

The Official Journal of the Society for  
the Advancement of Contraception

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# Advances in Contraception

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# **NATURAL FAMILY PLANNING AND REPRODUCTIVE HEALTH AWARENESS**

## **Expanding options and improving health**

*April 2-5, 1997  
Levey Conference Center, Georgetown University*

*Guest Editors*  
**Max Elstein, Victoria H Jennings,  
John T Queenan, Jeffrey Spieler**

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## Foreword

A meeting on "Natural Family Planning and Reproductive Health Awareness Expanding Options and Improving Health" was held April 2-5, 1997, at Georgetown University in Washington, D C The objectives of the meeting were to

- \* review the state-of-the-art in Natural Family Planning (NFP) with an emphasis on integrating NFP into a variety of service delivery systems,
- \* provide a forum for reaching consensus on issues of importance to the NFP field with the members of the scientific community who participated in the meeting,
- \* explore issues relating to Reproductive Health Awareness,
- \* develop recommendations for future work in NFP and Reproductive Health Awareness, and
- \* prepare documents and other materials for broad distribution

The focus of the meeting was on the role of NFP as a component of reproductive health and on expanding its availability through a variety of service delivery structures The meeting began with a reexamination of some of the scientific bases of NFP, considering recent data on the relative likelihood of pregnancy from intercourse on different days of the cycle as well as on possible changes in fecundability and focusing on the implications of these data for NFP Advances in technologies to predict and detect the fertile days in a woman's menstrual cycle were reviewed The safety of NFP as determined by multicenter case controlled and cohort studies was presented, and factors that influence the efficacy of natural methods were examined Models of NFP service delivery were reviewed, barriers to integrating NFP into reproductive health services were identified, and strategies for overcoming these barriers were considered Finally, possible applications of the underlying components of NFP - self-observation and awareness communication with partner and providers gender concerns and sexuality - to other reproductive health issues were discussed

This meeting was a joint effort of the Institute for Reproductive Health, the United States Agency for International Development (USAID), the Society for the Advancement of Contraception (SAC) and institutions and individuals who have collaborated with these organizations All participants have been involved with the Institute for Reproductive Health in the implementation of field projects, as technical advisors, and/or as co-sponsors of activities

SAC is delighted to have collaborated with the Institute for Reproductive Health, which is based in the Department of Obstetrics and Gynecology at the Georgetown University Medical Center, and was founded in 1985, pursuant to a grant from USAID. The Institute's purpose is to improve reproductive health and the acceptability, availability, and effectiveness of NFP, with a focus on developing countries.

USAID regards family planning as a key reproductive health intervention and supports natural methods of family planning as part of its informed choice approach. SAC has long supported natural methods of family planning, featuring them prominently at recent conferences thereby ensuring a wide spectrum of family planning choices.

For purposes of the discussion at this meeting, the following definitions are key:

#### *Natural Family Planning*

Methods for planning and preventing pregnancies by observation of the naturally occurring signs and symptoms of the fertile and infertile phases of the menstrual cycle, with the avoidance of intercourse during the fertile phase if pregnancy is to be avoided.

World Health Organization, 1982

#### *Fertility Awareness*

Basic information and education on male and female reproductive anatomy and physiology as it relates to fertility. For a woman, this includes the ability to identify and interpret the signs, symptoms, and patterns of fertility throughout her menstrual cycle. For a man, it includes understanding his own reproductive potential. For both women and men, it contributes to their knowledge about their combined fertility at different stages throughout their lives, and to their ability to communicate about fertility issues with health providers and one another.

Institute for International Studies in Natural Family Planning, 1988

#### *Reproductive Health Awareness*

An educational approach that helps people learn to observe their own bodies, understand its normal changes, and know what is healthy and typical for them. It also helps them think about and understand socio-cultural factors including sexuality and gender issues that influence their reproductive health, to communicate appropriately with partners, health care providers, their children and parents, and others about reproductive health concerns, and to make decisions that can have a positive effect on their reproductive health.

Institute for Reproductive Health, 1997

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The following format for the meeting was adopted. A number of subjects in the field were identified to which specific questions were addressed. The papers were circulated to all participants prior to the meeting, their essence was presented and subjected to peer review by the lead discussant as well as the other participants. Consensus statements were developed and agreed upon following the discussion, and recommendations for future action were developed.

### **Acknowledgments**

The organizers of this meeting wish to thank Georgetown University's Department of Obstetrics and Gynecology for its hospitality and support during the meeting, USAID for financial support for this event and publication, the Board of Directors and the Secretariate of SAC for its editorial and organizational assistance, and the many institutions that shared their resources to make the meeting possible. These include Family Health International, CARE International, John Snow International, the Pathfinder Fund, the Population Council, Johns Hopkins University, Baylor College of Medicine, the World Health Organization, Trinity College-Dublin, the University of Auckland School of Medicine, Centro Ambrosiana Metodí Naturalí, Università Degli Studi di Padova, CEMICAMP, The University of Manchester, Royal Postgraduate Medical School – London, New Zealand Association of NFP, Frauenklinik des Stadt Krankenhauses, INER-ITALIA, International Planned Parenthood Federation, Department of Health – the Philippines, Duke University, Fundacion SAMEN de Cooperacion Amsterdam-Mendoza, UNIPATH, Unidad de PFN-Chile, University of Washington School of Medicine, University of Oxford, FOCUS on Young Adults, International Center for Research on Women, Princeton University, National Institute of Environmental Health Sciences, and Loyola University Medical Center.

We offer our special thanks to Ms Magaly Penuela-Alonzo and Ms Josephine Ferrigno of the Institute for Reproductive Health, Dr Jan Blancato of Georgetown University's Institute for Human Genetics, Ms Jeanne Bradshaw of SAC, and Mr Philip Johnstone of Kluwer and his colleagues. Without their tireless assistance neither the meeting nor the publication would have been possible.



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**Purposes**

- 1 To cultivate universal scientific and social exchange between physicians scientists researchers and industry representatives interested in contraception
- 2 To provide a forum for new ideas in fertility regulation
- 3 To hold meetings and sponsor relevant continuing medical education programs
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- 5 To generate greater interest in contraception in the medical community and the public at large
- 6 To assist the press in providing accurate contraceptive information to the public

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## I. Pregnancy and timing of intercourse

**What is the relative likelihood of pregnancy from intercourse on different days of the cycle? What are the implications for Natural Family Planning?**

*Chair* John T Queenan, M D , Georgetown University

*Discussant* James Trussell, Ph D , Woodrow Wilson School, Princeton University

*Consensus* Timing of intercourse relative to ovulation is critical to achieve or avoid a pregnancy. Statistical models can help to identify the probability of pregnancy due to a single or several acts of intercourse during days of the cycle relative to the day of ovulation. A fertility window can thus be identified based on these models. Most pregnancies result from intercourse within the few days leading up to ovulation, although the fact that some occur further away from ovulation indicators has important implications for NFP. It is also important to bear in mind that not all cycles are actually viable for a given woman and that the probability of having potentially fertile cycles differs across women. Although differences have been found in cycle variability in several studies over the last 30 years, these differences are more likely to be due to variations in the design of the studies and the quality of the data collected than to actual changes over time.

### *Presenters*

Alberto Ferreira Poblete, Ph D Candidate, Royal Postgraduate Medical School, UK  
**The probability of conception on different days of the cycle with respect to ovulation: an overview**

Clarice Weinberg, Ph D National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, USA  
**Model-based approaches to studying fertility and contraceptive efficacy**

Guido Masarotto, Ph D University of Padua Italy  
**Probability of conception on different days of the menstrual cycle: an ongoing exercise**

## **The probability of conception on different days of the cycle with respect to ovulation: an overview**

**A FERREIRA-POBLETE**

*Royal Postgraduate Medical School University of London London UK*

### **Abstract**

Several mathematical models have been developed over the past thirty years to investigate how the probability of conception changes on the different days of the cycle with respect to ovulation. A problem general to all models is to estimate the day of ovulation. Since the most fertile days are those close to ovulation, less precise estimates of this event will lead to less accurate estimates of the probability of conception on a given day of the cycle.

Given that a reference point for ovulation is available, the first model considered conception as dependent only on the timing of intercourse. Conception was found to be most likely to occur on only six days in each cycle. However, the model is biologically unrealistic because it assumes that all ova can be fertilized and lead to a viable pregnancy. There are other factors that affect the probability of conception, including whether the ovum is viable or not. Recent models have extended the idea of cycle viability to allow for differences between cycles within couples and for the introduction of couple specific covariates. In a second group of models the probability of conception depends mainly on the time of intercourse and the survival times of sperm and ovum.

A graphical summary of the results available in the literature is presented. Conception probabilities have been found to be significantly different from zero from five days before ovulation to the day of ovulation itself. On average, less than half of the cycles are viable in women, although recent studies suggest that different cycle viability between women should also be taken into account. Survival times for sperm and the ovum have been estimated to be 1.4 days and 0.7 days, respectively. Sperm would have a 5% probability of surviving more than 4.4 days and a 1% probability of surviving more than 6.8 days.

## Introduction

Models to estimate the expected time to conception according to the number of cycles of exposure to intercourse have been available for quite a long time [1]. However, these models did not take into account the timing of intercourse within each cycle, which is critical to the event of conception.

To create a model which will find the probabilities of conception on different days of the cycle, ovulation must be estimated accurately, since women are most fertile at that time. However, knowing the time of ovulation exactly is not an easy task. Ultrasound scans can be used to track the development of the follicle to the precise point of ovulation, but the method is impractical for other than a very small number of individuals. Generally, studies must rely on less accurate reference points for ovulation, such as the basal body temperature (BBT) shift, the quality of mucus or hormonal events like the peaks in the luteinizing hormone or estradiol. Clearly, inaccurate reference points will lead to biased estimates for the probabilities of conception on different days of the cycle with respect to the true time of ovulation and to longer "windows" with a significant risk of pregnancy.

Over the last 30 years two different models have been developed to estimate probabilities of conception. Barrett and Marshall [2] proposed a model where the probability of conception depended only on the timing of intercourse. Royston [3], on the other hand, related the probability of conception to the survival time of sperm and the ovum. The next two sections of this paper will present these two models and further modifications proposed in the literature. The results section will present estimates for these models as found in the literature. These estimates have been taken directly from the published results and have not been verified in all cases.

### *Data available*

So far only two studies have provided adequate data from which probabilities of conception could be estimated. The data analyzed by Barrett and Marshall [2] were obtained from a prospective study involving 241 women using the BBT method of natural family planning (NFP) to avoid pregnancy. A total of 103 pregnancies were observed clinically after 6 weeks of gestation. The second study, presented by Wilcox et al. [4], was intended to estimate the risk of early loss of pregnancy in women who wanted to become pregnant. A total of 198 biochemically detected pregnancies were observed in 221 women. The reference point for ovulation was selected to be the peak in the ratio of estrone-3-glucuronide (E-3-G) to pregnanediol-3-glucuronide (PdG).

Differences in the design and aims of the two studies would be expected to affect the comparability of estimates obtained from the two sets of data. First, coital patterns of couples in the two studies were probably different. Presumably, women trying to become pregnant would have more frequent intercourse on days closer to ovulation since this is the most fertile time. Conception probabilities would then be estimated more precisely on days close to ovulation but with very wide confidence intervals on days further away from ovulation. On the other hand, women wanting to

avoid pregnancy would have less intercourse on days close to ovulation but relatively more precise estimates of those probabilities further away from ovulation

Differences between the two studies also appeared in the definition of pregnancy. The Barrett and Marshall [2] study included only those pregnancies observed clinically six weeks after conception, while the early pregnancy study (EPS) [4] included pregnancies observed as early as one week after conception. Of these pregnancies, 22% ended before six weeks so they would not have been detected by Barrett and Marshall.

Finally, the protocol in the Barrett and Marshall [2] study only allowed parous women to take part in the study, having had children was taken as evidence of fertility. On the other hand, the EPS [4] study included nulliparous women, some of whom might have had undetected impaired fertility. With only these two data sets available for comparison, it is difficult to know the full effect that differences in study design would have on the estimated conception probabilities.

A third data set from which probabilities of conception were estimated came from a WHO study [5] where 725 women entered a prospective trial of the ovulation method of NFP. The reference point for ovulation in this study was the day when slippery mucus was noticed. However, poor data on the timing of intercourse and problems with the recording of all acts of intercourse did not allow an accurate estimate of daily conception probabilities, so it will not be considered any further.

### The Barrett–Marshall model

The original model proposed by Barrett and Marshall [2] assumed that each day of intercourse had an independent effect on the probability of conception. Let  $p_k$  be the probability of conception due to intercourse only on day  $k$  and  $X_{jk}$  a binary covariate taking the value 1 when the  $i$ th couple had intercourse on day  $k$  of cycle  $j$  and 0 otherwise. Then according to the model, the probability of conception in cycle  $j$  is

$$\Pr(\text{conception cycle } j | \{X_{jk}\}) = 1 - \prod_k (1 - p_k)^{X_{jk}}$$

The theory of generalized linear model [6] may be used to obtain estimates for the parameters  $p_k$ . From these estimates, the probability of non-conception due to one or several acts of intercourse in the cycle can be calculated by multiplying the quantities  $(1-p_k)$  for those days where there was intercourse. More intercourse during one cycle would result in a higher probability of conception as intuitively required.

The two main assumptions made by this model are that each day of intercourse has an independent effect (that is to say, each batch of sperm acts individually) and that the daily probabilities of conception are constant across couples and cycles.

### *Schwartz's cycle viability model*

Although the above model is statistically straight-forward to handle, it is biologically over-simplified. In reality conception does not only depend on the timing of intercourse but on several interacting factors such as the penetrability of mucus and the capacity of the ovum to be fertilized. Schwartz et al [7] allowed these factors into the model by including a cycle viability parameter which represented all the hormonal, uterine and ovum-related factors which are favorable to conception. The probability of conception in a given cycle could then be separated into two distinct elements: the probability that the cycle is viable,  $A$ , and the probability of fertilization,  $F$ , due to intercourse on different days of the cycle conditional on cycle viability. The probability of fertilization was assumed to depend only on the timing of intercourse, so the formulation proposed by Barrett and Marshall [2] could be applied to estimate it. The probability of conception is then

$$\Pr(\text{conception in cycle } j | \{X_{ijk}\}) = AF = A \left[ 1 - \prod_k (1 - p_k)^{X_{ijk}} \right]$$

In this model cycle viability is considered a dichotomous outcome, so that each cycle is either viable or not viable. The estimate of  $A$  can be regarded as the proportion of viable cycles to be expected in every woman. However, given that fertility differs from woman to woman, we should expect variations in the proportion of viable cycles across women. A simple way to allow for these differences is to model cycle viability as dependent on a set of covariates. Thus, instead of the single parameter  $A$  we would have a function  $A(\mathbf{U})$ , where  $\mathbf{U} = [U_1, U_2, \dots, U_m]$  represents a vector of covariates.

Royston [3] proposed the use of a linear regression model and used as a single covariate the age of the woman centred around the mean. In other words,

$$A(U) = \alpha_1 + \alpha_2 (U - \bar{U})$$

where  $U$  represents the age of the woman,  $\alpha_1$  represents  $A$  at the mean age ( $\bar{U}$ ) of the sample and  $\alpha_2$  represents the change in  $A$  for each additional year. Weinberg et al [8] proposed to use a logit link instead of the identity link proposed by Royston [3]. This seemed a more appropriate choice given that  $A$  is a probability, required therefore to be between 0 and 1. Cycle viability would be introduced in the model as

$$A(\mathbf{U}) = \frac{\exp[\alpha \mathbf{U}]}{1 + \exp[\alpha \mathbf{U}]}$$

where  $\alpha$  represents a vector of parameters. Weinberg et al [8] fitted this extended Barrett–Marshall [2] model and found prenatal exposure of the women to cigarette smoking to have a statistically significant effect on the cycle viability parameter.

Other unknown covariates could have a significant effect on the probability of cycle viability but those data are not available due to the limited information recorded about the couples in fertility studies.

*Modelling heterogeneity in cycle viability*

The convenient assumption made until now that cycle viability is the same in each cycle, between and within women, is not biologically plausible. Women with lower fecundability would be expected to have a lower probability of cycle viability in all their cycles and the opposite for women with high fecundability. If we do not take into account the correlation between the outcomes of viability of different cycles in the same woman, we will obtain biased estimates and underestimated standard errors for the conception probabilities.

Zhou and Weinberg [9] proposed a model based on generalized estimating equations [10] which allowed the estimation of population-averaged cycle viability parameters and corrected standard errors. Although the problem of the correlation between responses is taken into account, the estimates only describe differences in the population-averaged response between groups of women with different risk factors. A second problem with this approach is that estimates will be affected by time of follow-up in the study. In other words, estimates in a study where women are followed for 12 months will be different from estimates in a study lasting 24 months.

To obtain estimates interpretable for the couples, Zhou et al [11] developed a random-effects model where variations in the mean cycle viability between couples were modelled as a couple-specific random effect with an appropriate distribution. There are substantial advantages for using the random-effects approach instead of generalized estimating equations. First, we can obtain an estimate for the variability of cycle viability between couples. Second, the estimates will no longer depend on the length of the study.

The main problem with the random-effect model is choosing an appropriate distribution for the cycle viability random effect that will make computations possible and at the same time is biologically plausible. Zhou et al [11] modelled cycle viability as a random variable with the same value within couples but independent and identically distributed with a beta distribution between couples. This distribution has the advantage of being constrained to the interval 0 to 1, like a probability. Nevertheless, there is no reason to believe that other distributions could not be used instead. Ideally, we would use an unspecified distribution for the cycle viability random effect so that the data would decide the shape of the distribution. This possibility has not been investigated so far.

The change from a cycle viability parameter identical across all cycles to a random effect which models the correlation between cycles belonging to the same woman does not change in any way the interpretation of the model. We will still obtain a probability of conception for any given cycle, but the precision of the estimates will improve thanks to more precise standard errors. We could even calculate the value of the cycle viability parameter for each woman, although these predicted values would relate only to the selected sample and would not represent the entire population of women. Covariates could also be introduced to further model the cycle viability random effect, leading to different distributions of the random effect in different groups of women.

Another aspect of the models for conception probabilities which has not been fully

exploited is the introduction of covariates to model the daily probabilities of fertilization  $p_k$  due to intercourse on day  $k$  alone. For example, covariates could have a transient effect (affecting just one day) or a long term effect (affecting several months). Zhou and Weinberg [9] proposed using the expectation–maximization algorithm to model these covariates and looked at the possibility that having intercourse on two consecutive days might diminish the potency of sperm on the second day.

### Royston’s model

Royston [3] considered that the Barrett–Marshall [2] and Schwartz et al [7] approaches were unsatisfactory because they did not directly represent effects of important elements such as the survival of sperm and the ovum. There are two main disadvantages which could be solved by using a different modelling strategy to estimate the probabilities of conception.

First, only those daily probabilities of conception which are statistically significantly different from zero are estimated in the model. For days not included in the model, the daily probabilities are assumed to be zero. However, the number of days excluded from the model will depend on how “statistically significantly different from zero” we want those probabilities to be. Since different users of contraceptive methods based on NFP may be willing to accept different risks of conception, the statistical definition of significance will in many cases differ from the women’s acceptance level to become pregnant.

Second, as the number of estimated daily probabilities of conception increases, so does the number of quantities to be estimated from the data, an extra parameter per day will be required in the model. This has strong statistical implications, since a larger number of parameters usually leads to lower efficiency when comparing groups of women or different models and may also lead to difficulties in estimation.

### *Formulation of the model*

Royston [3] assumed that the probability of fertilization was dependent only on three factors: the functional lifetime of sperm and the egg, and the time of ovulation relative to a reference point such as the post-ovulatory BBT shift. Assuming that sperm and egg have a negative exponential survival distribution with different mean lifetimes and that the probability of fertilization is 1 at the exact time of ovulation, the probability of fertilization,  $F_t$  at time  $t$  is

$$F_t = \begin{cases} \exp \{ -(t_{ov} - t) / \lambda_s \} & \text{if } t < t_{ov} \\ 1 & \text{if } t = t_{ov} \\ \exp \{ -(t - t_{ov}) / \lambda_e \} & \text{if } t > t_{ov} \end{cases}$$

where  $\lambda_s$  is the mean survival of sperm,  $\lambda_e$  is the mean survival of the egg, and  $t$  is the time of intercourse with respect to time of ovulation  $t_{ov}$ . For times of intercourse

before ovulation, the probability of fertilization falls exponentially according to the capacity of survival of sperm, at the time of ovulation, the probability of fertilization is one, and after ovulation, the probability falls according to the survival of the egg

To obtain the probability of conception in a given cycle, we need to multiply  $F_i$  by the probability that the cycle is viable,  $A$ . Again, this could be chosen to be a single probability or a function of covariates,  $A(\mathbf{U})$

$$\Pr(\text{conception in cycle } k | \{X_{yk}\}, \mathbf{U}) = A(\mathbf{U})F_i$$

The mean survival of sperm and the ovum ( $\lambda_s$  and  $\lambda_e$ ) and the cycle viability parameter  $A(\mathbf{U})$  can be estimated using maximum likelihood. Once these estimates are obtained, the probabilities of conception due to intercourse on different days of the cycle can be found.

Royston [3] defined the model in a continuous time scale instead of a discrete scale of days. Hence, to obtain daily probabilities of conception, Royston [3] averaged the continuous probability of conception obtained with the model over  $\pm 1/2$  day for each day.

Even though this model seems mathematically more complicated than previous ones, it is based on very simple principles. It also has two advantages over the Barrett–Marshall [2] model. First, we do not need to restrict the fertile window to a set of days with statistically significant probabilities of conception. We can obtain probabilities of conception for as many days in the cycle as we require. The second advantage is that the model has only four parameters, independent of the arbitrary size of the fertile window. Hence Royston's [3] model is more efficient than that of Barrett and Marshall [2]. Third, the estimates for the parameters can be easily explained in practice to any NFP user. The final advantage is that covariates can still be included to model the cycle viability of the couples, which means that the extensions to the Barrett–Marshall [2] model can be implemented in this model.

### *Some modifications*

Weinberg and Wilcox [12] proposed a somewhat different formulation of Royston's [3] model. Conditional on viability of the cycle, the hazard for fertilization was determined by the survival time and potency of sperm before ovulation and by the same factors together with the survival time of the ovum after ovulation.

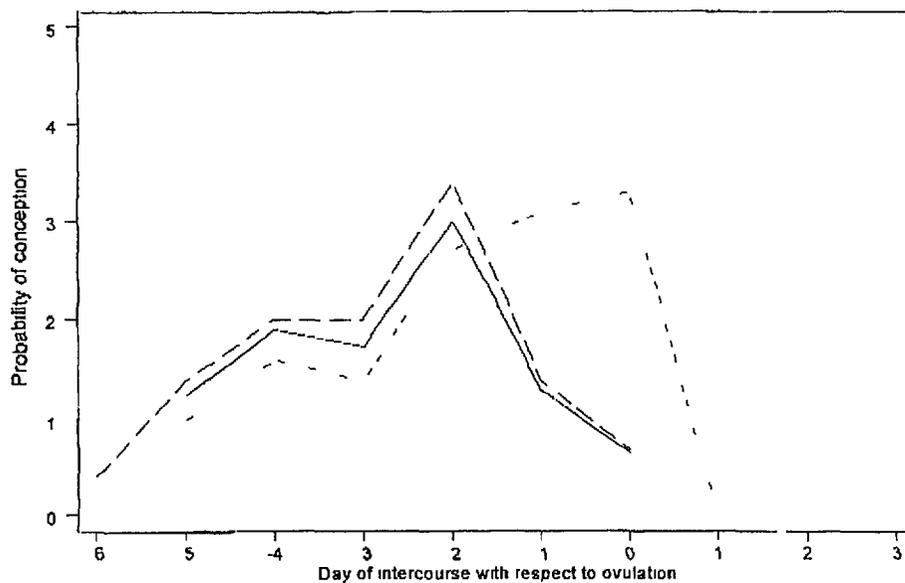
Royston [3] estimated the probability of fertilization to be 1 at the exact time of ovulation, whereas Weinberg and Wilcox [12] allowed the possibility that a viable ovum might survive the 'attacks' of sperm at the exact time of ovulation when the egg is in optimal condition for fertilization. Also, the survival time of the ovum was now assumed to follow a uniform distribution up to one day after ovulation. In other words, the capacity of the ovum to be fertilized no longer fell exponentially but was constant over a fixed time up to 24 h after ovulation and zero thereafter.

There is an important problem relating to the estimation of the parameters in this model. For ovum survival times of less than a day, it is not possible to estimate

uniquely the parameter for the potency of sperm. This is a consequence of time being measured discretely in days with the first observation after ovulation occurring on day +1, when the ovum is likely to be extinct. In fact, as the survival time of the ovum becomes shorter, the potency of sperm increases towards infinity, reflecting the need in real life for sperm to be more potent if it is to fertilize an ovum that does not survive more than a few hours. Since it is not possible to determine the mean survival of the ovum and the potency of sperm uniquely, the value of one of the parameters would have to be fixed to estimate the other. However, this implies assumptions about quantities which have not been precisely estimated elsewhere.

## Results

This section will present the main results obtained in the literature when applying the two groups of models discussed previously to the two data sets mentioned in the introduction. Figure 1 shows the estimates for the daily probabilities of conception if intercourse took place only on that day according to Barrett and Marshall [2], Schwartz et al [7] and Wilcox et al [13] using the Barrett–Marshall [2] model. Figure 2 presents graphically the estimates obtained when using the model proposed by Royston [3] and the modified model by Weinberg and Wilcox [12]. Day 0 corresponds to the day of ovulation, negative numbers correspond to days before ovulation and positive numbers are for days after ovulation.



**Figure 1** Estimates for the probability of conception due to intercourse on individual days with respect to ovulation. The continuous line corresponds to estimates by Barrett and Marshall [2], the broken line corresponds to estimates by Schwartz et al [7], the dotted line corresponds to estimates by Wilcox et al [13].

### *The Barrett–Marshall model*

When Barrett and Marshall [2] applied their model to the data they had collected, they found a statistically significant probability of conception in a fertile window extending from 5 days before the onset of ovulation to the day of ovulation itself. Within this window the probabilities increased quite steadily up to 2 days prior to ovulation and dropped to zero the day after ovulation (Figure 1). They erroneously assumed that ovulation occurred at the same time as the BBT shift, when in fact it takes place on average 2 days earlier. Taking this into account, the peak probability of conception would occur on the day of ovulation itself.

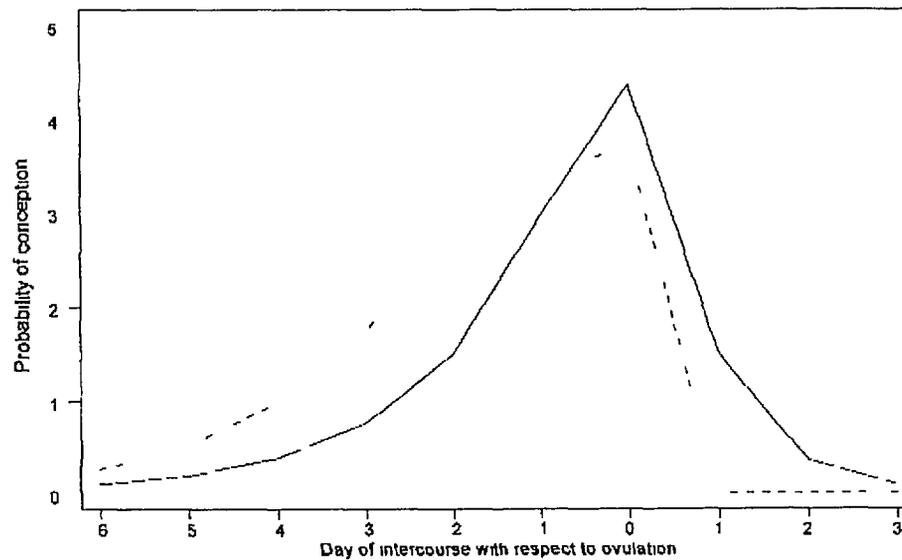
Schwartz et al [7] applied their cycle viability model to the same data set and found that the proportion of viable cycles  $A$  for every woman was on average 0.52 (no confidence interval was given for this result). Nevertheless, as seen in Figure 1, once the estimate for the cycle viability parameter is multiplied by the corresponding daily probabilities of fertilization, the estimates for the probabilities of conception are not very different from those found by Barrett and Marshall [2].

Weinberg and Wilcox [12] applied the Schwartz–Barrett–Marshall [2,7] model to the EPS data [4]. The cycle viability estimate was found to be 0.37 (95% CI 0.31–0.48). This estimate is slightly lower than the one found by Schwartz et al [7]. There were statistically significant probabilities of conception from 5 days before ovulation to the day of ovulation itself. These probabilities increased almost continuously up to the day of ovulation, and were zero the day after ovulation. Differences between these estimates and those found in previous studies could be due to differences in the design of the studies. Estimates by Weinberg and Wilcox [12] should be more precise because the ratio between hormones used as a reference point estimates ovulation more accurately than the BBT shift used in the Barrett and Marshall [2] study.

Only two covariates have been considered so far to model the cycle viability parameter. Royston [3] found that age of the woman had a statistically significant negative effect on the probability of cycle viability. Weinberg et al [8] found that exposure of the women to cigarette smoking while being in their mother's womb also had a negative effect on the probability of cycle viability. Zhou and Weinberg [9] showed that intercourse on 2 consecutive days did not have a statistically significant effect on the potency of sperm on the second day of intercourse. No further work has been done to identify other significant covariates due to the lack of information available on couples' behavior and characteristics.

### *Royston's model*

Royston [3] estimated the mean survival of sperm to be 1.47 days (95% CI 1.08, 1.86) and the mean survival of the ovum was estimated to be 0.70 days (95% CI 0.48, 0.92) using the Barrett and Marshall [2] data. The estimated proportion of viable cycles for all women was found to be 0.57, which is very similar to the Schwartz et al [7] estimate of 0.52 presumably because both were based on the same data. From these estimates a range of days for sperm survival can be calculated using the exponential



**Figure 2** Estimates for the probability of conception due to intercourse on individual days with respect to ovulation. The continuous line corresponds to estimates by Royston [3] the dotted line corresponds to estimates by Weinberg and Wilcox [12]

distribution. Sperm would have a 5% probability of surviving more than 4.4 days and a 1% probability of surviving more than 6.8 days. These survival times reflect the possibility of observing a pregnancy outside the 6 day fertile window estimated by Barrett and Marshall [2] and confirmed in later studies.

Figure 2 shows that the probability of conception reaches its peak on the day of ovulation and falls off exponentially before ovulation according to the survival of the sperm and after ovulation according to the survival of the ovum. If we compare these estimates to those found using the Barrett and Marshall [2] model, we see that the probabilities of conception are now concentrated around the time of ovulation. We have already mentioned that an inaccurate reference point for the time of ovulation could lead to biased estimates for the probabilities of conception and a greater number of days in the fertile window. Royston [3] allowed for these imprecisions of the reference point of ovulation in his model by assuming (based on external data) that the BBT shift had a normal distribution and occurred on average 2 days after ovulation with a standard deviation of 1.25 days. The estimates found by Royston [3] must be viewed as the theoretical probabilities of conception if the exact time of ovulation were known.

Weinberg and Wilcox [12] applied their modifications of Royston's [3] model to the EPS [4] data. They estimated the mean survival of sperm to be 1.39 days (no CI was given). The maximum likelihood estimate for the mean survival of the ovum occurred in the interval (0, 1), but as mentioned earlier, it was not possible to identify uniquely

its value nor the value of the parameter for the potency of sperm. The probability of having a viable cycle was estimated to be 0.37 (95% CI 0.31, 0.45). The daily probabilities of conception were found to increase up to the day of ovulation and were zero thereafter. However, not taking into account the imprecisions in the reference point for ovulation leads to higher probabilities of conception over more days.

## Conclusions

This paper has summarized models and results available in the literature on the probabilities of conception due to intercourse on different days of the cycle with respect to ovulation.

The probability of conception has been found to be highest on the day of ovulation. A fertile window with statistically significant non-zero probabilities of conception can be defined as 5 days before ovulation to the day of ovulation itself. Since the mean survival of the ovum has been estimated to be less than a day (the only available estimate being 0.70 days [3]), the width of this window is most likely to be due to the survival of sperm and the inaccuracy of the estimated time of ovulation. Given that the model is based on probabilities statistically significant at the 5% level, pregnancies can still occur if intercourse takes place on days outside that window.

Cycle viability estimates range between 0.57 for the Barrett and Marshall [2] data found by Royston [3] to 0.37 for the EPS [4] data found by Wilcox et al. [13]. These differences are most likely to be due to differences in the population studied. Age of the woman and her prenatal exposure to cigarette smoking have been found to reduce significantly the probability of having viable cycles. However, further work is required to determine other influences on cycle viability.

The mean survival of sperm was found to be between 1.4 and 1.5 days, but significant probabilities of conception up to 5 days before ovulation seem to imply that the survival distribution of sperm falls off very slowly. The mean survival of the ovum was found to be less than a day, however, it is still unknown whether its survival distribution is exponential, uniform or some other form.

Although Zhou and Weinberg [9] presented a method to include covariates that would affect the individual daily probabilities of fertilization, this method has not been widely used due to the scanty data available for the individual days of the cycle. Intercourse on 2 consecutive days was found to have a nonsignificant effect on the potency of sperm on the second day of intercourse [9].

## Further research

Further work in the area of daily conception probabilities is still needed to obtain biologically sensible models and to examine covariates which could be included in those models. Covariates influencing cycle viability are the simplest to obtain since they only need to be collected once per cycle. Further studies are needed where the socioeconomic characteristics of the couple and the clinical history of the woman are recorded.

It is biologically plausible and has been shown that cycle viability is less variable for one woman than across women. Hence more random-effects models are needed to model within women variation. Different distributions for this random effect should be considered until a biologically and statistically appropriate candidate is found. Another possibility is to consider an unspecified distribution for the random effect which will allow the data to determine the shape of the distribution.

Further research should also look at modelling cycle viability as a continuous outcome instead of a dichotomous event. It would seem biologically more plausible that the probability of a viable cycle would be graded from zero (complete infertility) to one (full fertility), with as many levels as necessary.

The possibility of combining the two models discussed in this paper should also be considered further. The Barrett and Marshall [2] model allows the introduction of daily covariates (for example, the effect of several acts of intercourse on the potency of sperm) but does not directly take into account the survival of sperm and the ovum. On the other hand, Royston's [3] model does not allow the introduction of daily covariates but is biologically more realistic since it assumes direct dependence on the survival of sperm and the ovum. Combining both models could allow the use of covariates at the same time as the survival time of the sperm and the ovum to model the daily probabilities of fertilization.

Finally, none of these will be of practical use unless more accurate and extensive data are also available. Further studies should address the problems of collecting accurate daily data for different acts of intercourse and obtaining a sufficiently precise reference point for ovulation. Recent studies involved the use of detailed daily diaries to record intercourse and a sophisticated electronic device [14] to measure daily urine concentrations of sex steroids and to indicate the fertility status of the woman in a simple way. The day of ovulation was estimated according to the peak concentration in luteinizing hormone.

### Acknowledgements

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## Model-based approaches to studying fertility and contraceptive efficacy

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### Abstract

Statistical methods recently developed to aid in identifying environmental exposures with reproductive toxicity can also be applied to trials of interventions undertaken specifically to impair fertility, i.e. methods of contraception. Although only applicable in a trial that includes a reliable benchmark for identifying the day of ovulation, the proposed measures of contraceptive efficacy derived from such a trial offer certain interpretive advantages over the more traditional approaches of evaluating contraceptives. Extensions of the same models also allow one to evaluate efficacy under any assumed pattern of imperfect use. One can also evaluate methods based on biomarkers for the fertile phase of the cycle, such as hydration of the cervical mucus, that may prove to be enormously helpful to couples who wish to use periodic abstinence as their method. In prospective studies of fertility, couples who occasionally use a barrier method should not be excluded from the study, but can be retained, without biasing the estimates for fertility parameters.

### Introduction

Approaches for assessing and comparing methods of contraception are based on estimating either the pregnancy rate or the fraction of pregnancies prevented (over some specified duration of follow-up) either under conditions of 'perfect use' or of 'typical use' of the method [1]. Such estimates can be influenced by the biological reproductive capacity of the couples studied, their frequency and pattern of intercourse, and their motivation (level of compliance with the method) and therefore do not always provide a generalizable quantification of the protection inherent to the method [1]. Because of the influence of such factors, some investigators have resorted to proposing highly restrictive protocols where couples must agree to have intercourse according to a rigid schedule set by the investigator. Only an optimistic investigator will trust the data arising from such a behaviorally demanding protocol.

The purpose of this paper is to propose two other approaches to design and analysis of contraceptive clinical trials. The proposed approaches are to be used in a setting where intercourse is unrestricted and intercourse records are maintained daily by participating couples, and where the investigator has available a reliable benchmark for dating ovulation. For methods used sporadically, e.g. condoms, the approaches to be described allow simultaneous estimation of both the relevant fertility parameters and the contraceptive efficacy parameters.

## Background

Barrett and Marshall [2] analyzed data from a cohort of couples using natural family planning (NFP), by applying a model that assumes that batches of sperm introduced to a woman's reproductive tract on different days co-mingle to present independent competing risks of fertilization to the ovum. If  $X_{jk}$  denotes an indicator variable that is 1 or 0 depending on whether there was or was not intercourse on day  $k$  (indexed relative to ovulation) for couple-cycle  $j$ , then the probability of conception in cycle  $j$  is representable as

$$\Pr(\text{Conception} | \{X_{jk}\}) = [1 - \prod_i (1 - p_k)^{X_{jk}}] \quad (1)$$

The parameters,  $p_k$ , can be estimated by maximizing the corresponding binomial likelihood and are each interpretable simply as the probability that conception would have occurred with intercourse only on day  $k$ .

This model is over-simplified and was later modified to be biologically more realistic by taking into account the fact that timing of intercourse is not the only factor that determines conception.

Schwartz *et al* [3] recognized that for a pregnancy to be observed in a particular cycle a viable ovum must have been released and must have produced an embryo that was properly transported to a receptive uterus, where it implanted without rejection and then survived at least long enough to be clinically detected. The constellation of such factors, which must be favorable for pregnancy even to be possible, has a probability, say  $A$ , which can be incorporated as a multiplicative permissive factor into model (1) as follows:

$$\Pr(\text{Conception} | \{X_{jk}\}) = A [1 - \prod_i (1 - p_k)^{X_{jk}}] \quad (2)$$

The event that all non-intercourse-related factors are favorable to gestation was termed 'cycle viability' [4] and  $A$  can be thought of as the proportion of cycles that are viable, i.e. in which pregnancy is even biologically possible. Conception requires two coincident events: the cycle must be viable and fertilization must occur. This terminology is, however, a bit misleading in that 'cycle viability' seems to suggest that the factors involved are all dependent on the woman, when in fact male factors can also influence the  $A$  parameter. For example, if the sperm that successfully fertilizes a viable ovum is itself abnormal, then this can cause failure of the cycle to produce a recognized conception.

**Table 1 Comparison of conception probabilities,  $A_{pk}$ , in relation to day of intercourse**

<i>Day of intercourse</i>	<i>British NFP cohort (Royston)</i>	<i>North Carolina</i>
-8	0 001	-
-7	0 001	-
-6	0 024	-
-5	0 037	0 100
-4	0 014	0 155
-3	0 122	0 139
-2	0 228	0 274
-1	0 229	0 312
0	0 359	0 331
+1	0 168	-
+2	0 075	-
+3	0 004	-

The fit of this basic fertility model to data from a study carried out in North Carolina [5] is shown in Table 1, with estimates from the original British study shown [6] for comparison. The day indexed by 0 is the approximate day of ovulation. For the British data the day of ovulation (day 0) is assumed, as in Royston [6], to be two days before the first day of temperature elevation (designated as day 2 here), the day of ovulation for North Carolina is based on urinary hormones [7]. The numbers shown are estimates for the probability of conception for a cycle with intercourse only on the specified day. Some important caveats are in order. The alignment of the days is uncertain, because different benchmarks were used for ovulation. Another problem with comparing the two sets of estimates is that the North Carolina pregnancies included very early losses that were only detected by a highly sensitive assay for hCG and would not have been recognized as conceptions in the British study. The estimate for the  $A$  parameter was 0.37 for the North Carolina data, and 0.38 for the British data [6].

Part of the motivation for conducting such studies is to estimate the fertile interval, the days in the cycle when unprotected intercourse can cause pregnancy. The North Carolina data are consistent with the possibility that the fertile interval is only 6 days long in that no pregnancies could be attributed unambiguously to days outside that interval and the estimates for  $p_k$  were 0 outside that 6-day interval. The British data suggest a wider interval. This has relevance to natural family planning in that the width of the fertile interval is the minimal length of time abstinence would be required in a hypothetical NFP method that uses a (not yet developed) perfect method to identify that fertile interval.

Weinberg *et al* [4] developed computationally feasible methods for allowing covariates such as age to be incorporated into the Schwartz *et al* model as influencing

the cycle viability parameter, through what is called a generalized linear model. This work was later extended by Zhou and Weinberg [8], who developed an approach that allows the day-specific fertilization probabilities,  $p_k$ , also to be influenced by factors other than day of the cycle, such as exposures experienced by the man. The method is computer insensitive, but is flexible enough to allow for exposures that might change from day to day, such as abstinence time, or characteristics of the cervical mucus. One can also take into account statistical dependencies that arise in the data due to the fact that multiple cycles may be studied for the same couple.

These models were developed to allow identification of environmental exposures that are reproductively toxic, but in fact they can be used to evaluate any exposure that may impair fecundability. In particular, one can quantify effects of contraceptives that work by blocking sperm, such as condoms, or contraceptives that work at the level of the cycle, such as oral contraceptives. Another application is to evaluate putative markers for the fertile phase, such as properties of the mucus, that could be used to improve methods based on periodic abstinence.

## Proposed approaches

### *Cycle-based methods*

The simplest application is to evaluate a contraceptive method that works at the level of the cycle, e.g. IUDs that modify the uterine lining, oral contraceptives that work by disrupting ovulation, or interventions that work by preventing implantation. This category would include most methods other than barrier methods and natural family planning and the method to be proposed is closely related to an approach that has been used to evaluate the efficacy of emergency contraception [8].

Let  $C_j$  be 1 for a cycle where the method is used, and 0 for a control cycle where no contraception is used. Then model (2) can be adapted to allow for possible effects of the contraceptive, by incorporating an efficacy parameter as follows:

$$\Pr(\text{Conception} | \{X_{jk}\}, C_j) = (\beta^{C_j}) A \left[ 1 - \prod_i (1 - p_k)^{X_{jk}} \right] \quad (3)$$

If the trial is randomized and includes a control group of couples who are not using any method of contraception, then one can estimate  $\beta$ ,  $A$ , and the  $p_k$  by applying standard maximum likelihood methods [9]. If no control group is included, one can still estimate  $\beta$  directly, conditional on an assumed set of values for the fertility parameters,  $A$  and  $p_k$ . Taking the logarithm of model (3) and treating the logarithm of  $A \left[ 1 - \prod_i (1 - p_k)^{X_{jk}} \right]$  as an 'offset' in a generalized linear model with a log 'link' and intercept constrained to be 0, will permit estimation of  $\beta$  by means of any standard statistical package that can fit generalized linear models (e.g. GLIM or SAS - GENMOD). The offsets are key in that their use controls effectively for variation across cycles in the likelihood that conception would have occurred without contraception, i.e. that controls for variation in risk secondary to the patterns of intercourse.

Given that  $\beta$  has been estimated, how is this parameter to be interpreted? Examination of model (3) reveals that  $1 - \beta$  should provide an estimate for the per cycle fraction of pregnancies prevented. To see this, note that the probability of conception in a cycle that uses the method divided by the probability in a cycle that does not use the method, but that has exactly the same pattern of intercourse, would be  $\beta$ . Note that this is not the same algebraically as the fraction of pregnancies prevented over some longer follow-up duration, which in general will depend on the length of follow-up considered.

If the contraceptive under study is used under conditions of less than perfect use, e.g. the woman does not always remember to take the pill, then effects of this noncompliance can also be assessed by an extension of model (3) that accounts for the actual usage pattern. Of course, this can be done only if some measure of compliance, e.g. a urinary marker, is included with the protocol. One can then assess efficacy under typical patterns of imperfect use of the method, and also extrapolate what would obtain under perfect use conditions.

#### *Sperm-obstruction methods*

For a contraceptive that works by modifying the effect of intercourse, either by killing sperm or by obstructing the passage of sperm through the female cervix, a different model must be defined. Let  $C_{jk}$  denote an indicator variable that is 1 if the method was used on day  $k$  in cycle  $j$  and 0 if the method was not used on that day. In place of (3), we now apply the following model:

$$\Pr(\text{Conception} \mid \{X_{jk}\}, \{C_{jk}\}) = A \left[ 1 - \prod_i (1 - \gamma^{C_{jk}} p_k)^{X_{jk}} \right] \quad (4)$$

Again, in a trial where couples are randomized either to use or not to use the method of contraception, one can estimate the  $\gamma$  parameter for contraceptive efficacy and also the fertility parameters  $A$  and  $p_k$ . If all couples are assigned to use the method but use is sporadic, i.e. the method is not used for every act of intercourse, then given a large enough study one can still estimate all the parameters, using the method described by Zhou and Weinberg [9]. The estimates will be valid, provided only that nonuse is unrelated to the couple's underlying reproductive capacity to conceive—an assumption required by all approaches to evaluating a contraceptive. If the trial includes no control group, one can nevertheless estimate  $\gamma$  by assuming values for the fertility parameters  $A$  and  $p_k$ .

This  $\gamma$  parameter has a different efficacy interpretation. The fraction  $1 - \gamma$  is interpretable as the fraction of pregnancies prevented only for cycles in which there was only one act of intercourse. As a concrete example, for a condom study the parameter  $\gamma$  can be thought of as the probability that the condom breaks or slips off. In general, the fraction of pregnancies prevented will decline slightly with increasing frequency of intercourse. Because of this, the  $\gamma$  parameter should be interpreted as a day-specific rather than a cycle-specific efficacy measure. Again, one can use the estimated efficacy parameter here,  $\gamma$ , to estimate the fraction of pregnancies

prevented under any particular pattern of intercourse with less-than-perfect use of the method

#### *Methods based on periodic abstinence*

Methods that require avoidance of intercourse during the fertile phase of the menstrual cycle do not fall into either of the above categories. The usefulness of such an approach depends on a trade-off between protection and marital health. On one extreme, such methods can be made perfectly effective, by requiring abstinence on all days. With NFP at its potential best, i.e. both efficacious and acceptable to its practitioners, abstinence would be required only on days when the woman is actually fertile, to achieve this ideal requires an accurate, simple and inexpensive method to identify those fertile days.

The statistical approach described above can also be adapted to evaluate putative markers for female fertility. If, for example, one had a home kit able to characterize (either as a yes/no or as a quantitative measurement) a property of cervical mucus thought to facilitate transport of sperm, then the usefulness of such a kit could be evaluated in a clinical trial, provided good intercourse records are kept, a reliable benchmark for ovulation is available, and a variant of model (4) is applied in the analysis. This variant would model each of the  $p_k$  day-specific probabilities according to a generalized linear model that includes the scaled or continuous candidate measure of the cervical mucus as a predictor. In this way, the approaches we have described should be useful in efforts to improve the efficacy and acceptability of NFP.

#### **Discussion**

The proposed methods offer advantages over the usual strategies for evaluating contraceptives. If a noncontracepting (randomized) control group of couples is included in the design, the parameter estimates for contraceptive efficacy should not be influenced by the underlying reproductive competences of the particular cohort studied. The parameter estimates should thus be generalizable across populations. Similarly, differences in the frequency and patterns of intercourse are inherently adjusted for by the modeling, again making the estimates generalizable across populations with different sexual behaviors. The latter result will hold even in a study with no noncontracepting comparison group, provided good and relevant estimates for the fertility parameters are available as is a reliable benchmark for ovulation.

While the paper has focused on the use of models (3) and (4) for quantifying the effectiveness of contraceptives and for identifying better markers for the fertile phase to aid in NFP, there are direct implications for studies of fertility. If a cohort of couples is under study to develop improved estimates of  $A$  and the  $p_k$  and the length of the fertile interval, then there may be couples included (perhaps those using NFP) who occasionally resort to a barrier method of contraception, such as the condom. The exclusion of such cycles should be avoided for two reasons: 1) their exclusion

wastes valuable and usable information, and 2) such cycles may correspond to times of high libido and eliminating them may produce bias. The method described (model (4)) allows such cycles to be included and to contribute appropriately to the estimation of the fertility parameters of interest.

### Acknowledgements

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# Probability of conception on different days of the menstrual cycle: an ongoing exercise

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## Abstract

The design of the European Multicenter Study on the probabilities of conception in different days of the menstrual cycle is reviewed. Some results, based on part of the data, are presented. These can be summarized as follows:

- a) Estimates of the probabilities of conception are lower than the ones previously reported in the literature,
- b) A strong effect of the man's age on fecundability was found. No evidence of a similar impact of the woman's age was demonstrated,
- c) The number of days with 'most fertile' mucus and parity affect fecundability.

## Introduction

Knowledge of the extent and location of the so-called 'fertile window' – that is, the set of consecutive days around ovulation in which the conception probabilities differ from zero – is useful for several applications in the field of natural regulation of fertility. Also useful is the knowledge of the pattern of these probabilities of conception within the fertile phase for the purpose of either avoiding or achieving pregnancy. In addition, it is important to determine the characteristics of the partners and of the cycles because they affect these probabilities. Among the applications of this knowledge are the following:

- 1 To compare the reliability of different rules for the determination of the so-called 'unsafe period' on the basis of objective evidence free from the confounding factor of differential behavioral components,

- 2 To compare the same rules in terms of duration of the required period of abstinence at the same rate of possible failure,
- 3 To find new methods with shorter intervals of abstinence linked to control of uncertainty deriving from biological variability,
- 4 To provide indirect estimates of the reliability of physical and biochemical devices for fertility detection,
- 5 To elaborate and test new algorithms making reference to the more usual 'clinical' indicators, basal body temperature (BBT) and mucus, separately or jointly,
- 6 To verify the probability of conception associated with different types of mucus,
- 7 To evaluate the sensitivity of the calculated parameters by comparison of results drawn from evidence collected in different sites or obtained through different models,
- 8 To provide estimates of these parameters for distinct categories of subjects,
- 9 In infertility management to suggest the optimal days to achieve pregnancy

This paper describes an ongoing study to obtain new estimates of the chance of conceiving on a given day of the cycle conditional to 'unprotected' intercourse taking place only on that specific day. The objective of the study is to obtain more precise and informative estimates of the time of fecundability than the few already available in the literature [1-7].

Fecundability, defined as the likelihood of conception in a cycle under a regimen of natural fertility, is usually qualified as total (counting each union of two gametes), apparent (counting all detected pregnancies, usually early in gestation), and effective (counting only conceptions leading to a live birth). In the following, we limit our attention to pregnancies ascertained through a positive test.

### **The European Multicenter Study on the probabilities of conception on different days of the menstrual cycle**

This paper reviews the basic characteristics of the study, describes some models that can be used to analyze the type of data we are collecting, and presents some preliminary results, based on a part of our data.

Information was gathered for several hundred pregnancies. Taking into account the precision of the previously obtained estimates, in particular those computed using the Barrett and Marshall data, the aim of reducing the statistical error, the time required for gathering adequate information and the available resources, a target of some 500 pregnancies was planned. It was clear that recourse should have to be made

to the cooperation of a few natural family planning centers operating in Europe and structured enough to carry out this kind of work. The main problem was to ensure the collection of good data in a delicate field involving sexual behavior. A good relationship and reciprocal trust between subject and instructors were considered essential for the success of the study.

After a few random pilot studies, a plan was made to recruit seven European centers, located in Verona, Milan, Lugano, Paris, Lyon, Dusseldorf, Brussels and London. A central coordinating center was established in Padua. All centers used the so-called 'sympto-thermal method' for natural fertility regulation. It was possible to obtain for each cycle daily information of BBT, characteristics of mucus, intercourse episodes, menstruation, and episodes of stress or illness. Couples strictly adhering to the practice of only unprotected intercourse were taken into consideration. Data were collected about partners' age and number of previous pregnancies. Only couples who were married or in a stable relationship entered the sample, which included women from 18 to 40 years old at the time of contact with the center. Procedures for eliciting informed consent and ensuring absolute anonymity were rigorously followed. The prospective study started four years ago and up to now a total of 468 pregnancies and 6434 cycle charts from 767 women have been collected for electronic processing. Further documentation is still incoming to Padua and some more work remains to evaluate the entire set of data. In the meantime, though the courtesy of Professor Trussell, it has been possible to include the data collected by John Marshall. Professor France also made available the documentation gathered in a previous prospective study with other purposes. These additions enrich the possibilities of analysis and can lead to further conclusions.

In the Results section, only the experience of the INER center, Italy (Verona) was considered. INER, Italy operates mainly in the Venetian region (1) but also in some provinces of the nearby region of Emilia-Romagna.

### The Schwartz-Barrett-Marshall model

The basic framework for the analysis of the collected data has been described by Barrett and Marshall [1]. For each cycle, the observed outcome (conceive or not conceive) can be viewed as a Bernoulli random variable with parameter (the probability of conception in that cycle) that depends on the number and the timing of intercourse events.

Barrett and Marshall [1] assumed that (i) different intercourse events have independent effects on the outcome and (ii) the probability of conception following intercourse only on day  $j$ ,  $\pi_j$ , say, is constant between couples and cycles. The probability of conception in cycle  $i$  is

$$\alpha_i = 1 - \prod_j (1 - \pi_j)^{x_{ij}} \quad (1)$$

where  $x_{ij} = 1$  if there was intercourse in day  $j$  of the cycle  $i$  and  $x_{ij} = 0$  otherwise. Estimates of the parameters can be obtained through standard likelihood calculations.

Schwartz *et al* [5] observed that not all cycles may be 'viable' For example, it may happen that the embryo does not survive long enough for the conception to be recognized If  $k$  is denoted as the probability of 'viability', then the probability of conception becomes  $k\alpha_i$  (The Schwartz–Barrett–Marshall (SBM) model) Observe that we can let  $k$  and/or the  $\pi_j$ 's depend on some covariates, e.g. the age of the woman or the type of mucus In this way the effects of these factors on fecundity can be studied In the next section only  $k$  varies In particular, a logistic regression type relation between  $k$  and the covariates is assumed Formally, it is supposed that

$$\log \left[ \frac{k}{1-k} \right] = z_i' \gamma \quad (2)$$

where  $z_i$  denotes the vector of covariates for the  $i$ -th cycle and  $\gamma$  are regression parameters Significance of these parameters can be checked using likelihood ratio tests

For other extensions of this model see Royston [9] and Zhou *et al* [10]

## Results

### *Description of the data set*

The data used in this paper were collected in the Verona center From the start of the study to mid-January 1997, 1111 charts collected by 169 couples were sent by this center to Padua Table 1 shows the couples classified according to the age of the woman, the age of the man, and the number of children Table 2 presents the cycles

**Table 1** Couples classified by age and number of children

	<i>Women</i>	<i>Men</i>
<i>Age</i>		
<25	17	5
25–29	81	69
30–34	53	63
35–39	18	25
≥40	–	8
<i>Children</i>	<i>Couples</i>	
0	116	
1	42	
2	14	
3	4	
4	1	

**Table 2 Cycles classified by number of intercourse events**

Intercourse events	1	2	3	4	5	6	7	8	9	10	11	$\geq 12$
Cycles	57	111	136	197	162	129	84	51	37	28	18	49

**Table 3 Estimates of the probability of conception No heterogeneity**

<i>Day of intercourse</i>	<i>Day 0 is the first day with high temperature</i>	<i>Day 0 is the first day with high temperature</i>	<i>Day 0 is the peak day of the mucus</i>
-9	0 04		
-8	0 09		
-7	0 02		
-6	0 03		
-5	0 08	0 10	0 11
-4	0 08	0 09	0 15
-3	0 24	0 24	0 09
-2	0 25	0 24	0 14
-1	0 03	0 07	0 15
0	0 00	0 00	0 14
+1	0 04	0 05	0 05
+2			0 00
+3			0 14
<i>k</i>	0 25	0 25	0 26

**Table 4 Estimates of the probability of conception SBM model with covariates**

<i>Day of intercourse</i>	<i>Probability</i>	<i>Covariates</i>	
-9	0 03	Constant	2 34
-8	0 10	Age of man	-0 13 ( $p < 0 001$ )
-7	0 02	Number of children	0 56 ( $p = 0 002$ )
-6	0 04	Day of fertile mucus	0 12 ( $p = 0 018$ )
-5	0 11		
-4	0 09		
-3	0 24		
-2	0 24		
-1	0 04		
0	0 00		
+1	0 04		

The probabilities of conception have been computed establishing age of the man = 30 number of children = 0 day of fertile mucus = 3

**Table 5** Values of  $k$ 

<i>Day of fertile mucus</i>	<i>Age of the man</i>			
	20	30	40	50
<b>No child</b>				
1	0.47	0.19	0.06	0.02
5	0.58	0.28	0.09	0.03
10	0.72	0.41	0.16	0.05
<b>Two children</b>				
1	0.73	0.42	0.17	0.05
5	0.81	0.54	0.24	0.08
10	0.89	0.68	0.37	0.14

classified on the basis of the number of intercourse events. It should be observed that the sample includes mainly young couples (the average age is 28.5 years for the woman and 31 years for the men) and that more than 2/3 of the couples have no children.

The day of the rise in temperature was determined using the '3 over 6' rule suitably adapted to take into account episodes of illness or special events. Because it was not possible to determine the day of the rise in 169 cycles, these were excluded. The number of conceptions detected by a chemical test in the remaining cycles was 110.

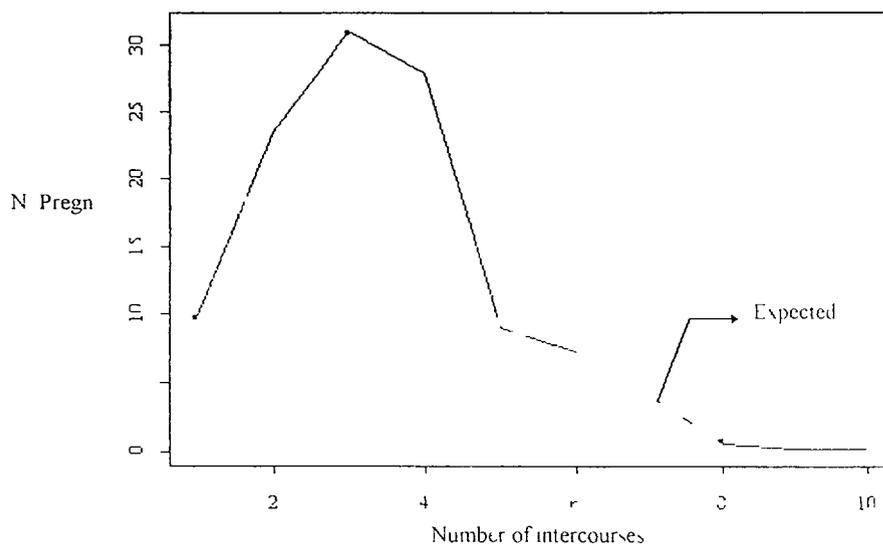
The peak of the mucus was used as a reference point as well. This information was missing for 68 cycles resulting in a reduced sample of 1042 cycles with 125 conceptions.

#### *Estimation of the probability of conception: no heterogeneity*

Table 3 shows the estimates of the probability of conception obtained fitting the SBM model without any covariate. Three sets of estimates, obtained for different choices of reference point (BBT rise or peak of the mucus) and of length of the fertile window, are given.

#### *Estimation of the probability of conception: evaluation of the effect of some possible covariates*

For this exercise, we used a fertile window lasting from day -9 to day +1 of the BBT rise. We considered four possible covariates: (i) the age of the woman, (ii) the age of the man, (iii) the number of children, (iv) the number of days with 'most fertile' mucus during the fertile window. The study protocol defines as 'most fertile' mucus with appearance 'transparent, like raw egg white, stretchy/elastic, liquid, watery, reddish'.



**Figure 1** Quality of fit in relation to frequency of intercourse

associated with a feeling of 'wet, slippery and smooth' The age of the woman was not significant ( $p = 0.729$ ) Table 4 shows the estimates of the remaining parameters Table 5 shows some values of  $k$  for various combinations of the three covariates included in the model The large range of these values is noteworthy

#### *Some checks on the basic assumptions of the SBM model*

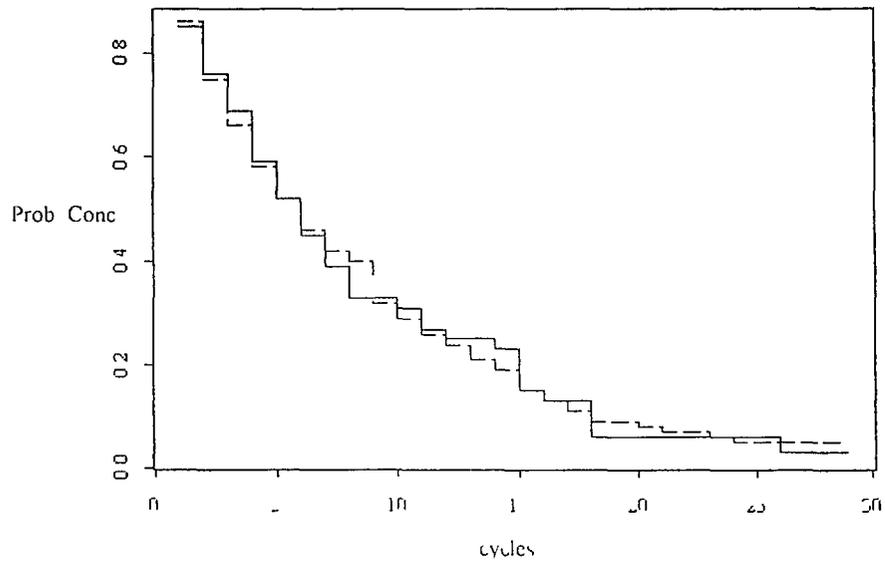
We made some numerical and graphical checks on some of the assumptions of the SBM model

#### Goodness of fit in relation to the frequency of intercourse

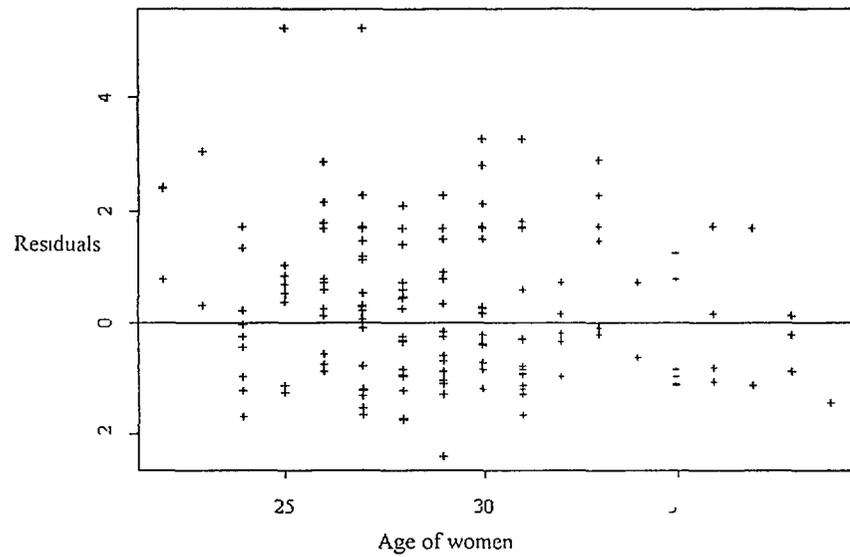
Figure 1 shows that observed and expected pregnancies classified according to the events of intercourse occurring in the fertile window are in good agreement Using the number of intercourse events as an additional covariate did not improve the fit ( $p = 0.105$ )

#### Independence between the cycles

The results of subsection 2.3 are based on the assumption that the considered factors are able to explain all the variations in fecundity between the couples Violations of



**Figure 2** Distribution of the number of cycles that a couple need to conceive. Continuous line: observed distribution; Broken line: expected distribution.



**Figure 3** Pearson residual versus age of the woman.

this hypothesis can result in some bias, since the most fertile couples conceive sooner and so they contribute a smaller number of cycles

Now, let  $N_i$  be the number of women that provide information on at least  $i$  cycles,  $P_i$  the number of observed pregnancies during the  $i$ -th cycle. The observed distribution of cycles that a couple need to achieve a pregnancy can be estimated by

$$S_i = \left[1 - \frac{P_i}{N_i}\right] \quad \left[1 - \frac{P_i}{N_i}\right], \quad i = 1, 2, \quad (3)$$

In a similar way the distribution expected under the model can be obtained. Figure 2 shows the two graphs. No large difference can be seen.

To obtain a different check we add to the the covariates also the number of previous cycles without conception. The improvement in fit is not significant ( $p = 0.841$ ).

#### Age of the woman

The age of the woman was not significant. Since this variable is correlated with the age of the partner and with the number of children, we fit a model with only the age of the woman. However, the age of the woman was still not significant ( $p = 0.998$ ).

A graphical check of this finding can be obtained in the following way. Let  $y_{ij}$  be the observed outcome (1 = conceive or 0 = not conceive) for the  $i$ -th woman during the  $j$ -th cycle. Furthermore, denote by  $\eta_{ij}$  the probability of conception for that woman and that cycle predicted by the SBM model without covariates. Then a Pearson-like residual can be computed as

$$r_i = \frac{[\sum_j (y_{ij} - \eta_{ij})]}{\sqrt{\sum_j \eta_{ij} (1 - \eta_{ij})}} \quad (4)$$

Figure 3 shows a plot of the  $r_i$  against the age of the woman. No particular pattern can be observed.

#### Discussion

These findings are derived from limited data which will need to be confirmed by the total database. Additionally these results cannot be taken as representative of conditions pertaining the whole population. The sample excludes, for instance, cases of sterility or subfertility. They are valid for a population with the biological characteristics of potential clients of a natural family planning clinic. In addition, some refinements in the modelling strategy seem necessary. For example, it seems important to let also the  $\pi$ 's depend upon some possible covariates (e.g. type of mucus on day  $j$ , previous intercourse, age of the partners, in particular the man). In this way, information about couple-to-couple and cycle-to-cycle variation in the length of the

fertile window can be obtained. Furthermore, these data can be used to address such questions as the relation between sex of the baby and timing of sexual intercourse.

#### Level of fecundity

Our estimates of the probabilities of conception are lower than those previously reported in the literature. For example, our estimate of  $k$  is 0.25. The point estimate of the same parameter computed by Schwartz *et al* [5] using data collected by Marshall in the 1960s was 0.52. Weinberg *et al* [6] obtained an estimate of 0.38 using data collected during the Early Pregnancy Study conducted in the United States about ten years ago. This finding is suggestive since it points to a decrease in fecundity over the last three decades. However, it should be noted that the observed differences are, at least in part, due to differences in designs of studies and to statistical errors. With regard to the first point, for instance, Marshall [1] included also women over forty and of 'proven fertility'. With reference to precision of the estimates, it should be mentioned that a 95% likelihood based confidence interval for  $k$  can be computed in [0.32, 1] on the basis of the data used by Schwartz *et al* [5] and in [0.20, 0.32] using our data.

#### BBT rise or peak of the mucus

Bearing in mind that the sample is not large and that the difference between the day of the BBT rise and the peak is something more than 2 days on average, the patterns of the probabilities of conception, around the two reference points, look similar. However, the fitted probabilities decrease faster if BBT is used. This may suggest that time of ovulation is more correlated with the BBT rise than with the peak.

#### Age of the partners

Our data point to a strong effect of the age of the man on the probability of conception. We found no evidence of a similar impact of the age of the woman. It should be appreciated that the women participating in the study are less than 40 years old, at least at the time of first contact. Hence, it can only be concluded that the ability of a woman to conceive does not vary between 20 and 40 years of age.

#### Mucus

The number of days with 'most fertile' mucus is a factor that could explain cycle-to-cycle variations in fecundity. Our results suggest using a model of fecundity based jointly on basal body temperature and mucus. This kind of model would seem to have potential for natural family planning application.

### Couple heterogeneity

We found that the number of previous children affects fecundity. This variable can be viewed as a proxy for the differences in the biological capability to conceive between couples not explained by the other covariates.

### Acknowledgements

We wish to thank B. Colombo for the continuous help and encouragement, J. Trussell for providing the Marshall data, F. Bassi, S. Camporese, G. Cengherle and L. Miolo for their continuous help in coding, communication with the local sites, building and checking the database, and all the people who made the European Study on Fecundability possible. We particularly thank the Institute for Reproductive Health at Georgetown University for financial support.

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## II. Natural family planning and fecundability

**Has there been a decline in fecundability in the last several decades? What are the implications for the practice of NFP, including use of NFP for avoiding and achieving pregnancy?**

*Chair* David Katz, Ph D , Duke University, Chapel Hill, North Carolina

*Discussant* Michael Zinaman, M D , Loyola University, Chicago

*Consensus* Fecundability is influenced by both sperm numbers and sperm quality, as well as factors related to the menstrual cycle and female reproductive functions. Data have been reported that there are geographically localized regions where declines in sperm numbers have occurred. However, these data should be interpreted with caution. Appropriate statistical analysis should be performed, and biases in subject selection should be avoided. Small decreases in sperm production probably do not produce measurable reductions in fecundability, but they may forecast future problems. Studies of populations of men exposed to known toxicants or other adverse conditions may contribute to the understanding of global trends. Comparable data on changes in female reproductive health are not available. Overall, consequences of the complex interactions of biological, behavioral, and environmental factors upon fecundity are not fully understood. Reduced semen quality may, in principle, diminish fecundability and affect the number of days of the fertile time. These putative changes in male reproductive health, and possible changes in the female, should not alter the present teaching and practice of NFP.

### *Presenters*

C Alvin Paulsen, M D , University of Washington, USA

**Is male reproductive health at risk longitudinal semen analysis studies**

Guido Masarotto Ph D University of Padua Italy

**Recent perspectives on male and female fecundability**

Michael Zinaman, M D , Loyola University School of Medicine, Chicago, USA

**Incidence and implications of altered semen quality on family planning**

## **Is male reproductive health at risk? Longitudinal semen analysis studies**

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Since the report of Carlsen et al in 1992 [1] which suggested that there was evidence that a decline in sperm production in normal adults had occurred over the past 50 years, considerable attention has been paid to that notion. This hypothesis was strengthened by data on Parisian men who had submitted semen samples for donor insemination over several decades [2].

On the other hand several reports have rejected that concept. They have stated that the aforementioned data [1] were incorrectly analyzed, moreover, there were biases in the selection of the men studied and other methodological problems which led to erroneous conclusions [3-5].

Despite the inherent difficulty in directly correlating fertility status to semen analysis studies, the data derived from semen examination remain useful in assessing male reproductive health, provided the analyses follow proper statistical guidelines.

Berman et al [6] have reviewed the methodological issues involved in semen analysis and stated certain important features. These included the need to log transform the sperm concentration data to obtain a normal distribution, which is necessary for statistical interpretation of the data. Secondly, there is a need to obtain multiple semen samples so that appropriate reduction to within individual standard deviation may be achieved. In most instances, collecting three to six separate semen samples from each subject will suffice. These techniques increase the power in "between individuals" comparisons which give increasing validity to the statement that possible changes have or have not occurred. Other reports have concurred with these approaches [7-9].

We examined the semen data collected from 510 healthy adult men. These data spanned a 21-year period (1972-1993). The information included sperm concentration, semen volume, and sperm morphology on samples obtained from these volunteers after 2-7 days of sexual abstinence. These studies were performed in the same laboratory by the same two technicians using standardized techniques previously reported [10]. Serial samples were obtained (median number 6). These normal volunteers either served as controls or were studied during a pre-drug intervention period of a minimum of three months for fourteen different clinical trials. The

geometric mean sperm concentrations ( $\pm 95\%$  CI) varied from  $49.2 (42-57) \times 10^6/\text{ml}$  in the first trial in 1972-3 to  $51.96 (43-62)$  in the last study in 1992-3. The highest geometric mean observed,  $76.4 (56-103) \times 10^6/\text{ml}$ , was in the 11th trial, which was conducted in 1987-9. The data obtained in the first trial showed the lowest geometric mean value. There was no significant decrease in sperm concentration during the period studied, nor in semen volume or total sperm per ejaculate. Sperm morphology was assessed in only 395 of the 510 volunteers. A slight but statistical increase in percent normal oval forms was noted but was not considered biologically important. Thus our data do not reveal any decline in semen quality over the past 21 years [11].

Our data do not rule out the possibility of a deterioration in male reproductive health in other geographical areas, or in certain small populations which are vulnerable as a consequence of environmental toxins such as exposure to DBCP [12], or in male fetuses whose mothers were exposed to agents such as diethylstilbestrol [13,14]. Careful attention should be given to that possibility.

Finally, our semen analyses, as well as those of other investigators, are not able to answer the important question of whether a certain male is fertile or infertile. For example, in the World Health Organization (WHO) clinical trials carried out to evaluate agents that could be used for male contraception a reduction in sperm concentration to  $\geq 5 \text{ m/ml}$  is still associated with pregnancies [15]. However, a steady decline in sperm concentration over time may represent an early warning that might forecast a future problem.

### Acknowledgements

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## **Incidence and implications of altered semen quality on family planning**

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### **Abstract**

Alterations in the expression of the human genome, or interference with its products, can be induced in the male reproductive system by chemicals mimicking or antagonizing naturally occurring hormones. Opportunities exist for disruption at the hypothalamus, pituitary and testis levels. Recent concerns generated by the increased incidence of testicular cancer, congenital anomalies of the male genitalia and possible alterations in human semen quality have been linked to the environment.

The report by Carlsen in 1992 [1] suggested that semen quality has deteriorated over the past six decades. More recent reports suggest that the decline may be globally non-uniform and regional in nature. The effects of any such declines upon overall pregnancy rates are generally unknown, although some studies have attempted to address them. A preliminary review of the impact of a small decrease in sperm concentrations suggests that a directly measurable reduction in fecundity does not occur, but that future problems could be anticipated. Decrements in semen quality will alter the epidemiological probabilities of pregnancy due to coitus on different cycle days and may thereby change the duration of the fertile time. Current understanding of the implications of altered semen quality on relative fertility is not sufficient to change our current teaching and practice of NFP.

### **Introduction**

Since the 1992 publication by Carlsen and colleagues [1], which suggested that semen quality has dramatically deteriorated from 1930 to 1990, a potential link to adverse environmental exposures has been suggested. Subsequent reports from Paris [2] and

Scotland [3] suggested that in these locales deteriorations in semen quality also occurred. However, other studies have either failed to confirm such finding in their locales, or have questioned particular studies on methodologic grounds [4-6]. For example, it has been suggested that data have been incorrectly analyzed [7,8]. Data transformations are required to enable parametric statistical analyses. Multiple semen specimens per man are needed in order to reduce the within-individual uncertainties in the analyses.

The search for reproductive hazards has shed light on potential mechanisms by which semen deterioration could develop. Well delineated links have been made between environmental exposures and reproductive anomalies in the animal world. Convincing data exist in animals, where environmental exposures have dramatic and precise effects upon the integrity of the male reproductive system [9]. Similar advertent (DES) [10] and inadvertent (pesticides) [9] outcomes in the human have occurred, with consistent adverse effects on the male reproductive system. The increasing incidences of testicular cancer and congenital anomalies of the male genital tract have served to heighten the concern.

While current reports cannot confirm or deny that serious changes have occurred in the human, the question arises as to what degree of decline in semen quality would be necessary to produce a detectable change in fertility or an increased time to pregnancy. The importance of this type of information is exemplified by the history of DES exposure. Men exposed prenatally to DES were found to have a significantly increased incidence of congenital anomalies of their genitalia [9]. A follow-up study of these same men [11] has since shown that they appear to demonstrate similar fertility to their unexposed controls. While this finding is reassuring, neither study is able to ascertain whether alterations in semen result from DES exposure.

Semen quality is a complex consequence of both the numbers of sperm and the functional integrity of those sperm cells. No single measure of individual sperm quality can insure that the cell is functionally competent. However, alterations in a number of (possibly correlated) properties can indicate compromise of cell functionality. There remains uncertainty regarding salient semen variables to measure, and degrees of change to indicate biological significance and concern. Figure 1 is a qualitative rendition of current thinking regarding the relationship between semen quality and the likelihood of fertilization and pregnancy itself. It is notable that this is a non-linear relationship, with a plateau region above a certain level of semen quality, and a steep decline below a threshold. Recent findings from an ongoing study of semen quality, female cyclicity, coital timing and fertility shed additional light on these issues.

## Methods

In 1987, a prospective trial of 210 presumed normally fertile couples was initiated by the first author of this paper [12,13]. Briefly, couples were recruited who had no known evidence suggesting reduced fecundity and who were discontinuing contraception in order to achieve pregnancy. Couples were excluded when menstrual

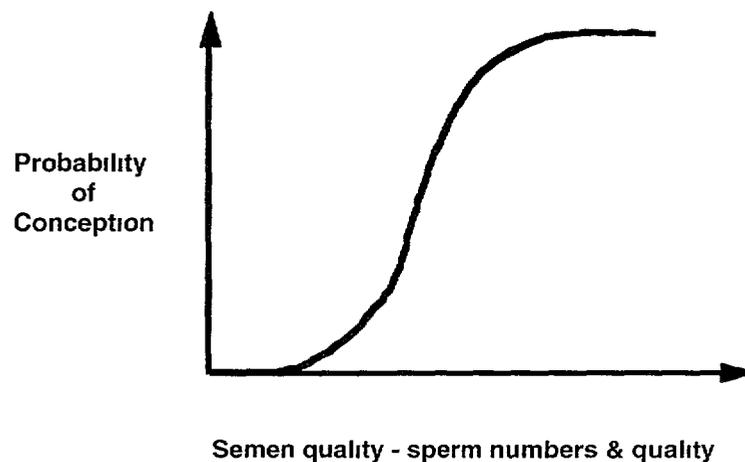
history or other evidence suggested compromised female fecundity. Women were required to be less than 38 years of age, but there was no age restriction on the men. Women kept a menstrual and intercourse diary and collected daily morning urine samples that were analyzed for LH and hCG. Blood samples, taken as soon as predicted menses were missed, were analyzed for hCG to establish the existence of chemical pregnancy.

Men provided pairs of semen samples with recommended and reported abstinence intervals at the start of the first three menstrual cycles of study. If pregnancy occurred in the first cycle, a second pair of semen samples was obtained. Couples were counseled on coital timing and frequency to optimize chances of conception. Midcycle postcoital tests were performed to verify active coitus for each cycle.

## Results

During the first three months of participation, 116 (58%) of the 200 couples for whom data were analyzed conceived. At the end of one year, 163 (82%) achieved pregnancy. During the first cycle, 59 (29.5%) achieved pregnancy. Of the remaining couples not already pregnant, 29.9% and 16.8% achieved pregnancy during the second and third cycles, respectively.

Figure 2 shows the proportion of couples who conceived in the first 3 months stratified by the sperm concentrations of the male. While considerable overlap between quintiles of sperm counts exists, there is a consistent increase in pregnancies with increasing sperm counts except at the highest levels. This is similar to the qualitative relationship depicted in Figure 1.



**Figure 1** General relationship between semen quality and probability of conception

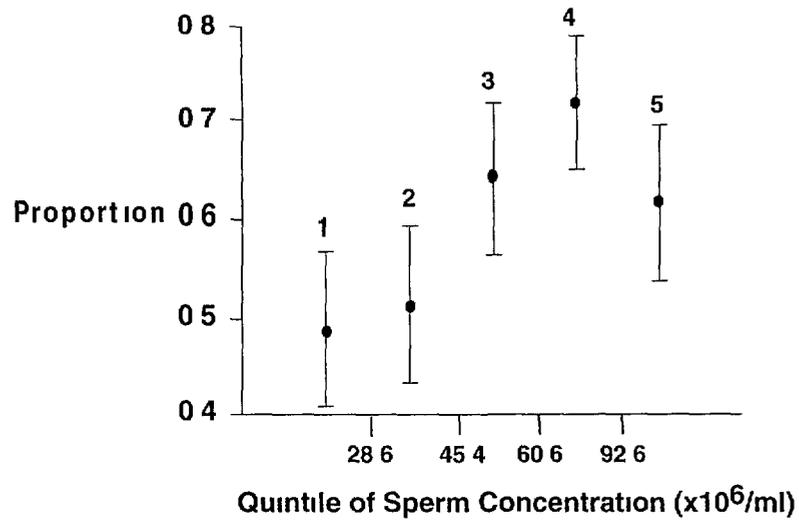


Figure 2 Proportion of couples pregnant within 3 months by quintile of sperm concentration

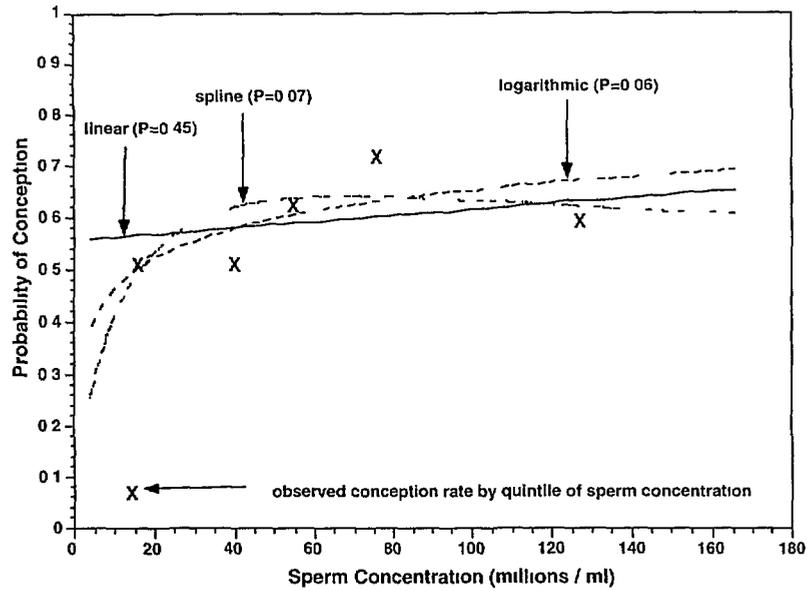
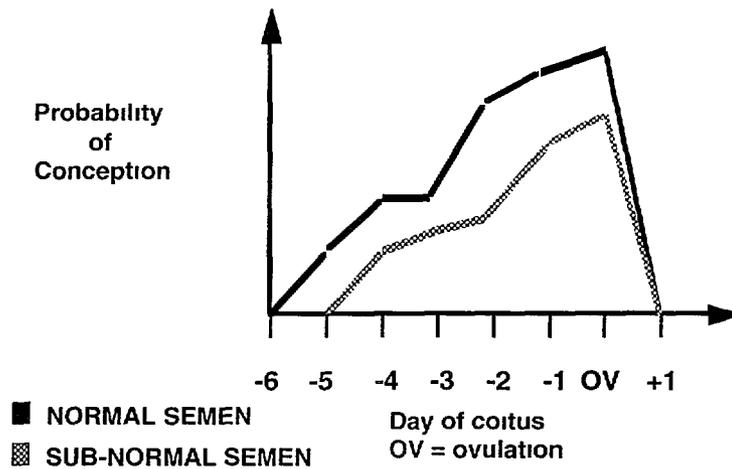


Figure 3 Probability of conception within 3 cycles



**Figure 4** Putative impact upon fecundability of a change in semen quality

Figure 3 presents the probability of achieving pregnancy in the first 3 months as stratified by sperm concentration. Representing the non-normally distributed semen concentration by a spline fit or logarithmic transformation gives the most suitable representation of the relationship between sperm concentration and pregnancy in those couples who conceived rapidly versus those who did not. In both cases significant declines in rapid conceptions can be appreciated at sperm concentrations below 40 million.

## Discussion

Successful use of NFP relies upon an understanding and delineation of the fertile time. Complex interactions of oocyte maturation, female reproductive tract secretions and sperm survival produce the fertile period and underlie NFP's success. The recent suggestion that semen quality has deteriorated could be an important factor in the success of NFP. Couples in whom the males have a reduced semen quality might well enjoy greater success with NFP. The overall probability of conception could be reduced and the duration of the fertile time could be shortened. These possible outcomes are illustrated qualitatively in Figure 4. In theory, they would require less abstinence and NFP could thereby gain greater acceptability.

While it is unlikely that any globally uniform changes in semen parameters have occurred, it is quite feasible that localized exposures in susceptible populations have been and will continue to be identified. The implications for fertility in these settings are essentially unknown. Studies to date are limited, providing little practical

guidance in this regard. In the absence of azoospermia, there are no abrupt changes in fertility that can be identified due to minor progressive changes in semen quality.

In this report we have provided early evidence from a new study of semen, cyclicity, coital timing and pregnancy. This study is seeking to develop models of fertility, or at least perturbations in fertility, as based upon relationships of objective human semen parameters, measures of pregnancy and other variables. While results are encouraging in their preliminary form, we have no significant information at present that warrants any change in NFP teaching or practice.

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### III. Detection of the fertile time

**What advances are being made to detect the onset of the fertile time? What is the experience with them to date?**

*Chair* Jeff Spieler, M S , USAID

*Lead Discussant* John France, Ph D , University of Auckland, New Zealand

*Consensus* Several advances have been made in the development of objective methods to accurately predict and detect ovulation. These focus upon both endocrine markers and properties of cervical mucus. The technology of measurement is becoming simplified, user-friendly electronic devices can now translate dipstick hormone measurements into predictions of the fertile time. As this technology is refined, accurate information is needed on user acceptability and effectiveness. Further simplification will contribute to greater acceptability. A goal for future methods is to identify the six-seven most fertile days in all cycles. Research is also needed on the extent to which new devices will attract new users to NFP, couples interested in combining fertility awareness and for those not religiously or ethically opposed to barrier methods, and/or be an alternative for existing NFP users. If the new technology is to be useful for people in the public sector in developing countries, it must be made simpler and available at sufficiently low cost.

*Presenters*

Antonio Martinez, M D , Institute for Reproductive Medicine, Argentina

**Prediction and detection of the fertile phase of the menstrual cycle. An overview**

Keith May, Ph D , Unipath, Bedford, UK

**Monitoring reproductive hormones to detect the fertile period. development of Persona – the first home use system**

David Katz Ph D Duke University Durham, North Carolina USA

**Analysis of pre-ovulatory changes in cervical mucus hydration and sperm penetrability**

# Prediction and detection of the fertile phase of the menstrual cycle: an overview

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## Abstract

Distinct means have been developed to answer an increasing demand and need for methods that can accurately predict and detect the fertile phase of the menstrual cycle and fit various indications and changing situations of women's reproductive life

Methods based on the detection of direct fertility markers, such as hormonal tests and ultrasound, are more objective and accurate than traditional markers based on indirect markers, but cost and dependence on supplies limit their application. Nevertheless, these methods could be used during a few cycles either as support in the teaching phase or in difficult cases and for specific indications. Likewise, some new devices designed to facilitate recording and calculation of fertility signals could be combined with clinical methods to improve prediction and detection of the fertile phase.

Besides the search for new fertility markers and the development of new methods, the possibility of combining already existing methods would certainly improve use-effectiveness and acceptance.

## Introduction

Accurate prediction and detection of the fertile phase of the menstrual cycle is of immense value for those engaged in either promoting or controlling fertility. This period is defined as the time of the menstrual cycle when conception is possible. The duration of the fertile phase will depend on the lifespan of the gametes in the female genital tract and this may vary from couple to couple and even from cycle to cycle. The fertile phase of the menstrual cycle is strictly related to the time of ovulation [1].

In the majority of animal species the fertile phase is limited to a relatively short period and becomes evident by the phenomenon of estrus. Changes in sexual behavior and attractiveness are synchronized with ovulation to maximize chances for fertilization [2]. The human female, however, does not show these cyclical changes

externally. Therefore it has been necessary to develop alternative methods to determine the time of fertility during the menstrual cycle [3].

These methods rely on the identification of substances or biological phenomena which in a direct or indirect way reflect the physiological changes that take place during the process of follicular maturation and ovulation.

### **Fertility markers**

Biological indicators of the fertile phase are various in their nature and modality of expression and may lie at varying physiological distances from ovulation itself. In a previous publication we classified the available fertility markers according to their main characteristics [4]. Consequently, those indicators directly related to changes taking place at ovarian level were defined as direct markers, including the ovarian morphology, the reproductive hormones and the intraovarian regulatory proteins, whereas those reflecting variations observed in different target organs were considered indirect markers, and were further qualified as biochemical, biophysical and clinical. Additionally, considering the temporal relationship between the appearance of their specific signal and the time of ovulation, fertility markers were classified as prospective, immediate or retrospective depending on whether they allowed the prediction, detection or confirmation of the ovulatory event, respectively.

Tables 1 to 3 give an overview of fertility markers according to the proposed classification. While many of them already have an established clinical application, others are only of scientific interest or are currently under investigation. A detailed analysis of these markers can be found in Reference [4].

### **Methods for the prediction and detection of the fertile period**

We could define as a method any specific methodology or technique that is based on the identification of a fertility marker, or a combination of markers, which allow us to predict, detect or confirm the occurrence of ovulation.

Until recently, there have been few reliable methods which could determine the time of fertility with acceptable accuracy. Research in human reproductive physiology has resulted in major advances in the knowledge of the process of ovulation and has allowed the finding of more reliable indicators. Accordingly, different methods and techniques have been developed for the identification of markers and signals that in a direct or indirect way reflect the physiological changes that take place during the ovarian cycle [3].

A classification of actual and potential methods for the prediction and detection of the fertile phase of the menstrual cycle is presented in Table 4. This is based on the nature of the markers, either direct or indirect, as well as whether they use single or multiple markers. Additionally, their time relationship with ovulation has been considered. Following this division, methods used to delineate the fertile period could be further defined as

**Table 1 Direct fertility markers**

<i>Marker</i>	<i>Signal</i>	<i>Timing</i>
<i>Ovarian morphology</i>		
Follicle growth	Size	Prospective
Blood flow	High peak velocity	Immediate
Vascular resistance index	Decrease	Prospective
Vascularization	Granulosa vessels	Immediate
Intrafollicular appearance	Detached cumulus	Immediate
Follicle morphology	Collapse	Retrospective
<i>Hormone</i>		
LH	Surge/peak	Immediate
Estrogens	Surge/peak	Prospective
Progesterone	Rise/surge	Immediate/retrospective
Estrone conjugates	Rise	Prospective
Pd-3 G	Rise	Retrospective
E1G/Pd3G ratio	Rise/peak	Prospective
Inhibin*	Rise/peak	Prospective/retrospective
Renin*	Rise/peak	Prospective/immediate
<i>Intraovarian regulatory proteins</i>		
FRP*	Rise	Prospective
FAIP*	Rise	Prospective
Activin*	?	?
Growth factors*	?	?

\*Potential markers

- 1 Prospective methods, which will identify the initiation of the preovulatory phase, thus predicting ovulation,
- 2 Immediate methods, those indicating the actual occurrence of the event, thus detecting ovulation, and
- 3 Retrospective methods those which define that ovulation has occurred confirming the end of the fertile phase

It should be clarified that while the problem of predicting ovulation and monitoring the ovarian function covers a wide variety of clinical and nonclinical settings, the presented classification emphasizes methods intended for home use

#### **Alternative methods**

It can be assumed that the accuracy of a method will be related to its physiological

**Table 2 Biochemical and biophysical indirect fertility markers**

<i>Marker</i>	<i>Expression</i>	<i>Signal</i>	<i>Timing</i>
<i>Biophysical</i>			
BBT	Int /External	Rise	Retrospective
Electrical resistance	Saliva	Peak	Prospective
	Vaginal secretions	Nadir	Immediate
Crystallization	Cervical mucus	Ferning	Prospective
	Saliva	Ferning	Prospective
Light transmission	Cervical mucus	Increase	Prospective
Electrostatic charge	Body surface	Negative to Positive	Immediate
<i>Biochemical</i>			
a Enzymes			
Peroxidase	Cervical mucus	Drop	Prospective
	Saliva	Peak	Prospective
Alkaline phosphatase	Saliva	Peak	Immediate
Diaminobenzidine peroxidase	Cervical mucus	Peak	Immediate
<i>N</i> acetyl $\beta$ D glucosaminidase	Saliva	Peak	Immediate
Arylsulfatase	Saliva	Peak	Immediate
$\beta$ Glucuronidase	Saliva	Peak	Immediate
b Ions sugars and proteins			
NaCl	Cervical mucus	Rise	Prospective
	Milk	Increase	Prospective/Retrospective
Phosphate	Saliva	Peak	Immediate
Glucose	Cervical mucus	Increase	Immediate/Retrospective
	Saliva	Increase	Prospective
Sialic acid	Cervical mucus	Decrease	Prospective
	Saliva	Rise	Prospective
Soluble proteins	Cervical mucus	Decrease	Prospective
Mucoglycoproteins	Cervical mucus	Increase	Prospective
CA 125	Cervical mucus	Increase	Prospective
24K protein	Endometrium	Increase	Prospective/Retrospective
Sialoglycoprotein	Endometrium	Increase	Immediate

distance from the ovulatory process. Consequently, methods based on direct markers will offer the highest reliability, whereas those relying on indirect markers are inaccurate and less specific. On the other hand, direct methods depend on more elaborate supplies with related costs and need for continuous provision. Methods based on clinical markers allow the user greater autonomy and are almost costless. Moreover, with traditional NFP methods, the definition of the start and end of the abstinence period is calculated by women according to their own perceptions. This condition generates an unbalanced responsibility for the decision to abstain from sex

**Table 3 Clinical indirect fertility markers**

<i>Marker</i>	<i>Timing</i>
Cervical mucus changes	Prospective/Retrospective
Cervix modifications	Prospective/Retrospective
CVF volume	Prospective/Retrospective
Cycle calculations	Prospective/Retrospective
Cyclical moulting	Immediate
Vaginal cytology	Prospective/Retrospective
Corpus luteum biopsy	Retrospective
Endometrial biopsy	Retrospective

**Table 4 Classification of methods for prediction and detection of the fertile period based upon direct or indirect fertility markers and their relation to the time of ovulation**

<i>Marker</i>	<i>Method</i>	<i>Timing</i>
<i>A Direct methods</i>		
LH peak	Urinary test	Immediate
E-1 G rise	Urinary test	Prospective
Pd 3-G rise	Urinary test	Retrospective
E 1-G/P d G	Home ov monitor	Prospective–Retrospective
Follicle development	Ultrasound	Prospective–Retrospective
<i>B Indirect methods</i>		
1 Single markers		
Temperature	BBT	Retrospective
CM crystallization	PG/53	Prospective
SER peak	Electrical device	Prospective
VER nadir	Electrical device	Immediate
Guaiacol peroxidase	CM test	Prospective
CM hydration	Sensor device	Prospective
CVF volume	Volumetric	Prospective–Retrospective
CM changes	OM	Prospective–Retrospective
Cycle rhythm	Calendar	Prospective–Retrospective
2 Multiple markers		
Rhythm + CM + BBT	STM	Prospective–Retrospective
Rhythm + BBT	Electrical device	Prospective–Retrospective

CM cervical mucus BBT basal body temperature OM ovulation method STM symptothermal method  
 CVF cervicovaginal fluid SER salivary electrical resistance VER vaginal electrical resistance

and can be accompanied by the partner's feelings of doubt about this assumption. Methods using objective markers that can also be interpreted by the man may stimulate male participation and increase their commitment to use the method correctly.

A feasible response to these confrontational situations could be the combination of traditional methods based on clinical markers (i.e. the ovulation method (OM), the symptothermal method (STM) or the calendar) with other method or methods that utilize a more objective and accurate marker (i.e. LH test, progesterone test, ultrasound). This would focus on signal interpretation and help to confirm the clinical observations. Such an approach could be useful as NFP support during a few cycles, either during the teaching phase or for difficult cases and for specific indications. The particular situation and other practical reasons, such as its relative accessibility, may further determine the choice of a certain combination.

Additionally, the appearance of new devices marketed for the detection of the fertile period offers the alternative of combinations with traditional methods to improve user's compliance and method efficacy. From a practical point of view some potential combinations are suggested:

- 1 The OM + Rovumeter. In this case, the Rovumeter would add the volumetric changes of cervicovaginal fluid (CVF) as another fertility marker [5]. Moreover, CVF self-sampling could allow a better observation of mucus changes to those women with low mucus secretion or difficult mucus perception.
- 2 The OM + Babycomp/Bioself/Rabbit or similar. These electronic devices would complement the mucus symptom with the BBT and cycle calculations as extra fertility signals [6]. In fact, this would become a kind of sophisticated STM for users who feel insecure with the OM alone.
- 3 The STM + Babycomp/Bioself/Rabbit or similar. In this combination, the device would facilitate and improve the calendar calculations and BBT shift detection, increasing method accuracy and probably of users' acceptance. To our knowledge no studies comparing traditional methods alone with combined methods in terms of efficacy, continuation rates, number of days of abstinence and user's satisfaction, among other parameters, have yet been published.

### Conclusions

In recent years, programs dealing with women's reproductive health have become aware of the increasing demand and need for methods that can accurately predict and detect the fertile phase of the menstrual cycle [7]. This is evident not only in the medical subspecialty of reproductive endocrinology but also in couples who use periodic abstinence and fertility awareness methods for family planning and for educational purposes [8]. Strategies aimed to answer these requirements should be oriented to pursue the following points:

- 1 Identification of new fertility markers The rapidly growing knowledge of reproductive physiology has demonstrated the existence of multiple substances, many of them still under investigation, which are involved in the reproductive process Further research in this area will expand the possibility to identify new indicators to be used as potential markers of the fertile period and therefore need to be encouraged and supported
- 2 Development of new methods for the prediction and detection of the fertile phase At present the most widely used NFP methods, such as the calendar, the ovulation method (OM) and the symptothermal method (STM) are based on clinical markers However, there is a high proportion of failure or discontinuation rates with these methods related to difficulties of the users to clearly identify fertility signals and to determine the period of abstinence The assistance of new technologies and improved methodologies will undoubtedly contribute to the development of new methods based on other biological indicators This approach should consider a close cooperation between laboratory scientists, industry, and people experienced in field programs
- 3 Improvement of the reliability and acceptance of existing methods Though for many couples, prediction and detection of the fertile period with traditional indirect methods represents a reliable option, for other situations these are clearly inadequate or insufficient The possibility to combine traditional methods with new methodologies such as hormonal tests or electronic devices could add objectivity and accuracy in the detection of the fertility signals, decreasing imprecision and uncertainty and improving method reliability and acceptance This could be an interesting alternative that has not yet been explored
- 4 Expanding the availability of methods offered by NFP services There are different requirements in the prediction and detection of the fertile period according to different conditions in women and even at different stages of a woman's life Currently there is no method that fits all these variables satisfactorily The possibility that programs dealing with NFP are able to offer a diversity of methods which have been developed to match particular indications would certainly improve user compliance and efficacy of the method

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## **Monitoring reproductive hormones to detect the fertile period: development of Persona – the first home use system**

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### **Contraceptive choices**

Why do we need new methods of contraception, particularly family planning methods based on detection of the fertile period? Over the last 10 years Unipath has conducted extensive research into the attitudes affecting contraceptive choice. Surveys show that at any one time 15–25% of women are dissatisfied with their current method of contraception and at any one time 20% of women wishing to avoid pregnancy are not actively using any contraception.

There are many factors which influence a woman or a couple's choice of contraception, including

- Lifestage
- Stage of the relationship
- Reliability
- Ease of use/convenience
- Potential for side-effects
- Previous experience with other methods

Throughout our market research and our subsequent acceptability studies which have been carried out in parallel with our clinical trials, we have found that the elements that constitute a woman's ideal method of contraception are embodied in a method which

- Has no side-effects
- Involves no drugs and devices (is non-invasive)

- Is non-interruptive
- Is simple
- Is reliable

There is currently no ideal method of contraception which answers all these needs in every detail but many of the attributes of this consumer's ideal can be answered by a new method based on detection of the fertile period

### **Development of Persona**

The concept of a home use test or tests to monitor changes in reproductive hormones to prospectively identify the fertile period was first raised about 20 years ago as a result of the work done by the World Health Organization Task Force in Human Reproduction. The first product which realized this concept, Persona, was launched onto the UK market in September 1996.

During the 1980s, Unipath conducted further research on the key hormone markers and also on consumer attitudes to contraceptive choice. Before product development could proceed in the late 1980s, two key technological advances were required:

- 1 The development of one-step immunoassays which are simple enough to use at home. Unipath introduced the first one-step home pregnancy test in 1988. The technology has been further enhanced to allow the development of the dual hormone assays required in Persona.
- 2 Advances in microelectronics allowed the development of an intelligent hand-held monitor capable of reading, storing and using the information on the hormone changes.

### **Markers of the fertile period**

Potential fertility, which can be defined as the time during each menstrual cycle when coitus might lead to pregnancy, is dependent upon ovulation, i.e. the release of a viable egg. The length of the fertile period is determined by the lifespan of the sperm and egg. The lifespan of sperm and their ability to reach the egg is dependent upon the reproductive hormones and the physiological changes they produce.

The type and quality of cervical mucus affects both the lifespan and motility of sperm. The appearance of fertile mucus which can support sperm survival for several days is triggered by rises in estrogen (estradiol in blood and metabolites such as estrone-3-glucuronide (E-3-G) in urine). In the absence of fertile mucus, sperm viability and motility are greatly reduced. The rise in estrogen is therefore currently the best marker of the start of the fertile period. The rises in estrogen also lead to the

release of luteinizing hormone, which triggers ovulation. The temporal relationship between the rise in LH and ovulation is well documented and normally within the range of 24–36 hours. As the egg is only fertilizable for 12–24 hours, the rise in LH can be used to indicate the end of fertility.

Persona uses E-3-G to indicate the start of the fertile phase and LH to indicate the end of fertility.

### **Persona – the Unpath personal system of contraception**

Persona consists of a small hand-held monitor and disposable test sticks. The test stick converts E-3-G and LH into colored signals which can be read by the monitor. On the first day of menstruation the user presses the M button on the monitor, which then indicates day 1 of the cycle. For the first few days it will display an M symbol. Each day the monitor will indicate the fertility status by the use of a red or green light. On the days the monitor requires the user to do a test (16 tests in the first cycle, 8 in subsequent cycles) it will indicate this by a yellow light. The test stick is inserted into the urine stream and the cap is placed over the exposed end and then inserted into the monitor. The monitor compares the levels of signal produced with those on previous days, looking for significant changes in E-3-G and LH. When the monitor detects a significant change in E-3-G it changes the fertility status from green to red. Detection of LH allows the system to indicate by use of an O symbol the expected time of ovulation and also uses this information to indicate the end of fertility by switching the light to green. As the monitor stores the information, it is able to target the tests to maximize the chances of locating the rises and becomes personalized to the user's cycle lengths and patterns.

### **Conclusions**

There is a continued need to increase the range of methods of family planning available. The level of dissatisfaction with, or non-use of, contraceptive methods by a significant proportion of the population indicates that a significant gap still exists between currently available methods and the consumer's vision of the ideal product. Methods based on the detection of the fertile period fulfill many of the criteria identified by women trying to describe their ideal method of contraception. Persona is the first home use method which monitors hormones in a woman's urine to provide a simple and reliable way to detect the fertile period.

Clinical trials on the efficacy and acceptability of this new method have been completed and are now being prepared for publication.

## **Analysis of pre-ovulatory changes in cervical mucus hydration and sperm penetrability**

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### **Abstract**

Changes in cervical mucus occur during the proliferative phase of the menstrual cycle and are known to correlate with receptivity to sperm and to the endocrine milieu. Prior studies, however, have often lacked biological incisiveness and technical objectivity and precision. This study analyzed daily changes in mucus water content (hydration) prior to the LH surge (LH+0) in normal women, in relation to daily levels of serum LH, FSH, estradiol and progesterone, and to daily tests of sperm penetration of the mucus. Cervical mucus was studied for 12 cycles in 10 ovulating women. Three to ten mucus specimens were collected per cycle, over the days LH-8 to LH+0. Each specimen was subjected to measurement of both water content (hydration) and penetration by spermatozoa from fresh specimens of normal human semen. For the latter, a new microscale assay was developed and applied, which was amenable to very small volumes of mucus. The new technique determines objective measures of both the numbers of penetrating sperm (motile and non-motile) and the distance penetrated by the forwardmost vanguard sperm. In these experiments, variations in semen quality were controlled by performing a companion penetration assay in an artificial 1.5% polyacrylamide gel.

The patterns of change in mucus hydration varied quantitatively among women, with preovulatory baseline levels ranging from 93.8-96.5%. All normal cycles (as defined by endocrine profiles) displayed a significant increase in hydration over a one-day period occurring 3-4 days before the LH peak. The magnitude of this shift varied among women between 2 and 3% (absolute

hydration), a distinction well within the precision of the hydration assay This quantum increase in hydration was more pronounced than the corresponding increase in serum estradiol on the same day The change in mucus hydration, and the associated increase in sperm penetrability, were more consistent among cycles than the changes in reproductive hormones

There was a strong but non-linear correlation between mucus hydration and sperm penetrability Once the value of hydration rose above approximately 97.5%, there was a substantial increase in penetrability This 'cut-off point' in sperm penetrability was in the middle of the range of hydration values (across women) which preceded the quantum jump in hydration – which, itself, preceded the surge of LH Hydration began to increase approximately 2 days before measurable increases in sperm penetration of the mucus *in vitro*

These results demonstrate that mucus hydration may be a valuable marker of the approach to ovulation and delineation of the fertile period They also provide new methods for assessing sperm penetration into both large peri-ovulatory and very small samples of collected mucus

## Introduction

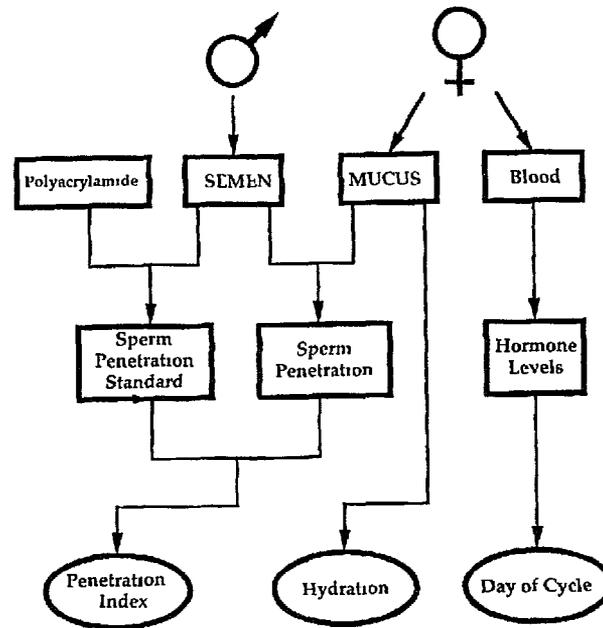
Cyclic changes in human cervical mucus properties are associated with varying levels of reproductive hormones, and relate to the function of the cervix in modulating sperm transport [1,2] There is threefold interest in measurement and interpretation of these properties

- 1 They are central to the basic understanding of how cervical mucus functions,
- 2 They are valuable in the clinical assessment of cervical function, and
- 3 They are important to women who utilize self-monitoring of mucus in estimation of the fertile time of the menstrual cycle, e.g. for natural family planning

There has been considerable historical interest in the physicochemical basis for the conspicuous cycle changes in mucus A fundamental property of all hydrogels is the water content, or hydration, and this has been shown to be a principal determinant of cyclic changes in human cervical mucus properties [3] However, despite the obvious physiologic and physicochemical motivation for studying cervical mucus hydration, it has received surprisingly little attention, particularly in clinically motivated work

The objectives of the present study were to (Figure 1)

- 1 Collect daily specimens of mucus from normal women, from the outset of self-recognition of post-menstrual mucus production until the LH surge
- 2 Measure the water content (hydration) of each mucus specimen



**Figure 1** Experimental plan

- 3 Measure the receptivity of each mucus specimen to fresh seminal sperm. This requires a control procedure to account for the natural variability in human semen.
- 4 Measure levels of LH, FSH, estradiol and progesterone in blood specimens collected daily.
- 5 Analyze the relationships between cycle day and status (in relation to the day of the LH surge and levels of the other hormones), mucus hydration and the measures of mucus receptivity to sperm. On the basis of these analyses we then sought to determine
  - a) Does mucus hydration undergo characteristic changes early in the cycle that correlate with the time of ovulation? How do these changes correlate with the overall endocrine profile of the cycle?
  - b) Do these changes in hydration correlate with measures of mucus receptivity to sperm?

In pursuing these objectives, it was necessary to perform objective, quantitative analysis of *in-vitro* sperm penetration into very small volumes of mucus, many of which possessed high viscoelasticity. Contemporary tests of sperm penetrability [4] were not adequate for such measurements, and it became necessary to develop an improved technique to accomplish this aim.

## Materials and methods

### *Measurement of mucus hydration*

Mucus hydration was measured as % H<sub>2</sub>O by weight on a 10 µl aliquot of each mucus specimen. The aliquot was transferred to a standardized glass microhematocrit tube that had been acid washed and pre-weighed. The mucus-containing tube was weighed, frozen, and then lyophilized for 40 h. Now containing dehydrated mucus,

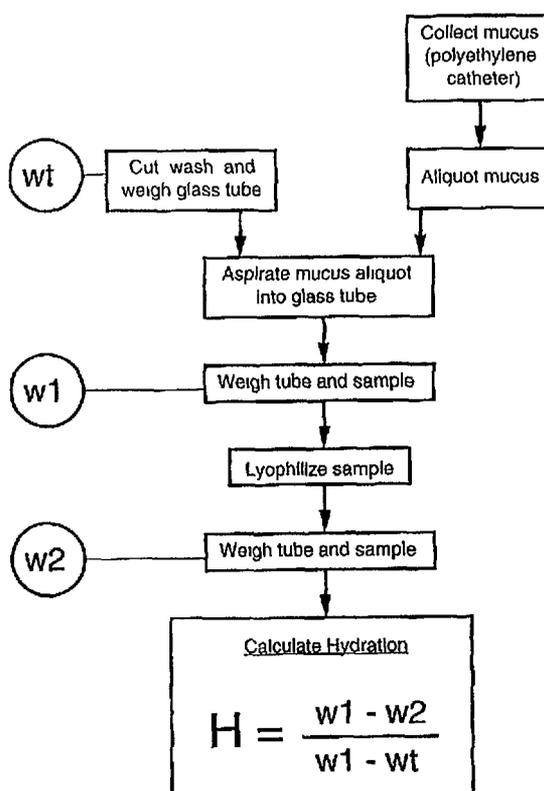
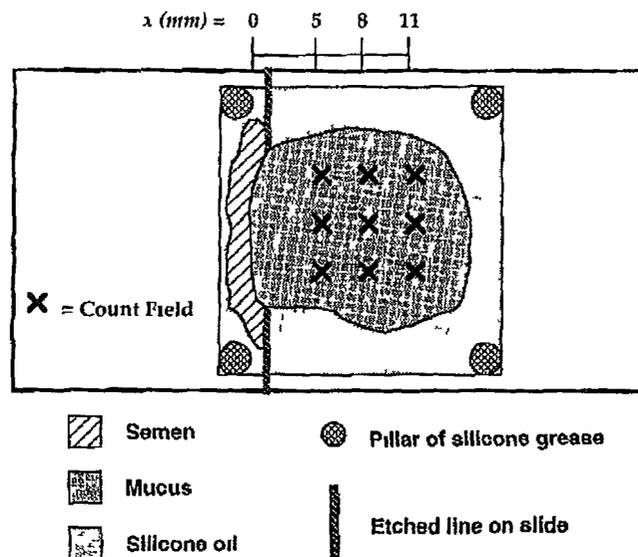


Figure 2 Mucus hydration measurement

it was reweighed. Calculation of mucus hydration followed directly (Figure 2). This assay was validated in replicate testing, including analyses in artificial gels with varying hydrations. Individual hydration measurements were accurate with an average error of 0.15% with respect to true hydration values, and a maximum error of 0.25%. Interassay coefficients of variation ranged from 0.04–0.10%.

#### *Quantitation of sperm penetration into small aliquots of mucus*

Each mucus specimen was subjected to a new sperm penetrability assay using fresh human semen (Figure 3). The assay utilized 20  $\mu\text{l}$  of mucus in a sealed plane slide preparation with a depth of 150  $\mu\text{m}$  (obtained by supporting the coverglass with silicon grease impregnated with glass microspheres of this diameter). The left margin of the mucus was positioned adjacent to a straight groove scored into the glass slide. A 7  $\mu\text{l}$  semen aliquot was applied to the left margin of the mucus. The presence of the groove helped create a relatively straight semen–mucus interface in the center of the preparation. Such an interface was necessary in order to obtain a standardized position of reference for quantitative assessment of sperm penetrabilities into different mucus specimens. After 30 min of semen–mucus contact, a video recording was made of the preparation, using phase contrast optics. This focused upon the interface, and sets of microscopic fields 3, 5, 8 and 11 mm from the mean position of the interface (Figure 3). Our microscopic optics were such that playback of the video recording revealed all spermatozoa throughout the depth of the preparation in each field. Sperm numbers were easily counted on the video screen, and sperm motility thus objectively measured.



**Figure 3** Mucus penetration assay

Although the semen in this study was obtained from men who routinely produced clinically normal specimens, there was natural variability in sperm concentration and motility across these specimens, resulting in different degrees of sperm penetration of individual mucus specimens. Analysis of sperm penetration of mucus controlled for this semen variability by performing a parallel test, using an artificial 1.5% polyacrylamide gel as a substitute for mucus. This standardized gel has properties physically similar to, though not duplicating mucus. Measures of sperm penetration into mucus were then normalized by their counterpart values in the artificial gel.

In the new assay objective, quantitative measures of the numbers of penetrating sperm and the position of an effective vanguard sperm 'front' were computed as follows. The data on normalized sperm count versus position in mucus fit an exponential function of the form

$$C = C_0 \exp(-ax) \quad (1)$$

Here  $C$  is normalized sperm concentration (with respect to the artificial gel), and  $x$  is the distance from the semen mucus interface. The parameters  $C_0$  and  $a$  were determined from least squares/regression analysis. Equation (1) is a reasonable approximation to a more rigorous mathematical model of how sperm numbers accumulate in mucus as a function of position from the interface and time. Exponential models have been used previously to analyze sperm penetration into gels [5]. A measure of the total numbers of sperm in the mucus was computed as the area under the curve ( $A_m$ ). The extent of sperm penetration into mucus was defined as the position of the right hand tail of this exponential curve, denoted  $L$ . The parameter  $L$  was obtained as that value of  $x$  at which the value of  $C$  reached a small value commensurate with the precision of measurement of sperm numbers in this assay, representing an uncertainty of one sperm per microscopic field measured.

## Results

Data were obtained for 12 cycles from 10 women (Figure 4). Mucus specimens were collected over the range of days LH -8 to LH +0 (the day of the LH surge). Values of mucus hydration during the initial collection days ranged from 93.8–96.5% among women. Values on days LH -2 to LH +0 ranged from 98.0–98.8%. All normal cycles (as defined by endocrine profiles) displayed a significant increase in hydration over a one day period occurring 3–4 days before the LH peak. The magnitude of this shift varied among women from 2–3% (absolute hydration), a distinction well within the precision of the hydration assay. This quantum increase in hydration was more pronounced than the corresponding increase in serum estradiol on the same day.

The new technique for measuring sperm penetration into very small volumes of mucus worked very satisfactorily. Regression analyses for the fits of the data to an exponential model yielded  $r^2$  values always greater than 0.90.

There were strong but non-linear correlations between mucus hydration and measures of sperm penetrability. Figure 5 illustrates the relationship for hydration

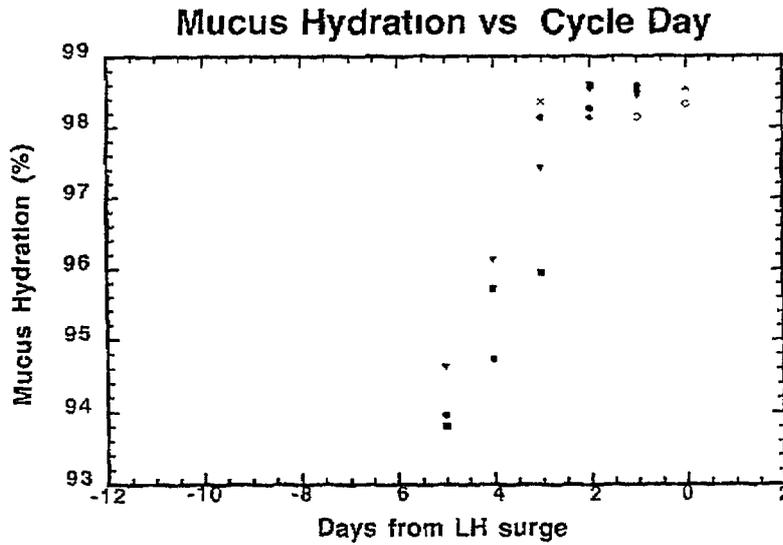


Figure 4 Mucus hydration vs cycle day

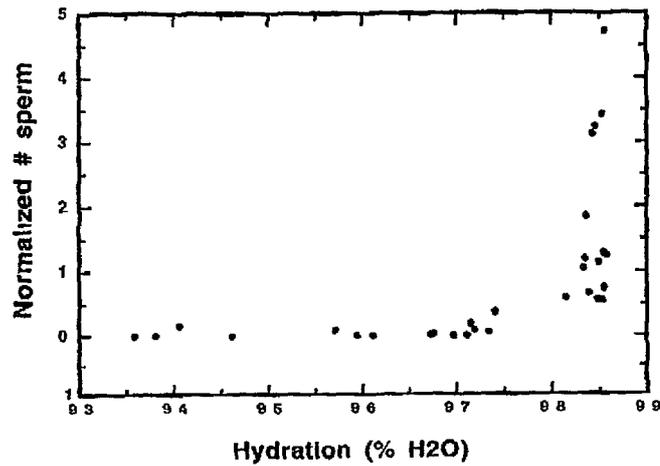


Figure 5 Mucus hydration vs normalized number of penetrating sperm. Normalization is with respect to penetration of control polyacrylamide gel.

vs the total numbers of sperm penetrating the mucus aliquots. Once the value of hydration rose above approximately 97.5%, there was a substantial increase in penetrability. This 'cut-off point' in sperm penetrability was in the middle of the range of hydration values (across women) which preceded the quantum jump in hydration – which, itself, preceded the surge of LH. Hydration began to increase approximately two days before measurable increases in sperm penetration of the mucus *in vitro*.

## Discussion

Our results show that human cervical mucus hydration can be measured with high accuracy and precision using simple benchtop procedures. Notably, values of hydration were not confounded by the presence of cells in the mucus, which had a negligible effect. The initial results suggest that this fundamental physicochemical gel property has systematic relationships with progression of the proliferative phase of the human menstrual cycle and also with penetration of sperm into mucus *in-vitro*. Such findings, if supported by additional data, are significant in several ways. The systematic, but non-linear relationship between hydration and objective measures of sperm penetration may be quite useful in using values of hydration to discriminate between 'good' and 'bad' mucus receptivity to sperm (in the absence of anti-sperm antibodies). A value of hydration equal to 97.5% may be a useful cut-off point in this regard.

As a biomarker of the progression of the proliferative phase of the cycle, the day of the rise in hydration preceded those of significant (detectable) rises in estradiol and in sperm penetrability, these events all occur several days before the LH peak. Thus, measurement of mucus hydration may be useful in monitoring the onset of the fertile time of the menstrual cycle.

The new technique for measuring sperm penetration into very small aliquots of mucus may have very broad applicability when small volumes of mucus are available.

## Conclusions

- 1 Human cervical mucus hydration is relatively low in the early proliferative phase, and undergoes a quantum increase that often precedes the preovulatory rise in estradiol.
- 2 There is a systematic, non-linear relationship between mucus hydration and *in vitro* sperm penetrability, which undergoes a steep increase at hydration values  $\geq 97.5\%$ . This value may therefore serve as a cut-off point in interpreting measurements of hydration as predictive of mucus receptivity to sperm.

- 3 Measurement and interpretation of hydration may be of value in the basic science and clinical assessment of mucus, and are also a potential instrument for application in natural family planning

### Acknowledgements

This work was undertaken as project N1B1 supported by the Institute for Reproductive Health, Georgetown University, which is gratefully acknowledged. The technical assistance of Mr Ashley Yudin and Dr B L Lasley is also appreciated.

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## IV. Natural family planning effectiveness

**How effective are current methods of NFP, and under what conditions? What are the factors that influence effectiveness? What information do we have about simplified methods, based on calendar and standard rules?**

*Chair* Martha Brady, M S , The Population Council, New York

*Lead Discussant* Jeff Spieler, M S , USAID

*Consensus* NFP and family planning methods based on fertility awareness use various indicators to identify the fertile time and different rules to guide couples as to when to abstain or, if the couple chooses to do so, have protected intercourse. Estimates of NFP effectiveness vary due to many factors including

- \* study design
- \* age of both members of the couple
- \* how couples manage their sexual relationship during the fertile time
- \* clients understanding of the rules and ability to apply them
- \* the quality of training and support
- \* motivation to use the method and thereby avoid pregnancy

New research is needed on calendar method effectiveness, including the application of simple rules, and on the effects of the quality of training on effectiveness. NFP effectiveness should be reported as lifetime probabilities of pregnancy during perfect and imperfect use. Alternatives to clinical trials are needed to evaluate the acceptability and effectiveness of NFP in a variety of service delivery settings. The attitude of health service providers toward NFP may influence its acceptability and effectiveness. Given the fact that couples who identify themselves as NFP users do not always comply with the requirement for abstinence during the fertile period, estimates of efficacy should take into account the implications of alternative behaviors to unprotected intercourse on the identified fertile days.

*Presenters*

Virginia Lamprecht M S , Georgetown University, USA

**Natural family planning effectiveness: evaluating published reports**

Anibal Faundes, M D , CEMICAMP, Brazil

**Simplifying NFP preliminary report of a pilot study of the 'collar' method in Brazil**

John Bonnar, M D , Trinity College, Dublin, Ireland

**Alternatives to vaginal intercourse practiced during the fertile time among calendar method users in Ireland**

Gunter Freundl, M D , University of Dusseldorf, Germany

**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**

Margaret France, M S , New Zealand NFP Association, Auckland, New Zealand

**Natural family planning in New Zealand a study of continuation rates and characteristics of users**

## Natural family planning effectiveness: evaluating published reports

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### Abstract

*Objective* To equip the reader with the tools necessary to evaluate studies of natural family planning (NFP) effectiveness found in the literature and to make recommendations for future NFP effectiveness studies

*Design* Current standards to evaluate contraceptive method effectiveness are reviewed A framework for evaluating reports on NFP is presented

*Results* Most NFP studies found in the literature are flawed in design and do not calculate pregnancy rates correctly The results from the few well-designed studies are presented

*Discussion* Many factors influence NFP effectiveness, and these factors must be considered when evaluating published studies and designing future studies

### Introduction

Natural family planning (NFP) methods are "based on observations of naturally occurring signs and symptoms of the fertile and infertile phases (times) of the menstrual cycle Awareness of the fertile phase can allow a couple to time intercourse either to avoid or to achieve pregnancy Natural family planning thus provides an alternative for those who, for any reason, cannot or do not wish to use pharmacological or mechanical contraceptives" [1]

Estimates of NFP effectiveness in the literature vary widely [2] There are many reasons for this variation First, NFP is not just one method Different NFP methods use different indicators to identify the fertile time and have different rules for abstinence, and, therefore, must be considered and evaluated separately Second, investigators use different techniques to calculate pregnancy rates, making it difficult

to interpret the results and compare estimates of effectiveness among studies. Third, many published reports omit important information necessary for evaluating the study results. Many reports do not describe the study population adequately, do not state how long couples were followed, or do not describe how couples were taught to use their method or how well couples understood how their method works. Some fail to account for all pregnancies and for couples lost-to-follow-up. Very few have the requisite information necessary to calculate separate pregnancy rates during perfect and imperfect use. Almost none report on the possible use of withdrawal or barrier methods during the fertile time.

The purpose of this paper is to equip the reader with the tools necessary to evaluate critically a report in the literature on NFP effectiveness. The factors that must be considered are presented as a framework consisting of a series of questions that one must consider when evaluating reports. The current standards for evaluating contraceptive effectiveness studies are reviewed, and estimates of the effectiveness of the NFP methods from well-designed studies are presented. In addition, recommendations for the design of future studies to evaluate the effectiveness of NFP are offered.

#### **Framework for evaluating NFP effectiveness**

Contraceptive method effectiveness is defined as the proportionate reduction in the per-cycle pregnancy rate caused by use of a method [3]. Because ethically women cannot be randomly assigned to use either a contraceptive method or no method, effectiveness cannot be readily measured. However, pregnancy rates or probabilities can be measured directly because the number of pregnancies and the number of cycles each woman uses a method are observed. All studies in the literature, with the exception of those evaluating emergency contraceptive pills, really measure pregnancy rates<sup>a</sup>. Nevertheless, the term 'effectiveness' is often loosely used, as it is in this paper, to mean how well a method works.

To evaluate a report on NFP effectiveness, one must consider the design of the study and the methods used to calculate pregnancy rates or probabilities. A framework for evaluating a report of NFP effectiveness is presented as a series of questions:

- 1 Is the study a survey or clinical trial?
- 2 What NFP method is being tested?
- 3 How was the method taught?
- 4 What are the characteristics of the study population?

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<sup>a</sup>In addition, the term pregnancy rates or probabilities of pregnancy are preferred to the term failure rates or probabilities of failure because the word failure may be used to describe other events such as condom breakage and because the term may be incorrectly understood to imply that the effectiveness rate is the complement of the failure rate; it is not because not all women would have become pregnant if no contraceptive method was used.

- 5 How are pregnancy rates calculated?
- 6 What rates or probabilities are reported?
- 7 How are pregnancies classified?

*Is the study a survey or clinical trial?*

To evaluate the effectiveness of a contraceptive method, it is desirable to have a sample representative of the population who actually will use it

Surveys which use a population-based sampling frame are more likely to achieve a representative sample than are clinical trials [4] However, since survey data are cross-sectional, it is possible to collect information about correct and consistent use of a method and the timing of pregnancy based only on recollection Bias is introduced if a respondent cannot remember when she did or did not use her method and whether she used it correctly In clinical trials, current use of a method is monitored more closely so that it is easier to determine if a method is being used correctly during each cycle

Clinical trials can be either retrospective or prospective Retrospective studies generally use existing clinic records as a data source, while prospective studies recruit participants and follow them into the future for a period of time Prospective trials are considered to be stronger in design, because the investigator can specify and collect the information he or she needs (not only what is available in clinic records), because participants are generally easier to contact in case of missing or incomplete data, and because information is generally collected more frequently and thus is less likely to suffer from recall bias

Clinical trials can also be comparative or non-comparative Comparative studies are stronger in design than non-comparative studies, especially if couples are randomized into comparison groups Randomization increases the probability that any differences in pregnancy rates found between the groups are due to the method used, and not due to differences in the characteristics of the participants in each group

Almost none of the NFP studies found in the literature are clinical trials that feature randomized comparison groups Among well-designed studies, two related studies conducted in Colombia [5] and in Los Angeles [6] randomized participants into two groups In each of the two studies one group was instructed to use the (Billings) ovulation method (which uses cervical secretions alone to identify the fertile time), and the other group was instructed to use the symptothermal method using Thyma's Double-Check<sup>b</sup> In both studies, the method using multiple indicators (i e the symptothermal method) demonstrated lower pregnancy rates<sup>c</sup>

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<sup>b</sup>The latter approach uses cervical secretions and a calendar calculation to identify the start of the fertile time The end of the fertile time is identified using basal body temperature and cervical secretions

<sup>c</sup>The differences were statistically significant in the study conducted by Wade et al in Los Angeles and not in the study conducted by Medina et al in Colombia

### *What NFP method is being tested?*

Very often in review articles a single estimate is provided for the overall effectiveness of NFP methods. Published reports of the National Survey of Family Growth (NSFG) have a single category named 'periodic abstinence' which includes all variations of calendar rhythm as well as all other 'modern' (fertility indicator-based) methods of NFP [7]. The practice of grouping all NFP methods together with calendar rhythm masks the differences in the effectiveness of various NFP methods<sup>d</sup>.

The length of time couples are asked to abstain varies among NFP methods and according to the particular rules taught to a couple for a given method. Therefore, when evaluating a report, it is important to determine what NFP method is being tested, and what specific rules are used to identify the fertile time.

NFP effectiveness is a function of the accuracy of the indicators to identify the fertile time, the rules which mark the start and end of the fertile time, and the behavior of the couple during the fertile time. NFP methods that use multiple indices (i.e. the symptothermal methods) appear in general to be more effective than methods in which a single indicator is used (e.g. cervical secretions).

Prolonged abstinence (as is required with methods employing very conservative abstinence rules) may make it more difficult for couples to obey the rules and to use the method correctly and consistently. Abstinence rules vary even among methods that use the same indicator(s). For example, the (Billings) ovulation method requires on average about 17 days of abstinence per cycle [8] while the modified mucus method requires only about a week of abstinence per cycle [9] even though both of these methods use cervical secretions (mucus) alone to identify the fertile time.

### *How was the method taught?*

Since the successful use of NFP depends upon a woman's ability to correctly identify the fertile time, how the method is taught must be considered when reviewing a report. Unfortunately, many reports on NFP effectiveness do not adequately describe the teaching rules or methodology used.

If data related to teaching are collected, it may be possible to identify the factors that are related to successful NFP use by comparing different teaching approaches. If a particular teaching approach appears to enhance more effective use of a method, it can be replicated in other studies and integrated into NFP programs.

Ideally, a report on NFP effectiveness should include a detailed description of the content of the teaching (including the rules for abstinence), the total amount of time spent teaching, and the distribution of lengths of time it takes for a couple to become autonomous<sup>e</sup>. Since NFP involves behavior change from both partners, it is important for a report to state whether one or both parties were taught to use the method.

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<sup>d</sup>Investigators using the National Survey of Family Growth usually group methods of periodic abstinence together because too few women use each of these methods to support separate analyses.

<sup>e</sup>Defined as correctly observing and charting of symptoms, a recognition of fertile and infertile days and an adjustment of sexual behavior to correspond with intention. (Source: Kambic R, Martin M. Evaluating client autonomy in natural family planning. *Adv Contracept* 1988; 4: 221.)

*What are the characteristics of the study participants?*

It is important that study participants reflect as closely as possible the population who will actually use the method, especially with respect to characteristics that may affect method effectiveness, such as age, coital frequency, and education. On the other hand, when comparing results from studies of different contraceptive methods, it is important that the different study samples have similar characteristics. These two goals may conflict. For example, since NFP is a couple method, many couples who use NFP choose to do so only when they are in established relationships. Thus, there may be more relatively older women in NFP effectiveness studies than in studies of other methods. One investigator reported that 37% of the women in the study were aged 35–44 years [10]. Since we know that fecundity tends to decrease markedly in the late 30s, the reported pregnancy rates may be relatively low due to the age of the participants. When comparing results across methods, one can, however, always standardize to a common population [11].

*How are pregnancy rates calculated?*

Many investigators have recognized the importance of distinguishing between pregnancies associated with user error and pregnancies attributable to the inherent inadequacy of the method itself. By convention, all pregnancies that occur during a menstrual cycle in which an NFP method is used incorrectly are labeled user pregnancies. Only those pregnancies that occur during a cycle during which an NFP method is used perfectly are classified as method pregnancies. Perfect use does not imply that the method did not fail, only that the abstinence rules for that method were followed.

Until recently, the standard procedure was next to compute separate method and user pregnancy rates (pregnancies divided by exposure). In this standard procedure, all exposure from both perfect and imperfect user cycles was included in the denominator of both method and user failure rates. To understand the logical error in these calculations, consider the following simple example. Suppose that there are two method pregnancies (that occurred during perfect use) and eight user pregnancies (that occurred during imperfect use) during 100 woman-years of exposure to the risk of pregnancy. Then the common calculation is that the user pregnancy rate is 8% and the method pregnancy rate is 2%, the sum of the two is the overall pregnancy rate of 10%. By definition, however, method pregnancies can occur only during perfect use and user pregnancies cannot occur during perfect use. If there are 50 years of exposure with perfect use and 50 years of imperfect use in the total of 100 years of exposure, then the method pregnancy rate would be 4% and the user pregnancy rate would be 16%. Method (or theoretical) pregnancy rates have almost always been calculated incorrectly, because investigators remove only the pregnancies attributable to improper use from the analysis, although they retain all exposure. For example, among the 13 clinical trials of periodic abstinence reviewed by Trussell and Grummer-Strawn, 'method only' calculations (all incorrect) were found in 10 of the published reports [12].

It is not possible to compute pregnancy rates during perfect and imperfect use unless information on rule-breaking is reliably collected for each cycle of use. The correct way to calculate pregnancy rates during perfect use is to divide the number of pregnancies that occur during perfect use by the number of cycles of perfect use. The correct way to calculate pregnancy rates during typical use is to divide the total number of pregnancies by the total number of cycles. The correct way to calculate pregnancy rates during imperfect use is to divide the number of pregnancies that occur during imperfect use by the number of cycles of imperfect use. If there are several ways to use a method imperfectly, separate failure rates for different types of imperfect use can be calculated in order to discover which contraceptive rules, when broken, entail the highest risk. This approach was used in an analysis of effectiveness of the (Billings) ovulation method based on data from a trial conducted by the World Health Organization in the late 1970s, it revealed, for example, the very high risk of pregnancy due to intercourse during times of stress [12]. Overall, only 3.2% of women became pregnant during a year (13 cycles) of perfect use.

*What rates or probabilities are reported?*

The risk of pregnancy can be expressed as Pearl pregnancy rates or life table probabilities. Results from NFP effectiveness studies are difficult to compare, because until recently, most studies reported the results using Pearl pregnancy rates.

The Pearl rate is computed as the number of pregnancies divided by the number of cycles multiplied by 1300 (or 1200 if data are collected in months). This rate expresses the number of pregnancies that would occur per 100 woman-years of being exposed to the risk of pregnancy. The Pearl rate is flawed because it suffers from duration bias. In general, the longer a study runs, the more effective a method will appear – because more fecund or less careful users tend to get pregnant sooner than less fecund or more careful users – leaving a pool of users comprising women who are increasingly less likely to get pregnant.

Most NFP studies in the literature report effectiveness using Pearl pregnancy rates. Since these studies differ in the maximum number of months couples are followed, the results are not directly comparable. For example, in one study of the (Billings) ovulation method, couples were followed for up to 22 cycles [13]. In the WHO study of the same method, couples were followed for only up to 13 cycles in the effectiveness of the trial [14]. Most published reports from other studies of the (Billings) ovulation method do not state how long couples were followed. Since many NFP studies in the literature report only Pearl rates, how can the results of these studies be interpreted? Studies are strictly comparable only where couples were followed for the same maximum length of time, such as one year.

Contraceptive effectiveness can also be expressed as life-table probabilities of becoming pregnant within specific periods of time since initiating use of a method. Life tables are preferred to Pearl rates because they are not subject to duration bias. The probability of becoming pregnant is calculated for each cycle of follow-up in the study. The complements of these probabilities are multiplied together (cumulative

probability of 'surviving' or not becoming pregnant) and subtracted from 1.0 to provide an estimate of the probability of becoming pregnant. The life table provides a cumulative probability of becoming pregnant for any given time interval, such as 6, 12, or 24 months. Life tables can be reported as single-decrement (gross) or multi-decrement (net) probabilities. Gross probabilities are preferred, because they can be readily compared to those from other studies.

Most of the NFP studies that report results using life table probabilities provide only net probabilities from multi-decrement life tables. Multi-decrement life tables provide probabilities for all the reasons for leaving a study, treated as competing risks. Net pregnancy probabilities are not readily compared across studies because they are influenced by the number of discontinuations (exits) for other reasons.

A few NFP effectiveness studies have reported 12-month (or 13 cycle) life table gross probabilities of pregnancy during typical use. Table 1 shows the results of prospective clinical studies evaluating the effectiveness of NFP methods based on cervical secretions and various multi-index (symptothermal) methods. There is a relatively wide range of pregnancy probabilities for both categories of NFP methods (2.5% to 37.2% for methods based on cervical secretions and 2.5% to 26.1% for multi-index methods). These are the best estimates available of the effectiveness of 'modern' fertility awareness-based methods of NFP during typical use. Ideally, estimates should be available during perfect use as well and be reported at intervals of 3, 6, 9, and 12 months (or 3, 6, 9, and 13 cycles), a convention that would allow an assessment of how effectiveness varies over time.

Life tables can also be used to compute probabilities of continuing use of a method. As with pregnancy rates, single-decrement life tables must be used if comparisons are made for specific reasons of discontinuation among studies. Net probabilities can be used to evaluate relative frequencies of different reasons for discontinuation within a single study. Since continuation with a contraceptive method is an indicator of its acceptability, it is desirable for an investigator to report the gross discontinuation probability for all method-related reasons combined.

### *How are pregnancies classified?*

NFP is the only method of family planning that can be used to achieve as well as to prevent pregnancy. Thus, it is essential that clear guidelines for classifying pregnancies are developed before a study begins. Some NFP studies have required that pregnancy intention be stated at the beginning of each cycle [15] while others have relied on client recall to classify pregnancies as method or user failures.

Some proponents of NFP have suggested that, since NFP is not like any other method of family planning, there should be more than two categories for pregnancies that occur during NFP use. One NFP expert proposed the following categories: method-related pregnancies (those that occur despite following the rules for avoiding pregnancy), teaching-related pregnancies (that result from an error in applying the rules, because either the method was not taught correctly or the couple did not learn correctly), informed choice pregnancies (when couples decide to have intercourse to

**Table 1 NFP studies reporting 12-month single-decrement (gross) life table probabilities of pregnancy during typical use**

<i>Reference (year)</i>	<i>Method</i>	<i>Percent becoming pregnant</i>	<i>Comments</i>
Freundl <i>et al</i> (1996)	STM <sup>a</sup>	2.5	Prospective multicenter trial comparing two variants of STM among European women aged 19–45
Freundl <i>et al</i> (1996)	STM <sup>b</sup>	7.8	
Thapa <i>et al</i> (1990)	OM <sup>c</sup>	2.5	Non-randomized comparative study of OM vs MMM among new users (women 20–39) Three cycle learning phase followed by a 13 cycle effectiveness testing phase (statistic in table relates to effectiveness phase) Couples spacing rather than limiting experienced higher probabilities of pregnancy by a ratio of 4:1
Thapa <i>et al</i> (1990)	MMM <sup>d</sup>	10.3	
WHO (1981)	OM <sup>c</sup>	19.6*	Non comparative study of OM among new users (women aged <39) 869 women entered a 3 cycle learning phase, of these 725 entered a 13 cycle effectiveness phase (statistic in tables relates to effectiveness phase)
Wade <i>et al</i> (1981)	OM <sup>c</sup>	37.2**	Comparative randomized study (OM vs STM) among new users (women aged 20–39) 430 out of 1247 entered the effectiveness phase which followed a learning phase of 3–5 cycles (Statistic in table relates to effectiveness phase) STM indicators to identify the fertile time included a calendar calculation and observation of cervical secretions and BBT
Wade <i>et al</i> (1981)	STM <sup>f</sup>	13.9**	
Rice <i>et al</i> (1981)	STM <sup>g</sup>	8.3	Non comparative multicenter study of STM 102 women aged 19–44 entered the study
Medina <i>et al</i> (1980)	OM <sup>c</sup>	29.2	Comparative randomized study (OM vs STM) among new users (women aged 18–39) 241 out of 566 women entered the effectiveness phase which followed a learning phase of 3–5 cycles (Statistics reported for effectiveness phase) STM indicators same as in Wade (1981)
Medina <i>et al</i> (1980)	STM <sup>f</sup>	26.1	
Klaus <i>et al</i> (1979)	OM <sup>c</sup>	15.8*	Non comparative study of new and experienced OM users 33% of women aged >34 years
Johnson <i>et al</i> (1978)	OM <sup>c</sup>	26.4	Simultaneous surveys conducted among new acceptors of various methods of NFP in 63 centers in Australia
Johnson <i>et al</i> (1978)	STM <sup>h</sup>	14.3	
Johnson <i>et al</i> (1978)	STM <sup>i</sup>	13.3	

**Table 1 (footnotes)**

<sup>a</sup>STM (symptothermal method) indicators for variant A Calendar calculation and cervical secretions to mark start of fertile time BBT secretions and palpation of cervix to mark the end of the fertile time

<sup>b</sup>STM indicators for variant B Cervical secretions to identify start of the fertile time BBT to mark the end of the fertile time

<sup>c</sup>OM (ovulation method or Billings method) Cervical secretions used to identify the start and end of the fertile time Rules described in Billings *et al* (1974)

<sup>d</sup>MMM – modified mucus method a simplified method using cervical secretions to mark the start and end of the fertile time Rules described in Dorairaj (1980)

<sup>e</sup>OM (ovulation method or Billings method) Cervical secretions used to identify the start and end of the fertile time Rules described in WHO (1981)

<sup>f</sup>STM Thyma's double check STM cervical secretions and a calendar calculation to identify the start of the fertile time and cervical secretions and basal body temperature to identify end of the fertile time

<sup>g</sup>STM indicators used a calendar calculation (shortest cycle in past 12 cycles minus 19) to identify the start of the fertile time BBT to identify the end of the fertile time Some centers taught couples to observe cervical secretions also although teaching of this indicator was not consistent across centers

<sup>h</sup>STM indicators for variant A cervical secretions plus calendar calculations (shortest cycle minus 20 or 21 to identify the beginning of the fertile time cervical secretions and BBT to identify the end of the fertile time

<sup>i</sup>STM indicators for variant B cervical secretions only to identify the start of the fertile time cervical secretions and BBT to identify the end of the fertile time

\*Only net probabilities available

\*\*Probabilities recalculated by James Trussell

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achieve a pregnancy without declaring their intentions previously), and unresolved pregnancies (those with insufficient data to categorize more precisely) [16]

Classifying pregnancies using the above categories may be used for determining why a pregnancy occurred, which may be helpful in evaluating the quality of training by teachers and how clients were taught to use NFP. However, for the purpose of comparing NFP methods with other contraceptive methods, we suggest that

- 1 Pregnancies be classified as intentional only when a couple reports prior to the pregnancy cycle an intention to use the method to become pregnant
- 2 All unintentional pregnancies be used in the analysis of pregnancy risk during typical use
- 3 All unintentional pregnancies occurring during cycles where NFP rules were followed be used in the analysis of pregnancy risk during perfect use

In conclusion, the framework outlined above can be used to evaluate published reports on NFP effectiveness, as well as to provide guidance in the design of future studies. Better estimates of NFP effectiveness can be achieved only if future studies on NFP effectiveness are better designed.

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## **Simplifying NFP: preliminary report of a pilot study of the 'collar' method in Brazil**

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### **Abstract**

Natural methods of fertility regulation are acceptable in most cultures. Many couples worldwide do not wish to use contraceptives or do not have access to them but wish to limit their family size or lengthen the time between births. Barriers to expanding use of natural family planning (NFP) methods include a lack of providers who can teach NFP and a lack of time to teach and follow couples during the initial months of NFP use. If simple yet effective methods of NFP are available, then NFP could be introduced to a wider audience. Recently, calendar rules have been revised that use a set interval to identify fertile days. These new rules provide better coverage of fertile days and require less abstinence than the rules traditionally used with the calendar method. One of these new rules is being field tested in a pilot study in Brazil. Couples are asked to abstain from day 9-19 (inclusive) of the menstrual cycle, using a beaded necklace (the 'collar') as a mnemonic device. Focus groups with the teacher-monitors and in-depth interviews with female and male users were carried out to evaluate the acceptability of the 'collar' method. A preliminary analysis of these focus groups and interviews from the first site is presented.

### **Introduction**

Natural methods of fertility regulation are acceptable to most cultures. Many couples worldwide do not have access to contraceptives or do not wish to use them, but want to limit their family size or increase the interval between births. While the use of natural family planning (NFP) would help many of these couples to realize their fertility goals, many barriers limit the introduction of NFP to wider audiences. These

barriers include the lack of trained teachers, lack of provider time to teach NFP, lack of teaching materials, lack of models to guide program leaders in how to integrate NFP into existing family planning programs, and the view that modern NFP methods are too complicated to teach

Compared to other methods of family planning, NFP costs relatively little once learned. However, since NFP use requires couples to be able to identify the fertile time accurately, teaching couples to observe and interpret a woman's fertility signs requires more providers' time in the initial months of use than offering other methods [1]. Thus, many providers are reluctant to offer this method because they lack the time to teach NFP, others perceive that NFP is too complicated for couples to learn and less effective compared to other methods.

## Methods

Recently, new revised and simplified calendar rules to identify the fertile time have been developed [2] that provide less abstinence and better coverage of the fertile time than the rules developed by Ogino and Knaus in the 1930s. Some of the new rules identify the fertile time using a set interval of days. One of these rules, which requires couples to abstain from days 9–19 (inclusive) of the menstrual cycle, provided that the woman's cycle length was between 27 and 31 days, is being field tested at 13 sites in Brazil to determine the acceptability of the method.

Couples use a beaded necklace (the 'collar') to count the days of the menstrual cycle. A red bead marks the first day of menses, followed by 7 brown beads, 11 white beads, and then 11 brown beads again. The brown beads represent unfertile days and the white beads represent fertile days. A black rubber non-slip ring is moved along the length of the necklace once each day. When a woman's menses starts, she places the black ring on the red bead. The next day, she moves the black ring one bead to the first brown bead. When she gets to the first white bead, the couple abstain until the black ring reaches the first brown bead after the white beads, eleven days later. She then continues to move the black rubber ring forward each day. If she starts bleeding before reaching the red bead, she moves the black ring forward to the red bead when bleeding begins, if the red bead is reached before menses starts, it remains on it until menses begins, and is moved forward the next day on. Another important characteristic of the collar is that the white beads are fluorescent and shine in the dark. This makes it easy for both the man and the woman to be aware that she is at the time of possible fertility.

## The pilot study

The present study was designed as a preliminary pilot evaluation to determine if couples understand how to identify the fertile days and follow the rules and if the method is acceptable to them. Couples were recruited into the study and taught how to use the 'collar' method by a group of community-based monitors working under

the direction of the Pastoral de Criança. Each monitor is assigned about 25 families to provide essential infant and child care, such as promotion and support for breastfeeding, monitoring immunizations and child development, and teaching how to prepare and use rehydration salt. The monitors register all births and child morbidity and mortality and report to the pastoral central office.

Acceptability of the method is measured using a structured questionnaire and in-depth interviews with female and male users of the method, and focus group discussions with all the project monitors who agree to participate. At the time of preparing this preliminary report 207 monitors had been trained and 1015 couples had been screened, 30% were eligible, 9% attended a one-day education program, and 6% (64 couples) started using the method. The depth interviews of users and focus groups with monitors had been carried out in 7 sites, but analysis was completed for only one village, where 17 monitors had been trained and eight couples had accepted the method. The report is based on two focus groups with four and six different monitors, and in separate in-depth interviews with each member of two couples, one who had discontinued and one who had continued using the method, carried out three months after initial acceptance.

## Results

### *Training of the pastoral monitors on how to teach the collar method*

The monitors judged that too much information had been given in only 2 days of training. Though they knew the method well, they had some doubts about the limits of the length of the menstrual cycle a woman should have to be able to use the method. They understood the concept of fertile/infertile periods of the cycle, but felt uncertain of their capacity to teach others. They thought it would be useful to have the support of a video tape.

In addition, the monitors felt that they did not have the credibility to teach family planning because they and the couples considered family planning methods to be high technology controlled by the medical profession. They suggested that sanctioning by physicians would be very important for acceptance of the method.

“People from here do not believe in their peers. They believe that people from the large city know about this, not people from here.”

### *Appearance of the collar*

There were clear indications that the collar's appearance was considered an asset by the women, but men did not mention it. Women liked the collar and found it pretty. Some monitors said that it looked nice because it shone in the dark.

“I found, you know, the collar something very pretty, a vision at night, I found the collar so beautiful!” (A woman monitor)

### *Usefulness to recognize the fertile/infertile periods*

Women said that it was easy to understand that the brown beads correspond to the infertile days and the white beads to the fertile days of the cycle. Men also liked the way the collar facilitated the use of the calendar method. Women, men, and the monitors all independently stated that the collar was a practical and easy way to learn how a woman's body functions and how to practise periodic abstinence.

### *Why the collar was preferred over other contraceptives*

The main reason women and men preferred the collar over other methods was that they considered it safer (than the pill) for women's health. The monitors also felt that the main advantage of the collar was the lack of side-effects. Some said its very low cost was also an advantage.

After using it, women found that talking about the method led to better communication and more tenderness between partners. Men also found that learning about the method led to a greater understanding of their wives' bodies and improved their relationship.

"It helped to make us to talk a lot more to each other, have a better understanding, and to become more affectionate to each other" (man)

### *Acceptance of the collar*

The main obstacle to acceptance of the collar, according to the monitors, was doubt about its effectiveness. However, some monitors recalled that the same doubt initially existed with the pill, and thought that after some time, couples would trust the collar just as they now trust the pill. Men said that they also doubted its effectiveness, but had been reassured after their three months' experience with it.

"People do not trust the collar because it is being offered just now. It is like when the pill just appeared. Nobody knew about it, nobody trusted it. But now everybody trusts the pill, you know. The same with the collar. When everybody becomes informed about it, everybody knows how to use it, everybody will use it" (monitor)

According to the monitors, the collar was better accepted by younger and more educated couples. They emphasized that men's participation in the training session was essential to improving acceptance.

### *Acceptance of the eleven-day abstinence period*

According to women, the main problem was the length of the abstinence period, particularly during the two month abstinence required by the study protocol during the switch from the pill. This was not as much of a problem for the women, but they complained about the lack of collaboration by their sexual partners.

Men also said that they did not like the length of the abstinence period, but those who had used the method for some time had solved the problem, either by using the condom or limiting their love-making to expressions of love other than coitus

The monitors also felt that the main inconvenience of the method for couples was the long period of abstinence, primarily when the male partner did not collaborate. Some monitors thought that this was a result of men being used to methods that allowed them to have sex at any time. Some monitors accepted the use of the condom during the abstinence period, some did not. They felt that some couples improved their relation by making love without penetration during that period. They also felt that couple's love-making was better after the period of abstinence.

#### *Practical problems with the use of the collar*

When the monitors were asked by the interviewers whether couples had any practical problems using the collar method, few were mentioned. Some stated that women appeared to have learned how to use the collar and had no problem remembering to move the rubber band from one bead to the next every day because many were already accustomed to taking a pill every day. Some monitors mentioned that some women who had left their homes for several days forgot to take the collar along, or only took their calendar, where they mark the first day of menses.

The monitors said that women with small children had kept the collar well hidden. The others kept it in a variety of places and hung it on the wall at night to be able to see it in the dark. One monitor using the method said that some men hated to see the white beads shining in the dark with the black rubber band over one of them, showing that they could not have sex when they wanted.

#### **Summary**

While volunteer couples have been difficult to recruit, and initial acceptance of the method was low, the experience of those who did accept the collar seems to indicate that this device is effective in helping couples to use NFP properly. An evaluation of the effectiveness of this method is required.

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## **Alternatives to vaginal intercourse practiced during the fertile time among calendar method users in Ireland**

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### **Abstract**

A pilot study was conducted in Ireland to test the effectiveness of the calendar method of contraception. A conservative rule was used, requiring on average 16 days of abstinence per cycle. Among the 19 couples who entered into the study and were followed for up to seven cycles, there were no pregnancies. Since the length of abstinence was relatively long, we collected data to determine how couples expressed love and affection towards each other during those days when the woman was potentially fertile. We also collected data about barrier method use during the fertile time. We found that almost all couples gave each other hugs and kisses to show affection although couples were taught to abstain from vaginal intercourse during the fertile time. About one-third of the couples avoided genital contact, while about half reported using oral sex and/or frottage (body rubbing). Twice as many men reported using masturbation compared to women, although about half of the couples practiced mutual (partner) masturbation. In addition, about one-fifth of the couples used condoms during the fertile time in some cycles. These findings show that a variety of sexual expressions are used by couples when vaginal intercourse is to be avoided. Knowledge about these alternative sexual expressions may be important for couples who wish to engage in sexual activity and to avoid pregnancy.

### **Introduction**

A study of the calendar method of contraception was designed to test the acceptability and effectiveness of the calendar method among couples in Ireland. The study was divided into two phases. The purpose of the pilot study (Phase I) was designed to determine the acceptability of the method, and a second, larger study (Phase II) was

to determine the effectiveness of the method

A study of calendar method effectiveness was proposed mainly for two reasons. First, the calendar method of contraception features advantages that are desirable for some couples. The method does not cost anything, is free from side-effects, and its use does not depend upon supplies or medical intervention. Second, few studies conducted in the past to test the effectiveness of the calendar method have been well-designed [1,2]. Many published reports fail to provide documentation of one or more of the following: the rule used to identify the fertile time, how the method was taught, whether the couple understood how the method works, or if and when the couples broke the rules. Thus, it is difficult to assess the effectiveness of the calendar method based upon the results of these studies.

In the pilot study (Phase I) in Ireland, the rule selected for the study was S-20, L-10, where S is the shortest cycle length in the past 6 cycles and L is the longest cycle length in the past 6 cycles. The first day of the fertile time is identified by subtracting 20 from S, and the last day of the fertile time is identified by subtracting 10 from L. Couples were asked to abstain from vaginal intercourse starting the first day of the fertile time until (and including) the last day (and night) of the fertile time. The rule was chosen because it was relatively easy to calculate the fertile time (as 20 and 10 are both multiples of 10) and was expected to cover the potentially fertile days for the vast majority of women. The rule required, on average, about 16 days of abstinence per cycle among the 19 couples admitted into the pilot study. Since the length of abstinence was relatively long, we collected data on what couples did during the fertile time to express love and affection to each other. We also collected data on the use of withdrawal or barrier methods.

The focus of this paper is to report the alternatives to vaginal intercourse that couples practiced during the fertile time, and to determine the factors related to these alternative sexual expressions. Knowledge about these non-coital practices may provide useful information for couples in various settings who have difficulty with abstinence in the fertile phase and wish to offer love and affection and sexual expression without coitus.

### **Volunteers and materials**

The data used in this analysis were obtained from the pilot study of the acceptability of the calendar method of contraception that was conducted in Dublin, Ireland in 1993-1994. Couples were recruited through family planning networks and through advertisements in the media. All couples admitted were in a stable union with at least one child and using some form of the calendar method or using no contraceptive method. Women were between 18 and 38 years of age, not breastfeeding, not using hormonal contraceptives, at least six months postpartum, had regular menstrual cycles (between 23 and 35 days) and knew the lengths of their past 6 cycles. Couples admitted into the study agreed to abstain from vaginal intercourse during the fertile time and use only the calendar method as their method of family planning. Slightly more than half of the women admitted into the study were aged 30 or less. Just over

half of the women had completed university education. Almost three-quarters of the couples had one or two children, and about one-quarter had 3 or 4 children.

At admission, basic demographic data were collected. Couples were also interviewed to determine the reasons why they chose to use the calendar method. All couples admitted into the study were given two classes of instruction about how the method works. The classes were taught by the study coordinator and took place in the couples' home. Each of the sessions was designed to last about one hour, but the actual time spent with the participants depended upon the rapport between the participant and the coordinator. The first lesson provided information about the menstrual cycle and the timing of potentially fertile days. The second lesson focused on calculating the fertile time based upon the woman's past cycle lengths using the S-20, L-10 rule. Each couple was given a workbook with text, illustrations, and exercises to complete to reinforce key concepts about the menstrual cycle, the fertile time, how to calculate the fertile time using the S-20, L-10 rule, and how to identify the fertile days for a particular cycle on a calendar.

To assess the acceptability of the method, and to determine if it was feasible to implement Phase II of the study, information was collected at the end of each cycle about cycle length, the number of days of abstinence required, timing and frequency of intercourse, risk taking, and the use of withdrawal or barrier methods during the fertile time.

In addition, each couple was interviewed in depth at the end of study participation, which lasted up to 7 cycles, to assess the couple's opinion and experiences of using the method. All interviews were conducted by the study coordinator in the couples' homes. Whenever possible, both the man and the woman were interviewed together. During these interviews, information was collected about what couples perceived were the advantages and disadvantages of the method, what they did on potentially fertile days to express love and affection when vaginal intercourse was to be avoided, whether or not they were satisfied with the method, and whether or not they planned to continue to use the method.

All data used in the analysis were obtained from admission and follow-up forms, as well as from the in-depth interviews. Analysis of the data was conducted by enumeration of events and using Chi-square tests of independence and logistic regression to identify relationships between couple characteristics and use of various alternative sexual practices. The data were analyzed using SAS statistical software.

## Results

A total of 19 couples contributed 120 cycles of method use. In 17 of these 120 cycles, condoms were used during the fertile time by 4 couples. In general, couples who combined the use of the calendar method with condom use tended to have longer periods of required abstinence ( $18 \pm 2.1$  days) compared to the 15 couples who never used barrier methods during the fertile time ( $15.4 \pm 2.5$  days).

While about half the couples stated that they were satisfied with using the method, 15 of the 19 couples stated that too much abstinence was required with the S-20, L-

10 rule. On average, 15.9 ( $\pm 2.7$  SD) days of abstinence were required per cycle (range 12 to 22 days). Among the six women whose cycle varied within a range of 3 days, the length of abstinence required decreased to 12 to 14 days per cycle.

Seventeen of the 19 couples completed the study. One couple dropped out of the study after 3 cycles of use because the amount of abstinence required was unacceptable (14 days per cycle), and one couple dropped out to become pregnant, also after 3 cycles of method use. No pregnancies were reported during the pilot study.

Ten of the 19 couples stated that they planned to continue to use the calendar method with the S-20, L-10 rule after the study ended, and 3 couples stated that they planned to use the rule in combination with other fertility indicators (e.g. cervical secretions and/or basal body temperature).

The greatest advantage of the calendar method that was cited among the 19 couples is that it is simple to use (16 out of 19). Nine of the men and 13 of the women elected to use the calendar method because it is free from side-effects. Six of the men and 5 of the women chose to use the calendar method for moral or religious reasons. Other reasons cited include increased couple communication and opposition to other methods.

All couples were asked about what they did during the fertile time to show love and affection to each other. Most stated that they gave each other hugs and kisses during the fertile time to show affection. About one-third of the couples avoided genital contact completely. Nine of the 19 couples reported using oral sex and 10 couples reported using frottage (body rubbing). Twice as many men (8) reported using masturbation compared to women (4), although 9 of the 19 couples practiced mutual (partner) masturbation.

Although it was not possible to demonstrate statistically significant results due to the small sample size, the use or non-use of these alternatives to vaginal intercourse does not appear to be related to the reason why a couple was using the calendar method (e.g. moral or religious reasons, or because the method is free from side-effects). Most of the logistic regression models tested showed non-significant relationships due to the small sample size. Certain trends were demonstrated across models. Women in the study who were 30 years old or less and those women who had attained at least a university education reported self-masturbation less frequently compared to women who were over 30 years old and had not attained a university degree. University graduates were also less likely to report oral sex, mutual (partner) masturbation, and frottage as compared to non-graduates. A larger probability sample is required to establish the relationships between various alternative practices and important variables such as age, education, number of children, and reason for using the method.

## Discussion

These findings show that a variety of sexual expressions is used by couples when vaginal intercourse is avoided. This has implications for counseling and teaching of NFP.

**Acknowledgements**

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## **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**

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### **Abstract**

A large prospective long-term study with users of natural family planning (NFP) methods has been conducted to analyze the relation between unintended pregnancy rates and sexual behavior with special reference to barrier method use in the fertile phase. Seven hundred and fifty eight NFP beginners, 19–45 years of age, 14 870 cycles, 28 unintended pregnancies were studied.

Of the couples, 54.2% use NFP only or predominantly and 45.9% use mixed methods (additional barrier method use in the fertile phase in 55.7% of the cycles). The overall pregnancy rate after 12 cycles of exposure is 2.2% according to the actuarial method. There is no significant difference between NFP users and mixed methods users and also no significant effect of duration of use in the first 5 years of exposure. During “perfect use” the pregnancy rate at 12 months is 0.63%. When only protected intercourse takes place in the fertile phase the pregnancy rate is 0.45%. The symptothermal method of NFP is most unforgiving for imperfect use (unprotected intercourse in the fertile phase). However, it is extremely effective when either abstinence or protected intercourse is used in the fertile phase.

### **Introduction**

Natural family planning (NFP) methods are based on observation of signs of the fertile and infertile phases of the menstrual cycle. This allows a couple to time intercourse either to avoid or to achieve pregnancy [1]. In the former case, by definition, abstinence is required in the fertile phase. However, quite a number of couples who practice NFP are sexually active in the fertile phase including the use of

barrier methods The variation of sexual behavior of NFP users in Germany and its changes over time has been published recently by our group in this journal [2] The present paper addresses the relation of sexual behavior and effectiveness with special reference to barrier method use in the fertile phase We are interested in the overall unintended pregnancy rates for NFP only users and for the mixed methods users (those who additionally have protected intercourse in the fertile phase) and in the changes of the pregnancy rates during the first 5 years of NFP use Furthermore pregnancy rates are calculated for the "perfect users" of the method and for different kinds of "imperfect use"

For 12 years a prospective ongoing study of German NFP users has taken place at the University of Dusseldorf The main aim is service evaluation of NFP teaching in Germany Various data evaluations have already been published [2,3] At present, the total data base consists of 1365 women and 26 403 cycles A self-developed computer program provides data collection, statistical evaluation, supervision and organization of the NFP teachers, and administration With this program, interim results can be reviewed at any time The recruitment is nearly "automatic" as the NFP teachers of the German NFP organization "Arbeitsgruppe NFP" ask their clientele to participate for at least one year All women are accepted including women with irregular cycles, women who have discontinued oral contraceptives, and women who are premenopausal, are breastfeeding, have had an abortion, and are trying to conceive Within the prospective study, a woman may first use NFP in the postpartum situation, then may be in the use-effectiveness study for some cycles, and then try to achieve a pregnancy

### **Materials and methods**

For the present data analysis, those women have been selected who want to avoid a pregnancy, are between 19 and 45 years of age, are NFP beginners at study entry and report their sexual activity on the cycle charts, in addition to physical examinations Each participant also states on each chart whether or not she wants to become pregnant in the next cycle Pregnancies are classified as "intended" or "unintended" on the basis of the statements made before conception As it is a long-term study several changes of family planning intention could happen Therefore only intervals of "avoiding pregnancy" have been accepted With these conditions the subgroup for the present analysis consists of 758 women and 14 870 cycles The median time the women stayed in the study is 15 cycles

The study participants – and in about 50% of the cases also their partners – have been instructed in small groups in the symptothermal method of NFP The standardized teaching process includes 4–5 meetings within the first 3 months of use and is supported by teaching material [4]

The symptothermal method we use is based on a "double-check" approach to determine the beginning of the fertile phase (observation of cervical mucus and calculation rule) and on two indicators to determine the end of the fertile phase (mucus observation and temperature measurement)

*Characteristics of study population*

Table 1 shows the socio-demographic characteristics of the study group. The study population is quite young, with nearly 70% of the women being below 30 years of age. We did not select women with "proven fertility" in order to avoid excluding the younger ones who are more fertile and sexually more active.

**Table 1 Socio-demographic characteristics of the participating women (percentages,  $n = 758$ )**

Age at admission ( $n = 758$ )*	
19-29	69.3
30-39	27.7
40-45	3.0
Education ( $n = 742$ )*	
Low level	12.5
Median level	62.7
High level (university)	24.8
Occupation ( $n = 735$ )*	
Working or in training	61.2
Housewife	38.8
Marital status ( $n = 742$ )*	
Married	62.3
Unmarried	36.4
Divorced	1.3
Religion ( $n = 739$ )*	
Catholic	77.7
Others	17.3
None	5.0
Number of previous pregnancies ( $n = 753$ )*	
0	54.7
1-2	28.7
$\geq 3$	16.5
Family planning intention ( $n = 692$ )*	
Spacer	81.8
Limitter	18.2

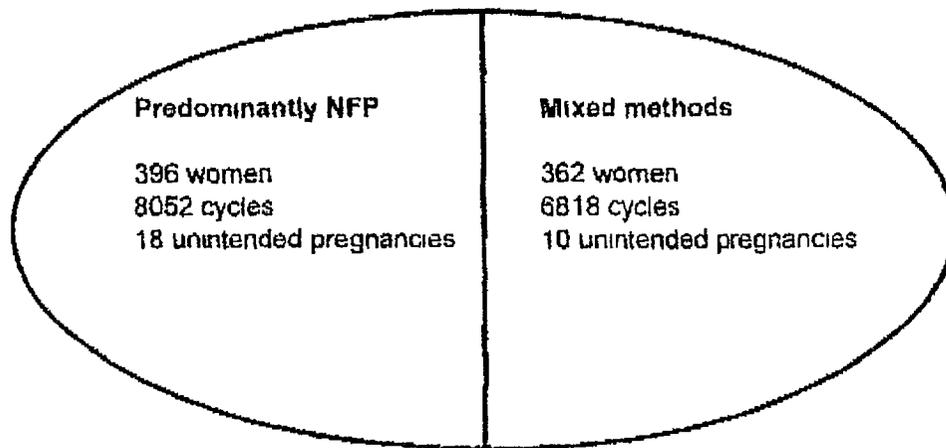
\*Where these numbers do not total 758, the remainder are women for whom there is no information.

### *Calculation of pregnancy rates*

We use the well-known actuarial method (or Kaplan–Meier method) to estimate the rates for 3 different events. The events are “unintended pregnancy”, “negative drop-out” and “lost-to-follow-up” which may compete. Since we consider one cycle as the time unit there is no difference between the results obtained by the actuarial method and the classical life-table method. Most people dropped out of the long-term study because they wished to discontinue participating in the study – however they continue using NFP. At the moment 8.8% of the total numbers studied are still active. Therefore, in this long-term study the total drop-out rate is not striking, but reflects those women who experience difficulties or dissatisfaction with NFP (i.e. negative drop-out).

### **Results**

Seven hundred and fifty eight women – all beginners concerned with avoiding a pregnancy with NFP – with 14 870 cycles experienced 28 unintended pregnancies (Figure 1)



**Figure 1** Study participants 758 women 14 870 cycles 28 unintended pregnancies

Part of the data is included in the European multicenter study [5]. We have already shown that there are three principle groups of NFP users: those who use NFP only, those who use predominantly NFP (barrier method use in the fertile phase occurs very rarely) and those who frequently/regularly combine the fertility awareness knowledge of NFP with barrier method use. As the first two groups are very similar concerning socio-demographic characteristics and sexual activity [2] these have been

combined as “predominantly NFP users” and compared to the “mixed methods users” The predominantly NFP users comprised 396 women with 8052 cycles and 362 women with 6818 cycles were the mixed methods users (18 vs 10 unintended pregnancies) In the “predominantly NFP” group there was barrier method use in 2.9% of the cycles, and in the “mixed methods” group in 55.7% of the cycles

Table 2 shows the overall pregnancy rates (due to method and user failure) and drop-out rates in relation to NFP experience After about one year of exposure (12 cycles) the unintended pregnancy rate is 2.2% It cumulates in the second year up to 5.0%, in the third year up to 6.2%, in the fourth year up to 7.5% and after 5 years of use it is 7.5% Lack of NFP experience (first 6 cycles of NFP use) is not associated with a higher probability of pregnancy

**Table 2 Use-effectiveness and drop-out rates of the symptothermal method (all NFP users)**

<i>Ordinal cycle number</i>	<i>Women exposed</i>	<i>Cumulative cycles of use</i>	<i>Probability of unintended pregnancy % (<math>\pm</math>SD)</i>	<i>Probability of negative drop out % (<math>\pm</math>SD)</i>	<i>Probability of lost-to follow up % (<math>\pm</math>SD)</i>
1	758	758	0	0	0
3	736	2249	0	0.67 ( $\pm$ 0.30)	0
6	650	4289	0.59 ( $\pm$ 0.29)	1.96 ( $\pm$ 0.52)	0.58 ( $\pm$ 0.29)
12	452	7505	2.22 ( $\pm$ 0.62)	7.48 ( $\pm$ 1.11)	2.40 ( $\pm$ 0.64)
18	283	9476	5.01 ( $\pm$ 1.10)	10.34 ( $\pm$ 1.40)	2.65 ( $\pm$ 0.86)
24	204	10871	5.01 ( $\pm$ 1.10)	13.77 ( $\pm$ 1.76)	3.09 ( $\pm$ 0.81)
36	107	12588	6.17 ( $\pm$ 1.35)	21.18 ( $\pm$ 2.55)	3.91 ( $\pm$ 1.14)
48	63	13584	7.49 ( $\pm$ 1.87)	27.50 ( $\pm$ 3.31)	7.30 ( $\pm$ 2.24)
60	39	14193	7.49 ( $\pm$ 1.87)	32.84 ( $\pm$ 4.01)	9.05 ( $\pm$ 2.80)

The drop-out with so-called negative reasons (dissatisfaction or difficulties with NFP) is 7.5% after one year, 13.8% after two years, 21.2% after three years, 27.5% after four years and 32.8% after five years (Table 2) However, indicating difficulties with NFP does not mean that they stop using NFP The lost-to-follow-up rate is very low 2.4% in the first year, 3.0% after two years, 3.9% after three years, 7.3% after four years and 9.0% after five years

In the first years the separate Kaplan–Meier curves show slightly lower pregnancy rates for the mixed methods users compared to the predominantly NFP users However the differences are not significant (log rank test  $p=0.3221$ ), only the drop-out with negative reasons is significantly higher in the mixed methods group (10.6% after 1 year vs 4.6%, log rank test  $p=0.0101$ ) (Tables 3 and 4)

**Table 3 Use-effectiveness and drop-out rates of the symptothermal method (predominantly NFP users)**

<i>Ordinal cycle number</i>	<i>Women exposed</i>	<i>Cumulative cycles of use</i>	<i>Probability of unintended pregnancy % (±SD)</i>	<i>Probability of negative drop out % (±SD)</i>	<i>Probability of lost-to follow up % (±SD)</i>
1	396	396	0	0	0
3	383	1172	0	0 51 (±0 36)	0 26 (±0 26)
6	340	2236	0 86 (±0 49)	0 19 (±0 70)	0 85 (±0 49)
12	234	3910	2 95 (±0 98)	4 57 (±1 16)	1 54 (±0 69)
18	157	4977	5 83 (±1 59)	6 81 (±1 59)	1 54 (±0 69)
24	116	5761	5 83 (±1 59)	8 28 (±1 87)	2 31 (±1 03)
36	58	6732	6 88 (±1 88)	14 31 (±2 97)	2 31 (±1 03)
48	34	7254	6 88 (±1 88)	23 76 (±4 84)	8 80 (±3 79)
60	22	7590	6 88 (±1 88)	29 01 (±5 76)	11 84 (±4 73)

**Table 4 Use-effectiveness and drop-out rates of the symptothermal method (mixed methods users)**

<i>Ordinal cycle number</i>	<i>Women exposed</i>	<i>Cumulative cycles of use</i>	<i>Probability of unintended pregnancy % (±SD)</i>	<i>Probability of negative drop-out % (±SD)</i>	<i>Probability of lost-to follow up % (±SD)</i>
1	362	362	0	0	0
3	353	1077	0	0 83 (±0 48)	0
6	310	2053	0 30 (±0 30)	2 06 (±0 77)	0 30 (±0 30)
12	218	3695	1 43 (±0 72)	10 58 (±1 92)	3 32 (±1 10)
18	126	4499	4 13 (±1 51)	14 09 (±2 32)	3 85 (±1 21)
24	88	5110	4 13 (±1 51)	19 81 (±3 02)	3 85 (±1 21)
36	49	5856	5 42 (±1 98)	28 72 (±4 18)	5 67 (±2 16)
48	29	6330	8 20 (±3 34)	31 91 (±4 56)	5 67 (±2 16)
60	17	6603	8 20 (±3 34)	36 69 (±5 35)	5 67 (±2 16)

*Pregnancy analysis*

Of the 28 unintended pregnancies, three were method failures. Another one occurred when condoms had been used in the fertile phase and the other 24 occurred in cycles in which unprotected intercourse took place during the fertile phase. This means that those who at times used barrier methods also had cycles without barrier use, and where unprotected intercourse took place during the fertile phase.

*Perfect/imperfect use of NFP*

The custom of calculating separate method and user failure rates with the same denominator of cycles exposed is strongly criticized from the statistical point of view [6]. Therefore the suggestions of Trussel and Grummer-Strawn have been followed and the pregnancies have been related to the proper risk set. Method failure rates can be measured only when the method is used perfectly, and user-related pregnancy rates when the method is used imperfectly.

Perfect use means that the couple strictly practices abstinence in the fertile phase. Seen from the standpoint of NFP, imperfect use implies that there has been some kind of sexual expression in the fertile phase (increasing the risk of pregnancy).

During perfect use (perfect cycles of imperfect users included) the pregnancy rate per year is 0.63% (Table 5). There are various pregnancy rates during different types of imperfect use: the pregnancy rate per year is very low (0.45%) when only protected intercourse takes place in the fertile phase of every cycle (which indicates perfect use for mixed method users).

Genital contact in the fertile phase (including coitus interruptus) leads to a pregnancy rate of 4.54% per year (if there has been genital contact in every cycle). Unprotected intercourse in the fertile phase yields a pregnancy rate of 8.96% per year. 5.9% of the cycles have protected and unprotected intercourse in the fertile phase. The pregnancy rate per year with this behavior is 4.33%. This means that in the latter group the unprotected intercourse episodes are located more at the beginning or end of the fertile phase and are therefore associated with a lower risk of conception, whereas during the highly fertile days intercourse episodes frequently are protected. The pregnancy rate of 8.96%, however, resulted from a high number of unprotected intercourse episodes occurring at the extremes of the fertile time.

The same table shows some differences when the basis for categorizing the sexual behavior is the fertile phase as determined by the woman herself (Table 6). The most striking one is that there are nearly 2000 more "perfect use" cycles, i.e. cycles in which the women apparently think that they have used the method correctly, and 8 more unintended pregnancies. As a result, the number of cycles decreases in other groups.

*Always perfect users*

A very interesting question is how many couples always use the NFP method perfectly and what is their pregnancy rate. 45 women (5.9%) always used the NFP method perfectly in 646 cycles with 0 pregnancies.

**Discussion**

Many international studies deal with the effectiveness of the symptothermal method of natural family planning [1, 3, 5, 7–10]. However, they mostly calculate mere Pearl indices. Rarely, has a life-table approach been used and never have the pregnancy

**Table 5** Pregnancy rates in relation to perfect and imperfect use of the symptothermal method (objective definition)<sup>1</sup>

<i>Sexual behavior in the fertile phase</i>	<i>Cycles (n)</i>	<i>Cycles (%)</i>	<i>Unintended pregnancies (n)</i>	<i>Pregnancy rate % per cycle (<math>\times 10^{-4}</math>)</i>	<i>Pregnancy rate % per year<sup>2</sup></i>	<i>Confidence interval (<math>\times 10^{-4}</math>)</i>
Abstinence	6161	41.4	3	4.86	0.63	1.00–14.20
Abstinence most probable	1705	11.5	0	0	0	0
Genital contact	841	5.7	4	47.32	4.54	7.37–103.45
Unprotected intercourse	2364	15.9	17	71.91	8.96	42.16–115.98
Protected intercourse	2917	19.6	1	3.43	0.45	0.09–19.10
Unprotected and protected intercourse	882	5.9	3	34.01	4.33	7.02–98.68

<sup>1</sup>Fertile phase determined by the investigator

<sup>2</sup>Acc to the formula  $p = 100 \times (1 - (1 - P)^{13})$  where P is the probability per cycle (pregnancies/cycle)

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**Table 6 Pregnancy rates in relation to perfect and imperfect use of the symptothermal method (subjective definition)<sup>1</sup>**

<i>Sexual behavior in the fertile phase</i>	<i>Cycles (n)</i>	<i>Cycles (%)</i>	<i>Unintended pregnancies (n)</i>	<i>Pregnancy rate % per cycle (<math>\times 10^{-4}</math>)</i>	<i>Pregnancy rate % per year<sup>2</sup></i>	<i>Confidence interval (<math>\times 10^{-4}</math>)</i>
Abstinence	8011	53.9	11	13.73	1.77	6.73–24.54
Abstinence most probable	1705	11.5	1	5.86	0.76	0.15–32.64
Genital contact	866	5.8	3	34.64	4.41	7.15–100.49
Unprotected intercourse	1073	7.2	11	102.51	12.54	60.46–181.94
Protected intercourse	2694	18.1	1	3.71	0.48	0.09–20.68
Unprotected and protected intercourse	521	3.5	1	19.19	2.47	0.48–106.17

<sup>1</sup>Fertile phase determined by the woman herself

<sup>2</sup>Acc to the formula  $p = 100 \times (1 - P)^{13}$  where P is the probability per cycle (pregnancies/cycle)

rates been attributed to the perfect or imperfect use of the symptothermal method. The latter is not possible because the sexual behavior of the participants is unknown.

The current study is unique because of its large data base with detailed daily information about sexual behavior, including barrier method use in the fertile phase. 54.2% use NFP only or predominantly NFP with occasional barrier method use in 2.9% of the cycles. 45.9% are mixed methods users with barrier method used in 55.7% of the cycles.

In both groups the pregnancy rates were low with no significant differences between the first months of use (learning phase) compared to the following 4 years of use. This reflects our effective teaching approach.

As the risk of pregnancy depends on the frequency and timing of intercourse we refer to a recent analysis of part of the same data [2] where we found a mean frequency of intercourse episodes per cycle of 3.9 ( $SD \pm 2.6$ ), the mixed methods users having significantly more episodes ( $4.3 \pm 2.9$ ) than the predominantly NFP users ( $3.3 \pm 1.5$ ). Unfortunately there are no similar studies with daily reports about the frequency of intercourse in European countries with which to compare our data.

We have already shown that the mixed methods users, besides being sexually more active, are younger than the predominantly NFP users. More frequently they are working or still in training outside the home, are unmarried, having a lower or medium level of education and a higher percentage of irregular cycles [2]. In view of these findings the low pregnancy rate for this subgroup is even more remarkable. Those women who are working or in training, who are unmarried and have not yet had children, also belong to the more consistent NFP users ("consistent" defined as "no unprotected intercourse in the fertile phase") [3]. Thus, in Germany not only family planning limiters seem to be motivated NFP users, but also young women, who are working or are still training, are strongly motivated for effective contraception in the near future, intending to acquire professional skills before the first child.

It is important to recognize those women who use the method consistently but not correctly. The pregnancy rate per year with "objective perfect use" cycles increases from 0.63 to 1.77 with the "subjective perfect use" cycles. According to our experience this occurs either in women who do not understand the NFP method correctly (risk group) or in women who probably have a latent desire for a child and the unintended pregnancy indicates that the subconscious is at work.

It is astonishing that only a small number of couples (5.9%) always use the method perfectly. It may sometimes be difficult to use this method correctly and consistently. The different pregnancy rates for the various types of imperfect use express the specific motivation of the couple. The sexual behavior in the fertile phase seems to be conscious and risk-related and is most telling.

The symptothermal method is unforgiving for imperfect use (unprotected intercourse in the fertile phase), however it is extremely effective when either abstinence or protected intercourse is used during the fertile phase.

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## **Natural family planning in New Zealand: a study of continuation rates and characteristics of users**

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### **Abstract**

This study has determined long-term continuation rates of clients who attended clinics of the New Zealand Association of Natural Family Planning and became autonomous users. It has also identified factors which might influence the continuation of NFP use.

A total of 509 female subjects, 452 of them with their male partners, were enrolled in the study at the beginning of clinic teaching. Once autonomous they were sent questionnaires at 6-monthly intervals for a period of 24 months. Time out was allowed for pregnancy. The number of female subjects entering the 2-year follow-up phase of the study was 406 (79.8%). Of these 164 completed 2 years of use with 102 (20% of study entrants) using NFP and 62 (12.2%) using fertility awareness in combination with a barrier method.

Subjects for whom NFP was their first family planning method, who were Catholic or who gave religion as their reason for choosing NFP were more likely to continue long-term use.

The majority of subjects (>90%) were highly satisfied with NFP use, with the most common reasons for satisfaction being self-awareness, freedom from drugs, naturalness and effectiveness. The difficulties reported related to abstinence and cycle interpretation.

### **Introduction**

Knowledge of the extended use of natural family planning (NFP) is limited and particularly in the context of the outcome of a normal NFP teaching service.

Information on continuation rates has largely been derived from effectiveness studies [1–3] for which subjects are specifically recruited, and those who become pregnant are classified as discontinuers regardless of whether or not they returned to use of NFP following their pregnancy. This paper will report findings from the New Zealand NFP Continuation Study, which has sought to identify a true continuation rate of NFP use by allowing those couples who experience a pregnancy, planned or unplanned, to resume their participation in the study. Further aims include identification of factors that influence the ongoing use of NFP, identification of satisfaction/dissatisfaction with NFP, and the identification of the extent of use of fertility awareness combined with a barrier method (FA/B) among clients of an NFP teaching service. The study was not designed to determine use effectiveness rates.

### Methods

All new clients who attended clinics of the New Zealand Association of Natural Family Planning (NZANFP) from 1 April 1986 to 31 March 1988 and who had the intention, at least initially, to avoid conception, were invited to enroll in the study. Male and female partners were admitted and followed up separately, when the male partner was unwilling to take part or unavailable, the female partner was admitted alone. The subjects were classified at entry according to whether NFP would be their initial family planning method or an alternative after using other methods, and whether the female partner was breastfeeding.

Subjects undertook and completed in the normal manner their clinic instruction in the symptothermal method (the standard method taught by the NZANFP). After they had reached autonomy, i.e. after they and their teacher agreed, in consultation, that they were able to use the NFP method without further clinic teaching, the subjects entered the continuation phase of the study. In this phase they were sent questionnaires about their NFP use and associated experiences at 6-monthly intervals for a total period of autonomous NFP use of 24 months. Those subjects who became pregnant stated on the questionnaire whether they wished to continue with NFP after their pregnancy, and if so, whether they were willing to continue in the study. If they were willing they received their next questionnaire after completion of 6 months of NFP use. Subjects who discontinued the study indicated their reasons on the appropriate 6-monthly questionnaire.

Couples were identified from the questionnaires as NFP users and FA/B (fertility awareness/barrier) users. Regular FA/B users and those who used 'an occasional barrier in a difficulty' in more than two cycles out of six were separately classified as the FA/B group. The couples who very occasionally used a barrier method (in <2 cycles out of 6) were retained in the NFP users group, as the incidence tended to be sporadic.

The study had approval from the Auckland Hospital Research Ethics Committee.

## Results

A total of 509 females (median age 26 years) and 452 male partners (median age 28 years) enrolled in the study. In their attitude towards future pregnancy, 75.4% of the females and 75.2% of the males wanted more children (42.2% for both sexes within two years), 10.6% of the females and 11.8% of the males did not want any more children. The remainder were uncertain. Of the female subjects, 46.2% had at least one child.

During clinic teaching, 151 (29.7%) of the enrolled subjects, 120 of them with an enrolled male partner, discontinued before reaching autonomy although 48 wished to continue in the study. A total of 406 female subjects entered the two-year follow-up phase of the study.

At the completion of the follow-up phase 164 females and 143 males remained in the study. At this time 102 female subjects (20% of females at entry) were true NFP users and 62 (12.2%) were FA/B users. When comparing the personal characteristics of the female partners in the two groups with the female subjects overall at entry, significant findings relevant to long-term NFP use were identified ( $\chi^2$  analysis) in religious affiliation, reasons for using NFP, and in the study entry classification (initial or alternative FP method, or breastfeeding mother). The comparative data are shown in Tables 1, 2 and 3, respectively. Among long-term NFP users there was a higher incidence of Roman Catholics ( $p < 0.001$ ), religious reasons were important for using NFP ( $p < 0.001$ ), and NFP was the initial method of family planning used.

**Table 1 Religious affiliations of long-term natural family planning (NFP) and fertility awareness plus barrier (FA/B) female users compared with female group overall at admission to study**

	Percentage at 2 years of use		Percentage at admission
	NFP (n = 102)	FA/B (n = 62)	(n = 509)
Anglican	5.9	9.7	9.6
Presbyterian	6.9	4.8	5.7
Catholic	45.1*	24.2	28.3
Baptist	2.9	6.5	3.5
Pentecostal	4.9	3.2	2.9
Other Christian denomination	9.8	4.8	6.1
Christian (unspecified)	15.7	24.2	17.7
Non-Christian	0.0	4.8	1.8
Mormon	0.0	1.6	1.0
Jehovah's Witness	1.0	1.6	1.0
No religion	5.9*	12.9	19.6
Did not answer	2.0	1.6	2.8

\* $p < 0.001$  vs admission

**Table 2** Reasons for using natural family planning (NFP) provided at admission to the study by long-term NFP and fertility awareness plus barrier (FA/B) female users compared with female group at admission to study

	Percentage at 2 years of use		Percentage at admission ( <i>n</i> = 509)
	NFP ( <i>n</i> = 102)	FA/B ( <i>n</i> = 62)	
Naturalness	42.2	48.4	41.1
Side effects, other methods	31.4	30.6	36.0
Dissatisfaction, other methods	15.7	21.0	18.7
Contraindications, other methods	2.0	6.5	4.1
Religious reasons	24.5*	9.7	9.8
Philosophical reasons	3.9	0	2.0
User recommended	1.0	3.2	4.1
Other	2.9	3.2	2.9

\**p* < 0.001 vs admission

**Table 3** Subject category at entry to study of long-term natural family planning (NFP) and fertility awareness plus barrier (FA/B) female users compared with female group overall at admission to study

NFP category	Percentage at 2 years of use		Percentage at admission ( <i>n</i> = 509)
	NFP ( <i>n</i> = 102)	FA/B ( <i>n</i> = 62)	
Initial FP method	25.5*	8.1	9.0
Changed from other methods	57.8**	77.4	73.5
Breastfeeding mother	16.7	14.5	17.5

\**p* < 0.001 vs admission

\*\**p* < 0.005 vs admission

by the couple (*p* < 0.001). The characteristics of the FA/B users, however, did not differ from the group overall at admission.

The level of satisfaction with the family planning method remained consistent among NFP users over time with in excess of 90% of male and female partners grading it good or excellent at 6 months and at 24 months. The good/excellent rating among FA/B users increased from 77% for males and 82% for females at 6 months to 90% for both sexes at 24 months. The change was not significant.

In each 6-monthly questionnaire subjects were asked to describe what they found most satisfactory about NFP use in the previous 6 months. Most users of FA/B also

**Table 4** The most satisfactory aspect of family planning method reported by male and female subjects for natural family planning (NFP) and fertility awareness plus barrier (FA/B) at 6 and 24 months of use Only the most common reported aspects are tabled as percent response

	At 6 months				At 24 months			
	NFP		FA/B		NFP		FA/B	
	F	M	F	M	F	M	F	M
	<i>n</i> = 118	<i>n</i> = 86	<i>n</i> = 69	<i>n</i> = 43	<i>n</i> = 61	<i>n</i> = 40	<i>n</i> = 39	<i>n</i> = 27
Self-awareness	23.7*	10.5	47.8	18.6	12.9	10.0	28.4	7.4
No drugs/devices	27.9	30.2	17.4	30.2	16.4	15.0	23.1	33.3
Naturalness	9.3	6.9	7.2	11.6	14.7	17.5	7.7	11.1
Effectiveness	5.9	12.8	5.9	16.3	9.8	17.5	12.8	14.8

\* $p < 0.001$  vs FA/B group at 6 months

answered this question. Responses most frequently provided are reported in Table 4 for the 6-month and 24-month time periods. Not all subjects responded to the question but, nevertheless, some interesting observations can be made. The value of self-awareness was reported more often by FA/B female users than NFP females particularly at 6 months when the difference was highly significant ( $p < 0.001$ ). The freedom from drugs and devices was commonly cited by males and females in both groups. The naturalness aspect of NFP was frequently given as a reason for using NFP at admission to the study (Table 2), now rated lower. Interestingly, a noticeable proportion (12.8–17.5%) of male subjects for both methods indicated effectiveness as the most satisfactory benefit. Although shared responsibility in family planning is promoted as an advantage offered by NFP, it was not as perceived as such by the users, male or female (consistently  $< 10\%$ , data not shown).

When users were asked if any difficulty had been experienced in NFP use during the previous 6 months, a change in response was observed between 6 and 24 months for NFP users but not for the FA/B users who answered the question (Table 5). For the NFP group, 56.7% of females said yes at 6 months compared with 33.8% at 24 months ( $p < 0.005$ ) while for males there was a change from 47.4% to 42.0% (ns). In the FA/B group, 62.4% of females experienced difficulty at 6 months, which was similar at 24 months with 62.5%, a percentage significantly higher ( $p < 0.005$ ) than for the NFP females at the same time period. Males in the FA/B group reported comparable difficulty to those in the NFP group, 54.3% at 6 months and 42.5% at 24 months.

Abstinence was the main reason for difficulty among male subjects (63–82.4%) including surprisingly those in the FA/B group. The major causes of difficulty for their female partners were abstinence (40.7–66.7%) and the experience of an unusual cycle (40–63%). With increasing experience, difficulty in understanding fertility symptoms and lack of confidence in the methods declined as reasons for difficulty.

**Table 5 Percentage of natural family planning (NFP) and fertility awareness plus barrier users (FA/B) reporting difficulty with the method after 6 and 24 months of use Female and male responses separately listed**

Difficulty	At 6 months				At 24 months			
	NFP		FA/B		NFP		FA/B	
	F n = 127	M n = 110	F n = 93	M n = 70	F n = 80	M n = 69	F n = 48	M n = 40
Yes	56.7	47.4	62.4	54.3	33.8*	42.0	62.5	42.5
No	42.5	43.9	22.6	27.1	65.0	50.1	31.3	50.0
No answer	0.8	8.8	15.1	18.6	1.3	7.2	6.3	7.5

\* $p < 0.005$  vs NFP at 6 months and FA/B at 24 months

**Table 6 Reasons for difficulty in use of family planning method reported by natural family planning (NFP) and fertility awareness plus barrier (FA/B) users at 6 and 24 months of use Note multiple reasons could be given Percent male and female responses are listed**

Difficulty	At 6 months				At 24 months			
	NFP		FA/B		NFP		FA/B	
	F n = 72	M n = 54	F n = 58	M n = 38	F n = 27	M n = 29	F n = 30	M n = 17
Abstinence	54.2	63.0	50.0	68.4	40.7	65.5	66.7	82.4
Understanding symptoms	22.2	22.2	25.9	13.2	14.8	13.8	13.3	17.6
Interpreting chart	20.8	18.5	19.0	36.8	18.5	13.8	3.3	17.6
Unusual cycle	55.6	46.3	43.1	39.5	63.0	5.1	40.0	23.5
Lack of confidence	30.6	25.9	27.6	15.8	11.1*	10.3	23.3	11.8

\* $p < 0.05$  vs NFP at 6 months

These data are summarized in Table 6

During the course of the study there were 259 pregnancies among 204 women. Of the 54 subjects at admission (10.6%) who did not want more children, 10 experienced one pregnancy. Among the 164 women who continued to 24 months of use there were 119 pregnancies among 89 women.

## Discussion

The present study has investigated the outcome, characteristics, and attitudes towards NFP of couples attending a national natural family planning teaching

service We have found that of 509 women who attended clinics of the New Zealand Association of Natural Family Planning to learn an NFP method, 102 (20%) continued as long-term users Considering that the large majority of subjects who had a history of use of other methods, this continuation rate perhaps is not surprising Indeed, the small minority of subjects (9%) for whom NFP was their first family planning method were significantly more likely to continue with the method Other significant characteristics of long-term users were being Catholic and having religious reasons for using NFP However, only ten (9.8%) of the committed users had all three characteristics

Similar to the experience reported for NFP services in Europe [4], a significant number of subjects having learned the fertility awareness basis of NFP, elected to use a barrier method of contraception (mainly a condom) during the fertile period At the completion of 24 months of user follow-up there were 62 females (12.2%) in this category While it is clear that many couples do attend NFP clinics with the intention of using FA/B as their family planning method, it is of interest that some of the FA/B users in our study considered they were using an NFP method Unlike the NFP group, long-term FA/B users had no special characteristics identifiable as different from the subjects overall at admission

Difficulties with use of the methods were reported by both groups, with abstinence and an unusual menstrual cycle being the most common reasons Surprisingly, abstinence was more of a problem for FA/B users who may be thought to have more opportunity for intercourse than NFP users Nevertheless, despite the difficulties, the large majority of couples in both groups were highly satisfied (good or excellent) with their method

The value of self-awareness, freedom from use of drugs and devices, naturalness, and effectiveness, were perceived as the most satisfactory aspects of NFP and FA/B use Shared responsibility and the enrichment of the sexual relationship were nominated by only a very small percentage of NFP and FA/B users

Finally, the incidence of pregnancy among the long-term users in the study indicates that NFP is an acceptable method to couples who are beginning or still completing their families

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## V. Natural family planning safety

**How safe is NFP, considering outcomes of pregnancies that occur among couples who use NFP to avoid pregnancy, including congenital anomalies, spontaneous abortions, and sex ratio? Are there differences in outcomes between planned and unplanned pregnancies? Is NFP useful for sex selection?**

*Chair* John T Queenan, M D

*Discussant* Jan Blancato, Ph D , Georgetown University

*Consensus* Rates of spontaneous abortion as well as the rates of major congenital anomalies are not increased in cohort studies of pregnancies occurring in users of Natural Family Planning. Overall, spontaneous abortion and anomaly rates also are similar in both planned pregnancy (i.e., those resulting from intercourse on or near the day of ovulation) and unplanned pregnancies due to method failure (i.e., those resulting from intercourse at the extremes of the fertile time). Rates are not affected by pregnancies conceived on specific days vis a vis date of ovulation. Further, no increased risks of Down syndrome or other abnormalities have been observed in cohort and case control study of NFP users, suggesting that the risk of abnormality due to aging gametes in vivo is not significant. A small subgroup of women with a history of previous pregnancy loss may have increased rates of spontaneous pregnancy loss if conception occurs at the extremes of the fertile time. NFP clients can be assured that conceptions during NFP use do not result in higher risks for adverse pregnancy outcomes. In addition, timing of intercourse vis a vis ovulation or planned status of conception does not influence sex ratio, birth weight or pregnancy complications.

*Presenters*

Joe Leigh Simpson, M D , Baylor College of Medicine, Houston, USA

**Pregnancy outcome in natural family planning users: cohort and case-control studies evaluating safety**

Ron Gray, M D , John Hopkins University, Baltimore, Maryland, USA

**Risk of spontaneous abortion associated with the timing of conception in NFP users**

Michele Barbato, M D CAMEN, Italy

**Effects of timing of conception on birth weight and preterm delivery of NFP users**

Patricio Mena, M D Universidad Nacional, Chile

**Pregnancy complications in natural family planning users**

## **Pregnancy outcome in natural family planning users: cohort and case-control studies evaluating safety**

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### **Abstract**

Conceptions involving aging gametes are of relevance to natural family planning (NFP) because women using NFP to avoid pregnancy abstain from intercourse during the fertile time of the cycle. To help verify the safety of pregnancies occurring among NFP practitioners, our group has, since 1986, conducted a large cohort study involving six experienced NFP centers. Timing of conception was determined from NFP charts, in which women recorded days on which intercourse occurred. The number of days from the most probable conception intercourse to probable day of ovulation was first determined, and used as an estimate of the time gametes remained in the genital tract before fertilization. Several studies have already been completed, cohort as well as case-control in nature.

*1 Spontaneous abortions* Three hundred and sixty-one conceptions occurred during the optimal time (day -1 or 0 relative to ovulation), and of these 33

resulted in spontaneous abortion (9.1%). Five hundred and seven conceptions occurred at non-optimal times during the cycle, and of these 55 resulted in spontaneous abortions (10.9%). These differences were not statistically significant (relative risk 1.19, 95% CI, 0.79–1.80) [1].

**2 Anomalies** Among 780 singleton births in 868 cohort pregnancies, 24 infants had major anomalies (3.1%) as of the present analysis [2]. This frequency is comparable to the general population. To further assess anomalies we employed a case-control approach. All consecutive births (live and stillborn) weighing 500 g or more taking place in 18 participating South American hospitals were examined for minor and major congenital anomalies. Mothers of malformed and control infants did not differ with respect to the reported frequency of NFP use, which overall was 6.3% of the 10,642 mothers interviewed (5,277 having a malformed infant, 5,371 controls). Of 262 discordant pairs, there were 28 or 10.69% mothers within the Down syndrome case group vs. 16/262 or 6.11% among matched controls [3,4]. The odds ratio was 1.84, 95% CI, 0.99–3.96, however, even this non-significant difference narrowed substantially when adjusted for maternal age (OR, 1.78, 95% CI, 0.84–3.75), parity (OR, 1.68, 95% CI, 0.87–3.24), maternal educational level (OR, 1.71, 95% CI, 0.86–3.44), or all three together (OR, 1.74, 95% CI, 0.83–3.64).

**Conclusions** Our findings should be reassuring to natural family planning users. The overall rate of spontaneous abortion was not increased in NFP users who became pregnant, nor to date was the rate of anomalies. Any contribution to Down syndrome or abortion due to aging gametes would have to be small.

## Introduction

Interest in the effects of timing of conception on pregnancy outcomes has long existed. In particular, it has been thought that prolonged retention (*in vivo* aging) of gametes in the female genital tract before fertilization may compromise the development or survival of the embryo. Prolonged retention of sperm in the female genital tract could arise as a consequence of the intercourse leading to conception occurring in the preovulatory phase, two or more days prior to ovulation. Prolonged retention of ova in the female tract could arise if the intercourse leading to conception occurs in the postovulatory phase, one or more days after ovulation. Conceptions involving aging gametes are of particular relevance to natural family planning (NFP) because women using NFP to avoid pregnancy abstain from intercourse during the fertile time of the cycle. Unplanned pregnancies arising by method failures among NFP users can occur outside the traditionally defined fertile range and thus could be associated with aged gametes.

To help verify the safety of NFP, our group has since 1986 conducted a large cohort study involving six experienced NFP centers. In 1992–94 we conducted an additional investigation using an ongoing South American case-control study

Results to date are summarized in this communication, complementing our previous publications [1,3-7]

### **Study rationale animal studies**

Animal studies have for decades provided experimental evidence for the deleterious effects of fertilization involving aging gametes. Both sperm and oocytes have been implicated. Brief mention of selected studies will suffice to illustrate the consensus in the biological community that led to our concern.

#### *Sperm retention in the male tract*

Fertilization of normal ova may occur by sperm retained for prolonged periods in the male tract prior to ejaculation. For example, Tesh and Glover [8] studied the effects of insemination by aged epididymal rabbit sperm. Sperm aged 4 weeks showed greatly reduced fertilizing capacity, sperm aged 7 weeks showed no fertilizing capacity. Many of the offspring sired with sperm aged 4 weeks showed structural abnormalities, principally involving the skeletal system or gallbladder. Martin-DeLeon and colleagues performed cytogenetic studies on blastocytes obtained from does inseminated with sperm collected from male rabbits who had undergone bilateral epididymal ligation. Eight of 72 blastocytes (11%) resulting from insemination with 7-27-day-old sperm showed chromosomal abnormalities, compared with only 1 of 125 (0.8%) controls [8]. The primary effect appears to be trisomy. Martin-DeLeon and Boice [9] also reported that trisomies induced by sperm aged 8-20 days were of paternal origin, as predicted. The same held true for trisomies occurring following sexual rest.

#### *Sperm retention in the female tract*

Deleterious effects may also occur following prolonged sperm retention in the female genital tract prior to fertilization. Martin-DeLeon and Shaver [10] observed abnormalities in blastocytes recovered from rabbits inseminated by sperm aged *in utero*. Fewer blastocytes were recovered from does inseminated with sperm aged 18-32 h *in utero* than from does inseminated with sperm aged 0-18 h *in utero*, moreover, 13 of 134 blastocytes (10%) in the group fertilized by older sperm were cytogenetically abnormal.

#### *Aging ova*

Post-ovulatory aging of ova is termed delayed fertilization. Witschi [11] was the first to establish that delayed fertilization leads to decreased fertilizability and structurally

abnormal embryos The species studied was *Rana temporaria*, a frog that releases ova directly into its abdominal cavity, ova were collected from the oviducts and deposited in the uteri prior to fertilization Fertilization involving ova retained 3–4 days at elevated temperatures resulted in (1) cleavage or gastrulation abnormalities, (2) defects in the neural folds, (3) abnormal division causing twins or triplets, (4) postaxial duplications causing polymelia or polydactyly, and (5) reduced organ sizes Using *Rana pipiens*, Witschi and Laguens [12] later showed that most of these malformed embryos had chromosomal abnormalities

In mice, Vickers [13] found that delayed fertilization significantly increased the incidence of polyploidy, but less often aneuploidy In rabbits, 15–20% of zygotes induced by delayed matings were trinuclear (polyploid) Shaver and Carr [14] verified cytogenetic aberrations due to delayed fertilization by studying 6-day rabbit embryos recovered after matings delayed up to 10 h following intravenous injection of chorionic gonadotropin The frequency of chromosomal abnormalities in matings occurring immediately after injection (a 6-h delay being the injection–ovulation interval) was 7% (5/73 blastocytes), compared to only 2% (1/58) in control animals having no delay

To summarize all animal data, fertilization involving aging gametes clearly may cause chromosomal abnormalities Rates of abnormalities differ between species Both sperm and ova may be involved

#### **Aging gametes in humans circumstantial evidence**

That aging gametes are potentially deleterious in humans obviously can be tested only indirectly, such as through outcomes following irregular coitus or periodic abstinence In 1968 the first attempt was made by German [15], who compared duration of marriage in various groups German's rationale was derived from observations of Kinsey *et al* [16], who concluded that coital frequency is inversely related to duration of marriage After corrections for age, German found that the length of marriage prior to the pertinent birth was longer in mothers delivered of trisomic offspring, thus, not age *per se* but rather decreased coital frequency accompanying increased duration of marriage seemed to be correlated with the maternal age-related increase in aneuploidy (trisomy 21)

Juberg *et al* [17] reported that the interval preceeding the birth of a trisomy 21 child was significantly greater than the interval preceeding a normal birth Milstein-Moscato and Becak [18] conducted a case–control study involving 20 mothers with Down syndrome offspring and 61 mothers with normal offspring Intercourse less than once per week during the conception cycle was reported far more commonly in mothers of Down syndrome offspring (75%) than in controls (10%), this finding was largely restricted to women under age 35 Juberg *et al* [19] also found that coital frequencies were lower in parents of Down syndrome probands than in parents of abnormal probands with non-chromosomal defects

Several investigators have compared Down syndrome rates in various religious groups, assuming indirectly that certain groups were practicing periodic abstinence

and, hence, were at increased likelihood for fertilization involving aging gametes Jongbloet and Paesrkote [20] and Mulcachy [21] believe that Roman Catholic populations have about a two-fold increased risk for Down syndrome compared to Protestants, and further that this difference reflects use of periodic abstinence in Catholics but not Protestants Sharav [22] found that the incidence of Down syndrome was significantly higher in the orthodox ('religious') than 'non-religious' Jews in Jerusalem The former practice mikve, taking a ritual bath 7 days after cessation of menstruation and prior to resuming intercourse Among 69 Down syndrome births, 47 (69%) occurred in religious hospitals and 22 (31%) in non-religious hospitals

If aging gametes predispose to chromosomal abnormalities in the human, one would expect not only increased liveborn trisomy but also increased spontaneous abortions because 50–60% of clinically recognized spontaneous abortions are chromosomally abnormal (50% trisomic, 25% polyploidy, 25% monosomy X) Boue *et al* [23] found that when conception occurred 15 days or more after the last menstrual period (LMP), the prevalence of polyploidy in abortuses was 32% When intercourse occurred (normally) less than 15 days after the first day of the LMP, the prevalence of polyploidy in abortuses was only 10% The mean delay between LMP and conception was 15 days for cytogenetically normal abortuses but 17 days for polyploid abortuses Delays between ovulation and fertilization in excess of 2 days were specifically associated with a non-significantly higher prevalence of polyploidy (35%) compared to delays less than or equal to 2 days (23%), no differences were observed with respect to monosomy X or autosomal trisomy In aggregate, these findings suggest that delayed fertilization could increase the risk of polyploidy in abortuses Thus, analysis of abortion rates in humans practicing NFP seemed necessary

### **Problems in assessing spontaneous abortions and anomalies in prior NFP cohorts**

In surprisingly few NFP cohorts have anomalies been assessed in offspring resulting from inadvertent conception [24–26] Fortunately, there was no evidence of untoward outcome in the NFP population reported by the World Health Organization [24], by France *et al* [25] and by Roetzer [26], however, the salutary conclusions of these studies have still been received with some scepticism in the scientific community because conclusions were at odds with the impressive animal data and with the circumstantial data reviewed above

Spontaneous abortion rates of 15% or less have been observed in many NFP populations Marshall (14.8%) [27] Guerrero and Rojas (7.8%) [28], World Health Organization (9.8%) [24], France *et al* (7.0%) [25] and Roetzer (8.3%) [26] France *et al* [25] reported that spontaneous abortion rates were similar (5%) among 779 women conceiving using NFP compared to 2718 women conceiving while using no contraception However, the above studies can be criticized for failing to take into account potential confounding variables, including maternal age Completeness of ascertainment is a concern For example the very low loss rates in both subjects and controls of France *et al* [25] are unexplained

In order to provide data that offer clinical reassurance for NFP users, a more rigorous study of both anomalies and abortuses was necessary. As a start, background information for variables known to be associated with fetal losses and anomalous liveborns needed to be collected. For example, frequencies of birth defects and spontaneous abortions are affected by smoking, drinking alcohol, prior history of pregnancy losses, maternal age and many other factors. Comparisons can be misleading if such important variables are not taken into account. Another pitfall is that surveillance for potential teratogens during pregnancy has not always been conducted, thus not excluding post-conceptual factors as an explanation for abnormal events. Gathering a family history is necessary because existence of a similar anomaly in the family would suggest Mendelian or polygenic/multifactorial etiology, absolving aging gametes as causative. Examination of neonates for congenital anomalies has rarely been performed in systematic fashion. This is essential if one expects to detect all anomalies present and if one hopes to recognize Mendelian defects or syndromes, which if inherited are obviously unrelated to periconceptual events. Selection biases must also be considered. If only a small portion of a larger population is under surveillance, how representative are those few studied? This bias is especially a concern in questionnaire-based studies, where increased likelihood exists that individuals experiencing an abnormal outcome will participate. Are individuals at increased risk for birth defects relatively more likely to be included in a given sample because they suspect the need for further medical consultation? Conversely, could subjects be angry at health care providers because of a prior adverse outcome and thus be more likely to ignore pleas for participation? The lack of follow-up was a pitfall of the otherwise well designed WHO study [24], of 175 pregnancies, 12 (6.8%) were lost to follow-up.

Finally, misclassification is a concern in NFP studies. Unless NFP experts analyze properly constructed charts, the proportion of NFP pregnancies due to method failure and the proportion due to user failure cannot be determined. Yet presumably only the former are at risk for aging gametes. Judging outcome on the basis of the exact coital day leading to conception obviously requires interpretable and accurately analyzable NFP charts. We considered all the above pitfalls and sought to minimize them in our cohort study.

### **Methods and materials cohort study**

The first of our two complementary studies to assess safety of NFP was cohort in nature. A cohort approach has the advantage of enabling investigators to gather data on the circumstances of conception, thus avoiding recall bias and allowing potential confounding variables to be assessed. We also collected NFP charts to determine the day of the most probable coital act leading to conception. Finally, we ascertained all fetal losses and conducted a systematic neonatal evaluation. By contrast, the retrospective (case-control) approach to be described below can only indirectly assess NFP safety. However, it has the strength of large sample size.

Our cohort consisted of women who became pregnant while using natural family

planning beginning in January 1987. They were identified in six highly experienced natural family planning centers located in Santiago (Chile), Lima (Peru), Bogota and Medellin (Colombia), Milan (Italy) and Washington DC. Only the first five centers were used for studies involving spontaneous abortions. Informed consent was obtained using a common consent form approved by each participating institution.

Timing of conception was determined from NFP charts in which women recorded days on which intercourse occurred. Daily changes in cervical mucus production and basal body temperature (BBT) shifts were charted. A preliminary study by our group had shown that interobserver agreement was highest for the day of peak mucus, thus, that sign was used as the preferred marker for estimating day of ovulation [29]. Most participants used the ovulation method mucus peak, defined as the last day of vulvar lubrication and/or stretchable mucus present at the vulva. If a chart did not clearly indicate a mucus peak, the day before the first day of the BBT rise was taken as the day of ovulation. (Many studies have shown a close correlation between the BBT rise and the mucus peak day.) All charts were reviewed by one investigator (RTK). Charts that proved difficult to interpret were reviewed by two investigators, who independently recorded the most likely day of conception intercourse relative to the estimated mucus peak day. Discrepancies between NFP chart interpreters were reconciled by consensus conference. None of the chart reviewers knew the outcome of the pregnancy at the time of their review.

The most likely day of ovulation was inferred from the timing of the mucus peak or, if necessary, the BBT shift. In analyses to date, we have not taken into account the theoretical possibility that an earlier act of coitus could have been responsible for the pregnancy. Rather, the act of coitus closest in time to the day of ovulation was considered to be that most likely responsible for conception. Taking other possibilities into account (earlier or later coital acts) could have been addressed statistically, but would have required untested assumptions and seemed very unlikely to alter results.

The number of days from the most probable conception intercourse to probable day of ovulation was then determined, and used as an estimate of the time gametes remained in the genital tract before fertilization. We assumed that the optimal survival time is less than 48 h for sperm and 12 to 24 h for ova, and that conception is highest when acts of intercourse occur on the day of ovulation or the day preceding ovulation. Thus, conceptions resulting from intercourse on the day before or the day of ovulation (day -1 or 0) were considered to be 'optimal' because the gametes involved in fertilization were likely to have been present in the genital tract < 48 h before syngamy. All other conceptions were classified as 'non-optimal' and were further stratified as non-optimally timed conceptions occurring either during the preovulatory phase of the cycle ( $\geq 2$  days before peak mucus, a time considered to correspond with ovulation) or during the postovulatory phase ( $\geq 1$  day after peak mucus).

All women using NFP and becoming pregnant were interviewed in order to gather information on their sociodemographic characteristics, reproductive history, and periconceptional events in the current pregnancy. The latter included the precise method of NFP used, pregnancy status with respect to being planned or unplanned,

dates of the last menstrual period, and presence or absence of behavior characteristic like smoking and alcohol consumption. At 16 and 32 weeks of gestation, follow-up information was obtained on complications of pregnancy, other illnesses, and use of medications (potential teratogens). Women who experienced a spontaneous abortion or other adverse pregnancy outcomes were interviewed in order to ascertain the date and circumstances of the event and to exclude cases of induced abortion. At birth, only a limited number of physicians performed the systematic examination for anomalies, using a lengthy check list. Genetic consultations were required for cases having multiple anomalies in order to exclude Mendelian tracts or syndromes. Additional details of study design are provided elsewhere [5].

Statistical analyses focused on the association between timing of conception and either spontaneous abortion or malformations. For data exploration we used bivariate tabulations and graphic displays. In our spontaneous abortion studies, we found that the association between timing of conception and spontaneous abortion risk in the index pregnancy differed between women with and women without a previous pregnancy loss. Thus, we stratified the population by prior pregnancy outcome, and also analyzed malformations by this stratification. Bivariate analyses estimated the relative risks associated with timing of conception. Logistic regression procedures were used to estimate the odds ratio among pregnancies conceived at optimal or non-optimal times of the cycle, after statistical adjustment for such potential confounding variables as maternal age, center, and pregnancy history. Statistical tests of relative risks or odds ratios were based on 95% confidence intervals. For statistically testing discrete variables we used the  $\chi^2$  or Fisher exact test and for linear trends in proportions  $\chi^2$  tests.

## Results of the cohort study

### *Spontaneous abortions*

Spontaneous abortion rates were assessed in 943 pregnant women identified in five centers between January 1987 and March 1983, as reported previously [1]. Fourteen NFP charts could not be used to estimate the timing of conception, 10 women did not record acts of intercourse and 4 charts were classified as 'uninterpretable' by the reviewers. Twelve multiple pregnancies and two ectopic pregnancies were further excluded from the analysis, and follow-up was incomplete for 47 pregnancies (5.0%). A total of 868 singleton pregnancies remained for analysis. Among these 868 pregnancies, there were 88 spontaneous abortions (10.1%) and 8 stillbirths (0.9%).

Three hundred and sixty-one conceptions were considered to have occurred during the optimal time (day -1 or 0 relative to the estimated day of ovulation), and of these 33 resulted in spontaneous abortion (9.1%). Five hundred and seven conceptions were considered to have occurred at non-optimal times during the cycle, and of these 55 resulted in spontaneous abortion (10.9%). These differences were not statistically significant (relative risk 1.19, 95% CI 0.79-1.80).

We further examined the association between timing of conception and the risk of

**Table 1** Relative risk of spontaneous abortion in relationship to timing of conception stratified in women with and without history of prior pregnancy loss

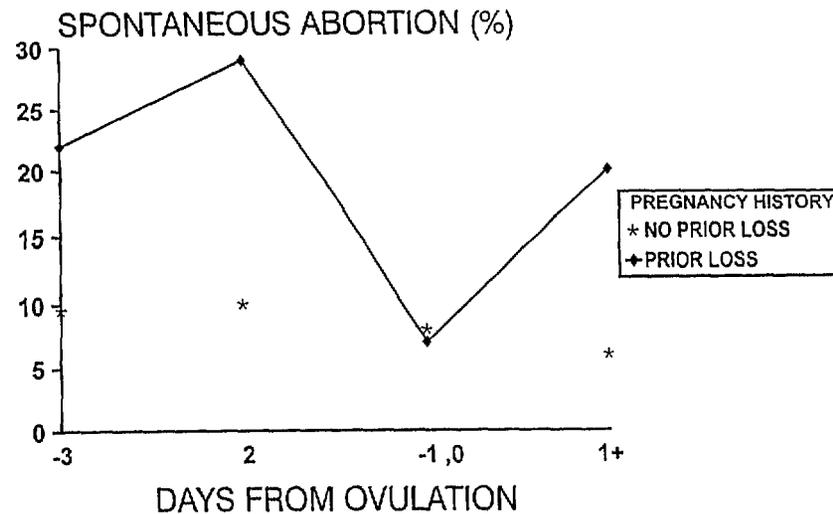
	Pregnancies (n)	Spontaneous abortions (n)	Relative risk	95% CI
All women				
Optimal timing	361	33 (9.1%)	1	0.79–1.80
Non-optimal timing	507	55 (10.9%)	1.19	
Women with no history of pregnancy loss				
Optimal timing (referent)	292	28 (9.6%)	1	
Non optimal timing	405	32 (7.9%)	0.82	0.51–1.34
Women with a history of pregnancy loss				
Optimal timing	69	5 (7.3%)	0.76	0.30–1.89
Non-optimal timing	102	23 (22.6%)	2.35	1.42–3.89

Modified from Gray *et al* [1]

spontaneous abortion among 171 women who had experienced a pregnancy loss and 697 women without a history of loss (Table 1). The spontaneous abortion rate among women with no prior loss and an optimally timed index pregnancy was 9.6%, whereas the rate among non-optimally timed pregnancies in women with a history of loss was, surprisingly 22.6%. This statistically significant difference (relative risk 2.35, 95% CI 1.42–3.89) was not observed among women with non-optimally timed conceptions who had no prior pregnancy loss (7.9%), nor among women with optimally timed conceptions who had a history of pregnancy loss (7.3%).

Figure 1 plots the age-adjusted rates of spontaneous abortion for conceptions during the preovulatory and postovulatory phases of the cycle. Among women with no history of pregnancy loss the rates of spontaneous abortion were relatively low and did not vary by estimated timing of conception *vis a vis* ovulation. In contrast, among those women who had previously experienced a pregnancy loss, the age-adjusted spontaneous abortion rates were lowest for optimally timed conceptions (7.3%). Rates were increased for both preovulatory and postovulatory, non-optimally timed, conceptions ( $\chi^2$  13.56,  $p = 0.0002$ ).

Logistic regression analyses were used to estimate the risk of spontaneous abortion associated with timing of conception and pregnancy history after adjustment for age (by single year intervals), planned or unplanned pregnancy status, and center. The adjusted risk of miscarriage increased with age but was unaffected by the planning status of the pregnancy. Relative to optimally timed conceptions in women with no history of loss, the risk of spontaneous abortion in the index pregnancy was increased only among women with non-optimally timed conceptions who also had a history of a pregnancy loss (odds ratio 2.63, 95% CI 1.32–5.23).



**Figure 1** Spontaneous abortion rate per 100 pregnancies by estimated day of conception among women with and without a history of pregnancy loss \*Statistically significant difference [1]

### *Anomalies*

This part of our study is still in progress, final data analysis being delayed until the largest possible sample can be accumulated. This will maximize power, a major concern in assessing rare malformations. Still, our multicenter cohort is the first cohort study to systematically and specifically assess anomalies. Our study is also the largest study looking at outcome of pregnancy in NFP users, the WHO study [24] had 175 pregnancies (12 lost to follow-up) or one-fifth the number of pregnancies in our study.

At the time of an earlier analysis, 868 pregnancies were available [2]. Defects were classified as major if they were either life-threatening or seriously impaired function. A structural defect was classified as major only if surgery was required. Among the 780 singleton births in the 868 pregnancies, 24 infants had major anomalies (3.1%). This frequency is comparable to the general population. No particular anomaly occurred with undue frequency. The sole hint of a positive effect occurred among 143 couples with a prior loss, a group in which we observed a non-significantly higher anomaly rate among women with a non-optimally timed pregnancy (days other than 0 or -1 with respect to the ovulation method peak). The relative risk was 4.1, but 95% CI was 0.45 to 33.8 (Table 2).

Overall, one can conclude that the frequency of major anomalies is not significantly increased in NFP users at the time of this analysis.

**Table 2 Major anomalies**

<i>Day of conception</i>	<i>No prior loss</i>	<i>Prior loss</i>
-1 or 0 from ovulation method peak (optimal)	3.4%	1.6%
Other days (non optimal)	2.4%	6.3%

Rates of major anomalies observed in 780 singleton pregnancies conceived during optimal vs non optimal times *vis a vis* ovulation. Data from abstract of Simpson *et al* [2]

### *Sex ratio*

The sex ratio at birth for 947 singleton births was 101.5 males per 100 females, which is not significantly different from the expected sex ratio of 105. The sex ratio did not vary consistently with the estimated day of conception relative to the day of ovulation, with the length of the follicular phase of the conception cycle, or with planned versus unplanned status of the pregnancy. We conclude that manipulation of the timing of conception cannot be used to select the sex of the offspring.

### **Methods and results in the case-control study for Down syndrome**

The cohort approach discussed above is in most ways the preferable experimental design for assessing the role of aging gametes in humans. However, as noted, an almost unavoidable pitfall is the less than optimal sample size. Power to detect an increase in individual anomalies is especially limited. For this reason we have conducted a complementary case-control study in South America, taking advantage of the long-standing Latin American Collaborative Study of Congenital Malformations (Spanish acronym ECLAMC [30]).

In the years 1992-1994 we gathered data by questionnaire on over 5000 case-control pairs. We were particularly interested in the relationship between women claiming to use NFP and age and occurrence of Down syndrome, given that this disorder is considered the sentinel defect associated with aging gametes. All consecutive births (live and stillborn) weighing 500 g or more taking place in 18 participating ECLAMC hospitals were examined for minor and major congenital anomalies. The like-sexed non-malformed liveborn occurring next in temporal sequence to the birth of a malformed baby was chosen as a control. Mothers having malformed infants and control mothers having normal infants were questioned according to a standard protocol designed to elicit information concerning fertility control. Specifically, they were asked whether they were using contraception when they became pregnant and, if so, which type. We queried for the various methods of

NFP, oral contraceptives, intrauterine devices, condoms, diaphragm and coitus interruptus (withdrawal) We made no effort to validate NFP usage, nor to distinguish planned from unplanned pregnancies We did not attempt to collect NFP charts, nor to determine if they even existed Rather, we sought merely to compare a large population of women who claimed to be using NFP with a population matched on the basis of sex of infant, time of birth, and location It should be emphasized that women claiming to have used NFP in this case-control study do not correspond to those in the cohort study The latter were participating in NFP center protocols and were thus complying with recommended guidelines

As reported elsewhere [3-7] mothers of malformed and control infants did not differ with respect to the reported frequency of NFP use, which overall was 6.3% of the 10 642 mothers interviewed (5277 having a malformed infant, 5371 controls) The frequency of NFP use among cases and matched controls was then compared by the discordant pair method and by the more sensitive but less specific unpaired method of matched case/controls Results by both methods were similar, and only those from the discordant pair method are presented here [3]

Updated data allow us to derive information from 262 discordant Down control pairs [4] Of the 262, there were 28 (10.69%) mothers within the Down syndrome group vs 16 (6.11%) among matched controls This odds ratio was 1.84, 95% CI 0.99-3.96 This near-significant difference held true when the discordant intrapair method was applied (odds ratio, 2.00, 95% CI 0.99-4.24) However, the difference narrowed substantially when the odds ratio (OR) was adjusted for maternal age (OR 1.78, 95% CI 0.84-3.75), parity (OR 1.68, 95% CI 0.87-3.24), maternal educational level (OR 1.71, 95% CI 0.86-3.44), or all three variables together (OR 1.74, 95% CI 0.83-3.64)

## Discussion

Neither our cohort nor case-control studies have in general provided evidence that pregnancies in NFP users - unplanned or planned - are associated with increased anomalies or spontaneous abortions The overall frequency of major malformation in 780 singleton births was 3.1%, comparable to the 2-3% expected in the general population Anomaly rates were not significantly higher in pregnancies conceived on days other than the day of ovulation or the day before Although our NFP cohort is several-fold larger than any previous such cohorts, caution is still appropriate in excluding effects on individual conditions The final cohort analysis will be forthcoming soon

Our case-control study is reassuring in also revealing no significant statistical association between NFP usage and Down syndrome The odds ratio was greater than 1 for an association between Down syndrome and women who claim to be using NFP, but this failed to reach statistical significance despite a sample size of over 10 000 mothers (262 discordant pairs) Assuming our cohort study is in agreement, the appropriate conclusion would seem to be that NFP methods are safe with respect to anomalies in general and Down syndrome in particular

Overall, we also found no significant association between spontaneous abortions and NFP and we did not observe a differential effect in the rate of spontaneous abortion *vis a vis* timing of the conception intercourse. Given that at least 50–60% of abortuses are chromosomally abnormal, we take this as further evidence, albeit indirect, that aging gametes do not play substantive roles in the etiology of human aneuploidy. The one subgroup in which we observed a statistically significant effect consisted of preovulatory- and postovulatory-aged conceptions among 171 women who reported a previous pregnancy loss, no excess losses occurred among 697 women without such a history. We have speculated that this phenomenon could be related to recurrent aneuploidy, but otherwise the biologic basis of any effect seems obscure [5]. We have also suggested that possibly these women might optimize their chances of successful pregnancy by using the ovulation method mucus peak or BBT rise to conceive during the optimal time of the cycle.

In conclusion, to date the overall rate of spontaneous abortion was not increased in NFP users who became pregnant, nor was the rate of anomalies. If any NFP subset were to show a significantly increased frequency of spontaneous abortions or anomalies, the overall effect would still be small. Conversely, aging gametes do not seem likely to play a major role in the etiology of Down syndrome. Our findings should be reassuring to NFP users.

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## Effects of timing of conception on birth weight and preterm delivery of natural family planning users

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### Abstract

*Objective* Various birth defects and untoward perinatal outcomes have been claimed to be associated with pregnancies conceived by gametes aged *in vivo* before fertilization. Thus, these outcomes were systematically assessed in pregnancies occurring in natural family planning (NFP) users. Our international multicenter cohort study of NFP pregnancies ( $n=877$ ) is by far the largest systematic study designed to assess pregnancy outcome and is of sufficient power to allow us to address the concern of low birth weight ( $<2500$  g) and preterm delivery ( $<37$  weeks gestation).

*Study design* In addition to gathering baseline medical data, evaluation was performed at 16 weeks, 32 weeks and at term. Data were collected in a systematic cohort fashion, verified by the five collaborating international

recruiting centers, and analyzed by investigators in the US. Most recruiting center principal investigators are obstetrician-gynecologists and, if not, have integral relationships with such specialists. Standard criteria could thus be applied within and among centers. In our cohort, birth weight was recorded accurately at delivery. Almost all of the deliveries occurred in hospitals, thus, data should be quite reliable. Neonatal examination for anomalies was usually conducted immediately after delivery, when birth weight was recorded.

**Results** Analysis of risk factors for low birth weight and preterm delivery showed that this population had a low risk profile. Low birth weight infants (<2500 g) and preterm deliveries were increased among women with a history of either prior low birth weight or preeclampsia in the index pregnancy. However, mean birth weight was unaffected by the timing of conception *vis a vis* ovulation or pregnancy history. Mean birth weight for the 877 singleton NFP pregnancies was 3349.6 g. The risk of preterm delivery was increased among older women who drank alcohol, but there were no significant effects of timing of conception *vis a vis* ovulation on preterm delivery. Results held when analysis was stratified according to whether NFP was being used for contraception or to achieve pregnancy.

**Conclusions** Our data do not appear to show striking differences between 877 NFP pregnancies and the general obstetric population. The timing of conception *vis a vis* ovulation does not exert significant effects on the birth weight or preterm delivery of resulting pregnancies, a reassuring finding for NFP users.

## Introduction

Natural family planning (NFP) users practice periodic abstinence. Thus, they would be expected to have an increased likelihood for pregnancies that have involved gametes aged *in vitro* prior to fertilization. Various birth defects and untoward perinatal outcomes have indeed been claimed to be associated with pregnancies conceived by gametes aged *in vivo* before fertilization. These outcomes were, therefore, systematically assessed in pregnancies occurring in natural family planning (NFP) users. Our international multicenter prospective study of NFP pregnancies ( $n = 877$ ) is by far the largest systematic study designed to assess pregnancy outcome.

Previous attention has already been directed to pregnancy loss [1], anomalies [2,3], sex ratio [10] and pregnancy intention [4] in this sample. Our cohort study also allows us to a) stratify pregnancy outcomes by planning status, and b) correlate pregnancy outcome based on timing of conception with respect to day of ovulation. This study involving 5 centers is of sufficient power to allow us to address the concern of low birth weight (<2500 g) and preterm delivery (<37 weeks' gestation).

Any potential deleterious effects of pregnancies conceived by gametes aged *in vivo* have generally been considered to be genetic in nature [11]. However, more generalized deleterious effects could be hypothesized. If an aging gamete contributes to the

zygote, early embryonic growth may be delayed and the number of cells in the trophoctoderm thus decreased. The placenta is derived from the trophoctoderm, thus, placental mass could be decreased. Decreased placental mass could result in inadequate transfer of nutrients across the placenta or inadequate blood flow. Either mechanism could lead to low birth weight infants. Premature deliveries could occur if production of certain hormones is decreased. We therefore took advantage of our cohort study to investigate whether low birth weight or preterm premature delivery occurs in pregnancies conceived with NFP.

### Materials and methods

NFP users who became pregnant (1987–1993) were identified in five NFP centers: two in Santiago (Chile), and one each in Bogota-Medellin (Columbia), Milan (Italy), and Washington DC (USA). Pregnancies among these NFP users were identified and followed up to delivery. Informed consent was obtained using a common consent form approved by each participating institution. In the 877 singleton pregnancies, the presence or absence of low birth weight and preterm birth was examined in relation to estimated timing of conception, and planned or unplanned pregnancy status. As described elsewhere [5], peak mucus day was considered to correspond to day of ovulation.

The day of ovulation was estimated from the timing of the mucus peak or BBT shift. The probable conception intercourse was the most likely intercourse that would lead to conception, as determined by the NFP chart reviewers. Timing of conception was defined as the time in days from the most probable conception intercourse to the probable day of ovulation, as defined in more detail below. This interval provides an estimate of the time gametes remained in the genital tract prior to fertilization. That is, the interval is a measure of the approximate 'age' of the gametes at conception. In this instance, aging of the ovum refers to the length of the interval between ovulation and probable conception date, aging of the spermatozoa refers to the length of the interval between intercourse and the probable conception date.

As soon as pregnancy was recognized (5th week of gestation), interview information was obtained on sociodemographic characteristics, past reproductive history and the periconceptional circumstances of the index pregnancy. This latter information included the method of NFP used (basal body temperature, cervical mucus or symptothermal) and whether pregnancy was desired or being avoided. The mother's obstetric history was recorded including prior adverse pregnancy outcomes, e.g. pregnancy loss, low birth weight (<2500 g) and preterm birth (<37 weeks), infections and illnesses since conception. At 16 and 32 weeks of gestation, follow-up information was obtained on prenatal care and weight gain during pregnancy, complications of pregnancy, other illnesses, use of medications, and exposure to toxins. After delivery, women were interviewed about complications of late pregnancy, labor and delivery, and information was obtained on birth weight, gestational age at birth and other neonatal characteristics. Birth weight was recorded accurately at delivery. Because almost all deliveries occurred in hospitals, data should be quite

reliable Neonatal examinations for anomalies was conducted at delivery, or shortly thereafter, at which time birth weight was recorded. If examination did not occur at that time, information was obtained a few weeks later. Irrespective, all infants were examined by a neonatologist using a check list to detect minor and major birth defects [3].

We used the International Statistical Classification of Diseases (ICD 9th revision, World Health Organization, 1975) [6] for coding illnesses and other conditions that affected the index pregnancy. Any liveborn infant weighing less than 2500 g at birth was termed low birth weight regardless of the length of gestation. A preterm birth was defined as one occurring before 37 completed weeks of gestation (259 days), determined as time since last menstrual period, regardless of birth weight. Of note is that hypertension of pregnancy was defined as an elevated blood pressure with systolic measurements above 140 mm of mercury, and a diastolic level above 90 mm of mercury. Anemia was diagnosed as a hematocrit equal to or less than 34%.

Conceptions resulting from intercourse on the day before or the day of ovulation (days -1 or 0) were considered to be 'optimal', because the gametes were likely to have less than 48 h exposure in the genital tract prior to fertilization. All other conceptions were classified as 'non-optimal'. The latter were further grouped as non-optimally timed conceptions during the preovulatory phase of the menstrual cycle (2 or more days prior to ovulation) or during the postovulatory phase (1 or more days after ovulation).

In this study pregnancy intention was ascertained from unequivocal information on the planning status confirmed from multiple data sources. When pregnancy was first recognized, information about the woman's pregnancy intention was obtained at entry into the study, and she was asked whether the pregnancy was planned. The information was verified by the NFP instructor who, after discussion with the woman and review of her NFP chart, rendered an opinion as to whether NFP had, indeed, been used to plan or to avoid a pregnancy. Subsequently, independent reviewers examined the NFP chart to ensure that the pattern of intercourse was consistent with the client's and NFP instructor's statements about pregnancy intention. In fact, there was excellent agreement between the pregnancy planning intention as stated by the woman and the NFP instructor's assessment [7]. The assignment of planning status was made without knowledge of pregnancy outcome. A planned pregnancy was defined as one in which the NFP user stated that her intention was to become pregnant and also one in which the NFP chart showed intercourse took place during the fertile period. Unplanned pregnancies occurred when the user stated the couple did not plan or desire a pregnancy, and were using NFP for contraception. Unplanned pregnancies were further categorized as method failures or user failures. Method failures occurred when the NFP user's intention was to avoid a pregnancy, the correct rules were followed and the couple had intercourse only outside the estimated fertile period, but despite adherence to the NFP method, a pregnancy occurred. With user failure, the couple did not desire a pregnancy, but, nonetheless, had intercourse on a day defined by the NFP method as potentially fertile either due to a deliberate departure from the NFP rules concerning abstinence or due to misunderstanding of the NFP rules.

We used bivariate analysis and graphical displays for data exploration. Bivariate and stratified analysis was also used to search for potential confounders or effect modifiers.  $\chi^2$  of Fisher exact tests, and  $\chi^2$  tests for linear trend in proportions were used for statistical tests of discrete variables [7–9]. Statistical tests of risk ratios or odds ratios were based on the 95% confidence intervals (CI).

## Results

Table 1 shows that women with non-optimally timed pregnancies were significantly older, of higher parity and less likely to be employed than women with optimal timing. On the other hand, women with optimally timed pregnancies reported more frequent pregnancy losses in previous pregnancies. With regard to planning status, unplanned pregnancies were more common among older, multigravid women. Women with unplanned pregnancies also more frequently reported prior low birth weight or prior preterm births. Women with unplanned pregnancies were more likely to be unemployed at the time of their pregnancy, and had a higher prevalence of current or previous smoking than the planners.

Overall, the prevalence of low birth weight (<2500 g) was 3.5% among 877 liveborn singleton infants. The rates of low birth weight and preterm deliveries were, thus, low in this population of women using natural family planning. Rates did not differ significantly by timing of conception or by status as planned versus unplanned pregnancy (Table 2). The prevalence of low birth weight was somewhat higher among optimally timed conceptions (4.4%) than among non-optimally timed conceptions (2.9%). This difference was, however, not statistically significant (Relative risk = 0.67, CI 0.33–1.33). Similarly, mean birth weight was unaffected by the timing of conception or pregnancy history.

As shown in Table 3, there is no evidence of an association between low birth weight and maternal age, employment, smoking or drinking. However, as would be expected, women with a prior low birth weight infant experienced an increased risk of low birth weight in the index pregnancy. The prevalence of low birth weight did not differ significantly between births to women with a history of prior pregnancy loss (3.9%) and those with no prior loss (2.4%), irrespective of timing of conception. There were also no significant effects of timing on preterm delivery. A consideration of medical factors arising during the index pregnancy indicates that low birth weight was more common in women who started prenatal care after 12 weeks of gestation, and among women with pregnancy complications such as preeclampsia and vaginal bleeding.

Table 4 shows selected risk factors for preterm births. Other than older age ( $\geq 30$  years), the only social or behavioral factor associated with preterm birth was alcohol use during pregnancy. The risk of preterm birth is increased among multigravid women ( $\geq 4$ ) and among women with a history of prior preterm birth. Preterm birth was more common in women with less antenatal care and in pregnancies with such complications as preeclampsia or vaginal bleeding. We provide more information on risk factors for low birth weight and preterm birth in Tables 5 and 6.

**Table 1 Selected characteristics of women by timing of conception and planning status**

Characteristics	Optimal timed pregnancies n = 362		Non-optimal timed pregnancies n = 510		Planned pregnancies n = 429		Unplanned pregnancies n = 448	
	n	%	n	%	n	%	n	%
Age (years)								
< 30	259	71.5	329	64.5	302	71.1	286	64.0
≥ 30	103	28.5	181	35.5**	123	28.9	161	36.0*
Parity								
0	206	56.4	176	34.4	258	60.1	124	27.7
1	106	29.0	172	33.6	122	28.4	156	34.8
2 or more	53	14.5	164	32.0**	49	11.4	168	37.5*
Prior low birth weight (parous women)								
1 or more	14	8.8	27	8.0	15	8.8	28	8.6
Prior pregnancy loss (gravid women)								
No prior loss	118	64.8	251	73.8	129	75.3	240	74.5
Prior loss	64	35.2	89	26.2**	71	24.7	82	25.5
Employment								
Never employed	62	17.1	105	20.6	67	15.8	100	22.4
Previous	77	21.3	171	33.5	95	22.4	153	34.2
Current	223	61.6	234	45.9**	263	61.9	194	43.4**
Smoking in pregnancy								
Never	229	63.4	289	56.7	291	68.5	227	50.9
Stopped	114	31.6	179	35.1	113	26.6	180	40.4
Current smoker	18	5.0	42	8.2 <sup>ns</sup>	21	4.9	39	8.7**
Alcohol in pregnancy								
None	336	92.1	470	91.8	395	92.1	411	91.7
Yes	29	7.9	42	8.2	34	7.9	37	8.3
Maternal weight								
< 50 kg	77	21.3	99	19.8	95	22.6	81	18.4

\* $p < 0.05$  \*\* $p < 0.01$  ns = differences not statistically significant Optimal conceptions = coital event leading to conception on day of ovulation or day before (0 -1) Non optimal conceptions = coital event leading to conception on all other days with respect to ovulation

**Table 2 Low birth weight (<2500 g) and preterm birth (<37 weeks) by timing of conception and planning status of pregnancy summary of main findings**

<i>Type of pregnancy</i>	<i>Total</i>	<i>Low birth</i>		<i>Total</i>	<i>Preterm</i>	
	<i>births</i>	<i>weight</i>	<i>%</i>	<i>births</i>	<i>births</i>	<i>%</i>
	<i>n</i>	<i>n</i>		<i>n</i>	<i>n</i>	
All pregnancies	877	31	3.5	869	59	6.7
Optimal timing of conception <sup>a</sup>	365	16	4.4	361	23	6.4
Non optimal timing of conception <sup>b</sup>	512	15	2.9	508	36	7.1
Type of non optimal timing						
Pre ovulatory (-2 -3 etc)	373	10	2.7	371	23	6.2
Post-ovulatory (+1 +2 etc)	139	5	3.6	137	13	9.5 <sup>ns</sup>
Planned pregnancy	429	16	3.7	424	26	6.1
Unplanned pregnancy	448	15	3.3	445	33	7.4 <sup>ns</sup>
Type of unplanned pregnancy						
User failure	312	9	2.9	310	21	6.8
Method failure	136	6	4.4	135	12	8.9 <sup>ns</sup>

ns = differences not statistically significant

<sup>a</sup>Optimal conceptions = coital event leading to conception on day of ovulation or day before (0 -1)

<sup>b</sup>Non optimal conceptions = coital event leading to conception on all other days with respect to ovulation

Eleven (35.5%) of the 31 mothers with low birth weight infants experienced complications during labor and delivery compared with 149 (17.6%) of mothers with normal birth weight infants. Among mothers with low birth weight, one or two mothers in each category had fetal malposition, fetal distress, preterm rupture of membranes, premature labor, premature placental separation, and preeclampsia. In addition to these conditions, mothers with normal birth weight infants also experienced fetal disproportion, uterine inertia, prolonged labor, cord complications, cervical dystocia, and infections. Similarly, 17 (28.8%) of 59 mothers with preterm births experienced a complication during labor and delivery compared with 142 (17.5%) of 810 mothers with normal birth weight infants.

### Comment

Overall, the 877 NFP pregnancies showed a low frequency (3.5%) of low birth weight (<2500 g) and preterm delivery (<37 weeks) (6.7%) (see Table 2). The risk of low birth weight and preterm delivery was predictably increased among women with a history of prior low birth weight or preeclampsia in the index pregnancy. The risk of

**Table 3 Selected risk factors for low birth weight (< 2500 g)**

<i>Risk factor</i>	<i>Total births n</i>	<i>Low birth weight</i>	
		<i>n</i>	<i>%</i>
<i>Socioeconomic and behavioral factors</i>			
Mother's age (years)			
< 30	588	20	3.4
30+	284	11	3.9
Mother's employment			
Never employed	167	6	3.6
Employed in the past	248	8	3.2
Currently working	457	17	3.7
Smoking			
Never	518	20	3.9
Stopped	293	10	3.4
Current	60	1	1.7
Alcohol use			
None	806	27	3.3
Yes	71	4	5.6
<i>Obstetric history</i>			
Gravidity			
Primigravid	355	16	4.5
Multigravid	522	15	2.9
Pregnancy order			
1	355	16	4.5
2	252	4	1.6
3	140	5	3.6
4+	130	6	4.6
Previous low birth weight (parous women)			
None	336	23	6.8
One or more	43	8	18.6*
Previous pregnancy loss			
Pregnant no loss	369	9	2.4
Pregnant prior loss	153	6	3.9
<i>Medical factors in index pregnancy</i>			
Prenatal care			
< 6 visits	119	4	3.4
6-7	119	8	6.7
8-9	275	7	2.5
10+	307	12	3.9

(continued)

Table 3 (cont)

<i>Risk factor</i>	<i>Total births n</i>	<i>Low birth weight</i>	
		<i>n</i>	<i>%</i>
First prenatal visit			
2-7 weeks of gestation	171	7	4.1
8-11 weeks of gestation	449	22	4.9
12+ weeks of gestation	207	2	1.0*
Vaginal bleeding			
No	683	21	3.1
Yes	194	10	5.4
Preeclampsia			
No	858	26	3.0
Yes	19	5	26.3**
Vaginal infection			
No	656	23	3.5
Yes	221	8	3.6
Anemia (< 34%)			
No	688	22	3.2
Yes	189	9	4.8
Prepregnancy weight			
< 50 kg	176	8	4.5
50-59 kg	431	19	4.4
60-69 kg	194	4	2.1
70+	61	0	-
Sex of infant			
Male	441	13	2.9
Female	435	18	4.1

\* $p < 0.05$  \*\* $p < 0.01$ 

preterm birth was increased among older women who drank alcohol. Our observations are well accepted from other studies. However, mean birth weight was unaffected by the timing of conception, i.e. whether the act of coitus leading to conception occurred optimally on the day of or one day before ovulation (as signified by the mucus peak or BBT increase) and all other conceptions were considered non-optimal. Mean birth weight for 877 singleton NFP pregnancies was 3349.6 g. In other words, there is no evidence of an association between timing of conception or planning status and low birth weight or preterm birth. Likewise, lack of association held when planned versus unplanned pregnancies were compared.

Table 4 Selected risk factors for preterm birth (&lt;37 weeks)

<i>Risk factor</i>	<i>Total births</i>	<i>Preterm births</i>	
	<i>n</i>	<i>n</i>	<i>%</i>
<i>Socioeconomic and behavioral factors</i>			
<i>Mother's age (years)</i>			
< 30	582	30	5.2
30+	282	28	9.9**
<i>Mother's employment</i>			
Never employed	165	10	6.1
Employed in the past	246	24	9.8
Currently working	453	24	5.3
<i>Smoking</i>			
Never	512	34	6.6
Stopped	293	19	6.5
Current	58	5	8.6
<i>Alcohol use</i>			
None	798	50	6.3
Yes	71	9	12.7*
<i>Obstetric history</i>			
<i>Gravidity</i>			
Primigravid	351	20	5.7
Multigravid	518	39	7.5
<i>Parity</i>			
Primiparous	379	21	5.5
Multiparous	490	38	7.8
<i>Pregnancy order</i>			
1	351	20	5.7
2	250	11	4.4
3	138	10	7.2
4	83	12	14.5
5+	47	6	12.8**
<i>Previous preterm births (parous women)</i>			
None	336	12	3.6
One or more	43	9	20.9**
<i>Previous pregnancy loss</i>			
Pregnant no loss	365	24	6.6
Pregnant prior loss	153	15	9.8

(continued)

Table 4 (cont)

<i>Risk factor</i>	<i>Total births n</i>	<i>Preterm births n</i>	<i>%</i>
<i>Medical factors in index pregnancy</i>			
<i>Prenatal care</i>			
< 6 visits	119	12	10.0
6-7	119	22	18.5
8-9	275	9	3.3
10+	307	15	4.9
<i>First prenatal visit</i>			
2-7 weeks of gestation	171	8	4.7
8-11 weeks of gestation	442	42	9.5
12+ weeks of gestation	207	8	3.9
<i>Vaginal bleeding</i>			
No	675	49	7.3
Yes	194	12	6.2
<i>Preeclampsia</i>			
No	850	55	6.5
Yes	19	4	21.1**
<i>Vaginal infection</i>			
No	648	45	6.9
Yes	221	14	6.3
<i>Anemia (&lt; 34%)</i>			
No	683	50	7.3
Yes	186	9	4.8
<i>Prepregnancy weight</i>			
< 50 kg	176	9	5.1
50-59 kg	427	35	8.2
60-69 kg	190	10	5.3
70+	61	3	4.9
<i>Sex of infant</i>			
Male	438	32	7.3
Female	430	27	6.3

\* $p < 0.05$  \*\* $p < 0.01$

**Table 5 Selected delivery complications by low birth weight (<2500 g) and preterm birth (<37 weeks)**

<i>Delivery complication</i>	<i>Total births n</i>	<i>Low birth weight n (%)</i>	<i>Total births n</i>	<i>Preterm birth* n (%)</i>
Any complication				
Present	160	11 6.9	159	17 10.7
Absent	717	20 2.8	710	42 5.9
Fetal malposition	9	1 11.1	9	2 22.2
Cephalopelvic disproportion	17	0 -	17	0 -
Fetal distress	28	2 7.1	24	4 16.7
Intrauterine growth retardation	1	1 100.0	1	0 -
Premature rupture of membranes	12	2 16.7	12	2 16.7
Premature labor	1	1 100.0	2	2 100.0
Uterine inertia	25	0 -	25	0 12.0
Prolonged labor	14	0 -	14	0 -
Umbilical cord complications	2	0 -	2	0 -
Placenta previa	2	0 -	2	0 -
Premature separation of placenta	3	1 33.3	3	1 33.3
Other severe bleeding	2	0 -	2	1 50.0
Oxytocin-induced labor	4	0 -	4	0 -
Eclampsia	6	1 16.6	5	0 -
Elective Cesarean section	27	1 3.7	27	1 3.7
Maternal infections	4	0 -	4	0 -
Others	2	0 -	2	1 50.0

Some individuals had more than one type of complication

\* $p < 0.05$  \*\* $p < 0.01$

This information was abstracted from the client's delivery records

Thanks to their high level of fertility and reproductive health awareness, NFP users may not only better choose and use any method of NFP but also better maintain their overall reproductive health. This awareness in fact comprises basic, generic knowledge of male and female reproductive physiology, the ability to apply that knowledge to one's personal health and the skills to discuss reproductive health issues with health care providers and partners. Moreover, being in the habit of daily observing and charting the different fertility markers, NFP users (planners or non-planners) may recognize very early whether pregnancy has occurred or not (just after the 17th or 18th day of BBT shift they may recognize pregnancy occurrence). This timeliness in recognizing pregnancy allows women to avoid at once any use of drugs or medications and to modify their smoking and drinking habits (principal cause of adverse pregnancy outcomes).

**Table 6 Selected complications in the second half of pregnancy by low birth weight (<2500 g) and preterm birth (<37 weeks)**

<i>Type of complication in second half of pregnancy</i>	<i>Total births n</i>	<i>Low birth weight n (%)</i>		<i>Total births n</i>	<i>Preterm birth<sup>a</sup> n (%)</i>	
Any complication						
Present	229	16	6.9	229	36	15.7
Absent	648	15	2.3	640	23	3.5
Threatened premature labor	58	4	6.9	58	10	17.2
Premature rupture of membranes	11	2	18.2	11	6	54.5
Intrauterine growth retardation	6	2	33.3	6	0	–
Placenta previa	5	0	–	5	1	20.0
Other bleeding	6	0	–	6	2	33.3
Oligohydramnios	4	1	25.0	4	1	25.0
Polyhydramnios	4	0	–	4	0	–
Contracted pelvis	1	0	–	1	0	–
Diabetes	7	0	–	7	3	42.8
General surgery	2	0	–	2	0	–
Jaundice	22	1	4.5	22	3	13.6
Anemia	10	0	–	10	0	–
Hypertension	13	3	23.0	13	2	15.3
Psoriasis/lupus	3	1	–	3	1	33.3
Preeclampsia	6	1	16.7	6	3	50.0
Hyperthyroidism	1	0	–	1	0	–
Hypothyroidism	1	0	–	1	0	–
Urinary tract infections	13	0	–	13	0	–
Vaginal infections	22	1	4.5	22	1	4.5
Other infections	25	0	–	25	2	8.0
Other illnesses	9	0	–	9	1	11.1

Some individuals had more than one type of complication

\* $p < 0.05$  \*\* $p < 0.01$

<sup>a</sup>Apparently information on gestational age at delivery was not available for a few women who had conceived during the prior postpartum amenorrheic period

Therefore, irrespective of whether pregnancies are planned or occur inadvertently among NFP users, clients can be assured they are not at increased risk for poor fetal outcomes as judged by low birth weight and preterm premature delivery

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## **Pregnancy complications in natural family planning users**

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### **Abstract**

A multicenter cohort study was designed to assess pregnancy outcome among natural family planning (NFP) users and provide the opportunity to address complications in NFP users by planning status and by timing of conception with respect to day of ovulation. There were 877 singleton births in this sample. Complications evaluated were abnormal vaginal bleeding, urinary tract infection, vaginal infection, hypertension of pregnancy, proteinuria, glycosuria, and anemia.

There was no significant difference in the mean age, number of prenatal visits or birth weight among optimally and non-optimally timed pregnancies or for planned and unplanned pregnancies. There were higher incidences of "parity 2 or more" and current smokers in the non-optimally timed pregnancies and lower incidences of prior pregnancy loss and "currently employed" in the

non-optimally timed pregnancies. There was little difference in pregnancy complications with respect to pregnancy timing, with the exception of a significant increased risk of vaginal bleeding late in pregnancy among non-optimally timed conceptions (11.5%) compared to optimally timed pregnancies (5.2%, RR = 2.2, 95% CI 1.3–3.7).

More differences were observed in pregnancy complication rates by planning status. Unplanned pregnancies were associated with significantly more late pregnancy bleeding, vaginal infections, proteinuria, glycosuria and medication use than planned pregnancies. Unplanned pregnancies had lower incidences of maternal anemia.

Complications of pregnancy were low in this NFP population, irrespective of planned versus unplanned status. Women with planned pregnancies had even fewer complications during pregnancy than women with unplanned conceptions, suggesting that women using NFP to plan their reproduction may be at particularly low risk.

## Introduction

A multi-center cohort study was designed to assess pregnancy outcome among natural family planning (NFP) users. In this cohort several previous publications have examined pregnancy outcomes such as spontaneous abortion [1], congenital anomalies [2,3], and effects of pregnancy planning status [5]. The current paper reports on pregnancy complications in NFP users and permits us to examine complications by planning status and by timing of conception with respect to day of ovulation. A companion publication examines low birth weight and preterm delivery [6].

Any potential deleterious effects of pregnancies conceived by gametes aged *in vivo* have generally been considered to be genetic in nature [7]. However, more generalized deleterious effects could be hypothesized. If an aging gamete contributes to the zygote, early embryonic growth may be delayed and the number of cells in the trophoctoderm decreased. Since the placenta is derived from trophoctoderm, placental mass could be decreased. In turn, this could lead to a variety of perinatal complications such as intrauterine growth restriction or premature delivery as a result of the placenta producing less hormones. Even disorders such as preeclampsia could arise, since its pathogenesis is thought to involve perturbations in establishing the uterine–trophoblast circulation. Although we consider the possibility of perinatal complications related to aging gametes to be remote, we took advantage of our cohort to investigate whether these complications occur with increased frequencies in pregnancies conceived with NFP.

## Materials and methods

NFP users who became pregnant (1987–1993) were identified in five NFP centers: 2 in Santiago (Chile), 1 in Bogota-Medellin (Colombia), 1 in Milan (Italy), and 1 in Washington DC (USA). There were 877 singleton births in our sample, among whom pregnancy complications were examined in relation to (a) estimated timing of conception vis-a-vis day of ovulation, and (b) planned or unplanned pregnancy status.

At enrollment, information was obtained by interview concerning socio-demographic characteristics, reproductive history and the circumstances of the index pregnancy. This latter information included the method of NFP used (basal body temperature, cervical mucus and symptothermal), the dates of last menstrual period, and exposures including smoking and alcohol consumption. We obtained information about prior adverse pregnancy outcomes (e.g. pregnancy loss, low birth weight and preterm birth) as well as infections and illnesses since conception in the current pregnancy. At 16 and 32 weeks of gestation, follow-up information was obtained on prenatal care and weight gain during pregnancy, complications of pregnancy, other illnesses and use of medications. After delivery, women were again interviewed about complications of late pregnancy, and information was obtained on birth weight, gestational age at birth and other neonatal characteristics. All infants were examined by a neonatologist using standardized procedures to record major and minor birth defects [3].

Information on pregnancy complications was obtained by interview and from medical records. Complications evaluated were abnormal vaginal bleeding, urinary tract infection, vaginal infection, hypertension of pregnancy, proteinuria, glycosuria and anemia. Complications of pregnancy were coded using the International Classification of Diseases 9th revision [8]. Any live-born infant weighing less than 2500 g at birth was classified as low birth weight regardless of the length of gestation, and preterm birth was defined as an infant born before 37 completed weeks of gestation as determined by the last menstrual period. These outcomes were considered separately. Hypertension of pregnancy was defined as an elevated blood pressure with systolic measurements above 140 mm of mercury and a diastolic level above 90 mm of mercury. Anemia was diagnosed if the pregnant woman had a hematocrit equal to or less than 34%.

The day of ovulation was estimated from timing of the mucus peak or BBT shift as described earlier [9]. The peak mucus day is known generally to correlate with the day of ovulation. The probable conception intercourse was the most likely intercourse that would lead to conception, as determined independently by NFP chart reviewers [1]. Timing of conception was defined as the time in days between the most probable conception intercourse and the probable day of ovulation. This timing variable provides an estimate of the period the gametes remained in the genital tract prior to fertilization. Conceptions resulting from intercourse on the day before or on the day of ovulation (days -1 or 0) were considered to be "optimal", because such gametes were likely to have resided less than 48 h in the genital tract prior to fertilization. All other conceptions were classified as "non-optimal". These were further grouped as



**Table 1a Selected characteristics of women by timing of conception and planning status**

<i>Characteristics</i>	<i>Optimal timed pregnancies n = 362 Mean ± SE</i>	<i>Non optimal timed pregnancies n = 510 Mean ± SE</i>	<i>Planned pregnancies n = 429 Mean ± SE</i>	<i>Unplanned pregnancies n = 448 Mean ± SE</i>
Age (years)	28.4 ± 0.26	28.97 ± 0.19	28.5 ± 0.23	28.96 ± 0.21
Prenatal visits	8.6 ± 0.16	8.7 ± 0.13	8.6 ± 0.15	8.68 ± 0.14
Birth weight (g)	3348 ± 25.8	3350 ± 20.2	3366 ± 23.4	3333 ± 22.0

**Table 1b Selected significant characteristics of women by timing of conception and planning status**

<i>Characteristics</i>	<i>Optimal timed pregnancies n = 362 n %</i>		<i>Non-optimal timed pregnancies n = 510 n %</i>		<i>Planned pregnancies n = 429 n %</i>		<i>Unplanned pregnancies n = 448 n %</i>	
<b>Parity</b>								
0	206	56.4	176	34.4	258	60.1	124	27.7
1	106	29.0	172	33.6	122	28.4	156	34.8
2 or more	53	14.5	164	32.0**	49	11.4	168	37.5*
<b>Prior pregnancy loss (parous women)</b>								
No prior loss	118	64.8	251	73.8	129	75.3	240	74.5
Prior loss	64	35.2**	89	26.2	71	24.7	82	25.5
<b>Employment</b>								
Never employed	62	17.1	105	20.6	67	15.8	100	22.4
Previous	77	21.3	171	33.5	95	22.4	153	34.2
Current	223	61.6**	234	45.9	263	61.9**	194	43.4
<b>Smoking in pregnancy</b>								
Never	229	63.4	289	56.7	291	68.5	227	50.9
Stopped	114	31.6	179	35.1	113	26.6	180	40.4
Current smoker	18	5.0	42	8.2**	21	4.9	39.9	8.7**

\**p* < 0.05 \*\**p* < 0.01

**Table 1c Selected non-significant characteristics of women by timing of conception and planning status**

<i>Characteristics</i>	<i>Optimal timed pregnancies n = 362</i>		<i>Non-optimal timed pregnancies n = 510</i>		<i>Planned pregnancies n = 429</i>		<i>Unplanned pregnancies n = 448</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>
Prior low birth weight (parous women)								
One or more	14	8.8	27	8.0	15	8.8	28	8.6
Alcohol in pregnancy								
None	336	92.1	470	91.8	395	92.1	411	91.7
Yes	29	7.9	42	8.2	34	7.9	37	8.3
Maternal weight < 50 kg	77	21.3	99	19.8	95	22.6	81	18.6

number of patients with singleton deliveries was 877. The background characteristics of these mothers are presented in Table 1.

There were no significant differences in the mean age, number of prenatal visits or birth weight among optimally and non-optimally timed pregnancies or for planned or unplanned pregnancies. Table 1 shows the number of births, and birthweight by timing of conception and planning status. Mean birth weight for 877 singleton NFP pregnancies was 3349.6 g. Mean birth weights were 3348.1 ± 25.8 g for the 362 pregnancies conceived at the optimal time of the cycle (days 0 or -1 from the mucus peak) and 3350.7 ± 20.2 g for the 510 pregnancies conceived at non-optimal times (days +1 or either -2 or ≤ 3). Mean birth weights were 3366 ± 23.4 for the 429 planned pregnancies and 3333 ± 22.0 for the unplanned pregnancies.

There was a higher frequency of "parity of 2 or more" and current smokers in the non-optimally timed pregnancies and a lower frequency of prior pregnancy loss and present employment in the non-optimally timed pregnancies ( $p = 0.01$ ). There was a higher frequency of "parity of 2 or more" and current smoking and a lower frequency of present employment in the unplanned pregnancies ( $p = 0.001$ ).

#### *Optimal versus non-optimal timing*

Table 2 shows overall frequencies of various complications during pregnancy.

There was little difference in frequency with respect to pregnancy timing, with the exception of a significant increased risk of vaginal bleeding late in pregnancy among non-optimally timed conceptions (11.5%) compared to optimally timed pregnancies (5.2%, RR = 2.2, 95% CI 1.3–3.7).

**Table 2** Pregnancy complications by timing of conception and by planning status

<i>Type of complication</i>	<i>Total births n = 877</i>		<i>Optimal timed pregnancies n = 365</i>		<i>Non optimal timed pregnancies n = 512</i>		<i>Planned pregnancies n = 429</i>		<i>Unplanned pregnancies n = 448</i>	
	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>	<i>n</i>	<i>%</i>
No complication	648	73.9	289	79.2	359	70.1	350	79.4	298	66.5
Vaginal bleeding (16 week visit)	116	13.2	45	12.3	71	13.9	51	11.9	65	14.5
Vaginal bleeding (32 week visit)	78	8.9	19	5.2	59	11.5**	22	5.1	56	12.5**
Urinary tract infection	130	14.8	57	15.6	73	14.3	64	14.9	66	14.7
Vaginal infection	221	25.2	87	23.8	134	26.2	86	20.0	135	30.1**
Hypertension	19	2.2	7	1.9	12	2.3	10	2.3	9	2.0
Proteinuria	227	25.9	94	25.8	133	26.0	95	22.1	132	29.5**
Glycosuria	177	20.2	67	18.4	110	21.5	73	17.0	104	23.2*
Hematocrit $\leq 34$	189	21.6	84	23.0	105	20.5	108	25.2	81	18.1*
Medication use	585	66.7	234	64.1	351	68.6	266	62.0	319	71.2**

Some individuals had more than one type of complication

\* $p < 0.05$  \*\* $p < 0.01$

### *Planned versus unplanned pregnancies*

Pregnancy complication rates by planning status resulted in more differences. Unplanned pregnancies were associated with significantly more late pregnancy bleeding, vaginal infections, proteinuria, glycosuria and medication use than planned pregnancies. Unplanned pregnancies had a lower incidence of maternal anemia.

### **Discussion**

Complications of pregnancy were low in this NFP population, irrespective of planned versus unplanned status. There was substantial use of prenatal care services, and mean infant birthweights were normal. These observations, along with other previous findings of low rates of spontaneous abortion, low birth weight, preterm delivery and infection during pregnancy suggest that this was a self-selected cohort of healthy mothers. Women with planned pregnancies had even fewer complications during pregnancy than women with unplanned conceptions, suggesting that women using NFP to plan their reproduction may be at particularly low risk.

The higher occurrence of later pregnancy bleeding (recorded at 32 weeks) noted among non-optimally timed pregnancies is difficult to explain, particularly since there was no significant difference at 16 weeks. It did not appear to have a clinical significance.

Our findings are very reassuring, suggesting a good prognosis for pregnancy outcome among NFP users.

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## **VI. Models of natural family planning service delivery**

**What are existing models for expanding the delivery NFP services? How can NFP be adapted to a variety of settings, including the public sector and multimethod family planning programs, that would lead to mainstreaming?**

*Chair* Douglas Huber, M D , Pathfinder/Boston

*Discussant* Nancy Harris, Ph D , John Snow International/SEATS

*Consensus* NFP services provided worldwide have primarily been offered by free standing NFP NGOs, who offer only NFP methods. As a result, there is limited experience in how multi-method providers can effectively and efficiently offer NFP and fertility awareness education. Efforts at mainstreaming need to take account of a number of factors. They include (a) provider attitude and skills, (b) NFP teaching methodologies, (c) the time it takes clients to learn the NFP method, and (d) implications of mainstreaming for staff utilization, deployment and supervision. Multimethod programs should include NFP and fertility awareness in their educational activities. In doing so, they need to consider how they will create a supportive program and policy environment and develop the capacity to provide services. Partnerships between multimethod providers (public and NGO) and NFP NGOs represent an approach for making fertility awareness education and NFP services more widely available. This approach, however, requires good communication among many types of service providers, program managers, donors and senior policy makers. Ovulation prediction devices offer the possibility of simplifying client use of a natural method and represent another approach for making NFP more accessible and easier to learn and practice. Operations Research is needed to provide guidance to help providers integrate fertility awareness education and NFP into their programs and services. Operations Research could assist this process by testing approaches for overcoming barriers and models for mainstreaming NFP including through public-private partnerships.

*Presenters*

Myrna Seidman, M A , M P H , Georgetown University, USA

**Requirements for NFP service delivery an overview**

Rebecca Infantado, M D , Department of Health, Philippines  
**Main-streaming NFP into the Department of Health of the Philippines opportunities and challenges**

Sandro Giroto, M D , INER, Verona, Italy  
**Comparing a public and private sector NFP program implications for NFP expansion**

Carlos Huezo, M D , IPPF/London, UK  
**Factors to address when periodic abstinence is offered by multi-method family planning programs**

Rosemary Kirkman, SAC, UK  
**Approaches for incorporating ovulation detection devices and home kits into learning NFP – implications for service delivery**

## Requirements for NFP service delivery: an overview

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### Abstract

This paper reviews the salient features of natural family planning (NFP) and how it is provided. It also reviews the issues that influence how NFP is mainstreamed including client needs, provider expectations and capabilities, service delivery strategies and policy questions. Ways providers could make NFP easier for clients to learn include incorporating fertility awareness in all family planning client education efforts, teaching NFP in groups, and using a competency-based approach to teach NFP. The question of whether NFP teachers need to be users is analyzed from historical and current perspectives, and four options are presented for organizing NFP services in multi-method settings. Finally, the policy issues that multi-method providers will need to address when NFP is incorporated into their choice of methods are discussed.

### Introduction

Our interest in considering models for main-streaming natural family planning (NFP) services is based on the recognition that NFP presents some unique requirements for providers and service delivery organizations. This stems from the history of NFP service delivery as well as from the unique features of NFP as a method. Current approaches for providing NFP have evolved from, and been influenced by the experience of church-based NFP NGOs that have taught NFP to thousands of women and couples throughout the world. The service delivery model that evolved in this context continues to work well within the private voluntary setting. Whether it can work well and the adaptations that may be needed for multi-method providers are the questions addressed in this paper. To consider these questions, the paper will review the salient features of NFP and how it is provided, and consider the implications for multi-method providers of incorporating NFP into their services.

First we will look at NFP as a method and key elements of the NFP service model

### **The characteristics of NFP as a method**

NFP is a knowledge-based method that relies for effective practice on client understanding, self-knowledge and the modification of behavior in accordance with the client's instructions. It requires service providers to provide clients with accurate information on the physiology of fertility, the signs and symptoms of the fertile period and how the beginning and end of the fertile period can be identified and monitored. It requires the provider to help the client correctly apply this knowledge to herself, follow the rules of the method and abstain during the fertile period if she does not want to become pregnant. To be practiced effectively, NFP must be well taught by the provider and well understood and correctly applied by the client.

To effectively teach the method, providers must be well trained in the method. They must understand the physiology of reproduction, and be able to identify and correctly interpret the signs and symptoms of fertility that clients report. They must also be able to clearly and effectively communicate this understanding to the learning client, including teaching the client how both to chart and correctly interpret the chart. The providers must have good teaching, coaching, and counseling skills. Because the method requires a significant amount of sexual abstinence each month, providers must be able to help their clients communicate with their partners and they need to help support couples to find other satisfying ways to express their love for each other. To be able to do this, they must respect their client's right to choose, have an open mind about the ability of their clients to learn the method and about its effectiveness if it is well understood and correctly applied.

Providers also need to maintain a teaching and counseling relationship with each client until the client demonstrates competency in the method and the ability to practice it without further assistance – in other words until the client is able to become an autonomous user. This can mean as many as four to six client contacts and teaching/counseling sessions over a 2–3-month period.

Because NFP began as part of a church-based voluntary movement, and NFP is still primarily provided by NFP/NGOs, most of its teachers are NFP users who grew up through the system. Their knowledge of the method is based on their use of it. Being an NFP user is one of the prerequisites that qualifies them to be trained as teachers. Most are non-professional volunteers who teach in their homes, the homes of their clients or in church or community-based facilities. Within the church setting, NFP is taught as part of family life and marriage education and enrichment. NFP is a mission, and the teachers are committed to enabling couples to use NFP without regard to the time it takes. In fact, when NFP is taught within the context of family life and marriage enrichment, the teachers may be motivated to keep couples in the program beyond the time necessary to develop mastery in the method. In this program context, teaching contacts can be numerous and instruction can extend over several months.

Most organizations that teach NFP are solely focused on the promotion and teaching of NFP. They are free-standing, single purpose groups, though some have connections to the health system.

The history of NFP's beginning has strongly influenced our perceptions of it. Our

challenge, however, is to extract NFP from its milieu and history and objectively examine the issues that will affect how NFP is offered by other providers. Four issues will influence how NFP is main-streamed. They are client needs, provider expectations and capabilities, service delivery strategies, and policy questions.

### *Client needs*

As noted earlier, a woman using NFP needs to be able to correctly identify her fertile and infertile days and adjust her behavior to her fertility intentions. The couple needs to be comfortable with and able to handle the required abstinence. NFP requires the woman to be aware of her body and the changes associated with the fertile time, and it requires the couple to communicate about and modify the timing of their sexual relations.

The three biggest barriers to client acceptance of NFP are

- 1 The amount of abstinence required,
- 2 The effectiveness of NFP compared to other methods, and
- 3 Difficulties clients may experience in learning the method, including the time involved.

The first two barriers are closely tied to the nature of the method, and have been discussed in previous papers addressing approaches for simplifying NFP.

There are four things that providers could do to make NFP easier to learn. The first is to incorporate fertility awareness education and counseling into their family planning programs and offer it to all their clients. Fertility awareness (FA) is the knowledge and skills that underlie natural methods. It includes basic information about fertility, and skills in self-observation and communication.

The needs of NFP clients to understand their fertility and communicate with their partners, is a need that all family planning clients have. This is borne out by numerous studies which have shown that a large percentage of women are poorly informed about their fertility, particularly about when during the month they are fertile [1]. If all FP clients were more knowledgeable about their fertility, NFP instruction could build on this knowledge and reduce the teaching time for NFP. This would benefit NFP, as well as enhance the quality of family planning education and counseling. Furthermore, if women understood their bodies and how methods act on their reproductive systems, it is likely that they would be more tolerant of the side-effects associated with some methods and less likely to discontinue because of them.

Teaching NFP in groups rather than individually is another way to decrease learning time. The efficiencies gained through group teaching were demonstrated by an IRH-supported study in Mauritius which showed that group instruction required one-third less time than individual instruction [2]. Experiences in other settings such

as the United Kingdom and the United States show similar results [3] Group teaching also provides better support to couples and has proved to be more interesting for teachers. Where it has been tried, it has been well received and shown to be a more efficient use of both teacher and client time than individual instruction.

In addition to simplifying NFP methods, NFP instruction in STM, OM and BBT could be streamlined. One way could be to make the instruction competency-based. In the definition of an autonomous NFP user developed by the Institute, the skills and conditions necessary for the method to be effectively practiced are stated. These include: able to chart correctly, correctly identify fertile and infertile days, follow the rules for abstinence, and does not require additional follow-up [4]. The definition provides the conditions for developing teaching and learning materials that can guide the client through the learning process. A competency-based approach would focus on the client's progress and skills in learning the method rather than on a fixed number of teaching sessions. Self-instructional and audiovisual materials that enable clients to learn the method at their own pace may be particularly suitable for both tailoring the instruction to client differences and reducing teaching time.

In addition, devices and home test kits which enable women to detect ovulation will make the practice of NFP easier and more reliable. When these devices are available at affordable prices, women will hopefully be able to use them with only the instructions inserted into the kit, and will be able to completely by-pass formal NFP instruction.

#### *Provider capabilities*

As discussed earlier, an NFP provider needs to be able to help clients identify their fertile cycle, and apply the rules of abstinence. NFP NGO providers are NFP users, this has led to the view that one must be an NFP user to become an NFP teacher.

The experience of using the method can certainly be a benefit, but competence and experience in NFP needs to be separated from the interest and ability to teach it. The two have been joined because NFP has received little support outside of the NFP network. As a result, those motivated to teach NFP in multi-method settings were usually self-selected. They were willing to teach it, and even subject themselves to the disdain of their colleagues, because they believed in the method. They believed in the method most probably because they were using it themselves.

Where the system promotes NFP as one method among many that a woman can choose, and where it respects and supports the provider, including making it possible for the provider to adequately devote her time to teaching it, it will become unnecessary for NFP use to be a condition for teaching it. Many experiences show that providers, irrespective of whether they are users, can be trained to the required level of competence to teach NFP. We do not yet have enough experience, however, to know how and whether provider attitudes can be changed to ensure that providers will give their best to teaching this method.

*Delivery strategies and options*

For trained providers to maintain their competence in NFP, they must remain active teachers and teach a minimum number of clients each month (at least 5). This necessity presents four options for organizing NFP services in multi-method settings.

In the first option the multi-method program arranges with outside NFP providers to teach NFP to their clients. This is done by referring clients to NFP NGOs or by providing space and inviting outside NFP teachers to teach in their facilities.

This approach requires a well-defined referral arrangement and an NFP organization, with available teaching capacity, that is willing to collaborate. It requires little change in the provider system and thus may be a highly feasible way to offer NFP. This approach in fact is the predominant way NFP clients in the public sector have been served.

A second approach is for the multi-method provider to use its staff, which has been trained to teach NFP and concentrate NFP services in designated sites. This creates capability in a few areas and also ensures that NFP teachers on the site will have an adequate client load to maintain their skills. It may mean, however, that NFP will not be easily accessible to all who wish to learn it.

A third approach is to designate one or two providers as NFP teachers in each site or area and adjust their work load accordingly. This approach can work where the demand for NFP is sufficient to keep the designated teachers active enough to stay skilled in their practice, and where supervisors and other staff honor this arrangement when they make work assignments. A fourth approach is to team providers in multi-method programs with teachers from an NFP NGO and jointly share responsibility for providing NFP. In the Philippines where this approach is being tried in a partnership arrangement between the Ministry of Health and the Philippine Federation of Natural Family Planning (PFNFP), government nurses and midwives do outreach, ascertain the initial client orientation, teach one couple session, and certify that the client has met the conditions of autonomy. The NFP teachers do most client instruction. This approach requires a good working relationship between government staff who are professionals and NFP staff who are volunteers – a relationship of mutual respect and trust.

In a 3-month pilot study in the Philippines of different models for main-streaming NFP, we observed that the teaming arrangements varied quite widely in terms of the number of NFP clients taught and the number of clients brought to autonomy. The models ranked highest on these two indicators consisted of a nurse/midwife who was either an NFP user or a fertility observer (a single/not sexually active woman charting her signs) teamed with a volunteer from PFNFP, the NFP NGO. These models were quite similar in performance to each other and somewhat more productive than the model that was teamed with a nurse/midwife non-NFP user with NFP/NGO volunteers.

Unfortunately, there are very few empirical data on these different options and not enough experience to assess their feasibility and effectiveness. The selection of an approach, however, will be influenced by the extent of the demand for NFP, the availability of providers trained in NFP and the existence of an NFP NGO willing to collaborate in training and service provision.

### *Policy questions*

There are also important policy issues that multi-method providers will need to address as they incorporate NFP into their choice of methods. The first is how NFP will be promoted and offered within the provider's system, as well as whether it will be a method available to all in all sites, only on request in a few sites, or only through referral, and whether its advantages and disadvantages will be presented without bias, or whether clients will get the message about NFP from providers' comments and non-verbal reactions. For NFP to be presented on an equal footing with other methods will require a major reorientation of providers, and clear commitment from the top of an organization for greater emphasis on truly respecting a woman's right to choose.

The second policy issue relates to whether all natural methods will be offered, including calendar rhythm. Among NFP providers, the calendar method has fallen into disrepute and many do not teach it, preferring to offer OM, STM, BBT, the more scientific methods of NFP. At the same time, the Demographic and Health Surveys have shown that rhythm users predominate among users of natural methods. To ignore calendar rhythm is to ignore the natural method that is in greatest use and perhaps demand. To teach it, however, is to risk promulgating a less effective natural method.

A third issue is whether NFP will be taught only as an abstinence method (as it is taught by NFP providers) or whether clients will be told of the option to use barrier methods during the fertile period. This is a policy question that needs to be carefully weighed.

If multi-method providers are to treat NFP as just another method, rather than as part of a way of life, it is incumbent on them to inform women of all of their options and risks, though there may be political and program costs in doing so. These costs will vary by setting, and the costs and benefits will need to be weighed by decision makers in government and NGO sectors assessing the approach that should be taken to main-streaming NFP.

### **Conclusions**

The main-streaming of NFP will require us to seriously examine NFP methods and service delivery requirements and implications for multi-method providers. We will need to consider the essential elements of NFP apart from its history as well as the requirements for NFP services which evolved along with its history. At the same time we will need to assess the strengths, constraints and possibilities for main-streaming offered by multi-method providers. From these analyses we will find the areas of mutual interest as well as feasible approaches for both NFP NGOs and their multi-method partners in this endeavor. Hopefully, this paper provides encouragement and guidance for this exploration.

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# **Main-streaming NFP into the Department of Health of the Philippines: opportunities and challenges**

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## **Abstract**

In 1994, the Department of Health (DOH) of the Philippines issued a circular which reaffirmed natural family planning (NFP) as one of the basic services to be offered in all government family planning service sites and urged family planning workers to develop competence in teaching NFP methods. Although the circular represented a major policy breakthrough for the main-streaming of NFP it found the department without the capability or experience to directly provide NFP services. The two approaches the department is taking to respond to this new policy initiative are described in this paper. The selection of these approaches was influenced by the devolution of central government authority to local government units. The approaches include developing department capability in NFP training, service provision and service installation and creating a supportive program and policy environment. DOH partnership with an NFP non-government organization (NGO) has been critical in developing NFP capability within the government sector, particularly in NFP training and service installation.

## **Introduction**

The promotion of the scientific methods of modern natural family planning (NFP) as part of the method mix of the Philippine Family Planning Program (PFPP) is quite recent. In 1989 scientific methods of NFP (basal body temperature, cervical mucus/ovulation and sympto-thermal) were officially added to the method mix of the PFPP, which also offered calendar rhythm and artificial methods. From 1989 to 1994, modern methods of NFP were offered alongside calendar/rhythm and other family planning methods. In 1994, the Department of Health (DOH) issued a circular removing calendar rhythm as a program method, and reaffirming NFP as one of the basic services to be offered in all family planning service sites. The circular also urged

family planning workers to develop competence in teaching NFP methods as soon as possible

Although the circular represented a major policy breakthrough for the mainstreaming of NFP it found the Department without the capability or experience to provide NFP services. This paper describes the approaches the DOH is undertaking to assure that NFP services are available nationwide. It also discusses the challenges the Department faces in meeting this objective.

The DOH is pursuing two primary approaches. One is developing Departmental capability in NFP training, service provision and installation, and the second is creating a supportive program and policy environment.

### **Background**

Devolution of authority from the central government to local government units (LGUs), which was implemented in the Philippines in 1992, has influenced the Department's strategies. Under devolution DOH authority extends only as far as the regions, and the Department can no longer mandate programs or supervise their implementation. The 142 existing LGUs function as autonomous entities, with the authority to determine local priorities and services. Training of service providers is now a local government responsibility along with determining whether providing NFP services is a high priority. Where local demand for NFP exists, however, the Department is expected to assist in the transfer of technology, or at a minimum in setting the training and service standards. To date, 49 LGUs with 1403 providers have requested assistance in NFP training.

### **The strategies**

Five strategies are being explored to build NFP service capability at all levels of the DOH. Because we have learned from experience that training is usually not sufficient to ensure service provision, the installation of a service support system is also being addressed.

The strategies for building DOH capability include training, follow-up coaching and mentoring, and establishing a collaborative relationship with the Philippine Federation of Natural Family Planning (PFNFP), an NFP NGO, for technology transfer and capability building. The strategies for service installation include developing and testing service delivery models that respond to the mix of resources locally available.

### **Developing institutional capability for service provision and installation**

The Department has teamed with the PFNFP, an NFP NGO, to develop an integrated NFP training system. A meeting on public-private partnership held by

the Institute for Reproductive Health in December 1993 helped solidify this relationship. Collaborative activities between the DOH and PFNFP have included the stationing of PFNFP teacher volunteers at government health facilities and more recently a pilot NFP training effort involving 15 LGUs.

The training and service installation system being developed for NFP links skills training with on-the-job mentoring and coaching to ensure that training leads to service provision. It also involves partnering between government health workers and NGO teacher volunteers.

As part of the training system, providers are required to complete self-instructional materials covering knowledge about NFP before the training begins. This makes it possible for the training to focus on competency based skill development. In NFP these skills include charting, correctly interpreting the signs and symptoms of fertility, applying the rules, coaching and counseling clients, and the conduct of husbands and couples sessions. On-the-job mentoring will be provided by experienced NFP teacher supervisors from the PFNFP network. It includes observing and coaching the provider and supporting the use of newly acquired skills to teach clients. Mentoring is an integral part of PFNFP's training protocol for service providers. The process takes three months from the end of training, which corresponds to the minimum number of cycles it takes to lead a couple-user to autonomous NFP use.

The pilot training of LGU service providers conducted jointly by DOH and PFNFP established the need for a mentoring period after training. When mentoring was not provided, LGU providers were unable to offer NFP instruction that enabled clients to become autonomous users. Mentoring was then instituted, and the providers were able to use their skills to teach clients, and a number of clients were able to become autonomous users.

Five staffing models for providing NFP services evolved during the pilot. These models resulted from the resources locally available to support NFP service installation, whether, for example, the LGU service provider was an NFP user, or whether there were NFP users who could team with LGU staff. The models included

Model 1 In which the nurse or midwife is an autonomous user (AU) backed up by trained community volunteers (AU)

Model 2 Nurse or midwife is a fertility observer (FO), backed up by AU volunteers

Model 3 Nurse or midwife (AU) provides all NFP services

Model 4 Service provider nurse or midwife (non-AU) is backed up by community volunteers

Model 5 Service provider is an autonomous user

As can be observed from Table 1 the models that produced the largest number of autonomous users per trainee had providers who were either NFP users or fertility observers (models 1 and 2). Those models, however, placed severe limitations on the

**Table 1 Comparison of service delivery models**

	<i>1</i> <i>AU</i> <i>with</i> <i>volunteers</i>	<i>2</i> <i>FO</i> <i>with</i> <i>volunteers</i>	<i>3</i> <i>AU</i>	<i>4</i> <i>Non-AU</i> <i>with</i> <i>volunteers</i>	<i>5</i> <i>Non-</i> <i>AU</i>
No trained	23	11	30	45	271
Estimated number of learning clients*	77	30	83	56	24
Estimated number of autonomous users*	23	10	23	13	0
Estimated percentage of clients who become autonomous (%)	29	33	27	23	0
Autonomous users per trainee	1	0.9	0.76	0.2	0

\*Data on number of clients and number of autonomous clients provided as estimates

possibilities for expanding NFP services Model 4, which teamed an LGU service provider (non-NFP users) with an AU volunteer, the most feasible model for expansion, was also one of the least productive models in the pilot

Recognizing the need to develop productive service teams has led to support of an operations research study to test approaches for strengthening and increasing the productivity of the "model 4" teaming model The study will involve a partnership between the DOH, local government units, and the PFNFP We hope it will also engage family planning NGOs, non-health government organizations and NGOs, hospitals and local church groups as we test various alternatives for expanding the NFP service delivery network

### **Creating a supportive policy and program environment**

In addition to training service providers, the commitment of Department personnel to the main-streaming of NFP needs to be strengthened The personnel need to gain an understanding of the method and develop an appreciation of the method's benefits and attraction for those who choose to practice it This is best achieved through a "soft sell", by introducing Departmental staff to fertility awareness and the knowledge about fertility that underlies NFP and can empower all women regardless of the method they use

As the department staff gain capability and NFP services become more widely available the Department will need to review and refine its implementation guidelines and clinical standards to ensure clear guidance and support for service providers

To address the need for accurate information on NFP services and clients, NFP has been included in the Department's Family Planning Information System and data on NFP users are being collected. In the redesign of the Department's family planning training system, fertility awareness and NFP will be part of the required knowledge for all entrance level trainees.

Another area requiring attention is the maximization of donor inputs into NFP. Major donors supporting NFP include USAID (The United States Agency for International Development), AusAid (Australian Aid) and UNFPA (The United Nations Fund for Population Activities). UNFPA supports the work of PFNFP and the expansion of the NGO NFP network enabling PFNFP to serve as a technical resource to the Department. AusAid has supported the development of IEC for clients and providers, and USAID supports family planning training and the expansion of NFP services. Donor contributions have been essential in ensuring the availability of NFP services and in supporting NFP capacity building. Because resources are limited and we have a big job to do, we must make sure that donor resources are well orchestrated and used where they will have the greatest benefit.

In areas where there is a demand for NFP and donor resources are not available, DOH support is provided on a matching basis with local support, in cash or in kind.

Working towards an efficient and coordinated use of the resources available for NFP, the DOH is in the early stages of establishing an NFP coordinating committee to bring together the major groups involved in training, research, materials development and NFP service provision. Committee members will share information, coordinate and develop joint activities, and contribute their know-how to help refine the technologies for NFP service delivery and expansion.

### **Summary and conclusions**

Our progress to date is a result of two important factors. One is a national environment that is conducive to government support for NFP. The Philippines is among the countries of the world with the highest reported acceptance of natural family planning methods. As shown by recent demographic surveys, natural methods are used by slightly more than 18% of married reproductive age women [1]. Simply stated, the demand for NFP exists and the government has responded accordingly.

The second is the international support for NFP that enabled us to develop in-country capability. Donor support helped us develop a training system and service protocol which includes NFP. It also helped strengthen PFNFP which is developing a national network of locally based NFP organizations. Although, at the present time most of the NFP capability resides in NGOs, the existence of that capability has enabled the DOH to develop public-private partnerships at the national level and encourage partnership arrangements at the local level. Most importantly, the existence of the capability has allowed us to move forward in promoting the expansion of NFP services.

Some challenges remain. The primary one is to substantially expand the NFP capability within the DOH and within local governments to encompass policy

formation, standards development, training, and technical and service delivery know-how

A second challenge is to obtain a more precise picture of the client demand for NFP, its location and its size. Knowing this will help us to set priorities for training and service installation. It will also give us the data for developing a phased-plan for expanding service capacity and addressing the demand.

The third challenge is to maximize our resources through partnership arrangements between government and NGOs, between national and local governments, and perhaps even among donors [2]. We must also address the sustainability of programs and services, so that the systems we set in place are adequately supported and sustained.

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## **Comparing a public and private sector NFP program: implications for NFP expansion**

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### **Abstract**

This paper synthesizes a six year collaboration between a natural family planning (NFP) non-governmental organization (NGO) and the National Health Service of the Emilia Romagna region in Italy. It also compares the public program experience with NFP services provided in the private sector in the adjacent region of Veneto. Midwives provided NFP services in government family health clinics while in the private sector NFP was taught by non-health laypersons in a church-based facility. The populations served by these two programs were different. Women in the public sector were slightly older and two-thirds were married. Forty percent of the clients had chosen to use NFP to achieve a pregnancy. The private sector client, recruited in part through pre-marriage counseling programs, was equally divided between married and single women, though the majority came for advice on avoiding or spacing pregnancies. In both regions NFP users were more highly educated than the general population.

### **Introduction**

In the social, cultural and scientific environment of the 1990s there are new requirements for family planning providers which they must consider when providing services. First, they must recognize the problems of human fertility and its biological, medical, demographic, sociological, psychological, cultural and ethical implications. They cannot ignore the sexual dimension of the couple's relationship, and the reality that the choice of family planning method has behavioral implications. The advice they provide must be personalized and tailored to the particular requirements of their clients. This is not only a woman's right but it guarantees greater effectiveness in

fertility control and in preventing abortion. It is therefore necessary for the provider in the public sector to acquire the necessary knowledge to provide full information and support to couples who want to use natural methods.

### **The NFP services**

The two NFP services which are compared in this paper were carried out in the Emilia Romagna and the adjacent Veneto, regions of Italy. The public sector collaboration was conducted in Emilia Romagna, while private sector services were conducted in the Veneto region, two areas with similarities and differences.

The Emilia Romagna region is one of the most advanced in Italy. Its standard of living is among the highest, and it has a well-developed social and health services network that exists in few other regions of Italy [1].

A 1989 survey of contraceptive use in the Emilia Romagna region showed that 16.3% of the couples in the region used periodic abstinence (14.3% Ogino-Knaus method). Coitus interruptus, however, was the most widely used method, used by 44% of the couples. Condoms and the IUD were each used by 20% of the population, while pills were used by 18% [2]. In a 1979 national survey of contraceptive use, 7% (6.8% Ogino-Knaus) were using periodic abstinence, and 48% used coitus interruptus, 10% pill, 10% condom and 18% did not use any method. Thus the profile of contraceptive use in the Emilia Romagna region showed a use of periodic abstinence more than twice that of the country as a whole [3].

### **Timing and services**

Providers in both sectors received essentially the same training. It consisted of 50–70 h of instruction followed by a practical session in which trainees taught other couples. Trainees also did self-observations of fertility signs and symptoms as part of their training and demonstrated their ability to distinguish the fertile and infertile periods. The courses in both the public and private sectors are of two years' duration to permit good self-observation in the first year and good practical training thereafter. Attendance at classes was regular, and trainees needed to pass both a written and oral examination to be certified as NFP teachers. They also needed to demonstrate competency in the method, in instruction and in organizing and managing an NFP service.

In the public sector, the trainees were midwives who were selected because of the important role they play in family planning services. No other selection criteria such as knowledge, use of NFP or their ethical/religious beliefs were used. Thirty-six midwives started the course and thirty-one completed. In the private sector the trainees were for the most part non-health professionals.

Services in the public sector were provided in public health facilities during 2–3 h sessions per week totally dedicated to NFP (referred to as NFP space). These centers were under the regional health authority while private sector services were provided in a diocesan-based facility. The services provided, however, were the same.

The public sector services were promoted through conferences and media publicity, while the private sector services were promoted through programs for engaged and married women and couples

### **Data collection**

The data reported in this study were collected in the public sector by 27 midwives between 1993 and 1996. In the private sector systematic data collection using WHO forms, as in public sector, began in 1988, and data were collected through 1996 by about 50 teachers [4]. Data are based on a registration form completed by NFP teachers at the time of registration, follow-up forms which recorded each cycle and a discontinuation form.

### **Results**

Table 1 compares NFP users in the public and private programs. From the table we can observe some salient similarities and differences between the two user groups.

The public sector users were on average slightly older than the private sector clients. Two-thirds were married and almost two-thirds had no children. Slightly more than 80% were either currently using contraceptives or had in the past, and 20% had used NFP sometime in the past. Ten percent had had an abortion. Forty percent were using NFP to achieve a pregnancy. Sixty percent cited medical and ecological reasons for using NFP.

The private sector clients were more equally divided between married and single women, 80% had no children, and two-thirds were interested in using NFP to avoid pregnancy. For almost half, their primary reasons for using NFP was ethical/religious. Less than 1% had experienced an abortion. A third were current or previous users of contraception and 19% had used NFP, a proportion that was similar to public sector clients.

The data recorded from the public sector midwives also reported on client discontinuation. Twenty-six percent discontinued, almost one-third of whom were lost to follow-up. Other reasons included planned pregnancy (16%), method too complicated (12%), health problems (9%), and change to other method (9%). Table 2 provides data on discontinuation.

### **Discussion and conclusions**

Most of the experience of NFP service delivery has been gained in the private sector, as only a few public programs have offered NFP, as was discussed at an Institute Conference on Public-Private Partnerships in NFP [5].

The first observation we can make is that it is feasible to provide NFP services in the government sector. In the Emilia Romagna experience, 889 women were seen by

**Table 1 Comparisons between public/private NFP users**

	<i>Public (%)</i> <i>n = 889</i>	<i>Private (%)</i> <i>n = 998</i>
Mean age (years)	29.38 ± 5.95	26.73 ± 4.73
Civil status		
Married	66.4	46.2
Single	30.2	53.5
Educational level		
University	15.2	9.7
S L certificate	59.8	65.1
Middle	21.2	23.7
Primary	3.7	1.5
None	0.1	0
Job		
Clerk	30.6	33.3
Housewife	13.7	10.3
Student	12.7	7.5
Worker	11.2	14.3
Teacher	9.5	14.1
Nurse	5.8	10.3
Children		
0	65.7	79.8
1	21.4	8.9
2	8.9	8.0
Induced abortion	10	0.5
NFP in the past	20.1	18.9
Contraception past/present	82.7	34.9
Reasons for NFP choice		
Medical	42.7	4.5
Ecological	20.8	4.0
Ethical/religious	16.4	45.8
Psycho-sexual	7.4	6.9
Multiple answers	12.7	38.7
NFP in order to		
Achieve pregnancy	40.7	10.9
Avoid pregnancy	35.1	12.9
Space pregnancy	20.3	66.7
Increase fertility awareness	3.8	9.5

**Table 2 Public users drop-out rates (%)**

Number		
225 (26% of total)	1993	9 8
	1994	35 0
	1995	36 0
	1996	19 2
Reasons		
Lost to follow-up		36 9
Moved away		4 2
Menopause		1 0
Diseases interfering with observation		1 4
Health problems		9 3
Privacy		1 4
Family problem		1 4
Too complicated method		12 1
Too much abstinence		0 5
Other methods		8 9
No longer useful		3 3
Unplanned pregnancy		0 5
Planned pregnancy		16 8
Autonomy		2 3

27 midwives over a four-year period, providing an average of eight to nine new users per midwife per year. Productivity of the midwives, however, varied widely from one user per midwife to as many as 120 users per midwife.

NFP users in the public sector had well defined characteristics. For example, a large percentage used NFP for medical/ecological reasons and a large number sought to achieve a pregnancy. Analyzing this further we found medical reasons were given mostly by women with less education (62% low education vs 36% medium/high education). Ecological motivation was found among the more highly educated group (22% medium/high compared to 16% low education). A similar pattern was found for ethical/religious motivations (18% medium/high as compared to 9% low education).

It could be that women with less education have more concerns about their health and seek NFP because it is free of side-effects. A higher percentage of women with less education also came to achieve a pregnancy (50% vs 37% among those whose education was medium-high).

In comparing NFP users in both the public and private sector to the general populations in the Emilia Romagna and Veneto regions we found that NFP users were more highly educated than the general populations. In Emilia Romagna (where the public program took place) 75% of the NFP users had either a university education or had completed secondary school. This compared to 37% in the general population. A similar pattern was found in Veneto region (Table 3).

We also found that the public and private sectors appeal to and serve different

**Table 3 Comparisons with general population (same age) (Census 1991) (%)**

	<i>Emilia Romagna region</i>		<i>Veneto region</i>	
	<i>General</i>	<i>NFP users (public)</i>	<i>General</i>	<i>NFP users (private)</i>
<b>Educational level</b>				
University	5 41	15 1	3 64	9 5
S L certificate	32 13	60 3	25 29	65 2
Middle	37 67	20 8	43 43	23 7
Primary	22 61	3 8	26 02	1 6
None	2 19	0 1	1 62	0 0
<b>Civil status</b>				
Single	38 4	29 7	38 41	53 3
Married	55 26	67 0	57 91	46 4
Divorced	5 18	3 3	2 45	0 1
Widow	1 17	0 0	1 23	0 2

groups The public user tends to be married (66%), seeking advice on how to achieve a pregnancy (40%) Among the private user group which was equally divided between married and single, the majority sought advice on avoiding or spacing pregnancy

The differences in the service settings, and the ways in which users learn about services, probably explain a large part of the client differences observed In the public sector, services are provided in a health clinic and clients learn about the services through education and promotion carried out by health workers The private sector promotes its services largely through pre-marriage courses and services are provided in a private facility that is part of a church complex In both settings, services are provided without cost

This comparison of the two programs indicates that different groups were reached by the services This finding underscores the need for expanded services in the government sector and for a partnership between the government and non-government organization sectors because most of the knowledge of how to provide NFP currently is found in private sector NFP groups

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## **Factors to address when periodic abstinence is offered by multi-method family planning programs**

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### **Abstract**

Multi-method family planning programs are committed to informed free choice of contraceptives. Thus they are expected to provide information and education, and facilitate access to services for those individuals and couples who want to practice periodic abstinence. Various factors affect the commitment and ability of multi-method family planning programs for providing periodic abstinence services. These factors include the effectiveness and cost of the method, attitude and technical competence of service providers, information and education strategies, and approaches for providing services. These factors are discussed in this paper. Information on providing periodic abstinence in a multi-method service situation is very scarce. The need for research, particularly operations research, for gathering information to guide program managers and service providers in the integration of periodic abstinence services is discussed.

### **Introduction**

It is estimated that approximately 32 million couples throughout the world practice periodic abstinence for family planning, the majority using the calendar rhythm method [1], often without proper teaching of the use of the method or any assistance from a service delivery facility. Services for couples who want to practice periodic abstinence have been traditionally available mainly from institutions that provide only natural family planning. However, couples vary in their family planning needs and preferences. Therefore it is important for family planning service providers to offer as many different methods of contraception as possible, including periodic abstinence. The International Medical Advisory Panel (IMAP) of the International Planned Parenthood Federation (IPPF) has stated that "Periodic abstinence may be

the choice for individuals and couples who cannot or do not want to use other methods of fertility regulation for a variety of reasons. Therefore it is important that family planning associations provide information on this method. They should assist clients who want to use this method either by teaching the technique or referring them to the appropriate service facility" [2]

Many individuals who want to use periodic abstinence may prefer receiving services in an environment in which informed free choice is the norm. These individuals would welcome and appreciate receiving services from a multi-method family planning program. The practice of periodic abstinence requires certain knowledge and understanding of the processes of sexuality and reproduction. This is called fertility awareness and involves biological and behavioral aspects. However the application of fertility awareness goes beyond the practice of periodic abstinence. For instance, it enables couples to understand when pregnancy is most likely to occur and when it is least likely to occur, and how other methods of contraception work. Fertility awareness also helps women to recognize changes that may indicate potential reproductive health problems, such as sexually transmitted diseases [3]. Therefore, education on fertility awareness should be part of all multi-method family planning programs.

The availability of periodic abstinence services in a multi-method family planning program opens the opportunity for clients to combine fertility awareness with the use of barrier methods during the fertile phase of the menstrual cycle [2], instead of practicing abstinence. It also facilitates services for clients who want to switch from periodic abstinence to another method and vice versa.

There are various factors that need to be addressed when periodic abstinence is offered by multi-method family planning programs. In this paper, effectiveness, cost, attitude of service providers, technical competence, information and education, services and operations research are discussed.

### **Effectiveness**

Efficacy depends on behavioral factors as well as the accuracy of the techniques used to assess the onset and end of the fertile period. Periodic abstinence can be a very effective method of contraception when couples are well trained in a technique for detecting the fertile period and when they are highly motivated and able to practice abstinence strictly according to the rules applying to the technique. However, a significant proportion of couples take chances and break the rules, exposing themselves to a very high risk of failure. The reported failure rates range from less than 2% to approximately 30% during the first 12 months of use.

One of the major concerns among policy makers and program managers of multi-method family planning programs is that the strict requirements of periodic abstinence would result in high failure rates. It should be taken into account that the population attending multi-method family planning clinics is more heterogeneous than the population attending specialized NFP centers. That heterogeneous population may be more exposed to factors that increase the risk of failure, such as

those related to the level of communication and understanding between the couple. There are very few data on effectiveness when periodic abstinence is provided by multi-method family planning programs. The Family Planning Association of the Philippines conducted a study between September 1988 and April 1990 to explore the feasibility of integrating periodic abstinence into its multi-method family planning program. With a good rate of follow-up for periodic abstinence acceptors of 94.2%, this study showed a Pearl pregnancy rate of 29.5% for this method. This study in the Philippines, still unpublished, highlights a number of problems encountered in the integration of periodic abstinence which resulted in a failure rate at the upper end of the range of those ever reported. However, more studies of this nature are needed to bring more light into this field and provide more guidance to program managers and service providers of multi-method family planning programs.

### **Cost**

Periodic abstinence services are very labor intensive. Each couple requires a great deal of time for the initial instructions and for follow-up during the early months of use, usually three months [4]. To ensure proper levels of skills in using the method and maintaining the motivation of the couple, it is often required that instructors visit couples in their home. Therefore, periodic abstinence can be more costly in terms of the service provider's time than for most methods of family planning. The cost can be reduced if clients are taught in groups. However, this can only be possible if there is sufficient demand for the method. Also, group teaching would sacrifice any possible advantage of providing personalized teaching, tailored to the needs and characteristics of each individual or couple.

Many family planning programs have adopted a system of cost recovery to contribute to the sustainability of the services. They charge clients receiving the necessary services and supply of contraceptives an amount of money appropriate to their financial capabilities. However, the implementation of a cost recovery system for the delivery of periodic abstinence services and its acceptability by the clients still waits to be properly tested and documented.

### **Attitude of service providers**

For the successful introduction of periodic abstinence in multi-method family planning programs, it is essential that service providers have a positive attitude toward this method as for any other method. Service providers should be able to put aside their personal preferences and prejudices and provide information, education, and counseling in an unbiased manner.

Service providers in many multi-method programs have a negative attitude towards periodic abstinence. The reasons for this attitude include

- Polarization of positions for and against the method. Thereby those who passionately promote the natural methods of contraception negate the legitimacy of other methods. And in turn those who promote family planning choices tend to ignore periodic abstinence.
- Perception that the method performs poorly in terms of effectiveness and use continuation.
- Perception that teaching the use of the method is excessively time consuming.
- The assumption that there is a lack of interest in the method among clients.

In order to improve the attitude of service providers, periodic abstinence should be introduced into family planning programs within the framework of quality of care. Being sensitized to the principles of quality of care, service providers should be reminded that clients have the right to information on the available options, free choice of methods, and access to services [5]. The providers must recognize that periodic abstinence may suit the characteristics and needs of some clients and so they should be prepared to service those clients with understanding and respect.

### **Technical competence**

The level of technical competence required depends on whether the service provider only provides information and general education on periodic abstinence to the clients or provides teaching of the use of the method as well.

All family planning service providers who include information and education in their normal activities should be able to discuss fertility awareness and periodic abstinence. Fertility awareness should be part of the curricula for basic training of providers of sexual and reproductive health and family planning services. Knowledge of fertility awareness and of the physiology of sexuality and reproduction provide the basis for learning not only about periodic abstinence but all methods of contraception and sexual and reproductive health. Through proper training and motivation, service providers should develop the confidence and competence to talk about sexuality and be good communicators, motivators and educators. For these kind of service provider, learning to become competent teachers of the periodic abstinence method should not be a major problem.

In addition to training, service providers also need access to updated information and practical service guidelines. Family planning programs should include the subject of periodic abstinence among the technical and programmatic information and service guidelines which are made available to service providers. For instance, a chapter on periodic abstinence is included in the IPPF Medical and Service Delivery Guidelines [6] which has been adopted or adapted by many family planning programs worldwide.

### **Information and education**

The least that can be done by a family planning program that promotes free choice is to include periodic abstinence in its information and education activities. Knowledge about a method is requisite to its acceptance and use.

The majority of people visiting family planning service outlets to initiate the use of a method of contraception already know what they want to use. A study conducted in 6 countries by the IPPF in the 1980s [7] showed that the proportion of clients who already had a method in mind when they visited the family planning clinic was greater than 87% in 5 of the 6 countries. This means that in order to enable people to make an informed choice among methods of contraception that includes periodic abstinence, information about the methods should be disseminated in the community. People also need to know where to obtain services for the method of their choice. Even if periodic abstinence services are available in a multi-method family planning clinic, people will assume that it is not, unless they are informed about it. Information about periodic abstinence should also be included in education activities within the service delivery sites. This will enable clients who have not yet decided on their method of contraception to consider periodic abstinence as one of the options. Clients who have learned about periodic abstinence will also contribute to the dissemination of information about the method.

### **Services**

Services for periodic abstinence basically refer to providing counseling to individuals and couples who are considering the use of the method, teaching the use of the method to those who have decided to use it, and providing users of the method with any assistance and support they may require. Relatively few people receive periodic abstinence services from multi-method family planning programs and published data on this type of experience are scarce. Among the IPPF affiliates in developing countries only three in Latin America (Mexico, Peru and Brazil) and three in East Asia (North Korea, Malaysia and Philippines) reported in 1995 3% or more of new users of a method of contraception using periodic abstinence, with the Family Planning Association of North Korea reporting the highest proportion (12%). A number of family planning associations report referral of clients to specialized NFP service providers.

Four main approaches have been described for helping clients who request periodic abstinence services from multi-method family planning programs [4 8 9]

- Training staff members in the delivery of periodic abstinence services
- Using specialized NFP instructors. These can be hired to work part-time or full-time depending on demand, to teach the method in family planning service delivery sites and/or to visit clients in their homes

- Referring clients to NFP teaching centers
- A combination of approaches For instance, the clients may receive education and counseling in a family planning clinic before being referred to an NFP teaching center, or trained staff of the program may divide tasks with a hired NFP instructor

The choice of approach depends on a number of factors including the potential demand for the service, the availability of adequate staff to be trained for providing the service, the availability of building facilities which would provide adequate space for teaching the method, the existence of nearby NFP teaching centers and the possibility of developing cooperation with the NFP teaching center

In most cases it is difficult to assess the potential demand and it is not possible to forecast the impact of providing periodic abstinence on other services provided by the program The most practical way to introduce periodic abstinence services is to do it on a pilot basis, testing more than one feasible approach After learning from an initial experience the program managers would be in a better position to introduce the method gradually on a larger scale

### **Operations research**

Operations research (OR) has been defined by Blumenfield as "the application of analytical methods designed to help the decision-makers choose between various courses of action available to accomplish specified objectives" [10]

As for other aspects of family planning, operations research has an important role in the integration of periodic abstinence into multi-method family planning programs OR would shed light on a number of questions such as potential demand, effectiveness and use continuation, cost, cost recovery, information and education strategies and approaches for service delivery

### **Conclusion**

There are various concerns and obstacles for integrating periodic abstinence into multi-method family planning programs The most important concern is probably the perception that the method performs poorly in terms of cost effectiveness However, it is widely recognized that this method of contraception can be very effective for individuals and couples who are able to learn the techniques for fertility awareness and have the motivation to practice abstinence accordingly There is very little information which can help program managers and service providers in the integration of periodic abstinence More research is needed in this regard to answer many of the still outstanding questions and operations research will undoubtedly show the way for meeting the needs of those clients in multi-method family planning programs who would like to use periodic abstinence as their method of contra-

ception In this way family planning program managers and service providers will cover the particular aspects of quality of care which refer to clients' rights to information, free choice and access to services

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# **Approaches for incorporating ovulation detection devices and home kits into learning NFP – implications for service delivery**

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## **Abstract**

This paper presents demographic data about use of NFP in Europe and the factors which have been identified as influencing that very low use level. Experience with a new ovulation detection device in clinical trials and observations of its over-the-counter promotions is discussed in the context of what is already known about how to maximize uptake of contraception in main-stream service provision.

Some suggestions are offered as to appropriate means of encouraging women who are using artificial methods or no method to understand enough about their natural fertile cycle to consider NFP as an acceptable option.

## **Demography**

Within the continent of Europe, use of NFP (rhythm method) was reported by Riphagen and Lehert [1] in 1984 to range from a low of 1% in the United Kingdom to 16% in Spain. This low use in the UK was confirmed by the General Household Survey census data 1993 [2] and of the 1% who reported that they used the safe period even fewer were properly trained NFP users. Riphagen identified that traditional NFP methods are perceived by his population sample as unreliable relative to the pill, IUD and condom. This consisted of 7696 women aged 15–44 years attending hospitals and clinics (France and Italy), general practices (UK and Germany), or sampled by home address (Spain).

Accurate fertility awareness techniques have previously required

- 1 genital touching
- 2 a relatively long learning phase under 'expert' guidance

3 adherence to a routine of assessment

4 periodic abstinence – or else the additional risk of failure of barrier methods

A survey by Oddens et al [3] of the effect of contraceptive prices on demand in eight western European countries found no correlation between the wide differences in choice of contraceptive methods between the countries surveyed and the actual cost to users. In general Oddens et al found that reliability, non-disturbance of sex life and ease of use were the main motives for choosing the contraceptive methods in current use.

The Persona system for identification of the fertile phase avoids the need for genital touching and the need to approach 'experts' for guidance. There is commercial profit in this particular fertility awareness method and therefore considerable effort has gone into attractive, direct-to-the-consumer advertisement.

General approaches which improve acceptance of any method [4] have been incorporated into the promotion of Persona.

- a To maximize access to good quality services. The system in the UK was made available through a well-respected and very popular pharmacy chain – Boots The Chemist – with high profile advertisement. Sales staff were involved in a pre-launch training program.
- b To provide good communication, Unipath included a helpline telephone number with each starter pack for Persona. This helpline has been very well utilized by purchasers.

The popularity of home pregnancy tests and other diagnostic kits confirms a widespread desire by many people to keep these aspects of personal life private, even where medical advice might be appropriate.

The use of ovulation detection systems still requires periodic abstinence, or else the additional risk of failure rate of barrier methods. Oddens et al [3] found that 72% of the UK population surveyed thought they would be unable to avoid intercourse on unsafe days if they chose the rhythm method. It may be that ovulation detection devices will have a future role as part of school sex education/self-awareness/assertiveness lessons. There is growing evidence [5,6] that properly integrated sex education programs do alert children to the need to control sexual desires and fertility and do not result in an earlier onset of coitus.

Ovulation detection devices still require adherence to a routine of assessment. For the Persona, the user needs to have it by her when she wakes in the morning in order to check whether the early morning urine specimen should be tested that day.

The Persona system is not suitable for women with irregular menstrual cycles or nearing the menopause, many of whom are unhappy about the artificial hormone milieu of the combined pill and would prefer a natural method if simplified.

### **Our experience**

The Community Family Planning clinic (Manchester, UK) provides services to a population of over 500 000 people. Women and men can attend on a walk-in basis. Provision of all established methods is free under the National Health Service and the clinic operates with a no-appointment system. In 1995/96 over 25 000 women and 1000 men came for contraceptive advice and supplies, of whom 58% chose the combined pill, 24% the condom, 3.5% the IUD, 5.9% Depo Provera and only 6 were actually recorded as using the rhythm method. However, in addition 12% of all patients attending for contraception did not have any contraceptive method recorded for that visit. This category would include those who were given information about NFP. Men are also welcomed when they attend with partners who request the pill, injectable, etc., but there is a need within 'main-stream' services for a wider range of methods which could involve both partners.

The Catholic Marriage Guidance Council has trained, traditional NFP teachers and most Catholics who wish to use NFP go to them rather than to a service for contraception. Persons who inquire in a general way about NFP as a method are informed that the clinic can provide free thermometers and temperature charts but will refer the client to trained NFP teachers to learn that method. Open access clinics allow an average of 10 min time per patient with the nurse and 15 min with the doctor. There is no cost for referral to volunteers for prolonged training sessions. Internal referral would not maintain the ongoing experience in teaching that is desirable. Prolonged training requirement is therefore a major deterrent to integration of traditional NFP. The requirement for a relatively long training period (e.g. compared to the 3 or 4 days required for vaginal cap or diaphragm) and for genital touching for the more accurate traditional assessment and for periodic abstinence also results in the vast majority of inquirers choosing a more immediately available contraceptive method.

An enthusiastic response to the traditional sympto-thermal method has been shown by those who have had experience of high technology, subfertility investigations. They already know about their fertile mucus and ovulatory cycle and these women are confident enough to work with their bodies to avoid the identified fertile time and are not too bothered about high efficacy.

Experience with Persona has been in comparative trials where a national advertising was directed to couples in stable relationships using condoms but willing to try a new method. This brought in large numbers of volunteers mainly using condoms who had never used natural family planning and who remained enthusiastic about Persona throughout the study. The study protocol was designed to collect data appropriate to over-the-counter sales of Persona, and no teaching on use of the system was permitted, only the information leaflet provided with the pack. Very few problems were seen with the use of the system but volunteers still found it difficult to abstain during the fertile phase. NFP teachers have proven to be good at talking to clients about sex and how to negotiate sexual activity or abstinence. This facility would be of great value to main-stream providers particularly linked with a general approach to 'sexual health'.

In general, attitudes change before behavior. The modern image, ease of use and commercial promotion of these new ovulation detection devices will have a spin off in changing attitudes towards fertility awareness as a method of birth control. Social marketing projects in developing countries and the lack of correlation between cost and popularity of methods in European countries suggest that some financial commitment may perhaps encourage compliance.

In one large family planning clinic in the UK a supply of Persona systems has been purchased, to issue free, in order to maintain the clinic policy of having all established methods available within the NHS. However, there is the problem of cost-effectiveness when public funding is used. An attempt has been made to sort out the poorly motivated individuals by placing an extra hurdle of a specific visit, by appointment, for counseling and medical appraisal, if the patient wishes to try Persona. Patients will still have the monthly outlay on test sticks which will be more expensive than purchase of condoms and must be seen in the context of completely free provision of other contraceptive methods.

Studies of other models of service provision must be undertaken for the population subgroups available in main stream community services, to assess both demand and continuation rates of NFP use when assisted by this ovulation detection system, and also to assess the use of Persona as an aid to teaching fertility awareness to younger girls.

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## **VII. Benefits of natural family planning and fertility awareness education**

**What are the benefits of providing NFP and fertility awareness education? What are the service delivery systems, provider, and user barriers that limit access to and use of NFP? What are barriers that impede the availability of fertility awareness information? How can these barriers be overcome?**

*Chair* Victoria Jennings Ph D Georgetown University

*Discussant* Nancy Williamson, Ph D , Family Health International, Research Triangle Park, North Carolina

*Consensus* NFP and fertility awareness education have many benefits. They need to be offered optimally by multimethod family planning services with the same level of counseling and support as other information and methods. Most non-governmental organizations (NGOs) that provide NFP meet only a small portion of the potential demand for services. Similarly, few private providers, including physicians and other health professionals, offer fertility awareness education and services in NFP. The reasons for this lack of services include (1) lack of accurate information by clients and providers about NFP and fertility awareness, (2) provider preference for medical methods instead of behavioral methods, (3) the perceived complexity of NFP methods and the time required to teach them, (4) management, monitoring, supervision, and training systems, which do not support NFP and fertility awareness education, (5) the barriers that exist between NFP NGOs and those involved in other family planning and reproductive health services, and (6) a lack of provider and client skills to deal with sexuality and gender issues that are central to successful teaching and counseling. The potential and actual demand for NFP and fertility awareness education, when they are offered adequately, needs to be documented. Accurate, accessible, user-friendly information needs to be developed and disseminated to providers and managers of family planning and other reproductive health programs and at the community level. Partnerships between NFP NGOs and public and private sector programs need to be fostered. Technical assistance is needed to deal with structural barriers that exist in multimethod family planning programs and with those that impede expansion of the capacity of NFP NGOs.

**Presenters**

Marcos Arevalo, M D , Georgetown University, USA

**Expanding the availability and improving natural family planning services and fertility awareness education providers' perspectives**

Sandro Giroto, M D , National Health Service, Italy

**The behavior of Italian family physicians regarding the health problems of women and, in particular, family planning (both contraception and NFP)**

Margaret France, M S , NZANFP, New Zealand

**The benefits and barriers associated with a national natural family planning service the New Zealand experience**

Margarita Diaz, CEMICAMP, Brazil

**Gender, sexuality and communication issues that constitute barriers to the use of natural family planning and other fertility awareness-based methods**

## **Expanding the availability and improving delivery of natural family planning services and fertility awareness education: providers' perspectives**

**M ARÉVALO**

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### **Abstract**

Despite the recognized benefits for clients and programs of providing natural family planning (NFP) services, few family planning programs offer NFP and few provide fertility awareness education. Furthermore, many non-governmental organizations (NGOs) that provide only NFP actually reach a very small percentage of the potential NFP users in the areas they serve. This paper discusses the results of interviews with selected family planning providers that were conducted to explore reasons why NFP and fertility awareness education are not offered in their programs, and with NFP providers to get their opinions on how to improve service delivery. The interviews were structured around some of the lessons learned from the successful incorporation of the lactational amenorrhea method (LAM) into several multimethod family planning programs. There is agreement that the need for NFP services\* is far from being met and that most clients lack the information and skills they could learn through fertility awareness education. The providers interviewed also acknowledged that offering these services would improve the quality of reproductive health services in general. Presented here are some ideas about why these services are not offered, as well as suggestions for integrating NFP and fertility awareness education into existing family planning programs.

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\*See Note section

## Introduction

Quality of care [2], client-centered services, and informed choice are major emphases in family planning programs, particularly since the landmark International Conference on Population and Development held in Cairo, Egypt, in 1994 [3]. Thus, offering all methods of family planning, including natural family planning (NFP) and providing fertility awareness education to clients should be the norm for family planning programs. However, few multimethod family planning programs offer NFP, and fertility awareness education rarely is given in either clinic or community settings. Existing NFP groups, mostly non-governmental organizations (NGOs), reach only a small portion of potential NFP users. This leaves an important gap in the delivery of reproductive health services, especially to certain groups such as

- those who prefer a natural method
- those who for health reasons cannot or should not use a hormonal, surgical or chemical method
- those who do not have access to commodity-based services and supplies or to surgical methods but do have access to providers (e.g. community health educators, health clinics) that could provide NFP services and fertility awareness education

## Materials and methods

### *Methodology*

Semistructured interviews were conducted with approximately 25 managers and high-level providers of reproductive health and NFP services in developing countries. Selection of interviewees was not randomized, they were associated with the author because of current or past work, and were chosen because of convenience.

All interviews were conducted by the author over a period of several months. In initial contacts no specific instrument was used, interviewees were asked to provide their points of view, experiences, etc. on why NFP services were not provided optimally and ideas on how to improve this situation. In subsequent contacts, interviewees were asked to provide additional ideas and to comment on other interviewees' ideas (which were shared during these subsequent conversations). Not all interviewees were contacted more than once. The author has summarized and organized comments.

## Results

Three general themes emerged from these interviews that suggest some reasons why NFP and fertility awareness education are not offered optimally.

- There is an important ideological gap between most multimethod family planning programs and some of the religious groups and institutions that promote natural methods, much time and energy is spent on dealing with philosophical differences
- There is not enough and appropriate information available to the family planning community on NFP and fertility awareness education, and existing information is not well disseminated
- Family planning institutions, both multimethod and NFP, lack appropriate support systems to deliver NFP services

These ideological perspectives, knowledge gaps, and support system deficiencies are reflected at all levels: policy and decision makers, service providers, and clients/potential clients

#### *Factors affecting mostly multimethod programs*

Several factors contribute to the preference of most providers in multimethod programs for hormonal, surgical, or barrier methods of family planning. A key factor is that many providers simply do not believe that NFP is effective in preventing pregnancy. A significant proportion of the information that is available on the effectiveness of natural methods is contaminated by mixing data of real NFP users with data from couples who believe they are using an NFP method, but who in reality are just basing their practices on inaccurate or insufficient information received from a variety of sources. This is further complicated by the claim of some NFP supporters who quote unrealistically high levels of effectiveness based on flawed studies [4]. For decades, part of the family planning message was that NFP did not work. This message, which was communicated at the international level and echoed by programs at the country level, has left a strong imprint in service providers' minds. Decision makers' and clients' perceptions about the effectiveness of NFP methods also are influenced by these data.

Another reason for these providers' preference for methods other than NFP is that traditional pre- and in-service training of family planning providers is oriented toward clinical approaches, use of technology, and the individual client. This training does not facilitate incorporation of methods that are less technology-dependent, more couple-oriented, and require a more holistic approach that relies on client education and counseling. This predominantly clinical perspective is sometimes reflected in decisions concerning other aspects of service delivery (site selection, working hours, client flow, etc.). Results are not always NFP-friendly. Furthermore, providers trained in methods that rely on commodities or surgical procedures are used to feeling in control of the outcome of providing family planning services. Handing over this control to the client, as happens with natural methods or with fertility awareness education, implies a change in the client-provider relationship, which is not always easy to make.

Another reason for not providing natural methods is that they are education-based and counseling-intensive, and thus require more provider time per couple served, at least during the time when clients are learning the method prior to reaching autonomy. Fertility awareness education also is perceived as time-consuming.

At least partly because of recent initiatives to increase availability and facilitate delivery of contraceptive methods [5], service delivery depends significantly on the initial client-provider contact, with follow-up contacts playing a lesser role. NFP methods, being more complex to teach to clients and more flexible, require more time for clients to learn and do not lend themselves well to these approaches.

Most multimethod programs only provide hormonal, barrier, and/or surgical methods, and their support systems and tools (funding and cost recovery structures, management systems, service delivery guidelines, training, monitoring, management information systems [MIS], evaluation, etc.) were created and designed specifically to provide commodity-based or surgical methods. These systems and tools do not necessarily lend themselves to the delivery of NFP services or fertility awareness education. The requirements of donors and their quantitative measures are an important part of the monitoring and evaluation systems of most family planning institutions, and an MIS based on couple-years protection, commodities and supplies distributed and used, income, etc., may not be consistent with the delivery of NFP and fertility awareness education. Delivering NFP services requires a more qualitative approach, which some family planning institutions only recently have begun to incorporate.

Currently, delivery of NFP services is not profitable for most family planning institutions. NFP requires more personnel time per couple served during the learning period, and, because clients do not receive any tangible goods, cost recovery is difficult in systems designed for commodity-based methods. The current need for family planning institutions to reach certain levels of self-sustainability exacerbates the need to minimize expenses and recover costs for services rendered.

#### *Factors affecting NFP institutions*

Additional themes emerged regarding the delivery of NFP services through NFP non-government organizations (NGOs) or other religiously-affiliated programs.

While many of those involved in NFP are driven by the desire to meet their communities' needs, others are more ideologically motivated. Political positioning often leads to concentrating more on lobbying, promotion, etc., and giving less priority to service delivery. Even the option of developing a referral system between family planning programs and NFP NGOs is not possible in many settings because the ideological differences between the two severely limit the success of such a system. While those who are technically knowledgeable about family planning and NFP may desire such a relationship, in this situation, just as in every other field of human activity, technically knowledgeable persons are not necessarily the ones who make technical decisions or policy. Partly because of this, proposals are sometimes stopped short of the stage of full implementation.

Reproductive health is still a controversial topic in some sectors, and some providers choose to dedicate their efforts to less polemic areas of healthcare

NFP programs and the institutions backing and/or implementing them lack appropriate support systems, which places them at a disadvantage for efficient delivery and management of services. Compared with support systems for other methods, support systems for NFP methods, where they exist, have been developed with much less technical support from the international community, and often are less advanced.

### **Discussion**

Given the many barriers to providing NFP and fertility awareness services through multimethod family planning programs, it would seem an obvious solution to simply rely on the many NGOs that provide only NFP to meet the need for these services. However, this approach may not have the desired result of expanding the availability of services.

The providers interviewed offered several suggestions for increasing the availability and improving delivery of NFP and fertility awareness education, through multimethod programs as well as through NFP programs.

- "Mainstream" NFP. NFP institutions by themselves may not be able to meet the demand for NFP services, so it is necessary for others to join the effort and provide services
  
- Develop more user-friendly NFP methods
  - simplified versions of existing methods (simple calendar, or blanket rule methods)
  - streamlined teaching approaches for existing methods
  - new methods/new approaches
  
- Develop support systems and tools appropriate for NFP methods which can also function in a multimethod environment
  - training methodologies and materials that enable providers to easily acquire the basic skills and knowledge necessary to deliver NFP services
  - service delivery protocols that help providers deliver NFP services in a time-efficient way while maintaining adequate communication with clients
  - clinic management systems flexible enough for delivery of education-based services
  - community outreach systems which include referrals to other programs
  - monitoring and evaluation systems which include impact indicators that are able to take NFP and fertility awareness education into account

- To raise NFP's credibility with policy and decision makers, service providers, and potential clients, it is necessary to make more information (especially on the effectiveness of NFP methods) widely available. This involves at least two strategies
  - clarification of existing information. Data from couples using NFP methods should be presented independently from data from couples not really practicing any standard method, data from flawed studies should not be disseminated in this context
  - implementation of operations research projects to document the results of providing simplified methods using appropriate support systems, if at all possible, these pilot projects should be carried out by existing multimethod family planning programs
- Establish links among all providers of family planning services (including natural methods), in order for referral systems to function. This may sometimes demand that providers overcome ideological posturing

One more way to promote provision of NFP methods and fertility awareness education is to highlight to institutions that there is a demand for those services, and/or for other methods in currently underserved population groups. Following are some suggested mechanisms for achieving this

- Carry out fertility awareness projects in conjunction with service delivery projects. Fertility awareness education may increase demand for family planning services (natural and other), which will
  - help multimethod programs see the benefits of providing NFP methods (by opening for them a market which they currently do not reach)
  - help move NFP institutions in the direction of expanded service delivery (by having more couples in their target population ask for family planning services)

### Summary

Provision of natural family planning services is a very controversial field of work, and some of the main parties involved are not ready for the necessary changes. It is necessary to be aware of the political context, but it is also important not to make the resolution of ideological conflict a requisite for quickening the pace on the technical front.

Two main thrusts of the strategy should be to tap the existing demand for NFP services, and to prepare the systems and tools that programs and providers will need to deliver quality services.

## Note

We define unmet need according to the framework (with some modifications) developed by Ruth Dixon Mueller and Adrienne Germaine in their article Stalking the Elusive Unmet Need for Family Planning Stud Fam Plann September/October 1992 [1] That is we include unmarried women and women who are using no method of family planning who may be interested in using NFP We also include women who are using a method that is theoretically effective but who are using it sporadically or inconsistently (in this case state that they are using NFP although they have little or incorrect information about how to use it) and women who are using a method that is unsafe or unsuitable for them (in this case women who want to use a natural method have contraindications to other methods etc but do not have access to NFP information or services) Finally we include women who are using other traditional methods largely undefined that have not been proven effective in preventing pregnancy

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## **The behavior of Italian family physicians regarding the health problems of women and, in particular, family planning (both contraception and NFP)**

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### **Abstract**

The hospital-centered trend that has dominated medical culture and the management of health care during this entire century has, in the last few years, undergone a reversal in Italy. Conditions in other countries suggest that similar changes have or will become increasingly common.

The family physician today manages many of the functions previously handled by hospitals and specialists. In the field of reproductive health, family physicians are responsible not only for diagnosis and treatment, but also for prevention and education. The present study considers this new context with the objective of investigating the knowledge and behavior of Italian family physicians in the field of women's health, with particular regard to family planning (including natural family planning), through (1) a qualitative study (focus groups) of a small group of family physicians and (2) a questionnaire sent to 500 family physicians throughout Italy. The results of the focus group are summarized in the form of obstacles that the family physician finds in providing family planning services and proposals for change. The results indicate that because of their holistic approach, the family physician is an appropriate provider of family planning services although continued use of specialists' services, changes in logistics of the family physicians' practice, increased gender sensitivity, and additional training and information are necessary. The results of the questionnaire (121 responses, 24.2%) indicate that the Italian family physician currently lacks certain important information.

about family planning and would require logistical support to provide these services but is interested in acquiring information and is an appropriate family planning provider. An additional challenge for encouraging family practitioners to provide natural methods is that they favor a "medical" approach rather than a "behavioral" one in their treatment preferences for several other conditions.

## **Background**

The current cultural and professional health care climate is one in which the force of re-evaluating distribution of economic resources under the redesigned Welfare System in Western countries manifests itself increasingly as a reversal of the old centralized tendencies to rely on hospitals and specialists. In this climate, the family physician has many patient management duties. These are mainly in the areas of prevention and education, and increasingly more patients ask for advice regarding family planning (both avoiding and achieving pregnancy). The family physician therefore assumes the role not only of a consultant on the subject of family planning (which the World Medical Assembly [Madrid, 1967, Paris, 1969, and Venice, 1983] [1] established as a "fundamental human right"), but of an educator and counselor to help women/couples understand their fertility and its relationship to their sexual and family lives. Thus, it is important to understand and analyze the knowledge and behavior of the Italian family physician regarding family planning and, in particular, natural family planning (NFP). In fact, according to the Health Reform Act of 1978, the family physician is available to the entire Italian population.

This study is significant because research concentrating only on family physicians [2] and/or on the topic of family planning is scarce [3-6].

## **Aims**

The scope of this research is to

- 1 Evaluate family physicians' knowledge of specific technical elements of family planning (e.g. menstrual cycle, indicators of fertility, effectiveness of family planning methods of Pearl),
- 2 Analyze the actual behavior of the family physician regarding women's health and family planning (both contraceptive and NFP),
- 3 Identify the causes of possible resistance to change in attitudes toward NFP,
- 4 Identify ways to meet the need of family physicians for information about NFP and to increase their interest in it, and

- 5 Consider the issue of family physicians' interest in patient management (in areas related to fertility and in other areas) via education and counseling or via medical treatment

## Methods

The study is divided into 2 parts

- 1 Qualitative research was conducted through a focus group [7,8], and data were analyzed according to a four-point grid. The four points are
  - a current sociocultural context,
  - b behavior of women,
  - c behavior of the family physician, and
  - d specific knowledge of contraceptive and NFP methods

Eight family physicians (of whom one was also a gynecologist) and one psychologist/sex therapist participated in this focus group

- 2 A questionnaire consisting of 19 questions was sent to 500 family physicians chosen at random from among addresses of a medical update journal, from an address list of 1300 names (only 1 mailing), comprising social and union membership rosters of family physicians in all of Italy. The questionnaire asked about
  - a knowledge of the menstrual cycle,
  - b knowledge and behavior in areas of contraceptive and methods of NFP, and
  - c behavior in addressing specific health concerns of adolescence

The questionnaire was pretested, and data were analyzed with SPSS [9]

## Results

Table 1 summarizes the findings of the focus group listing the obstacles to the increased involvement of family physicians in providing family planning services

- The first obstacle is the complexity of providing a holistic family planning service, given the many socio-cultural issues surrounding family planning and the rapid evolution of knowledge and behavior in the field of sexuality. Changing traditions, sexual behavior, and personal and family values contribute to the complexity. Because the family physician is the doctor of the person as a whole, it is necessary to consider a thorough revision of the training and continuing education of the family physician

**Table 1 Sexuality and family planning obstacles and proposals for general practice**

<i>Obstacles</i>	<i>Proposals</i>
1 Complexity of subject	1 a The family physician is the doctor of the whole person b Necessity of training/continuing education on a bio psycho-social model c Objectivity/neutrality respectful of emotionality that can spring from the complexity of the subject
2 Logistics the office of the family physician is full These arguments need time	2 a Visits by appointment b Help from non medical personnel c Flyers and educational material
3 The majority of family physicians are male	3 a It is simpler for the female physician b Depends on how established is the rapport of trust (education and prevention) c Utilization of female personnel
4 Management of sexuality and family planning as 'individual right'  To have one's own gynecologist" is to be emancipated	4 a The family physician is not exclusive b The gynecologist acts as consultant c The family physician directs persons to the gynecologist (system of specialist referral)
5 Technical specialist subjects	5 a Subjects which involve the whole person, the couple, the family b Recovery of knowledge and minimal ability c In the case of family planning, the family physician must be thorough and objective
6 Contraception little understanding of collateral effects/follow-up	6 a The family physician is the best person to monitor collateral effects, because he knows the patient fundamentally and follows her for a long period of time
7 NFP little firm knowledge	7 a Necessity for information packages for family physician and for woman/couple b Selection of the candidate for NFP c Educational, consultative, and behavioral services of the family physician d Educational for the couple and respectful of the person

- 
- Another obstacle is organizational problems: the quantity of daily work, the crowding of medical offices, and the lack of time and personnel are significant logistical problems for today's Italian family physician. The solution is to search for ways to reorganize the setting of the family physician, using the experience of other countries (e.g. the UK), to include flexible office hours, the use of trained non-medical personnel, and patient educational materials.
  - Gender issues present another obstacle. The majority of family physicians are male, although this has changed in the last decade and family practice is the area of medicine with the highest number of women. Regardless of the gender of the physician, sensitivity to gender issues and an ability to provide care to women in the highly sensitive areas of family planning and sexuality needs increased focus in the preparation of family physicians.
  - The commonly-held view that family planning is an "individual right", that sexuality is equal to "emancipation", and that going to a gynecologist is a status symbol also impedes the family physicians' role in family planning services. The family physician often is involved in the care of several family members and views their healthcare needs in this context. Family physicians need to develop special sensitivity to partners' needs in this area. Further, the family physician need not be excluded from the gynecologist/woman rapport. On the contrary, the gynecologist should act as consultant to the family physician, as is the case in other areas, as a network of specialist referral.
  - Another obstacle is the technical nature of family planning, which requires specific training and experience. Clearly, for family physicians to provide high-quality services, they must have specific knowledge (physiology, symptoms and observable signs of the menstrual cycle, function of the combined pill and its collateral effects, etc.) and skills (basic pelvic examination, Pap test, etc.), and the ability to give advice with objectivity and honesty. Because family planning and sexuality are subjects that profoundly involve the whole person and that overlap biological/medical, social, psychological, familial, and ethical spheres, the family physician is an appropriate provider. Although it may be the gynecologist who prescribes or administers a family planning method, it is important for family physicians, the providers who are responsible for following their patients, to have knowledge of collateral effects of family planning methods and of how to do follow-up correctly.
  - A major obstacle to family physicians' providing NFP is their lack of knowledge about natural methods. There is, however, great interest in learning more about the physiology of the menstrual cycle and fundamentals of the NFP methods, because these methods are perceived as very educational methods for couples, and respectful of the person (ecology of the person).

Tables 2 to 6 show the results obtained from the questionnaire. Of the 500 questionnaires mailed, 121 (24.2%) were returned within one month. Also, of the

request forms for further information about NFP (which were sent with the questionnaires), a total of 76, or 63%, were returned. Responses to the questionnaires are divided into five parts.

Table 2 shows respondents' knowledge of the menstrual cycle. The majority considered the menstrual cycle regular (multiple response) when it is from 28 to 32 days (57%) and from 25 to 35 days (53.5%), 13.2% state that regular cycles are those of less than 25 days and 7.9% that they are more than 35 days. None identified the period in which ovulation occurs in the few days before menstruation or immediately after. Fifty-six percent calculated it from 12 to 16 days preceding menstruation. Estrogen (63.1%) and progesterone (69.1%) were identified as directly responsible for changes in cervical mucus and basal body temperature (BBT). Follicle stimulating hormone (FSH) and luteinizing hormone (LH) were given an important role (from 15 to 25%).

Table 3 shows the behavior of family physicians with regard to family planning in general. A sizable percentage (42.5%) of family physicians give advice on family planning, although the majority (56.6%) have done so only a few times. The combined pill is the most often recommended (97.3%), and NFP is the least often recommended (53.5%). The pill is considered to be the most effective (96.1%), NFP the least effective (31.5%).

**Table 2 Understanding of the menstrual cycle**

1 Regular menstrual cycle (multiple answers)	- <25 days	13.2%
	- 25-35 days	53.5%
	- 28-32 days	57.0%
	- 28 days	58.8%
	- >35 days	7.9%
2 Ovulation (single answer)	- Immediately after menstruation	0.0%
	- In the middle of the cycle	18.0%
	- At the 14th day of the cycle	26.1%
	- Few days before menstruation	0.0%
	- From 12-16th day before menstruation	55.9%
3 Preovulatory cervical mucus is a function of (single answer)	- Estrogen	62.3%
	- Progesterone	17.9%
	- FSH	9.4%
	- LH	10.4%
4 Thermal rise is a function of (single answer)	- Estrogen	15.5%
	- Progesterone	69.1%
	- FSH	2.7%
	- LH	12.7%

**Table 3 Family planning in general**

1 In your general practice do you give advice on family planning methods? (single answer)	–	Never	0.9%
	–	Sometimes	56.6%
	–	Often	38.1%
	–	Rarely	4.4%
2 What advice? (multiple answers)	–	Combined pill	97.3%
	–	IUD	81.3%
	–	Barrier	70.2%
	–	NFP	53.5%
3 Efficacy of FP methods	–	Combined pill	96.4%
	–	IUD	36.9%
	–	Barrier	50.5%
	–	NFP	31.5%

Focusing on NFP methods (Table 4), few know NFP well. The majority know the Ogino-Knauss method (87.2%). The symptothermal method is less well known (16.5%). Books, magazines, and other written materials are the principal source of knowledge on these methods. Their principal advantage is believed to be that they do not require the use of drugs. The disadvantage most noted is poor efficacy. Few doctors (8.2%) often recommend them. They are interpreted as educational methods even if they are of poor efficacy and not highly acceptable. They are recommended only to women with regular cycles (82.1%), to women with ethical/religious motivation (78.9%), to women with health/ecological motivations (66.3%), to women in stable relationships (61.6%), and to those wanting to achieve pregnancy (51.6%). The respondents believe, however, that the family physician is the right person to provide correct information on NFP (95.5%), and the majority (60.4%) believe that it should be the family physician who teaches it. Eighty-three percent are interested in learning more about NFP.

Because of the growing importance in Italy of addressing the changing health needs of adolescents, a set of questions focused on family physicians' attitudes toward how these needs should be addressed.

As shown in Table 5, the majority (77.2%) believe that all adolescents over 15 years of age should be counseled by a family physician on the subject of sexuality. Only 1.8% responded that every adolescent girl should go to a gynecologist.

In considering behavioral therapy vs. medical treatment (Table 6), the behavioral approach is recognized as preeminent in confronting eating disorders (87% vs. 13%), for sexual problems (78% vs. 22%), and, to a lesser degree, for risk factors for cardiovascular diseases (65% vs. 35%). For family planning, however, the medical treatment approach prevails (57% vs. 43%).

**Table 4 NFP methods**

1 Do you know NFP methods? (single answer)	- Not at all	2 7%
	- Little	48 7%
	- Sufficiently	42 5%
	- Well	6 1%
2 What methods of NFP do you know?	- Ogino-Knauss	87 2%
	- BBT	82 6%
	- Billings	67 9%
	- STM	16 5%
3 Sources of your knowledge (multiple answer)	- University course	57 8%
	- Post graduate refresher course	15 6%
	- Colleagues	2 8%
	- Specific NFP courses	7 8%
	- Patients	11 9%
4 a) Advantages b) Disadvantages	Do not use drugs	
	Little efficacy	
5 Do you recommend them? (single answer)	- Never	27 3%
	- Rarely	64 5%
	- Often	8 2%
6 NFP methods are (multiple answer for each point)	a Very/rather educational	84 5%
	b Relatively ineffective	65 1%
	c Somewhat acceptable	45 0%
	d Relatively unacceptable	37 3%
7 If you recommend them, to whom? (multiple answer)	- Regular cycles	82 1%
	- Irregular cycles	5 3%
	- Adolescents	9 5%
	- Stable relationships	61 1%
	- Premenopause	6 3%
	- Breast-feeding	6 3%
	- After the pill	22 1%
	- To achieve pregnancy	51 6%
	- Ethical/religious motives	78 9%
	- Health/ecological motives	66 3%
	- Without children	27 4%
- With more children	14 7%	
8 Do you believe the family physician is the right person to provide NFP info	- Yes	95 5%
	- No	4 5%

**Table 4 (continued)**

9 Who should teach it? (single answer)	- Gynecologist	13 8
	- Family physician	55 3
	- NFP teacher (health)	20 2
	- NFP teacher (general)	10 6
10 Are you interested in knowing about NFP?	- Yes	83%
	- No	17%

**Table 5 Adolescence and sexuality to whom should they be referred?**

1 Consulting services	14 9%
2 Gynecologist	1 8%
3 Family physician if available	77 2%
4 Family physician directly requested	6 1%

**Table 6 Behavioral therapy vs medical treatment**

	<i>Medical treatment (%)</i>	<i>Behavioral therapy (%)</i>
Eating disorders	13	87
Sexual problems	22	78
Risk factors for cardiovascular diseases	35	65
Family planning	57	43

### Discussion and conclusions

The data from the qualitative research were analyzed according to a precise grid which demonstrates the obstacles and proposals for overcoming them (Table 1). Participants in the focus group were all around 40 years old, almost all male (one woman), professionally well-prepared and committed to the role of family physician. They agreed that sexuality and family planning are subjects that generally have been neglected by the family physician and relegated to specialists, for "cultural" reasons and because of professional circumstances. They also agreed that in the current health care environment, the modern family physician needs to engage in the management of these issues. They expressed belief that sexuality and family planning

are complex and specialized subjects, but that for only specialists to deal with them is not sufficient. For family physicians to play their appropriate role (i.e. the doctor of the individual and of the family), they should have solid internist training ("the ultimate internist"), and at least minimal and integrated knowledge and ability in several specialties (including gynecology and obstetrics). To provide appropriate family planning counseling, they must remain objectively aware of all the options and of the person who is the patient, whom the family physician knows well. Participants expressed some concern about the combined pill and its collateral effects relative to potential circulatory problems, rare but often totally unforeseeable. They lack knowledge of NFP, but desire to know more in order to inform the patient in a direct and comprehensive manner.

Regarding the menstrual cycle, elementary knowledge was not optimal: only 21.2% reported that the regular menstrual cycle is greater than 25 and less than 35 days. However, only 60–70% attributed to estrogen and progesterone a correct role in the cyclic changes of cervical mucus and basal body temperature, and none responded that ovulation occurs close to menstruation. Family physicians do provide family planning counseling, but they are not well-informed of efficacy, especially of the intrauterine device (IUD), barrier methods and NFP. As to the latter, respondents have little knowledge (only 6.1% know them well), and consider them of low efficacy, although they are considered important content in patient education. At the same time, family physicians consider themselves to be the providers patients should turn to for correct information about NFP (95.9% vs. 4.5%) and even for instruction in natural methods (60.4% > 21.7% health professional NFP teachers, 19.8% gynecologists, 10.4% non-health professional NFP teacher). There is, therefore, an apparent contradiction between family physicians' interest in NFP and their lack of knowledge about these methods. This may be because the family physicians understand that many of their patients would like to know more about NFP and that the educative/consultative role in teaching NFP is appropriate for the family physician. The vast majority (83% vs. 17%) want to know more. This number could rise if they recognize the efficacy of natural methods when NFP is well-taught and practiced correctly. The gap can be filled not only through revising training and continuing education, but above all, when logistics have changed (longer office hours, visits by appointment, health personnel) permitting the Italian family physician to dedicate more time to counseling patients, especially in those sectors where the behavioral approach is key. Again, the experience of colleagues in the UK is very significant [2]. That the combined pill is identified as the most scientific for its efficacy [3] demonstrates some doubt and a gap that can be filled specifically regarding collateral effects.

In conclusion, Italian family physicians 1) are not well informed about reproductive physiology, about family planning, or, in particular, about NFP, 2) are interested in methods of family planning but understand their cultural and professional limitations in this area, 3) can deepen their interest and enrich their practice if updated and supported logistically, 4) are very willing, if the conditions are met in point 3), to move to more behavioral and less medical treatment-oriented patient management in certain pathologies or situations, and 5) can become fundamental actors in the dissemination of correct information about NFP.

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## **The benefits and barriers associated with a national natural family planning service: the New Zealand experience**

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### **Abstract**

This paper provides a case study of a model for expanding natural family planning (NFP) from a small local program to the national level through the creation of a national association and the development of a public-private partnership. The experience of the New Zealand Association of Natural Family Planning (NZANFP) is analyzed in terms of both the benefits and barriers of using this model. Recommendations are given to guide others in developing a similar model.

### **Introduction**

Natural family planning (NFP) programs were formed in many countries throughout the world during the 1960s and early 1970s. In most cases, including New Zealand, they consisted of a small group of enthusiasts, grouped around Catholic doctors and based in the larger cities. Many of these programs have struggled with issues of expansion. While program leaders have seen the need to make NFP services available to people in rural areas and small towns, as well as to a larger number of people in urban areas, it has not been an easy task to accomplish while maintaining the quality of services, ensuring adequate financial resources for program support, and monitoring the impact and coverage of the program. An approach to expansion in some settings has involved partnerships between an NFP program (a non-governmental organization) and the public sector [1]. These public-private partnerships have a number of potential advantages, including sharing the cost of services, expanding services to meet the needs of underserved populations, and widening the range of methods available, as well as enhancing the legitimacy of the organizations involved in the partnership [2].

A variant of this approach is the one taken by the New Zealand Association of

Natural Family Planning (NZANFP) The Association has developed a strong internal infrastructure based on affiliates throughout the country, with each affiliate having the flexibility to meet the needs of the local area while also meeting the standards of the national association. At the same time, NZANFP has worked with the government to create a partnership which supports NFP services and expands both the availability of NFP services and the integration of NFP into the national family planning program.

### **Program development**

The New Zealand Association of Natural Family Planning (NZANFP) has been in existence since 1975. It is the only recognized provider of NFP services in New Zealand and provides a nationwide service. The administrative structure of the Association is illustrated in Figure 1.

NFP services began their evolution from small local group providers in 1973, when leaders of these groups from different regions of the country<sup>a</sup>, disturbed by evidence of NFP controversies in other countries, discussed the setting up of a national association to provide training and standardized teaching. These discussions resulted in the first national meeting in 1975, in which the NZANFP was formed, a national council was elected and the first national coordinator was appointed. The Constitution of the Association was adopted in 1977, by which time the NZANFP was incorporated as a non-profit organization.

Fortunately, the New Zealand government in 1975 set up a Royal Commission on Contraception, Sterilisation and Abortion. The new NZANFP made a submission to the Commission and, in its final report (1977), the Commission recommended that the government should provide funding for NFP services as well as for services provided by the Family Planning Association. This was highly significant in the development of the Association, as previously NFP had been supported by donations from Catholic sources. It meant that the NZANFP was able to develop as an independent provider within the public health arena.

Government funding through the Department of Health was provided from 1977, covering training and administration costs, and the National Coordinator's salary. In 1981, a medical and scientific advisory board was established and a Code of Ethics was adopted. Teachers continued to work in a voluntary capacity until 1982 when they agreed to be paid at an hourly rate. In the same year, a fertility education service was established, with the training of the first educators to work with school and community groups.

In 1990 government funding changed from a general grant to a contract for the purchase of set services. Two years later a radical change in the New Zealand health system was introduced, when the country was divided into four regional health

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**Figure 1** Diagram of the organizational structure of the New Zealand Association of Natural Family Planning a model for a national natural family planning program

authorities (RHAs) which were responsible for purchasing all health services in their areas. As a consequence, the NZANFP is now required to negotiate four separate annual contracts, and report quarterly to each of the four RHAs. While this reconstruction has caused much extra stress and expense to the Association, it also provided the opportunity for implementing a more structured and comprehensive monitoring of standards in all aspects of the Association's work.

What have been the benefits of forming a national association and what barriers has the association had to overcome? What difficulties remain?

### **Benefits**

The benefits of being structured as a national association are as follows

#### *Quality control/risk management*

Providing clients with accurate and appropriate information and having staff skilled in teaching and interviewing techniques are important elements of quality of care in family planning services [3]. Our national structure has made it possible to carry out standardized training and provide a consistent service throughout the country, so that rural areas receive the same quality of service as urban areas, and the whole country can be updated on any new developments, such as the lactational

amenorrhoea method, and new refinements in teaching techniques. In-service study days and seminars are a requirement of ongoing accreditation, and we have recently set up a two-yearly personal assessment and standards audit for all staff. National data collection and analysis give a sound base for future planning and along with this goes the necessity for reliable reporting and accountability. Client satisfaction surveys are carried out annually. Staff morale benefits from the sharing of ideas and problems. A national structure, with funding from the national health budget, allows independence from pressure groups. A central office provides a contact for international cooperation.

### *Financial*

In assessing the cost-effectiveness of an NFP service, it is essential to include the cost of program management and administration [4]. The cost-effectiveness of a central administration is self-evident. Duplication of staff and equipment is avoided, and large printing and stationery orders are cheaper. There is more flexibility in planning with a larger sum of money. In applying for funding, a national group can speak with a united voice. There is security for smaller, less economic clinics which can, if appropriate, be helped financially by stronger areas.

### *Health policy/social issues*

As governments and NGOs address the barriers of the Cairo and Beijing meetings to meet the needs of underserved people, the government of New Zealand has re-emphasized the importance of serving a diverse population. The government health policies, for example the priority of adolescent and Maori health, are more easily addressed within a national structure, which can draw on a wider experience, educate staff in all areas to be alert to varying cultural and social needs, and encourage networking and liaison with different ethnic groups. In addition, when the Association sees a need to contribute to health policy, the skills necessary to make representation are more easily found or developed within a national organization, and the voice of a national organization is more likely to be recognized.

### *Profile*

Communication experts agree that a national image with its own logo, pamphlets, and a consistent message makes more impact in advertising and promotional activities. Establishing links with other health professionals is easier when local groups have a national identity and can point to the success of such cooperation in other parts of the country.

### *Research*

Since its inception the NZANFP has had a strong interest in research. Major studies carried out within the Association have been the WHO Multicentre Trial of the Ovulation Method [5, 6], the NZ Continuation Study [7], and a study of the lactational amenorrhoea method [8]. This involvement has helped staff to develop an understanding of the significance of research and an interest in international NFP studies.

### **Challenges**

Challenges have of course arisen in the original establishment of the national association and in its ongoing development. In listing some of the major difficulties the NZANFP has faced, I will also indicate some of the strategies adopted to overcome these difficulties.

### *Staff attitudes*

Originally there was resistance from some teachers to moving from comfortable volunteer jobs in small communities to a position in a larger organization which set conditions and demanded some accountability. Over the years there has been intermittent resistance to new requirements, as more quality measures have been introduced to build up a more professional service. At times local needs are seen as more important than the national good.

Listening, communication, education have been the key to overcoming these difficulties. Opportunity is provided for regional discussion at study days, a quarterly newsletter is published and efforts are made to keep a broad representation and turnover of the National Council. With the development of a higher standard of teaching and a more professional approach over the years more of our staff have taken pride in these achievements and actively supported them. An annual conference gives an opportunity for all teachers to share views and an effort is made to keep personal support systems going among the teachers.

### *Geography and population*

New Zealand has a small population of 3.5 million spread over two main islands, with some small towns quite isolated. Sole teachers in rural areas need to be highly self-motivated to keep up the impetus of their teaching, education and promotional work. If client numbers drop, NFP can take a lower priority, with a consequent downward spiral in the service. Keeping on staff in such cases becomes uneconomic. Motivational problems also arise in larger centers when some staff may work only a few hours a week.

In an effort to overcome loss of staff early after training, the Association has recently introduced a bonding system for new trainees. To provide more consistent employment, the Association is appointing one person on a half time basis in two of the larger cities. There is a national correspondence service available and, in areas where the size of the service is not viable, serious consideration is given to whether the service should be continued.

#### *Funding/changes in government policy*

The setting up of four regional health authorities in 1992, each with different requirements and frequent staff changes, has posed several major barriers to our organization. These include the danger of fragmentation as we meet different priorities for different regions, the extra work and expense when one administrator has to negotiate four different annual contracts, the limitations on long-term planning with annual contracts and most seriously, a reduction of funding in one area affecting the whole Association.

This is the main barrier at the time of writing this paper. The newly elected government in New Zealand has announced a return to a single health purchasing authority in 18 months, so there is hope of a more sensible arrangement. Meanwhile, over the last few years we have persisted with a national perspective in our discussions with the RHAs, and made economies to manage the reduction in funding from one RHA.

#### *Acceptance by the medical and other health professionals*

The lack of acceptance by some medical people we put down partly to ignorance on the part of those who regard NFP as a less effective method or an 'alternative' fringe method, and partly to the threat to their control. The situation has improved over the years, and there are now more medical referrals to our clinics, although of these there are some doctors who are happy to refer patients having difficulty conceiving but not those wanting family planning advice. Cooperation from other health professionals such as midwives and nurses is now more common.

The progress we have made in these areas is the result of consistent education and networking over the years. Cooperation and cross referrals have been established with the New Zealand Family Planning Association (FPA), while in three of the larger cities NFP clinics are run by the NZANFP in FPA premises. Courtesy letters and referral letters when appropriate are sent to clients' family doctors or gynecologists. It has been found that such doctors are more likely to refer patients to NFP clinics in the future. Some practice nurses, trained as NFP teachers, offer NFP as part of their job in the medical center.

### *Meeting all cultural needs*

The NZANFP has as part of its policy a commitment to biculturalism, which refers to equality of service for the indigenous Maori people of New Zealand. Maori, along with the large Pacific Island population, are on the whole in a lower socio-economic group and less well served by health services. In New Zealand, NFP has a mainly white middle-class clientele and the majority of our staff come from this group. Over the last 5 years, through seminars and discussions, we have educated ourselves as far as possible on different cultures and established some areas of communication with Maori groups. While we have a small number of trained teachers from different ethnic groups, our plan is to have sufficient teachers to work within their own culture.

### **Conclusions**

Many of the barriers we have met are related to the size of our organization which is a natural consequence of the place of NFP in relation to other methods of contraception. On the surface NFP appears a more difficult option than other methods, and will probably always be a minority method. Our education service has a broader potential for growth than our clinic service, as education in fertility is relevant to everyone whatever method of contraception they may choose.

In summary, being a national service has enabled us to continue to improve the standard of service provided, it has given us the strength to meet new needs as they arise and to plan ahead to place NFP more firmly among the options always considered in the choice of a family planning method.

### **Recommendations**

The following recommendations are an approach to providing a high quality, professional and mainstream NFP service. They are based on the New Zealand experience but are applicable to all NFP programs, although their implementation will vary from country to country.

- 1 Establishment of a national organizational structure. This provides consistency of content and quality of services, a vision beyond local interests and a central administration for financial management, data collection and interaction with government.
- 2 Establishment of a national quality assurance structure. This should include setting specific standards for ongoing training, clinic teaching and administration, and regular audits to monitor these standards.

- 3 Partnership with the government health service This will provide funding, an opportunity to contribute to the health needs of all the population, and a recognition of NFP as an option in the range of family planning services
- 4 Cooperation with other family planning and health providers This will ensure that NFP is part of mainstream family planning and reproductive health services

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## **Gender, sexuality and communication issues that constitute barriers to the use of natural family planning and other fertility awareness-based methods**

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### **Abstract**

Fertility awareness-based methods of family planning are rarely offered through reproductive health services in Latin America, despite evidence that many women use them. Providers state that clients do not want these methods, but provider bias is evident. Providers overestimate the difficulty of learning and using fertility awareness-based methods, and they underestimate their efficacy. Both providers and clients have difficulty dealing with sexuality (which is central to fertility awareness-based methods). Many providers lack gender sensitivity, 'worsening' the unequal relationship between providers and clients. Experience has shown that when fertility awareness-based methods are well provided, they can have a positive effect on sexuality, self-understanding, and equality in the couple's relationship.

### **Introduction**

Data on contraceptive prevalence in Latin America show that in many countries the prevalence of use of family planning methods based on fertility awareness is higher than those of some of the so-called modern methods. For example, the most recent Demographic and Health Survey (DHS) [1] in Brazil shows that the prevalence of the rhythm method is 2.1% per 100 married or in union women who are fertile and 2.0% are using withdrawal, compared to 0.8% using IUDs, 1.1% using injectables. In the age bracket 25-29, when the fertility is very high, 3.9% of the women use the rhythm method and the prevalence of IUDs is 1.3% (DHS, 1996). Other countries in the region present an even higher prevalence of methods based on fertility awareness.

In addition, studies of contraceptive use by adolescents and young adults who are

beginning sexual activity show that more than half of young people initiate sexual activity without using contraception and more than half of those who use some method rely on rhythm, usually without being educated about its use [2] On the other hand, the statistics of the reproductive health/family planning services indicate that traditional and fertility awareness-based methods are not being used or are being used at a frequency far lower than that of IUDs or injectables

Most providers, when asked the reason for the lack of use of these methods in the clinics, answer that these methods are not chosen by women/couples even when they are offered in a context of real free choice among all other options available

These data raise the question "Are these methods really offered in a context of free option and not accepted by the users, or are they simply not offered adequately in the health services?"

To answer this question, it is helpful to review the experience of groups working with religious institutions to promote the use of fertility awareness-based methods, mainly the Billings method. Most of the institutions have shown that these methods, when offered with adequate information and counseling, are well accepted by a significant proportion of the population and that when they are used correctly have an effectiveness comparable with those of some modern methods [3]

These experiences, which are not unique to Latin America, suggest that the very low acceptance of these methods in services is mainly due to the fact that users do not have the opportunity of choosing them in a context of real free choice because the methods are not adequately offered. Further analysis of this situation is needed

### *Analysis*

Providers state that fertility awareness-based methods are not accepted by women/couples even when offered in a context of true free choice for the following reasons

- It is not easy to follow the directions and follow the rules
- Successful use requires the collaboration of partners who usually are not willing to participate in family planning
- It is difficult to accept abstinence (mainly by male partners)
- These methods have very low efficacy

Institutions that promote these methods and give adequate information on how to use them have reported very good results with the use of the rhythm method and the Billings method. On the other hand, in public sector family planning clinics, the time for counseling is very short, so women really do not understand properly the characteristics of the methods and do not learn how to use them. In addition, the lack of previous sexual education of the potential users and the lack of this service in the clinics make it difficult for women to accept methods that require some control of sexual activity

The lack of participation of men in family planning always has been considered an important barrier to the use of fertility awareness-based methods. Men usually do not participate in the choice of methods, and consequently it is difficult to obtain their collaboration for the use of these methods. However, this lack of participation resides more in the characteristics of services than in men's unwillingness to participate. Most family planning services are part of women's health services, where men do not feel comfortable because a specific space for them is not available and providers are not skilled in working with men. A few experiences in Latin America, i.e. Propater in Brazil and Profamilia in Colombia, have shown that when services encourage men's participation, the response of men is very positive.

Women's concern that their partners will not accept abstinence in the fertile period is strongly influenced by the providers' belief that sex is only sexual intercourse with penetration. Abstinence is presented in a negative way, as a period when sex should be avoided, instead of explaining that abstinence means to only avoid penetration with vaginal ejaculation, but that sexuality can be expressed in other ways such as caressing without intercourse or mutual masturbation during the abstinence period. The open discussion of these alternative practices may increase the acceptance of abstaining from sex with penetration.

Another problem in the acceptance of these methods is that they are perceived by potential users as having a very low effectiveness, a perception that is reinforced by providers. Certainly, effectiveness is one of the characteristics that women take into account in choosing a method, but it is not the most important for all women. Furthermore, when these methods are practised correctly and consistently, they are very effective.

Women should have the right to make a free choice based on a complete knowledge of all the characteristics of the method. Experience in clinics and some users' perspective studies have shown that safety is very important for many women in choosing their family planning method, with the possible side-effects and mode of use being as important as effectiveness.

The insistence on offering only highly effective methods means that very few providers offer fertility awareness-based methods. However, women using methods that are not their first choice or without being adequately counseled may also have a high rate of failures, as is shown by the high failure rates of the pill in routine use in Latin America.

Even LAM, which has proven to be highly effective in the first six months post-partum when correctly used, is not offered because most providers incorrectly think that this method has a very low effectiveness. The following example illustrates the difficulty of convincing providers of the efficacy of LAM.

In a training session which reviewed all family planning methods, all the trainees were surprised to learn that LAM is highly effective during the first six months after delivery. After the discussion, they theoretically accepted that LAM should be included as a valid option in the post-partum period. During a role play exercise, one of the trainees was not able to accept that a woman who had had four children had chosen LAM and tried hard to change her decision to a "more effective method". This situation illustrates how difficult it is to put into practice new knowledge that is

not consistent with previous knowledge and prejudices

This example illustrates another barrier to adequate service provision the providers' paternalistic attitude related to choice of methods. Providers have been trained to decide for their "patients." Commonly, a woman comes to a physician with an illness, expecting to be healthy, putting the power of decisions in the physician's hands. Women, who historically have not had power to decide about issues related to their own bodies, have not been able to assume the responsibility of taking care of their own health. Despite intensive training programs undertaken in Latin America, providers still feel that they have the responsibility of choosing the best method for the woman instead of giving the responsibility to women and helping them make their own appropriate choice. Because providers think that effectiveness is the most important characteristic of a method and the responsibility of choice is in their hands, it is easy to understand that providers choose for women methods the providers perceive to be effective.

These factors create structural barriers to services. How sexuality is seen by providers also interferes with the use of these methods.

To perform a complete analysis of the process of decision-making in reproductive health, it would be necessary to do a historical review of the construction of sexuality and gender identity in society and how this identity affects women's lives and reproductive decisions. Such a review exceeds the objectives of this paper. A more practical and objective analysis is presented that identifies the main factors influencing the acceptability and use of these methods in family planning services, focusing on issues related to sexuality, gender, and communication.

For a woman to make an adequate informed choice of family planning method, particularly if she is choosing a fertility awareness-based method, she needs to have some knowledge and skills that include, among others

- Knowledge of her own body and how it functions
- A good relation with her own body, free of fears and shame
- A realization that her body belongs to her and that she has the power over her body
- The power to make decisions about sexuality, (e.g. the woman should be able to accept or refuse sexual intercourse according to her needs, such as when she is fertile and thus at risk of getting pregnant)
- The skills and the power to talk with her partner about her body, her fertility, sexual intercourse, feelings and desires, thus contributing to a more equitable relationship
- The power to discuss with her partner the concept that family planning is a right and a responsibility of both the man and the woman
- Updated, unbiased and prejudice-free information about sexuality, reproduction and family planning methods

### Current situation

What is presently available to women in the region?

In the most qualified services, information is given through lectures where anatomy and physiology of reproduction are explained and contraceptive methods are described. In general, this information is given without taking into account that reproduction is closely linked to sex. The body is presented as a non-sexual entity. Only biological aspects are considered, without taking into account their interrelationship with sexuality and other socio-cultural issues. This is illustrated by the fact that in most clinics, the information about family planning is given without mentioning the word sex.

Even recognizing the enormous technological advances in reproductive health, cultural influences still tend to dissociate reproduction from sexuality, omitting the concept of well-being and pleasure that is inherent in sex.

In provider/client interactions, counseling or consultation, usually the relationship is not balanced. The provider has power conferred by knowledge and professional status and the information received by the woman is limited by this unequalitarian relationship. The provider is authoritarian and the client submits to this authority. This is more evident when the provider is a physician. The relation is still more conflictive when providers impose values that are not necessarily the same as the users' values.

Language is another factor that impairs communication and contributes to the imbalance in the provider/client interaction. Technical language used by the providers may not be understood by the users, contributing to inequality in the relationship and giving the provider power of decisions in matters related to sexuality.

Despite the transformations and profound changes in life styles and values that have occurred in the last few decades, many people still have a great deal of difficulty dealing with matters related to sex. The prevailing socio-cultural model greatly influences the construction of sexual and gender roles and how sexuality is lived and perceived. In general, health services work with a concept of reproductive health that gives priority to biological aspects, omitting or devaluing socio-cultural aspects.

Returning to the list of conditions necessary for women to choose and use fertility awareness-based family planning methods properly, it is easy to see that services are far from offering clients an orientation that takes into account issues of sexuality and gender and that communication skills also are not adequate. This probably is due to the fact that providers have great difficulty dealing with these issues also, just as their clients do, and did not receive adequate training to deal with these issues. In addition, they are part of the same culture that, on one side encourages people to think erotically about the body but, on the other side, is repressive and controlling, emphasizing norms and reinforcing taboos. In other words, health professionals may help to maintain the situation, but they also are victims of the system that impedes their becoming agents of change.

The principal impact of taboos is that they are greatly responsible for the maintenance of a state of lack of information, contributing to continued feelings of

anxiety and blame that sexual issues evoke Negative feelings – blame, shame, anxiety, fear – are the consequences of the meaning of sexuality that has been transmitted from generation to generation, where sex is seen only as the instrument of reproduction and accepted only in heterosexual relations within marriage This concept of sexuality has a very negative influence in the way sexuality is perceived and lived

A study in Mexico [4] on the meaning of sexuality through three generations of women showed that changes, when they occur, include advances and recessions, showing that the process of change is neither sequential nor continuous In the first generation (grandmothers), the family, school and church give the support for the transmission of knowledge of sexuality to the next generation, strongly maintaining the beliefs and practices prevailing in that time, having mostly a religious orientation

From the second to the third generation (mothers to daughters), information is influenced by other factors because a lot of new sources of information are now available, such as radio, television, cinema, and written information on family planning Women began to participate more in remunerated work and to be more affected by external influences through travel and other interactions All these influences, including the wider dissemination of pornography, made possible the construction of other meanings for sexuality Daughters perceived sexuality as an experience not exclusively related to reproduction and accepted desire and pleasure as components of sexuality Still, the central attitude that went through the three generations was the religious position that accepts sexuality only when legitimized by marriage [4] Despite all the changes in the way sexuality is currently understood, moral and religious censure greatly affects the way sexuality is lived

## Discussion

It is important to consider the role of family planning services in overcoming the barriers to providing fertility awareness-based methods

The current concept of family planning including reproductive health and rights demands the inclusion of sex education among its activities The main objective of sex education is to open a space for thinking about, and discussion of attitudes, roles, beliefs, values, behaviors, practices, and taboos about sexuality taking into account the person's physiologic, sociologic, psychologic and spiritual dimensions

Within this context, family planning can open possibilities not only to control the number of children a couple has but also to reconstruct the meaning of sexuality, from a repressive and blameful one to a healthier sexuality perceived and lived with pleasure In addition, a healthy sexuality may contribute to reconstructing gender roles and decreasing the power imbalance between men and women

It can also encourage individuals, mainly women, to have a better knowledge of their bodies and a better perception and consciousness of their own sexuality, allowing them to enjoy intimacy without fear, blame or shame It can also help people to reevaluate their emotional world, including the expression of tenderness and love, sharing the responsibility with their partners

Better and healthier sexuality may also help to make more effective the learning process of how to avoid an unwanted pregnancy through a better understanding of all family planning methods and their interaction with sexuality, allowing a real free informed choice of the best option. Women living a healthy sexual life have greater possibilities of using fertility awareness-based methods successfully.

It is clear that fertility awareness-based methods are fundamental for promoting a better knowledge of the person's own body and of the physiology of sex and reproduction, and it can contribute to women's empowerment and family well-being.

Experiences with community groups have shown that it is possible to improve women's knowledge about sexuality, that women/couples can use successfully the fertility awareness-based methods, and that better knowledge of sexuality brings important benefits for the woman and the couple. However, most of these experiences are with religious groups linked to the Catholic Church. As a result, the participation of people who are not religiously-motivated to use these methods is limited. The link with the church creates suspicion that they are only a way of religious proselytism and that they are not real methods.

The greatest challenge is to incorporate and add these methods to the available options in reproductive health services. The addition of these methods may bring important benefits to women, not only as a family planning method but also in their sexual and general well-being.

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## VIII. Reproductive health awareness

**What is Reproductive Health Awareness? How can it contribute to improving reproductive health and increasing appropriate use of services?**

*Chair* Victoria Jennings, Ph D

*Discussant* Lindsay Stewart, M P P H, Deputy Director/ Focus Project

*Consensus* Reproductive Health Awareness is an educational approach which helps people learn to observe and understand their own bodies and integrates gender awareness, interpersonal communications, and sexuality

Reproductive Health Awareness can improve the health of individuals and increase the appropriate use of services by improving self-knowledge of what is normal, early recognition and self-referral for abnormal findings, improved knowledge of what resources are available, and improved ability for self-advocacy with partners, providers and others. This participatory approach also has the potential to empower groups of individuals as well as the community to address critical health concerns.

Reproductive Health Awareness can be implemented through a variety of mechanisms including health facilities, educational systems, community services, and organizations.

*Presenters*

Margaret Marshall, C N M , Ed D , Georgetown University, USA

**Reproductive health awareness an integrated approach to obtaining a high quality of health**

Kimberly Aumack-Yee, M A , Georgetown University (consultant), USA

**Body/self awareness and interpersonal communications fundamental components of reproductive health awareness**

Zoe Kopp, M A , USA

**The potential contribution of sexuality and gender awareness**

Cecilia Pyper, M D , B S , L R C P , University of Oxford, UK

**Reproductive health awareness an important dimension to be integrated into existing sexual and reproductive health programs**

Anne Wilson, PATH, Washington, DC, USA

**The reproductive health awareness model a qualitative perspective**

## **Reproductive health awareness: an integrated approach to obtaining a high quality of health**

**M MARSHALL, V JENNINGS and J CACHAN**

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### **Abstract**

The Georgetown University Institute for Reproductive Health has evolved a multi-dimensional approach to reproductive health education which has grown from their work in natural family planning and fertility awareness. This cohesive approach offers help to community, educational, and health organizations in providing knowledge and skills development in body/self-care, gender awareness, sexuality, and interpersonal communications.

### **Introduction**

Health is "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." This World Health Organization definition years ago helped to broaden our view of health care as not being a narrow institution-based, health professional-led, authoritarian model of care. Increasingly the patient has moved from being a passive participant of care to a client or consumer of care who weighs alternatives, seeks second opinions, and assumes responsibility for prevention through self-examination, diet, exercise, early treatment, and accident prevention measures.

Though health education has become increasingly available through schools, community groups, mass media, the Internet, and other sources, many people still do not have access to the high quality reproductive health information needed throughout the life cycle to permit them optimum health, relaxed enjoyment of their sexuality, and an understanding of how cultural values may impede their full self-determination regarding reproductive and sexual issues.

Fathallah has developed the following definition of reproductive health:

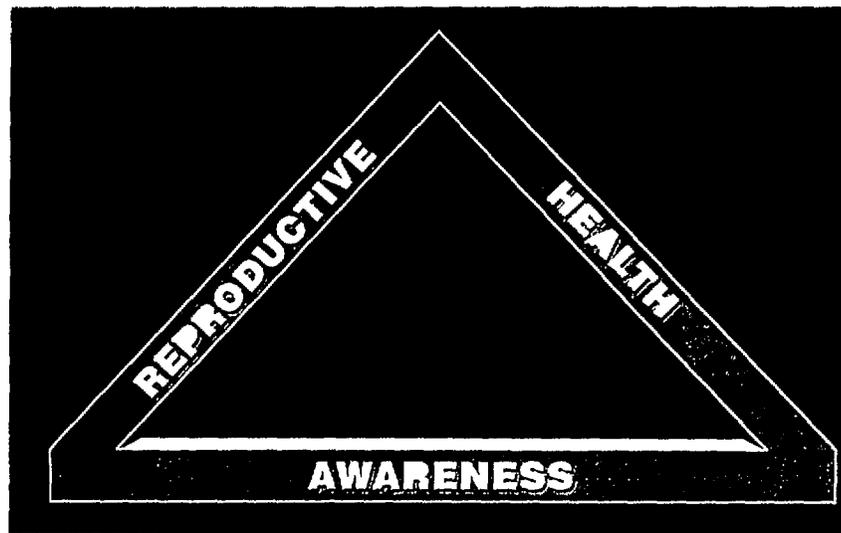
- people have the ability to reproduce and regulate their fertility,
- women are able to go through pregnancy and childbirth safely,
- the outcome of pregnancy is successful in terms of maternal and infant survival and well being, and
- couples are able to have sexual relations free of the fear of pregnancy and of contracting disease (Fathallah, 1988)

This definition, though a big step forward, does not encompass all the elements of reproductive health awareness (RHA)

#### **Definition of reproductive health awareness**

Reproductive health awareness is an educational approach that is designed to help people learn to observe their own bodies, understand its normal changes, and know what is healthy and typical for them. It also helps them think about and understand socio-cultural factors including gender issues that influence their reproductive health, to communicate appropriately with partners, health care providers, their children and parents, and others about reproductive health concerns, and to make decisions that can have a positive effect on their reproductive health.

Through RHA, people can learn to appreciate the regular functioning of their own bodies and reproductive systems, and use self-observation and their understanding of reproductive health to choose healthy behaviors, be advocates for themselves, seek medical attention when needed, and communicate appropriately with health care providers. Since people with RHA also understand what is normal for both men and women at different ages, they can actively participate in maintaining the health of their partners and children.

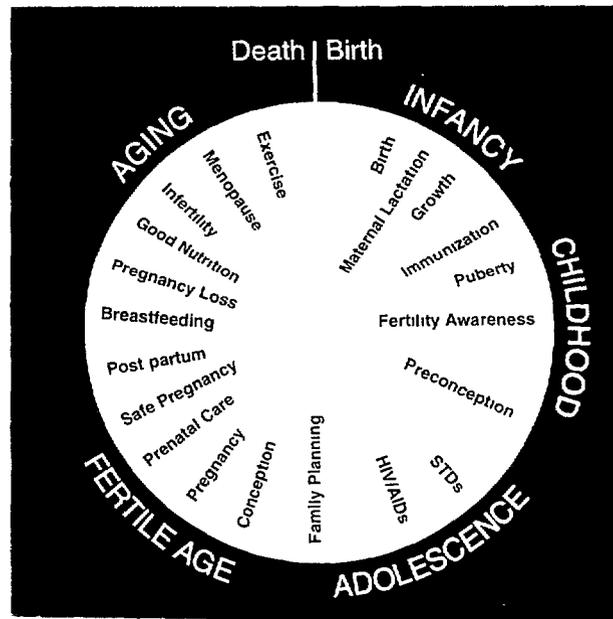


This approach places the emphasis on empowerment, on involving both women and men in reproductive health issues, on the role of the family and community in equitably allocating health resources and being responsible for actively participating in their own health care. These emphases are encouraged by the mandate of the recent United Nations conferences in Cairo and Beijing and meetings of other groups in which governments and NGOs have been charged with addressing these issues.

The RHA approach can be taught through community, educational, and health groups. No one group has the time, access, talent, or resources to teach all people all they need to know for a lifetime of health learning. It is an approach that can be integrated into ongoing programs, and coordinated with other community programs with complimentary interests.

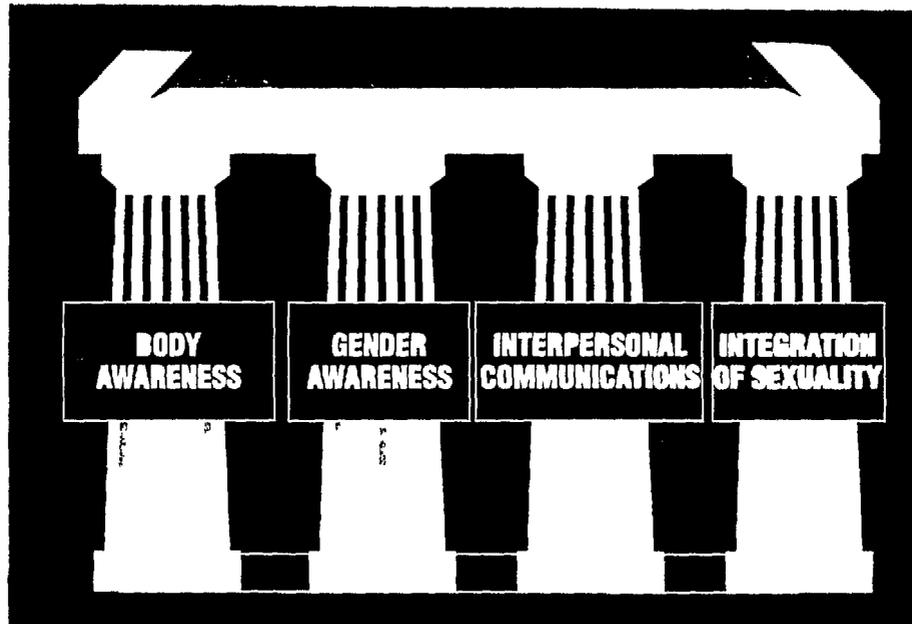
**Life cycle approach**

RHA deals with the life cycle from birth until death. It provides parents with the information they need to know in dealing with their own children on topics as diverse as care of newborns, giving factually correct information on anatomy and sexuality issues, and preparing boys and girls for puberty. It likewise provides adolescents and adults with the information and skills to actively shape their own reproductive health destiny in a manner which brings self-esteem, satisfaction with timing and spacing of children if desired, self and partner protection from disease, joyous expression of their own sexuality, and knowledge of normal body changes over time. Likewise the aging adult can learn about normal aging changes (e.g. menopause, andropause), recognize disease early, seek help for conditions such as incontinence and impotence without embarrassment, and creatively express sexuality throughout their lives.



### The pillars underlying reproductive health awareness

The RHA approach is based on four foundational supports, or pillars. Each pillar that supports RHA is crucial on its own, but only when the pillars are combined is the RHA program strongest and most effective.



#### Body/self awareness

Body/self awareness is how we learn to care for and respect our bodies. What and how we learn about body awareness colors our self-esteem, our views of how to treat the body, and how we view sexuality. Learning normal growth and development (maturation of the body, fertility awareness, signs of disease), preventative health practices (immunizations, low fat diet, routine testicular and breast examinations), and avoidance of high risk behaviors (smoking, unprotected intercourse), equips us with information which can change the course of our lives.

#### Gender awareness

Gender awareness requires looking at ourselves through the filter of our own culture. We learn how women and men are valued, whether or not gender-based violence is tolerated by the culture, and what practices are unfair, dangerous, or limiting (distribution of health resources, legislation protecting women and children).

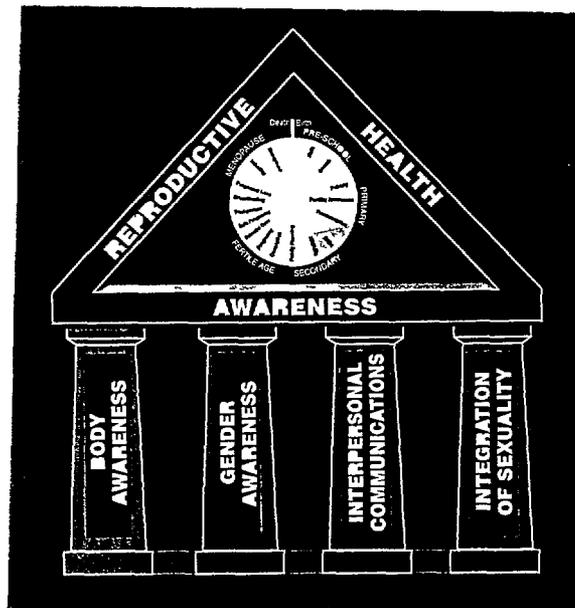
### Integration of sexuality

Although what we learn about sexuality differs at various ages, at every age we should hear positive messages and learn respect for the powerful and beautiful ability to express ourselves through our sexuality. It is important that as individuals we establish our own safe and healthy sexual norms, understand the norms of our society, and work to eliminate behavior that is violent and unsafe, making society safer for all.

### Interpersonal communications

The ability to speak openly with our partners, children, parents, and peers profoundly affects our relationships with people. We need to be able to communicate without embarrassment to health providers, negotiate sexual behaviors with partners, teach children with respect, correct information, and wisdom, and handle verbal conflict in a way that prevents escalation to violent behavior. We need to have the words and skills to communicate our joys and frustrations to those who share our space and lives.

### Why an integrated approach? What are the goals?



The goals of the reproductive health awareness approach are

- To empower people to understand and take action to meet their own reproductive health care needs
- To assist communities in understanding and achieving the benefits of high quality, accessible reproductive health care and information that meet the needs of community members
- To facilitate the incorporation of body awareness, sexuality, interpersonal communication and gender into reproductive health programs
- To incorporate positive cultural beliefs and healthy practices into the teaching and understanding of reproductive health

The reproductive health awareness approach has been integrated into ongoing programs through self-analysis and strengthening or integrating new components into community programs, educational programs, and health services. These programs are discussed further under "Integrating the reproductive health awareness approach into reproductive health programs" by Cachan and Marshall. As we examine how to better serve our families and communities, the RHA approach contributes to informed, positive, skilled, and highly functional healthy individuals.

# Body/self awareness and interpersonal communications: fundamental components of reproductive health awareness

K AUMACK-YEE

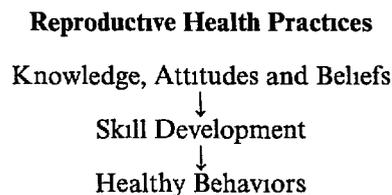
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## Abstract

To protect and advocate for their own reproductive health, people of all ages can greatly benefit from enhanced body/self awareness and strong interpersonal communication skills. Body/self awareness and interpersonal communications, along with gender awareness and the integration of sexuality, are the fundamental components of a new approach to obtaining high quality health called reproductive health awareness.

## Introduction

For people to make a change, or maintain a behavior that leads to a healthier life, they need more than just increased information about health care practices. They need to believe that the 'healthy' behavior is relevant and important to them, and that they can actually achieve it [1]. They also need to have the skills necessary to take action and incorporate this behavior into their daily lives. Before someone is able to actually quit smoking or use condoms on a consistent basis, the person typically goes through a process of change which includes the following stages: precontemplation, contemplation, preparation for action, maintenance and termination [2]. At every stage of the change process, people need to acquire the knowledge, attitudes, beliefs and skills necessary for the new behavior to be adopted and maintained.



The challenge to grow and change in ways that improve reproductive health is relevant to people of all ages. For example, a teenager decides to postpone sexual involvement and is able to resist peer pressure to have sex. A pregnant woman avoids drugs or medications which could harm her fetus. A young man checks his testicles each month for lumps or changes. The potential for developing these and other skills which lead to healthy behaviors can be greatly enhanced when individuals have a heightened awareness of themselves and their bodies, as well as strong interpersonal communication skills.

### **Potential benefits of body/self awareness**

#### **Body/self awareness leads to**

- Prevention practices
- Self-observation
- Early detection
- Self-referral for services

Body/self awareness is a fundamental component of the reproductive health awareness approach to education and service delivery. This component complements the typical information on growth and development, body functioning and hygiene that is taught in a variety of programs. Body/self awareness goes beyond presenting reproductive anatomy and physiology, to personalizing health information in ways that directly apply to an individual's everyday life and protect his/her reproductive health. As people develop body/self awareness they continue to learn more about their own bodies and how their bodies work throughout the various stages of their lives. They also learn about the reproductive system of the opposite sex, and how people can impact overall health through either disease transmission or preventive health practices. In addition to increasing knowledge about one's own body, there is a focus on raising awareness, exploring attitudes, and developing skills and behaviors that promote health (e.g. balanced diet or exercise) as well as developing skills to avoid behavior that can cause harm (e.g. unsafe sex, poor hygiene or substance abuse).

Enhanced body/self awareness enables individuals to better recognize what is normal and healthy for them by building on what they already know and observe about their bodies. Then, as people become comfortable with the idea of actively observing their bodies more closely, they can begin to practice specific techniques of self-observation and health monitoring on a regular basis. A few examples of these techniques include breast self-examination, testicular self-examination, checking the skin for changes or monitoring vaginal secretions during the menstrual cycle. Self-observation of the body can lead to early detection of a health problem and realization of the need to be checked by a health care provider. With early detection

and self-referral to appropriate services, body/self awareness can contribute to a person's ability to receive timely treatment for a health problem, and often much improved health outcomes. Through monitoring of the menstrual cycle, women and their partners are empowered to control their fertility through self-knowledge.

Body/self awareness assists people in a lifelong process of self-reflection and change toward healthier lives by fostering appreciation and value of one's own body and by developing skills to protect reproductive health.

### **Interpersonal communications – advocating for reproductive health**

Interpersonal communication is a key to good reproductive health. However, there are few opportunities to learn and practice the interpersonal communication skills that can enable them to become better advocates for their own reproductive health and negotiate healthy practices.

In many contexts, conversation about sex and sexuality is taboo. For religious, cultural and personal reasons many individuals feel uncomfortable or are un-equipped to talk with partners, family members, friends or health providers about reproductive health topics that directly affect their lives. For example, a woman leaving a family planning clinic with a bag of condoms may not feel ready, or able, to talk with her partner about using them.

The way people communicate greatly affects their relationships with children, partners, parents, friends, teachers, health providers and others. It can be challenging, and often very difficult, to share one's desires and beliefs about sex, intimacy and related health practices. When communication breaks down within families, or between providers and the individuals they serve, opportunities to protect and improve health are quickly lost. A pregnant teenager leaves home because her parents would 'kill' her if they knew she was having sex. A young man with a sexually transmitted disease (STD) finds it too difficult to tell his partner. A child fears puberty. An older man feels there are no remedies for improving sexual performance. An abused wife remains silent.

Integrating a component on interpersonal communications can help address these and other reproductive health issues. Since communication styles are strongly influenced by cultural and individual values and perceptions, skill development in interpersonal communications should reflect culturally appropriate norms and respect the unique differences of individuals [3]. Examples of topics that may be addressed include techniques for enhanced communication like active listening or eliciting feedback, models for negotiation and conflict resolution, ways to defuse a discussion before it escalates toward verbal abuse or potential violence, and opportunities to practice how one might speak with a partner or parent about a reproductive health issue such as a positive pregnancy test or STD diagnosis. By increasing opportunities to discuss and practice interpersonal communication skills, individuals can become better prepared to choose words and use effective nonverbal messages to express themselves openly, in ways that others can understand and respect.

**Table 1 Ideas for integrating reproductive health awareness concepts into programs**

	<i>Body/self awareness</i>	<i>Interpersonal communications</i>
Primary and secondary education youth	<ul style="list-style-type: none"> <li>- Teach ways to respect and care for the body (tooth brushing bathing etc)</li> <li>- Model appropriate hand washing and other health behaviors</li> <li>- Teach how to avoid injury and harm to the body</li> </ul>	<ul style="list-style-type: none"> <li>- Encourage development of self esteem</li> <li>- Talk about roles played by boys and girls on the playground and in the culture</li> <li>- Practice what to do and say if someone tries to touch private parts of the body</li> </ul>
Adolescents	<ul style="list-style-type: none"> <li>- Teach changes of puberty that adolescents may notice</li> <li>- Show girls ways to observe and note patterns of changes in their bodies related to their menstrual cycles</li> <li>- Assess cultural adornment practices of youth (lip stretching teeth filing body piercing tattooing etc) in the context of body awareness and appreciation</li> </ul>	<ul style="list-style-type: none"> <li>- Assist youth in learning assertive communication skills for responding to pressures to engage in harmful or risky behaviors</li> <li>- Discuss how media and culture influence values and choices about reproductive health</li> <li>- Talk about individual sexual rights and explore personal and familial beliefs about acceptable standards of sexual expression</li> </ul>
Fertile years	<ul style="list-style-type: none"> <li>- Teach couples how to observe and monitor their fertility</li> <li>- Distribute pamphlets which describe how to do a breast self examination and testicular self examination</li> <li>- Hang posters on the wall to promote pregnancy testing and early prenatal care</li> </ul>	<ul style="list-style-type: none"> <li>- Role play what someone might say to their partner regarding the desire to use condoms</li> <li>- Provide information and opportunities for practicing creative negotiation and conflict resolution techniques</li> <li>- Conduct parenting and child rearing classes which address parent/child communication issues</li> </ul>
Aging adults	<ul style="list-style-type: none"> <li>- Show how aging may affect the body and possible options for dealing with these changes</li> <li>- Explore avenues for support of those unable to care for themselves as before</li> <li>- Develop referral lists to assist those in need of accessing other services</li> </ul>	<ul style="list-style-type: none"> <li>- Discuss ways of dealing with sexual concerns such as change in libido decreased lubrication or erectile problems</li> <li>- Talk about changing roles in the family and impact on one's sense of self</li> <li>- Discuss experiences with interpersonal communication over the years</li> </ul>

Providers of community, educational and health services can also benefit from enhancing their interpersonal communication skills. By assessing and strengthening their own skills, providers can better engage the individuals they serve in meaningful conversation and assist them in finding their own ways to improve interpersonal communications with others. Providers can also practice how to ask sensitive questions such as those which help determine whether a person is engaged in a risky health behavior and if so to what extent [4,5]. With this information the provider

can then tailor education and counseling to address the individual's specific needs, taking into account the particular stage of behavior change the person might be in with regard to achieving healthy behaviors [6]. For example, if a woman has not thought about or does not recognize the risk smoking poses to her health, she can be given information to raise her awareness and be encouraged to consider giving up smoking. However, if she has recently stopped smoking, the provider can help her maintain the healthy behavior by discussing ways to reward herself for not smoking and how to avoid temptation to smoke in the future.

Programs which incorporate culturally appropriate ways to discuss and negotiate healthy behaviors can improve not only the health of the individuals they serve, but the health of others as well. As a result, enhanced interpersonal communication can become a vehicle through which individuals gain support, counter obstacles and implement a change toward healthier lives.

### **Ideas for community, educational and health providers**

The reproductive health awareness approach can be integrated into programs in a variety of creative ways. Table 1 provides ideas for incorporating elements of body/self awareness and interpersonal communications into existing programs for people of all ages.

By developing body/self awareness people can become more actively involved in their own health care. With strong interpersonal communication skills they have the tools to express their personal attitudes and beliefs about sexual and reproductive health, as well as to become advocates for and to negotiate behaviors that can keep them healthy. Body/self awareness and interpersonal communication are two of the four fundamental components of the reproductive health awareness approach. These components, along with the integration of sexuality and gender awareness, complement community, educational and health programs by developing skills and supporting behaviors that lead to healthier lives.

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# The potential contribution of sexuality and gender awareness

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## Abstract

To make well-informed decisions about reproductive health, individuals need information about their body, gender and sexuality as well as the communication skills to convey their choices to their family, partners and health care providers. Gender and sexuality are at the core of each individual's identity, understanding and acceptance of these aspects of ourselves is basic to our ability to have healthy relations with self, family and sexual partners. Throughout an individual's life cycle information is needed about gender and sexuality changes according to needs of their age group. A holistic approach to reproductive health is needed, based in the community where people live, in the schools where young people study and in the community health care centers where they receive services.

## Introduction

For individuals, both male and female, to attain their reproductive health goals they require knowledge and understanding of their own and another's sexuality and of gender issues. We begin and end life biologically defined as male or female. We also begin and end life as sensual, sexual beings. From the moment of birth, culture and society, through parents, family and friends begin to form an infant's gender identity (e.g. girls are such quiet babies, boys are full of curiosity). By the time an infant reaches age two her gender identity, how she perceives her own femininity, has been set [1].

Yet most people receive only the most rudimentary information, much of it incorrect, about two subjects which are at the core of their being: gender and sexuality. Most individuals lack information on the true biological differences between males and females, the nature of sexuality and gender. Therefore, parents pass on misinformation to their children that limits the children's potential or freezes them into roles that have negative personal and societal consequences in their lives.

and in their reproductive health. Even more basic than the three 'R's, to maximize one's potential, each individual needs complete and accurate information about gender and sexuality if we are ever going to make progress in our campaigns to empower women, lessen domestic and sexual violence, prevent unwanted pregnancies and decrease sexually transmitted diseases.

### **The role of sexuality awareness in reproductive health**

Despite the omnipresence of sexual themes in our cultures and in our daily lives and the inescapability of the fact that none of us would be here if our mothers and fathers had not had sex, mention of 'sex' has been missing from international family planning and reproductive health programs since their inception. Though a variety of political and religious reasons are given for this absence, an underlying reason for this is that reproductive health policy makers, program managers and providers are affected by the social taboos that surround sex and often perpetuate them. Sex and sexuality are areas in which irrationality, fear, confusion and misinformation thrive at great individual and societal cost. Sex is not synonymous with genital intercourse. Sex is the biological distinction of being male or female. We are born of one sex or another. We are also born sensual beings with sexual desires. Male infants commonly have erections, female infants experience vaginal lubrication and both can and do have orgasms. From a young age we have thoughts and feelings about sexuality and sexual acts whether or not we choose to explore our sexuality. Providing accurate information about sex and sexuality to individuals, communities and to health workers help to empower people to make their own decisions in the context of their relationships, beliefs, values and cultures.

A reproductive health curriculum that educates girls and boys, women and men about sexual development, sexual identity and sexual processes can help to end the silence about sex and sexuality which has resulted on an individual level in needless ignorance, shame and embarrassment about normal healthy bodily processes and on a societal level in epidemics of unplanned pregnancies and STDs. A comprehensive reproductive health curriculum can also help to identify problems, like sexual dysfunctions and encourage individuals to seek help. Individuals who are secure in their sexual identity and understand their sexuality are better equipped to make choices about when and with whom to have, or not have, sexual relations, when to seek services, and, consequently, enjoy improved reproductive health.

### **The role of gender awareness in reproductive health**

Until recently, gender considerations have been conspicuously absent in most reproductive health programs, and the consequences of this omission are being felt daily. HIV/STD prevention and family planning programs are struggling with a number of gender related issues. Not fully understanding or incorporating knowledge of the gender issues regarding sexual relations has impeded the full success of

programs Reproductive health programs now realize that the message of just saying 'no' to sex, or sex without a condom, is not a useful one to millions of women who are powerless to say no without suffering emotional and/or physical abuse or financial consequences Violence against women has largely been ignored as a woman's reproductive health issue, yet the abuse of women – emotionally, physically and sexually – by men has significant consequences for women's health and women's reproductive health [2] Family planning programs recognize that they have been hampered by a method mix heavily tilted towards women, as well as informational programs and a clinical infrastructure focused on women that did not fully take into account the responsibility and decision making role of males related to sexual relations and family size

To address gender related issues, educational interventions are needed which reach out beyond the doors of our clinics to males and females of all ages, not just to women of reproductive age Georgetown University's reproductive health approach can help educate males about how to be responsible partners in reproductive health Males who have information about reproductive health, as many studies have shown, are more likely to take a more active, supportive role in contraception and STD prevention [3]

### **Sexuality and gender awareness as components of a reproductive health approach**

Georgetown's reproductive health awareness approach incorporates gender and sexuality information and awareness as well as self care/body awareness and interpersonal communication skills into a comprehensive approach Without each of the four components/pillars to support reproductive health awareness, programmatic success will be weakened

Gender and sexuality awareness learning are lifelong processes, a single educational intervention at one stage of life is not sufficient In Table 1 several of the gender and sexuality awareness issues that apply to different stages of the life cycle are identified Learning about and being empowered to act upon the complex information needed to make well-informed reproductive health choices requires time, a participatory learning style and multiple approaches

### **Quality of care**

As international programs strive to improve the quality of services we are coming to realize the limitations of what quantity of information can effectively be transferred during client-provider interactions and the need to avoid information overload [4] A multi-dimensional reproductive health awareness approach can strengthen clinical programs and help to improve the quality of care by better preparing clients before they arrive at the clinic The approach can be used to educate staff who have not been trained in comprehensive reproductive health programs The approach taken by Georgetown University's Institute of Reproductive Health to integrate participatory

**Table 1 Sample gender and sexuality awareness topics throughout the life cycle**

<i>Age group</i>	<i>Gender awareness</i>	<i>Sexuality awareness</i>
Pre school	<ul style="list-style-type: none"> <li>– Girls and boys need the same amount of food love and attention</li> </ul>	<ul style="list-style-type: none"> <li>– Babies love to explore their new bodies and touch themselves everywhere including their genitals This is normal and they should not be punished for touching themselves</li> </ul>
Primary	<ul style="list-style-type: none"> <li>– Girls and boys need to be equally encouraged in educational and physical activities</li> <li>– Respectful treatment of people regardless of gender</li> </ul>	<ul style="list-style-type: none"> <li>– Difference between male and female bodies is noticed and interest in pregnancy and childbirth increases Children need simple truthful explanations</li> <li>– Autoeroticism increases and is normal</li> </ul>
Secondary	<ul style="list-style-type: none"> <li>– Information on the different roles females and males have in their culture and in other cultures</li> <li>– Every woman has the right to be free of gender violence</li> </ul>	<ul style="list-style-type: none"> <li>– Insecurity around bodily changes Adolescents need reassurance they are normal and that they look good</li> <li>– Hormonal changes lead to sexual desires and sexual reactions (wet dreams etc )</li> <li>– Roles and responsibilities in sexual relationships in their culture</li> </ul>
Fertile age	<ul style="list-style-type: none"> <li>– Awareness that males and females have comparable capabilities</li> <li>– An individual s value to his or her family is not solely related to the ability to have or father children</li> </ul>	<ul style="list-style-type: none"> <li>– Learn to define and accept their own sexuality and accept the differences in others sexuality</li> </ul>
Older adults	<ul style="list-style-type: none"> <li>– Understanding of the importance of workload equity within the family and equitable access to health care resources</li> </ul>	<ul style="list-style-type: none"> <li>– The ability to have and enjoy sex is life long</li> <li>– To safely enjoy sex after menopause many women need additional vaginal lubricant</li> </ul>

reproductive health education programs into clinical programs as well as into the community through a variety of modalities – youth groups, schools, men’s clubs and mother’s groups – can help to address a critical information gap

### **Conclusion**

As we strive to improve the quality of care of reproductive health services, in an effort to enable individuals to realize their reproductive health goals, as well as to address the broader issues of women’s health security, we must look at the limitations of the way we presently work [5] Neither health in general, nor reproductive health

specifically is solely contained within the field of medicine, health is a function of the interaction of several dynamics, including economics, politics and sociocultural factors. Yet the fields of reproductive health, family planning and population have traditionally relied on a medical model approach to address the wider range of health problems. Reproductive health calls for new dynamic approaches which more completely involve health care consumers on their own turf, and in their own terms.

Reproductive health decisions are some of the most important, complicated and difficult choices individuals confront in their life. Expecting individuals to make wise decisions with only some parts of the needed information is unreasonable. Gender and sexuality awareness information is an essential component of any reproductive health education program. If we expect individuals to make informed reproductive health decisions we need to examine the whole scope of the information that is required as well as the frequency, timing and methods of communications that are preferred by individuals throughout their life cycle. The reproductive health awareness approach is a dynamic, flexible approach that fosters active individual participation and can bring us closer to achieving reproductive health program goals.

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## **Reproductive health awareness: an important dimension to be integrated into existing sexual and reproductive health programs**

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### **Abstract**

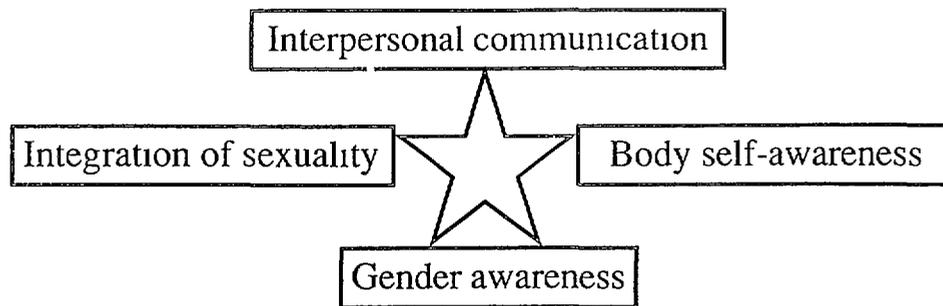
The ultimate goal of any sexual and reproductive health program is to ensure cost effectiveness, quality and sustainability. Reproductive health awareness is an educational approach which is both relevant and sensitive to many communities' existing sexual and reproductive health needs and concerns. When working with community groups, a participatory approach that includes reproductive health awareness concepts is a simple non-threatening way for programs to quickly expand beyond pure information giving and explore what reproductive health means to people. Although many community sexual and reproductive health programs do not use the term reproductive health awareness, they use techniques similar to the reproductive health awareness education approach, when facilitating discussions about sexual or reproductive health. If reproductive health awareness is identified and included as one of the dimensions of future sexual and reproductive health programs, this will hopefully strengthen the program's overall quality and effectiveness.

### **Reproductive health awareness**

Reproductive health awareness is an educational approach that is more than just promoting an understanding about how the reproductive parts of the body work. Reproductive health awareness promotes a more personal involvement by encouraging individuals to observe changes that occur in their own bodies. This involves both observing changes that are related to significant reproductive events, for example puberty, menstruation, pregnancy, breastfeeding or the menopause, it also involves observing more general changes, for example changes in relationships or feelings and in the ways people communicate. The reproductive health awareness education approach encourages discussions about what are normal sexual or reproductive changes or practices.

During discussions people identify 'the fact that individuals' experiences vary and recognize that there is a wide range of normal variation. An obvious example is the variation in the ages that children reach puberty, the size of breasts or testicles, or the length of menstruation. This information is a great relief for those people who consider themselves freaks because their own breasts or testicles differ from those of their friends. Relief is also felt by adolescents and women who thought their physiological vaginal discharge was a sexually transmitted disease.

Reproductive health awareness discussions also explore the range of normal variations in relationships, sexual practices, sexual feelings and gender preference. Although these vary from community to community, within each community people are encouraged to recognize that outside the normal variation of behavior, there are unhealthy sexual practices and ways in which people are exploited. In summary the dimensions included in reproductive health awareness are interpersonal communication, body self-awareness, gender awareness and integration of sexuality (Figure 1).



**Figure 1** The dimensions that contribute to a comprehensive sexual and reproductive health program (Adapted from Reproductive Health Awareness Institute for Reproductive Health)

### **Reproductive health awareness education approach alerts people to recognize when they have a sexual or reproductive health problem**

Having identified what is within the normal range, it is easier to alert people to notice any signs or symptoms that indicate a health problem and to seek appropriate health care early. For example, if men are encouraged to examine their testicles and become aware about what is normal for them, they are more likely to detect abnormal swellings of the testicles at an early stage. Women are encouraged to notice the difference between cyclical breast changes and abnormal lumps in the breast, or the difference between a normal physiological vaginal discharge and an abnormal discharge that may indicate a sexually transmitted disease (Table 1).

When people have a clear understanding about normal and abnormal signs and symptoms, they are in a stronger position to make informed choices about how to

**Table 1 Normal and abnormal variations**

	<i>Normal</i>	<i>Abnormal</i>
Anatomical	Normal variation in size and shape of reproductive parts of body	Abnormal signs e.g lumps in testicles or breasts
Physiological	Normal variation in signs and symptoms related to significant reproductive events e.g <ul style="list-style-type: none"> <li>- Puberty</li> <li>- Menstruation</li> <li>- Pregnancy</li> <li>- Breastfeeding</li> <li>- Menopause</li> </ul>	Abnormal signs and symptoms which indicate a health problem e.g <ul style="list-style-type: none"> <li>- Abnormal menstruation</li> <li>- Abnormal pregnancy</li> <li>- Abnormal discharge which may indicate an STD</li> </ul>
Psychological	Normal variation in relationships sexual practices sexual feelings and gender preference	Abnormal variation of behavior e.g unhealthy sexual practices or ways people are exploited

stay healthy and how to manage sexual or reproductive health problems. In addition to promoting sexual and reproductive health this information can correct myths and relieve anxiety.

Before these discussions we thought some things were normal that were abnormal and others things we thought were abnormal were in fact normal. For example we all thought it was normal for a man to sometimes get a discharge from his penis and we thought people had a sexual problem if they masturbated or had wet dreams.

(Participant from IPPF sexual and reproductive health project Tanzania)

### **Reproductive health awareness facilitates the process of people becoming confident to articulate their sexual or reproductive health concerns**

The reproductive health awareness education approach is a sensitive way to encourage young people and adults to discuss sexual or reproductive health. During introductory discussions the facilitators encourage individuals to develop their language and communication skills. Once the individuals feel comfortable about discussing reproductive health awareness, discussions expand to include relationships, sexual feelings and gender interaction. At this stage they are often more confident to reflect about their own lives, articulate some of their sexual or reproductive health concerns and explore the reasons why it is so difficult to bring about change. For example once people are able to discuss the signs and symptoms of sexually transmitted diseases, they will often explore how difficult it is to discuss having a sexually transmitted disease with their partner or health care provider [1].

## Facilitating family planning programs to expand their services to include sexual and reproductive health

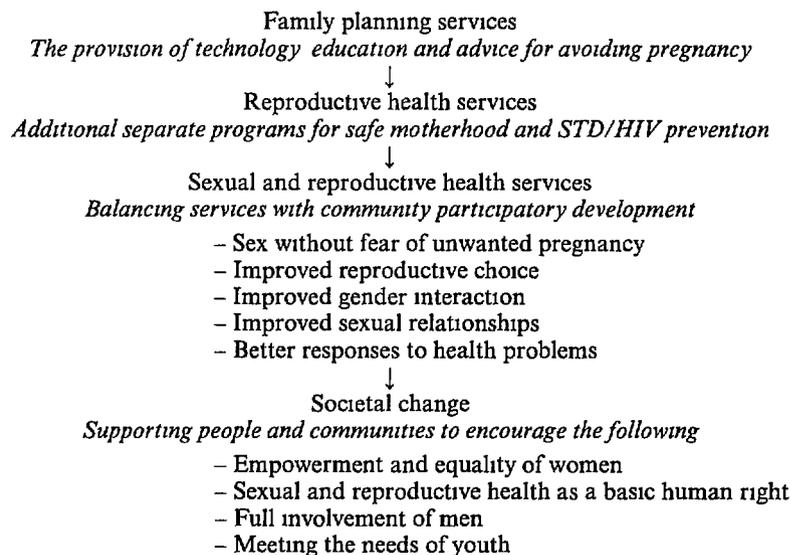
### *Improving sexual and reproductive health services*

Sharing of responsibility with communities for improving sexual and reproductive health services is easier said than done. Many Family Planning Associations are faced with the problems of lack of sufficient funds and an ever increasing demand for services from communities. When asked the reasons for sexual and reproductive health problems, many people blame their problems on inadequate services. Yet even when adequate services are provided they are not always used. As a health care provider from India explained:

Despite provision of mobile services at the doorstep of the people in rural areas, it has been seen that these are not only rejected but are highly resented. Since sexual and reproductive health is a highly sensitive and personal issue, it is important to help the community first analyse its concerns and existent behavioural patterns and thereafter themselves look for solutions which will be most relevant. This whole process requires extremely gentle sensitive and thoughtful yet focused facilitation.

In response to comments like this, Family Planning Associations are recognizing the importance of being responsive to the needs of their communities and expanding their services from pure family planning to include sexual and reproductive health. Table 2 shows the stages many family planning clinics are going through.

**Table 2** A conceptual framework for the way family planning services are evolving



Until recently many of the programs were focused primarily on educating and counseling individuals or couples. These programs are now recognizing that in many situations there is little that an individual can do unless sexual and reproductive health concerns are addressed within the wider community. Therefore the challenge for sexual and reproductive health programs is to focus on the barriers to sexual and reproductive health communication that exist within communities.

In response to this challenge, in 1993 IPPF set up a series of operations research projects funded and supported by Overseas Development Administration, to explore ways Family Planning Associations and communities could share the responsibility for improving sexual and reproductive health [2]. The central belief of all these sexual and reproductive health projects is that groups are more powerful than individuals and positive sustainable change is more likely to come about when individuals within community groups support each other or take action together. The overall objective of the projects is for the facilitators to work with community groups and support them in identifying and discussing their sexual and reproductive health concerns. The process of the sexual reproductive health approach is shown in Figure 2. The facilitator then encourages the community groups to develop and implement realistic strategies to address these concerns [3] and develop simple strategies that are achievable. The acronym SMART strategies helps the group clarify the strategies (Table 3).



**Figure 2** The process of the IPPF sexual and reproductive health approach in community groups

**Table 3 SMART strategies**


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The central belief of the sexual and reproductive health approach is  
*groups are more powerful than individuals*

Positive sustainable change is more likely to come about when individuals  
within community groups support each other or take action together

**SMART strategies**

The facilitator encourages the people in the community groups to  
address their concerns and develop simple strategies that are achievable

- Simple
  - Measurable
  - Achievable
  - Relevant
  - Time framed
- 

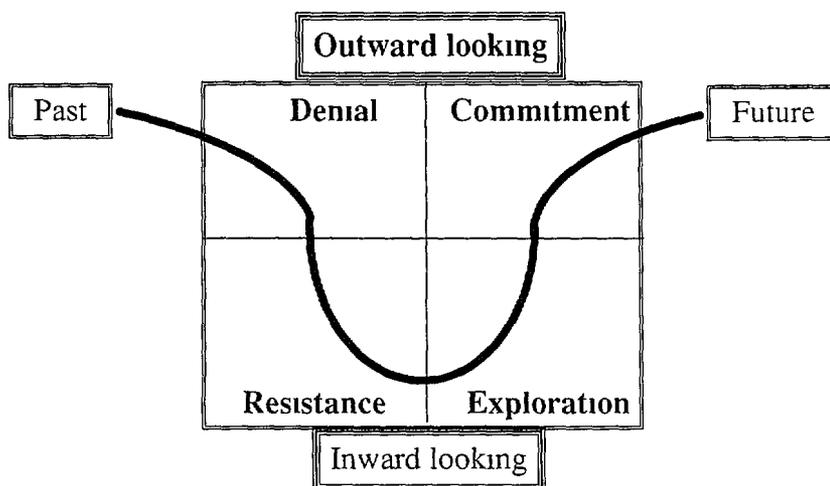
The experiences of these projects is that some communities are resistant to participating in programs about sexual and reproductive health. One of the most common reasons for the failure is that community leaders are deeply suspicious of the motivation of the health care providers, who they suspect are trying to encourage promiscuity by encouraging discussion about sexual or reproductive health. This happens most frequently when the traditional belief of the society is that sex and sexuality are secret matters which should not be mentioned.

Although many health care providers are aware that underlying this silence, there is a considerable amount of tension and unhappiness, they are also aware that despite counseling, many individuals are still unable to bring about change because they are too fearful of the consequences.

People are deeply upset at the level of abuse and manipulation of their lives in general and in their sexual lives in particular. Women are upset by being raped in their marriages, men are upset by sexual and economic manipulation, young people are upset by the lack of knowledge and their exploitation by adults, but most are fearful of communication of their serious concerns  
(Tony Klouda IPPF Sexual Health Project [4])

An approach that facilitates the successful implementation of sexual and reproductive health programs and moves the program quickly forward from denial and resistance to the people becoming actively involved in exploring the potential of the project and becoming committed to participate will be more cost-effective (Figure 3)

When working with community groups, a participatory approach that includes reproductive health awareness concepts is a simple non-threatening way for programs to quickly expand beyond pure information giving and explore what reproductive health means to people. The following is an example of the experiences of an IPPF community project in India



**Figure 3** A model for change (Adapted from Kanter *The Change Masters: Innovations and Entrepreneurship in The American Corporation* Simon & Schuster 1985)

In a poor urban area of Chennai health care providers were trained as facilitators. These facilitators tried to start a sexual and reproductive health program. They initially found they were distrusted until they befriended the children and played games with them. They got to know the parents who asked them about how to control the unruly rude behavior of their children. The facilitators used this opening to work with the parents and children and encouraged the parents to spend more time playing with the children. The facilitators gained the respect of the parents who then asked them about how to talk to their older children about puberty and adolescence. The facilitators organized activities such as body mapping and games to explore ways people communicated. When discussing and learning more about menstruation the young people were very interested to discover that menstrual blood was not dirty.

This resulted in discussions about the existing customs that ensured girls remained separate from the rest of the family and were not allowed near the kitchen while they were menstruating. The discussions with the adolescent groups expanded to discussions with their parents and grandparents. The community decided that they would change their practices and allow the girls to do normal activities during menstruation. Their community felt this change was very positive although surrounding communities were more skeptical and critical. This led to further discussing and more of the girls having their restrictions during menstruation lifted.

This example illustrates how discussions about menstruation facilitated the people to identify and address one of their sexual or reproductive health concerns. The facilitators found that discussing the normal events that happened at puberty led on

to focusing in more detail about people's understanding about menstruation. Later they used the information to address the community's concerns and ultimately bring about change in their community.

Although many community sexual and reproductive health programs do not use the term reproductive health awareness, they do use techniques similar to the reproductive health awareness education approach, when facilitating discussions about sexual or reproductive health. When planning future programs, if the dimensions that contribute to a comprehensive sexual and reproductive health program are clarified, i.e. body self awareness, interpersonal communication, gender awareness and integration of sexuality, then programs can be carefully organized to include these dimensions and ensure that they complement each other (Figure 1). This will hopefully strengthen the overall quality and effectiveness of future sexual and reproductive health programs [5].

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## **The reproductive health awareness (RHA) model: a qualitative perspective**

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### **Abstract**

The Reproductive Health Awareness model developed by Georgetown University Institute for Reproductive Health is responsive to the elements of quality of care articulated by Judith Bruce in 1989. The model encourages self-choice regarding family planning options, informed choice and flexibility to change family planning options with changing circumstances, and inclusion of men and the family. Providers utilizing the model must know the stages of behavior change and how to program care based on the client's knowledge and readiness, and how to communicate with clients such that they are facilitating care rather than prescribing it.

The continuing focus on improving the quality of reproductive health care studies has been reinforced by the impact of high quality education and services on the achievement of improving reproductive health. Clinic accessibility alone does not correlate with increased use or improved client health outcomes [1]. Making reproductive health services accessible without attention to quality is both counter-productive and wasteful [2]. This paper discusses several ways in which the reproductive health awareness (RHA) model is responsive to the elements of quality of care [3].

### **Choice of services**

A basic premise of the RHA model is that individuals are most likely to efficiently and effectively continue to use those services which are chosen by them rather than imposed by others. Emphasis on a life cycle approach to reproductive health care services and choices further acknowledges that choices must be flexible and responsive to the changing needs of individuals over the course of their fertile years and beyond. A woman/couple may have excellent reasons for changing her family planning method

many times over the span of her reproductive years. Her choice of a reliable method for delaying childbirth may be substituted for a method which will optimize her goal of healthy pregnancy for herself and her family. She may later choose yet another method which will support successful breastfeeding and yet another when she and her partner have determined that their family is completed. During those interim years she may also have multiple reproductive health concerns such as how to educate her own children regarding puberty, early recognition and self-referral for vaginitis, learning the normal sexual response cycle and how to prepare to meet her own partner's needs better. Her partner may have concerns about how specific reproductive health interventions may affect her health and well-being, as well as his own. The RHA model offers individuals the opportunity to choose those services which they perceive as most beneficial to them at a given point in time. The choices available are responsive to a complex combination of factors that motivate clients, including cultural framework, the impact of life events, availability and quality of services, and immediate health needs of the individual and other family members.

#### **Information provided to clients**

Information provided to clients is driven by the immediate needs of the client – in particular, the needs of the life cycle component in which she is currently functioning as well as the component into which she is preparing to move. Men are a critical component of the RHA model. Information dissemination addresses the individual, the couple unit and the larger family and community systems.

#### **Provider competence**

Providers within the RHA model must be knowledgeable about not only clinical information and resources but also behavior change stages. The RHA model places emphasis on body awareness, sexuality and gender issues. The demands the model places on the provider are much broader and more complex than those required of a more narrowly focused clinical model and it is not expected that fast-paced clinical services provide all the education and skill building needed by individuals. Building partnerships with schools and community groups is critical.

#### **Interpersonal relations**

A distinct attraction of the RHA model is its emphasis on improving health-seeking behaviors by establishing an early understanding and appreciation of the reproductive health systems and their capacities. Establishing a strong baseline knowledge facilitates related health care discussions regarding the recognition of symptoms which signal deteriorating health and encourage individuals to seek health care early in the course of illness. Interactions with clients reflect a commitment to privacy,

respectful language and behaviors, encouragement of participation and an appreciation of the larger context of the client's life situation

### **Follow-up or continuity mechanisms**

Because much of the reproductive health education occurs in the community rather than in clinical settings, many individuals may have fears about attempting to access clinical services which can be allayed, and the model can create linkages between the community and clinic-based resources. By placing the program focus in the community, a critical aspect of maintaining behavior change – maintaining a supportive presence – may be enhanced and may thus ensure a greater level of continuity, regardless of the specific reproductive health issue. For example, youth-focused mentoring programs which use the RHA model to provide information related to reducing sexual risk taking encourage youths to practice negotiation skills with the mentors and to use them as a continuing resource to explore ways of maintaining low risk behavior. The presence of the mentors in the community contributes to sustained behavior change.

By offering a unified comprehensive approach to care, the overall service system becomes driven by client-chosen priorities and enables those clients to highlight issues, such as violence, which have a profound impact on their ability to act on reproductive health preferences and choices. Implementing the RHA model provides an opportunity for providers to pinpoint issues, such as perceptions related to provider biases, which are unlikely to be reflected in epidemiologic data but which nonetheless have a powerful impact on utilization of services and continuation rates.

### **Appropriate constellation of services**

Utilization of the RHA model can generate information which more accurately and adequately informs the design and development of services. When clients are exposed to services which offer both quality and responsiveness to their immediate needs, they are more receptive to utilizing the services. Tailoring the menu of services to specific community needs and preferences can contribute to sustainability of those services as well as supporting positive health-seeking behaviors.

RHA customers include health systems, school systems, and communities. Where the RHA model has been implemented and is truly successful, the ability to more accurately assess health care needs may also include the ability to assess when self care is appropriate and adequate and additional services are not required.

The RHA model contributes to the decentralization of health care programs and to more effective ways of generating and maintaining community support. As it is tested in a broader array of settings perhaps the greatest challenge to this model is identifying and testing quantitative measures of the qualitative features of the program. This will greatly increase the credibility of the program as well as confirm whether and where RHA can best be promoted as a cost-effective program which can achieve sustained positive reproductive health behaviors.

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## **IX. Implementation of reproductive health awareness**

**How can a Reproductive Health Awareness approach be implemented in existing programs? What institutional changes are needed for incorporating Reproductive Health Awareness? What are the programmatic aspects to consider when designing these strategies?**

*Chair* Roberto Rivera, M D , Family Health International, Research Triangle Park, North Carolina

*Discussant* Mihira Karra, Ph D , USAID

*Consensus* Implementation of a Reproductive Health Awareness approach involves a series of steps that require the participation of the community and all other stakeholders. These steps include

- 1 Identifying the community's reproductive health needs and expectations beyond the public health perspective to include the psychosocial costs, the impact on others and the human rights discussion
- 2 Identifying the resources, channels, and networks that are or can be available to the community
- 3 Identifying the behavior and norms that need to be influenced at the organization, provider, community, and individual level
- 4 Developing and implementing appropriate strategies to reach the various audiences within the community
- 5 Monitoring and evaluating the impact of these strategies on target behaviors and norms. This includes developing additional indicators and methodologies to measure improved quality of life

This process places an emphasis on integration and coordination with various organizations, networks, and the community

Presenters

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Washington, DC, USA

**Issues to consider in operationalizing reproductive health**

Alan Andreasen, Ph D , Georgetown University, USA

**Changing behavior a challenge for reproductive health awareness**

Joan Schubert, M P H , CARE, Atlanta, Georgia, USA

**Breaking the mold expanding options for reproductive health awareness the CARE  
experience**

Jeanette Cachan, M A , Georgetown University, USA

**Implementing reproductive health awareness progress to date**

## Issues to consider in operationalizing reproductive health

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### Abstract

The International Conference on Population and Development (ICPD) served as the international launchpoint for a broadened reproductive health agenda, bringing global attention to a variety of underlying issues that impact on women's health and well-being, and highlighting the need to redress imbalances in gender equity that have had negative health and social consequences in particular for women and girls. To meet the challenges of the ICPD, programs must assess, prioritize and implement an expanded set of reproductive health interventions within an environment of diminishing resources. This paper argues that hidden social and health costs that particularly affect women must be included in the assessment and prioritization of reproductive health interventions. In addition, it argues that issues of gender and sexuality cannot be separated from the delivery of appropriate family planning and reproductive health care if we are to have a significant impact on improving the reproductive health of current and future generations.

This presentation is based on a paper prepared in 1996 for the United Nations Population Fund (UNFPA) [1]. The landmark International Conference on Population and Development (ICPD), held in Cairo, Egypt, in 1994, served as the international launchpoint for a broadened reproductive health agenda, bringing global attention to a series of long-neglected issues in the population and development field. In addition to embracing participation from the women's advocacy and the non-governmental organization (NGO) communities, which had not been seen in the preceding conferences of 1974 and 1984, the ICPD was characterized by an increasing recognition among population and development professionals of the multiple factors affecting women's health and well-being, a broader understanding of their resulting impact on both the family and society, and a move away from the more demographic orientation of the preceding decades towards a respect for

meeting the needs of individuals and couples. The ICPD Program of Action views reproductive health as a right of both women and men, and therefore directs governments and individuals to promote the empowerment of women in order to redress past imbalances in gender equity that have had negative consequences for women and girls [2].

Following the conference, the UNFPA was faced with the challenge of assisting member states in assessing, prioritizing and implementing a broadened set of reproductive health interventions within an environment of diminishing financial resources. The belief of UNFPA and many professionals in this field is that reproductive health is achievable, but that careful prioritization and assessment are necessary. Not all facilities are suitable for providing all possible interventions, and combining resources from both the public and private sectors will be required. In addition, community outreach efforts to develop an informed consumer public that both creates demand for services and holds programs accountable for providing those services will be essential.

There is no disagreement about the four focal areas that comprise a reproductive health program. These are:

- 1 Family planning, including the availability of a broad choice of contraceptive methods, appropriate counseling and attention to quality of care,
- 2 Safe pregnancy care, including prenatal, delivery and post-partum care of mothers and the newborn with attention to the management of obstetric complications and to the promotion of breastfeeding,
- 3 Prevention of unsafe abortion, including the treatment of complications and post-abortion family planning, and
- 4 The prevention, detection and treatment of STDs and HIV/AIDS

The differences emerge in discussions about the extent of effort and resources that should be devoted to each of these areas, and to the underlying social and gender-related factors that significantly increase the health and social consequences for women and adolescent girls.

### **Scope of the problem**

There is a considerable body of information available on the status of reproductive health globally, and a number of more recent research efforts are contributing to our understanding of the underlying social factors that affect disease-prevention efforts, contraceptive use, and the behaviors of young women and men. Here are some of the startling figures that underscore the need to address gender inequities in order to make significant gains in improving reproductive health.

- 1 There are an estimated 330 million new cases of STDs worldwide each year offering greater opportunities for HIV transmission [3], and women are becoming the fastest growing number of new cases of HIV infection. The spread of these diseases is growing rapidly among women and adolescent girls [3], and there is evidence in some countries of STDs present in girls under the age of ten [4]. This raises increasing concerns about the behaviors required to contain the spread of these diseases and address the healthy emotional and social development of both female and male children, who are socialized into gender roles at an early age. Women and girls are particularly vulnerable to STDs and their consequences because of the efficiency of male to female transmission, the gender-power dynamics that inhibit women's ability to negotiate with partners to take protective measures, and the greater likelihood that they will suffer in silence and sustain long-term consequences, neglecting their own health care needs while attending to those of their families.
- 2 There has been little progress in reducing maternal mortality rates in the developing world although appropriate medical technologies exist and the problem could be addressed through better staff training, better systems for identifying emergencies, and referral and transport for emergency cases. Despite declining infant mortality rates and fertility rates in many parts of the world, the global maternal mortality rate, according to the World Health Organization (WHO), has increased to 585 000 per year, with over 98% of these deaths concentrated in the developing world [5]. We need to ask why we are facing such obstacles in addressing this issue and examine the relationship to the low status of women. Take, for example, the issue of emergency obstetrical care. We know that a simple and non-technical item such as emergency transport to a facility is a key factor in saving the life of the mother, but women's lack of disposable income to pay for transport as well as the lack of a significant power base in the community to define mobilization of emergency transport as a priority impedes this essential access.
- 3 Our understanding of the level of reproductive morbidity worldwide is grossly inadequate. Approximately 40% of pregnant women develop complications requiring some form of care, although attention is focused primarily on the 15% who present with serious complications [5]. According to the 1993 World Development Report, in the 15–44 age range, women experience higher levels of disability than men, and in certain regions of the developing world this is due in large part to maternal causes: STDs and gender-based discrimination [6].
- 4 Approximately half of the world's population is under the age of 20 and this age group also constitutes a significant proportion of the reproductive age population [7]. Figures from the World Health Organization show that up to 60% of all new HIV cases are among the 15–24 age group, and of those, females outnumber males by a 2 to 1 ratio [8]. The foundations for healthy relationships between women and men are established early in life, and yet young people have relatively little access to the services and information they need to lead healthy sexually active lives or

the skills and support networks required to develop healthy social relationships with partners. It is these skills, in addition to the availability of contraceptives and STD-prevention information, that will impact on teenage pregnancy, the HIV-AIDS epidemic, and the spread of STDs.

### Assessment and prioritization issues

Implementation of a reproductive health approach will require assessment of the magnitude of the health problem, and establishing criteria for prioritization of potential interventions and for the use of available human and financial resources. However, assessment of the magnitude of the problem must reach beyond the standard public health measurements to examine some frequently overlooked dimensions [9]. These include the social and psychological costs, which are far more difficult to quantify than mortality and morbidity. For example, the social cost of infertility to a woman in a society that determines her worth by her ability to bear children can be ostracism, abandonment, or prostitution if she has no other means of familial or financial support. The second dimension is the impact on others, in addition to the individual affected. Most frequently cited examples are the impact of maternal mortality on the health and survival of the existing children, or the social and psychological costs of an adolescent pregnancy to both the mother and her child. The third dimension is the human rights dimension. For example, the coercive pronatalist policies in Romania in the 1970s and 1980s had dramatic health and social impact. Maternal mortality rates rose sharply when the right to both family planning and safe abortions was denied women [10]. The rights argument in the case of the HIV/AIDS pandemic provides another clear illustration. When infected individuals are afraid to come forward because of fear of ostracism, abandonment, dismissal from employment, or denial of treatment or health insurance, this lack of protection of their rights interferes with the health sector's ability to identify and treat infected persons and develop policies to appropriately contain the spread of the disease.

Approaches to assessment and prioritization should be both pragmatic (aimed at what is feasible under a given set of circumstances) and participatory (inviting diverse viewpoints) [9]. It is essential to include the various stakeholders to gain different perspectives on both the evident (health statistics, etc.) and hidden costs (social burden, etc.) of different conditions, as well as on the effective deployment of existing human and financial resources. These stakeholders include women's health advocates, policymakers, program managers and service providers (including field worker representatives in countries with active outreach programs), community groups, and researchers, and should cover the spectrum of public sector, private sector and the NGO community. In general, assessment and prioritization should be a dynamic process, undertaken through workshops promoting discussion of different viewpoints, review of available data on the reproductive health of the population as well as on the underlying social factors affecting women's health, and findings from operations research. Perhaps the most essential ingredient for success is the commitment by policymakers and program managers to act upon the recommenda-

tions emanating from these workshops Organizing for the operationalization of reproductive health is not a short-term process It may take a year or more to organize an adequate participatory assessment and prioritization exercise In addition, the phasing-in of appropriate new activities within the existing health service system may as is currently the case in India, need to be planned over a 5–10 year period [11]

### **Gender and sexuality issues in family planning programs**

There are some practical ways of addressing gender-based issues even within the context of family planning programs First, we need to consult women to learn how they prioritize their health concerns and how best to orient services to address those concerns Second, we need to improve our understanding of how sexuality and sexual behavior affect the health and social development of men and women Programmatic interventions cannot be designed in the absence of an awareness of how gender-based dynamics affect the ability of women and girls to protect themselves from unwanted pregnancy and STDs Third, counseling must incorporate messages that address STD prevention together with contraceptive protection Some women may choose to weigh their decision more heavily on their contraceptive requirements than their perceived STD prevention needs, or vice-versa, but they have a right to know, and we have a duty as providers to inform Fourth, while involving men is important we must be careful not to engage in approaches that reinforce gender inequality in decision making at the household level

The family planning community has been uncomfortable acknowledging that STD prevention cannot be addressed without an open discussion of sexuality and sexual behavior, which is where the reproductive health awareness approach has something special to contribute Ruth Dixon-Mueller in her paper “The Sexuality Connection and Reproductive Health” makes a profound statement about the state of the art “Sexuality and power relations based on gender underlie virtually all of the behaviors and conditions that [family planning] programs address” [12], including contraceptive decision making and use, potential exposure to STDs, and risk of unwanted pregnancy and abortion, among others Yet there has been little research on such issues as sexual partnerships (the number, timing, choice and social identity of partners), sexual acts (their nature, frequency and whether voluntary or involuntary) the sexual meanings attributed to specific behaviors (what constitutes appropriate male and female behavior such as image of manhood or ideals of femininity, beliefs surrounding virginity, etc), and sexual drives and enjoyment (how these contribute to sexual identity, differences in male/female perceptions of what gives pleasure) [12] A better understanding of these four elements and recognition of the fact that sexual relations are not always consensual or pleasurable and desired, could contribute to how we address these sensitive issues in the design of appropriate interventions to improve reproductive health behaviors and health outcomes for both men and women

Male involvement in reproductive health programs is important and should be

encouraged to achieve the following goals (1) to promote the kind of social change that will empower women, (2) to inform men about the reproductive health care options available to themselves and their partners in a manner that fosters couple communication, (3) to promote responsible and equitable relationships with their partners, resulting in healthy social development for women and men, and (4) to inform men about the health consequences of their negative sexual behaviors for themselves and others, including their partners and children, as well as the opportunities for changing those behaviors. In accordance with the ICPD Programme of Action, programs should direct their efforts in the area of male involvement to this broader range of objectives rather than on narrowly focused activities to increase contraceptive prevalence.

In conclusion, issues of gender and sexuality cannot be separated from the delivery of appropriate family planning and reproductive health care. If we are to have a significant impact on the reproductive health of the current and future generations, we must act quickly to improve our understanding of the behaviors and interventions that affect the spread of STDs and HIV/AIDS, the use of family planning and women's access to appropriate maternal health care. The design of appropriate interventions requires broader participation from a variety of stakeholders so that diverse viewpoints can be presented and attention can be given to addressing the underlying social and health consequences that have a particularly negative effect on the lives of women and girls.

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## Changing behavior: a challenge for reproductive health awareness

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### Abstract

Social marketing applies commercial sector ideas to programs to change behavior. It involves a mindset that is customer-focused, a process that starts with customers and continually returns to them for validation, and concepts to make change happen. Customer behavior models guide strategy. One useful model is based on stages of change and four behavioral influences: perceived benefits, perceived costs, the influence of others, and perceived behavioral control.

Effective use of social marketing to achieve an organization's social mission requires a broad, workable strategic framework for planning and action. This is true for promoting reproductive health awareness (RHA), as it is for other health related behaviors. The framework is based on the fundamental precept that social marketing is really all about influencing behavior – not merely creating awareness or changing attitudes. Given this behavioral “bottom line”, it follows that effective social marketing requires a mindset that puts the target customer at the center of every strategic decision. (For RHA the target customer is both the provider and the client.) It also means that the process of social marketing must begin with an attempt to understand target customers (often called formative research). The process must include constantly going back to these same target customers to gauge their likely reactions (pretesting research) during the development of a program. Finally the process also must include mechanisms that the social marketer can use to continually touch base with consumers to learn how the program is working (monitoring research).

The proposed model begins with a recognition that audiences make important behavior changes in stages rather than all at once. The stages are as follows:

*Precontemplation*

This is when customers have not really thought about undertaking the action or have concluded (temporarily) that it is not appropriate for them

*Contemplation*

This is when customers are actively thinking about taking the action but have not yet done so. This stage includes two components: (i) early contemplation, i.e. when they have just begun to evaluate that possibility and, (ii) late contemplation, when they are close to taking the crucial first steps.

*Action*

This is when customers are trying the new behavior.

*Maintenance*

This is when customers are settling into new patterns of behavior, presumably never to return to the "old" ways.

The challenges facing the social marketer differ, depending on the behavior change stage of the target market. The goal is to move target audiences to the next stage in the process, not to move them to the final stage in one leap! Thus, in precontemplation, the challenge is to overcome consumers' tendencies to selectively ignore or screen out social marketing messages in order to create awareness and interest.

The social marketing challenge at subsequent stages of the process is made much more complex by the many factors that influence behavior. Of these, four are most important:

- Perceived benefits: what good things could happen if the behavior is undertaken
- Perceived costs: what bad things could happen if the behavior is undertaken
- Perceived social influence: what important things other people or groups are doing or are urging
- Perceived behavioral control: whether consumers think they can actually carry out the behavior

Thus, the challenge at the contemplation stage is to reduce perceived costs and to increase perceived benefits, social influence, and behavioral control. During this maintenance stage, consumers must feel rewarded and must have frequent reminders to continue the desired behaviors.

This framework for understanding customers helps social marketers determine what to ask in formative research, what to look for in pretests, and what to monitor as programs roll out

It is also helpful in devising specific strategies and tactics to ensure that all behavioral influences are addressed and coordinated

Finally, the framework is flexible enough to be used by social marketers to influence not only target customers but also others who are critical to the program's success, including media gatekeepers, school teachers, distributors, politicians, and government bureaucrats, among others. What makes the framework robust is that, in each stage, the bottom line remains the same: the marketing managers need to influence behavior.

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## **Breaking the mold: expanding options for reproductive health awareness: the CARE experience**

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### **Abstract**

The early years of the CARE family planning and reproductive health program were geared primarily toward modern methods of contraception and providing services. However, new and fresh opportunities to address reproductive health awareness and natural family planning are now emerging as important options. In these programs, coordination and collaboration with other sectors such as food and nutrition, children's health and natural resource management, combined with more sophisticated approaches for assessing need and reaching communities with information, has resulted in more people being reached than ever before with appropriate options and opportunities for reproductive health awareness and care.

There are examples of CARE projects from India, Peru and Nepal where activities which feature working across development sectors and engaging communities to address their individual and collective RH needs are featured. Ways to disseminate information about reproductive health are being broadened to include creative combinations of interpersonal, mass and folk media, whether it be an informal one-to-one counseling session with flipcharts, a community mobilization event, a multi-media campaign or any combination thereof. Likewise the target audience need not always be the women of reproductive age nor should the RH messengers always be the medical and public health professionals. What is critical in all of these instances is to craft strategies based on appropriate research and need, continuously monitor progress, refine approaches as necessary, track results and evaluate the process and impact of interventions leading to behavior change. The challenge is not insignificant, but the rewards to be reaped through the improved programs are clearly worth striving for.

CARE's history dates back to 1945, just after the end of World War II, when millions of American citizens found a way to express their charity and concern for those affected by World War II by collecting, shipping and distributing thousands of tons of food to survivors of the conflict in Europe and Asia. Since its beginning over 50 years ago, the organization has grown to be one of the largest private non-governmental organizations (NGOs) in the world employing close to 100 000 people, 94% of whom are national staff at work in their own countries. Today, CARE reaches more than 25 million people in 63 developing and emerging nations in Africa, Asia, Latin America and Eastern Europe. Key sectors include emergency relief, food security, health and population, girls' education, water, income generation, and agriculture and natural resource management.

Family planning and reproductive health are new to the CARE portfolio. In the late 1980s, the organization conducted a comprehensive strategic planning exercise and found that rapid population growth was undermining the impact and accomplishments of its development work. After examining its organizational capabilities and comparative advantages, it was concluded that population and family planning activities would become a critical new sector for the organization.

Funding for the new initiative was secured from USAID in 1991 and now, six years later, family planning and reproductive health<sup>1</sup> is an established sector within the organization. Currently CARE has 61 projects operating in 30 countries around the world and which are funded by a variety of donors. For the most part, project focus is on rural, hard to reach populations although poor, peri-urban and slum communities are also beginning to enter the picture. Rarely does a CARE population project operate on its own as a vertical intervention. Instead, efforts are virtually always made to cluster, build on, work through and support other programs such as food and nutrition, agriculture, income, girls' education, primary health care and emergency relief. Partnership arrangements with local non-governmental organizations (NGOs) and ministries of health, as appropriate and possible, are also important elements of project design and implementation. In addition, models which feature community-based distribution networks complemented by quality clinical services are increasingly featured in project designs as a way to ensure better access and use of a wider range of contraceptive methods for more people.

Reproductive health awareness is a critical part of CARE's family planning programming and, depending on approach, includes strategies adapted to reach women, men, couples and other reproductive health 'gatekeepers' such as community leaders, traditional birth attendants and mothers-in-law. Although the early years of the program were geared primarily toward expanding knowledge about modern

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<sup>1</sup>Following the 1995 International Conference on Population and Development (ICPD), and a careful analysis of the potential impact of various reproductive health interventions, it was decided that CARE's reproductive health strategy would feature family planning, maternal health and HIV/STD prevention services.

contraceptive choice and providing services, a gradual, steady shift is taking place to include information and support for reproductive health awareness and natural family planning among programmatic options. Some of the more apparent reasons for these changes are as follows:

- 1 Organizational shifts are taking place within CARE creating new and fresh openings for reproductive health programming. Field assessments and sector clustering, long-range strategic plans, common monitoring and evaluation systems, and ongoing information exchange between the field and headquarters have unlocked new and significant opportunities to reach people with messages about reproductive and maternal health. As an example, the Integrated Nutrition and Health Program (INHP) of CARE India which began in October 1996 with support from Title II funds has the potential to reach almost 4.7 million pregnant or lactating women residing in 937 rural and tribal blocks in seven states of India. Information dissemination and community mobilization for reproductive health, which includes support for modern and natural family planning methods post-partum through collaborating networks of government, non-government, and community partners, are high on the list of priority issues to be addressed by this innovative food security project.
- 2 A learning curve is underway among CARE staff about reproductive health awareness, how to incorporate it into ongoing projects, particularly those that address children's health, family planning, and food, and ways to get at measuring the impact of interventions to promote and support it. Now, more than ever before, reproductive health, natural family planning, and lactational awareness methods (LAM), in particular, are being included with other ongoing awareness-building activities and counseling sessions as yet another family planning option, often with proven health benefits for the mother and child. An additional advantage of LAM, being discovered by many CARE family health promoters and community-based distribution (CBD) workers, is the comfortable and natural entry point created by a discussion about breastfeeding to introduce other child-spacing and reproductive health issues and services to communities, new parents, and individuals.
- 3 Introducing a systematic approach for incorporating natural family planning options within CARE reproductive health programs has the potential to address needs that may go much deeper than those which would normally surface in a 'traditional' modern method service delivery project. A systematic approach to natural family planning has the potential to (a) introduce the concept that fertility is within a woman's power to control (which is also key to the use of other spacing methods), (b) educate women about their bodies and control over their bodies, and (c) introduce an option which is not dependent on supplies, services, and staff – a variable that CARE project managers and the communities they serve are not always in a position to control. An added benefit is that, if introduced well, the systematic inclusion of natural family planning methods among the range of child-

spacing options may increase the involvement and support of men in family health and family planning

CARE's level of sophistication for reaching communities and building awareness about reproductive health issues has grown significantly over the past several years. Relatively speaking, it was not all that long ago that 'the health talk' was the furthest the organization wanted to venture into the world of information, education and communication (IEC). A common statement heard in the field and headquarters was, "but CARE doesn't do radio." Including a budget for IEC materials and interventions almost always meant an invitation for further discussion and debate with donors and others about cost justification.

Since then, the sector has witnessed a dramatic shift. Currently close to twenty country and project specific IEC strategies have been drafted and are being managed by CARE staff around the world. The health talk still has its place, but it is now reinforced and complemented by similar messages disseminated via a range of development sectors and employing creative combinations of mass and folk media, printed matter, quality counseling sessions and community support groups, as appropriate. What all of this means is that more people than ever before are being reached with important, accurate and appropriate information about the range of options open to them regarding reproductive health issues and care.

Some examples illustrating the range of approaches currently used by CARE to disseminate RH information in different parts of the world include

- 1 The 'Circle of Friends' peer support groups in Zambia,
- 2 Radio soap operas in Vietnam,
- 3 Traditional dance, theater, cloth and community events in Rwanda,
- 4 Local radio, video flipcharts, story cards, demonstrations and house-to-house visits in Niger,
- 5 Training videos, national campaigns and print materials in Cambodia,
- 6 Curriculum development for nurses and outreach workers in Palestine,
- 7 Brochures, posters and illustrated guidelines for developing educational materials in Bolivia,
- 8 Posters and method-specific brochures for audiences with low levels of literacy from the mountains, coast and jungle areas developed with a professional advertising firm in Peru, and
- 9 Participatory action plan development with local communities to support and train traditional birth attendants (TBAs) in Uganda

*India*

As an example of an awareness-building, community-based program with a significant reproductive health awareness component, the Integrated Nutrition and Health Program (INHP) of CARE-India (mentioned previously) works with government, non-government, and community partners to improve the health and nutritional status of women and infants. Implementation strategies are designed to enable women to attain and maintain optimal health and nutrition for themselves and their children, and to enhance the capacity of communities and counterparts to achieve this. Processes are selected which empower individuals and community groups to take action to make continuous improvements in their health status. This involves a shift in focus from provider-centered and center-based to people-centered and population-based approaches. The program emphasizes the implementation of integrated strategies which will enhance benefits to both women and infants, and converge health, nutrition, and family planning services and information dissemination. Interactive training materials, flash cards for discussion and problem solving and other visual aids have been developed and are examples of tools being used to facilitate learning and information exchange.

*Peru*

In Peru, the CARE Multi-Sectoral Population Project (MSSP) is working in a variety of ways to build awareness about reproductive health. The project's network of 1000 volunteer promoters working in 672 rural and peri-urban communities around the country provides information on family planning, sexuality, reproductive anatomy, personal hygiene, self-esteem, marital relations, the need for check-ups for gynecologic cancer, the fertility cycle, and the benefits of child spacing, in general.

The promoters facilitate individual and group IEC events on reproductive health, contraceptive method distribution (pill, condom, vaginal tablet and 3-month injectable), and referrals to MOH clinical facilities for long-term methods and other services. At the time of the project evaluation in mid-1996, volunteers had recruited and provided services to over 28 300 acceptors and provided referrals resulting in the provision of long-term methods to more than 1000 others. Pamphlets, posters and radio spots have all been used to disseminate information and reinforce interpersonal communications on reproductive health issues and family planning methods. By the end of 1996, volunteers had organized approximately 4680 group talks and distributed 227 500 pamphlets. The pamphlets were then shared with family and friends, furthering the net outreach effort of the volunteers' work and information dissemination.

What is unique about MSSP in Peru is that information about reproductive health and sexuality is being disseminated via a new group of one-on-one messengers – community volunteers – and not only the medical professionals. This approach has both its advantages and special challenges. Men and women are open to learning about reproductive health issues from volunteers, although, not surprisingly they are

somewhat embarrassed by the topic and volunteers are not always in a position to provide all the information needed or desired. On the other hand, medical professionals are frequently inadequately trained in counseling, so when they provide IEC, they may be misunderstood or perceived as insensitive. Additional training in counseling and IEC for both promoters and medical professionals is provided by the project on an ongoing basis and is a starting point for overcoming some of these challenges.

### *Nepal*

The CARE family health program in Nepal is an important component of a larger basic needs rural development project which addresses family planning, primary health care, agriculture, women's literacy, and income-generating activities. The project is committed to community empowerment and is actively engaged in projects focused on advancing sustainable development in ways defined by the people themselves. What CARE-Nepal has discovered through this approach, which includes awareness building on a variety of issues and community/institutional networking, is that when it comes to family health the results can be powerful and unexpected.

For example, in the remote and mountainous district of Bajura, fascinating work is being done in respect to how women and men perceive menstruation and bleeding. Traditionally in these communities, bleeding is seen as impure and when a woman is menstruating she becomes what might be best described as 'untouchable'. During this time a woman's movements are severely restricted. She cannot prepare food, greet neighbors or enter another person's home. Often she remains in a small shelter or hut where she is expected to squat for several days with limited outside contact. Even access to the local water source for basic hygiene is discouraged for fear that it will adversely affect the entire community.

Childbirth in the region – most probably because of the association with blood and the placenta – is an event that a woman experiences alone in a cow shed with no assistance. Traditional birth attendants and family members are usually present, but are severely constrained in their ability to assist the woman and are limited to not much more than calling out instructions/encouragement from the door of the shed.

With CARE's encouragement, families are now ensuring that the cow sheds are scrubbed down and the cows put to pasture in anticipation of a woman's delivery date. In one instance a traditional midwife deliberately had her sister-in-law give birth in her home and to everyone's surprise 'nothing bad happened to anyone in the community'. In another community women are beginning to make simple underwear and cloth napkins for use during menstruation. As was expressed by one woman, "Now that we know how to stay clean, it's no longer a problem that we're menstruating. People are accepting that we move about the community and we can even cook. It's so different."

There are various ways to build reproductive health awareness and disseminate information whether it be through an informal one-on-one counseling session,

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community mobilization events, a health talk, a multi-media campaign or any combination thereof. And the target audience need not always be married women of reproductive age. Policy makers, employers, family members, teachers, traditional healers, men, single women and spouses can also be important audiences to reach, depending on program goals and circumstances. Likewise, the most credible and influential RH messengers need not always be the family planning professionals or public health staff. What is critical in all of these instances, and particularly for IEC interventions including awareness-building activities which seem to draw the most scrutiny about cost-effectiveness from donors, is to craft strategies based on appropriate research and need, continuously monitor progress, refine approaches as necessary, track results and evaluate the process and impact of interventions leading to behavior change. The challenge is not insignificant, but the rewards to be reaped through improved programming are clearly worth striving for.

## **Implementing reproductive health awareness: progress to date**

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### **Abstract**

This paper describes the experience of various institutions in integrating a reproductive health awareness (RHA) approach into different health, school and community-based programs. RHA, an educational approach that evolved from the Institute's client empowerment approach to natural family planning and fertility awareness, is based on helping women and men to participate actively in their own family planning and reproductive health care by developing skills in self-observation, communication and self-advocacy. In addition to providing the Institute with an avenue for responding to the Cairo and Beijing mandates, RHA has also provided a means to introduce family planning, particularly natural methods of family planning, into programs and institutions. RHA has continued to evolve and strengthen during the process of field testing its contributions to existing reproductive health programs.

### **Introduction**

The Institute for Reproductive Health at Georgetown University has developed an educational approach, reproductive health awareness (RHA), that has evolved from the Institute's work in natural family planning and fertility awareness and continues to develop during the process of field testing its contributions to existing reproductive health programs. The overall goals of RHA are to empower individuals to become advocates for their own health, to enable communities to identify and obtain accessible and high quality reproductive health services for their members, and to assist institutions to make programs more relevant to the needs of those they serve. The realization of these goals through incorporation of the approach into existing programs has been the focus of the Institute's RHA implementation efforts in existing field projects.

### **Implementing reproductive health awareness**

The Institute's efforts in RHA implementation have included

- 1 Sensitization meetings with policy makers and program managers in selected institutions to develop an understanding of the RHA philosophy and support for RHA interventions,
- 2 In-country institutional assessments to determine the context in which to carry out these interventions,
- 3 Development of prototype training and educational materials, and
- 4 Training of community educators and health providers to enable them to implement RHA in their service delivery systems

The implementation of the RHA approach is currently being tested on a pilot basis in on-going programs of various agencies using distinct approaches for delivering RHA education in different settings a youth-serving program in Mexico, selected high schools in rural and peri-urban areas in Ecuador, and community development groups, and family planning organizations in Peru and Bolivia Each program is testing strategies for incorporating the RHA approach into their work, and each has selected particular content pieces and given different emphases to the elements of RHA, depending on the type of services they offer and the groups they serve However, they are all following a similar three-phase implementation process

- 1 Development of a specific RHA strategy for a selected program within the institution,
- 2 Implementation of the RHA educational approach and evaluation of the acceptability and utilization of RHA by the program and its beneficiaries in different contexts, and
- 3 Evaluation of the impact of RHA education on individuals and the community

During the last 16 months, these pilot demonstrations have completed the first two phases

In the first phase, implementing institutions either identified specific program areas into which RHA could be integrated or have designed new activities incorporating the RHA approach Programs have also identified key collaborators for the implementation of the interventions For example, in Ecuador the Centro de Planificacion Familiar (CEMOPLAF) secured the support of the Ministry of Education at the national level and the participation of local authorities in the development of an RHA-based sexuality education program for in-school youths

aged 14–16 In Bolivia, the Centro de Investigacion, Educacion y Servicios (CIES) carried out numerous sensitization meetings with community and conservative government leaders before designing an RHA-infused IEC strategy to support the introduction of reproductive health services in indigenous rural communities During this phase all pilot interventions collected baseline information on specific knowledge, attitude, beliefs and behaviors relevant to reproductive health and current status of the target groups These baseline data will be used in phase three to assess the impact of RHA on the clients served by these organizations

In the second phase, implementation of pilot demonstration projects is being carried out in family planning services by CIES in Bolivia and the Asociacion Benefica Prisma in Peru, a women-in-development program by Movimiento Manuela Ramos in Peru, a micro-enterprise development program by PRISMA in Peru, child survival and natural family planning activities by Catholic Relief Services in Bolivia, high school sex education by CEMOPLAF in Ecuador, and a youth-serving program by MEXFAM in Mexico Table 1 presents the key elements and beneficiaries of these interventions

Implementation activities in these programs began with training in RHA for client education and counseling staff, followed by review, adaptation and testing of their programs' current provider training curricula, client IEC materials, and/or counseling protocols to include greater emphasis on the client's self awareness Education in RHA targeting beneficiaries of the pilots is currently under way in most programs Monitoring and evaluation instruments have been developed at this stage of the implementation process Evaluation during this phase is limited to documenting the acceptability and incorporation of RHA into each pilot demonstration project

During the third phase, projects are expected to evaluate the impact of RHA education on individuals and the community The impact evaluation strategy seeks to establish linkages between outcome indicators at the institution, community and client levels and the specific contributions made by RHA interventions to programs Table 2 includes a list of possible outcome indicators for various RHA applications

### **Learning about RHA implementation**

After a year of implementating the RHA approach, there is general agreement among programs that RHA

- Enhances on-going programs, because it connects key components of reproductive health gender, body and self awareness, interpersonal communications and sexuality The introduction of RHA has been timely for programs which were interested in embracing the Beijing and Cairo comprehensive definition of reproductive health but did not know how to translate it into concrete program action concepts, such as quality of care, client-oriented services, empowerment of women and sexuality

**Table 1 Profile of reproductive health awareness pilot projects**

<i>Site/situation</i>	<i>Type of project</i>	<i>Beneficiaries</i>
Ecuador/CEMOPLAF	In school curriculum for adolescents aged 14–16 Total of 30 h of class room contact Semi rural areas	600 young adults aged 14–16
Peru/PRISMA	Family planning clinic semi rural areas/social development program/family planning training program	Men women and couples in 3 target communities served by the family planning clinic/ Women participating in income generating program/4 family planning NGOs
Mexico/MEXFAM	Extra curricular adolescent program for 14–16 year olds Total of 22 h of contact Urban areas	1000 young adults aged 15–21
Bolivia/CIES	Reproductive health education and service project in indigenous rural communities	13 000 women of reproductive age 3500 men and 1000 adolescents (90 communities in 1 province)
Bolivia/Catholic Relief Services	Child survival activities (integrating RHA and NFP) Rural areas	314 communities in 3 provinces
Peru/Manuela Ramos Women in Development/ Health Programs	Social development activities which emphasize strategies oriented towards gender considerations Peri urban area	Women and men seeking STDs/ AIDS counseling services
Peru/Ministry of Health/ Health Post	Family planning–primary health care services in peri urban area	Women attending health post

PROCOSI, a Bolivian non government organization (NGO) coordinating the reproductive health and child survival efforts of various donors stated “*The Reproductive Health Awareness comprehensive approach has the elements tools and guidelines to concretize new reproductive health mandates and standards*”

- Is valuable for moving from simple acquisition of knowledge to skills development, which is something programs were interested in but did not know how to achieve

**Table 2 Illustrative reproductive health awareness impact indicators**

Program type	Indicator
All programs	<ul style="list-style-type: none"> <li>- Increased knowledge about RH issues</li> <li>- Increased skills in identifying signs and symptoms of one's own body</li> <li>- Improved individual/community decision making capacity in reproductive health</li> <li>- Increased use of family planning and reproductive health services</li> <li>- Increased skills in communicating about RH with partner parents and health providers</li> </ul>
Young adults	<ul style="list-style-type: none"> <li>- Delay in onset of sexual activity</li> <li>- Decrease in unintended pregnancies</li> </ul>
Community/social development	<ul style="list-style-type: none"> <li>- Increased women's participation in productive activities</li> <li>- Increased the productivity of community development projects</li> </ul>
Family planning	<ul style="list-style-type: none"> <li>- Drop in method discontinuation</li> <li>- Increased attendance of couples to family planning counseling</li> <li>- Increased birth spacing in families in the projects</li> <li>- Reduction in female reproductive tract illness</li> </ul>

At PRISMA's family planning clinic in Trujillo Peru service providers who were asked about the value of the RHA training indicated *We cannot yet measure changes quantitatively although we can point to marked qualitative changes in our daily routines The first thing we have observed is a change in attitude in the health promoters and in their counseling skills which in turn translated into positive results on the people [clients] They [promoters] feel suited for and are more enthusiastic about their work in the community Promoters who would shy away from community activities such as group talks are now actively involved in performing them Promoters are also making the connection between body awareness and the use of family planning RHA has elements of anatomy and physiology that complement knowledge they acquired in previous family planning training in addition to hygiene and self recognition of reproductive tract infections which are relevant to other services we offer More importantly RHA training has enabled promoters to reflect on their own experience and internalize the equation knowing myself = caring for myself It is obvious to us that promoters acceptance of the RHA philosophy lies in the fact that RHA takes into account a whole set of complex health issues and*

*interpersonal relationships that impact on family planning decisions Our promoters feel prepared and confident to go out in the community they feel accepted” RHA was perceived by the health promoters in this program as providing additional information and skills to reach out to the community and to fill an unmet need which they had not been able to articulate before ‘RHA reversed a process of rejection within our community there was resistance in the community to the promotion of methods of family planning I am no longer afraid of approaching people and hearing here comes the family planning promoter again I can talk to them of many other things that interest them besides family planning I now see more than a potential IUD client I see someone whose reproductive health I care about”*

- Is perceived as contributing to increased service utilization

PRISMA tracked referrals and found an increase in the number of people seeking services at a family planning clinic following the incorporation of RHA messages into their community outreach activities

- Conforms with the institutional philosophy of knowing one’s communities and constitutes a useful tool for assessing community and individual health needs, cultural values, and gender-based problems (such as domestic violence and partner and family member involvement in number and spacing of children), and the means for exploring ways to address these factors

In Bolivia RHA is helping to open the way for reproductive health services in traditional rural communities, where information and health services have not been available in the past In a joint effort with local non government organizations, the Institute developed an educational strategy for a reproductive health project in a largely indigenous population in a rural province This pilot demonstration is not a case of incorporation of RHA into an existing program, but one in which a new health initiative is designed from the beginning with a RHA perspective From early assessments it was established that the target communities were traditional populations that needed other issues addressed before introducing family planning messages The implementing non government organization found the RHA perspective appropriate for exploring and addressing underlying issues in the community and appealing to programs seeking to serve conservative audiences The new reproductive health initiative has been already accepted in over 75 communities serving approximately 6500 men and women and is expected to double in the coming months [3] This is an instance – acknowledged by the institutions involved – in which RHA with its new way of approaching health education facilitated collaborative agreements to introduce new services linked to concepts of community empowerment and individual self-advocacy in reproductive health

- Can require a significant amount of time at early stages of implementation because it involves changing the way reproductive health information, education and services are delivered, as well as who delivers them

Two pilot programs felt RHA implementation involved changing established procedures and increasing providers work load. In Mexico a sexuality education curriculum with a RHA focus took more person hours to complete than a parallel curriculum but at the same time instructors and program managers acknowledged the new one was richer and more effective for developing self-reliance and observation skills. Programmatically the increase in teaching time posed a problem for a team of instructors with other competing responsibilities at the institution which they measure quantitatively. In Peru implementation of a pilot RHA intervention within the family planning service of a Peruvian public health post was perceived as too difficult and not effective. Service providers were already overwhelmed with their workload prior to RHA implementation and limited funding prevented hiring an educator or counselor to take on the client education task required by the RHA approach. Staff responsible for the RHA effort felt their priority was to achieve other numerical program goals (e.g. number of schools and students reached).

- Is easier to insert in programs that are in close contact with the community. Community based groups have a tradition of developing on-the-ground outreach strategies and adapting them to evolving conditions, as opposed to programs that operate from a health center. This is confirmed by the Institute's experience during RHA training.

When training teams from health and community programs no difference has been found in their ability to identify areas that can benefit from the RHA philosophy and ways of incorporating it into their training and educational activities. Nevertheless community program personnel quickly identify who can and how to deliver the RHA education while health teams have difficulties identifying how to carry the message to the community.

Interviews with RHA implementing institutions also indicate positive response at the individual and community level. Results from these interviews confirm that the RHA premise – *If I know my body how it functions and how to care for it then I can recognize my needs, communicate my reproductive health care needs and use available health care as necessary* – is being accepted as a valid option by health care providers and individuals. A case from Peru demonstrates that RHA implementation in a family planning service has been valuable in assessing and addressing gender-based problems, such as domestic violence, partner involvement in sexuality and family planning decision making. This service cited the example of a woman who had experienced painful intercourse for a long period but was afraid to discuss the matter with her husband. Following a community-based session with a promoter who had received health training infused with RHA, the woman had the skill and confidence to talk to her husband and deal with the problem.

Another example comes from a program in Ecuador working with teachers and adolescents in rural schools which has found that teachers trained in RHA are motivated by the responses and needs of their students to move beyond and include parents. The teachers feel confident in their ability to work with parents and are developing a special initiative to involve them in the school based program.

### Overcoming barriers in future RHA implementation efforts

RHA has been successful in addressing particular needs of institutions, from introducing sexuality education into schools, to familiarizing traditional communities with the concept of family planning and reproductive health, to assisting community health promoters in reaching their target audience with multiple health messages. Yet, when attempts have been made to extend the approach within some of these institutions, managers have been hesitant to extend the experience beyond the pilot effort. Despite the opportunities and preliminary results described by programs, the Institute recognizes that RHA implementation faces constraints in improving attitudes, skills and behavioral norms at the community and individual levels, and especially at the institutional level. Implementing institutions perceive the benefits of using the RHA philosophy and are pleased with the results obtained to date, yet they are not confident in their ability to incorporate the experience into their overall program, particularly in clinic-based counseling and service systems. Most important, comprehensive reproductive health is not yet part of the "organizational culture"

Some of the limitations identified by implementing institutions relate to the time factor, adjustments in providers' workload, and accountability. In two of the pilot interventions, implementation indicated that

- Time is required to improve clients' ability to get involved in their own reproductive health care through the exchange of information with the client, relevant to her or his condition and to what can be anticipated in the next stage of life. The RHA techniques for providing education convert health educators, counselors, and health providers from their traditional roles as givers of information and advice to facilitators of learning and empowerment. Facilitation is a time consuming effort, as it involves exploring clients' knowledge and needs, assisting them in making decisions. The facilitator role requires, in the short term, time and effort with the client that does not often yield immediate results, while risking failure to achieve target coverage and goals.
- RHA requires changes in established performance standards. Conventional measurements of performance reward and provide incentives to product-based services, where clear linkages can be established between service provider efforts and results (e.g. a counseling session resulting in a family planning method accepted). RHA outcomes use qualitative measures not easily evaluated in current systems.

### Areas for future action

Pilot RHA interventions have yielded valuable information about opportunities and constraints for developing institutional capacity in RHA at the program level that can guide future implementation efforts. Impact evaluation of these RHA interventions at the community and individual levels must be completed to complement the

process evaluation currently under way. It is recommended that alternative measures to address constraints found until now be identified and that complete results of the interventions be disseminated at the country level and within the international reproductive health community.

In future efforts for developing institutional capacity in RHA, it is advised that (a) early institutional assessments identify opportunities for RHA insertion institution-wide rather than only in a particular program area. The assessment would also ensure that the selected organization has the capability and intention of embracing the RHA philosophy institution-wide and can guarantee replication, and (b) commitment from the organization is secured to guarantee incorporation of RHA in all areas where the assessment identifies feasibility potential for success.

It is also recommended that the Institute for Reproductive Health continues to work, as it has until now, with organizations which have long-established norms, protocols, and programs. RHA involves a change in attitude and behaviors, which is a challenging and complex task in already-established systems. However, working with these programs provides an opportunity for significant impact because they also have systems which can incorporate new activities as well as linkages and experience to put changes into practice.

Results of the demonstration studies need to be compiled. This will include validation and dissemination of RHA premises and demonstration of its benefits for programs, communities and individuals. Efforts to date have also generated important outputs: the development and evaluation of training methodologies in RHA, the development and evaluation of concepts and messages and the context in which they can be presented; and the development and/or adaptation of RHA curricula and materials by collaborating organizations. These products need to be shared and adapted for incorporation into large-scale training programs, such as those from AVSC and CARE and in pre-service health provider education.

In documenting the RHA implementation experience, the Institute should aim at formulating prototype implementation models for the three experimental contexts: community, health and school programs, which can assist other programs interested in replicating the present experience. Finally, it is recommended that future efforts also build on the opportunities offered by the community-based groups and work with clinic-based programs to address the constraints that hinder and the conditions that facilitate RHA incorporation into services, communities and organizations. It is also crucial to seek the incorporation of RHA education into pre-service education programs to shape new attitudes in health professionals rendering them more favorable to client-oriented services and education.

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## **X. Future of natural family planning and reproductive health awareness**

**What are the implications of the findings and discussion of this conference for future directions in NFP and Reproductive Health Awareness?**

*Chair* Victoria Jennings, Ph D

*RECOMMENDATIONS* Recommendations were developed to address the major issues that were discussed during the meeting

### **1 NFP service delivery strategies for mainstreaming and expansion**

*Facilitator* Carlos Huezo, M D

Fertility awareness information should be part of basic client education offered by reproductive health/ family planning providers. It has implications for effective practice of NFP and other family planning methods as well as for other aspects of reproductive health.

- Family planning providers can enhance quality of care by adding fertility awareness education and NFP to the choice of methods offered
- International, national, and local organizations committed to reproductive health and quality of care should advocate the effective inclusion of fertility awareness education and NFP into family planning programs
- Institutions interested in incorporating fertility awareness education and NFP should receive necessary assistance and support to accomplish this. The assistance should include assessment of potential demand, identification of resources, planning the implementation (including adaptation of the organizational systems to incorporate NFP) training providers, developing service guidelines, and integrating these services into monitoring and evaluation systems
- Since little information exists on the integration of NFP into multimethod programs studies should be conducted on cost efficacy, acceptability to providers, and clients

- Since there is still much to learn in the integration of fertility awareness education and NFP into multi-method family planning services, operations research is needed to test different approaches to mainstreaming
- There is a great wealth of experience among specialized NFP organizations which could be of great assistance in carrying out the above steps. Therefore, collaboration between specialized NFP organizations and other programs should be encouraged

## **2 Reproductive Health Awareness next steps**

*Facilitator* Kimberly Aumack, M A

- Knowledge and awareness about the concept of Reproductive Health Awareness at all levels (individual, provider, policy, etc) should be increased
- Support for organizations and individuals to help them improve the skills necessary for their active participation in the Reproductive Health Awareness implementation process is essential
- Linkages should be created between organizations and institutions working with some of the Reproductive Health Awareness concepts to enhance integration of the whole approach
- Prioritization of tasks and steps to integrate Reproductive Health Awareness into on-going programs is important
- Development of an assessment and evaluation framework which includes methodologies to measure improved quality of life which go beyond the standard public health measures, core indicators which can be compared across projects, and adaptable tools, should be a priority
- Providers need training and technical assistance to move from a role of providers of information to reproductive health facilitators
- Appropriate curricula and materials which can be used to train groups and individuals in Reproductive Health Awareness are needed
- Operations research to show the impact of Reproductive Health Awareness and demonstrate how it differs qualitatively from other strategies is needed. Participatory research on the process of implementation is also needed

### 3 Safety and efficacy of NFP implications of findings

*Facilitator* Max Elstem, M D

- NFP is safe and effective and can be recommended as part of a family planning approach based on informed choice
- There is the need to prospectively evaluate the reproductive function of couples at the extremes of the potential fertile time of the cycle
- Data are needed on the characteristics of long term users of NFP to identify factors which facilitate continuing acceptance
- There remains a need to disseminate the existing efficacy data regarding various NFP methods to policy makers and providers
- Specific investigations on the acceptability and efficacy of simplified approaches to NFP are required

### 4 Devices for predicting and detecting the fertile time next steps and goals

*Facilitator* David Katz, Ph D and Cecilia Pyper, M D

- Devices to predict and detect potential fertility should be based on biological signs and must be designed for use by people in various geographical settings and socioeconomic groups with the goal of expanding the acceptability and use of NFP
- Basic issues regarding devices include
  - Measurement

	<i>Target Materials</i>	<i>Measurements</i>
Primary	Urine Mucus	Hormones Hydration
Secondary	Saliva  Intestinal fluid Other	Hormones and other biochemical and physical parameters Transdermal transition of hormones

- Behavior

*Ease of use non-invasive lifestyle compatible*

- Technology

*Safety robustness and reliability simplicity accessibility*

- Economics

*Cost of development cost of manufacturing cost to user subsidized marketing strategy, return on investment*

- Research and Evaluation

*Independent assessment availability of results*

## **5 Defining the fertile time implications of findings**

*Facilitator* Jeff Spieler, MSc

- Direct measurements of the day of ovulation (e.g. using ultrasound scans or hormone assays) will enable a more accurate determination of conception probabilities but would be less practical for NFP use
- Imprecise markers of ovulation, e.g. BBT rise, are less reliable for defining the probability of conception on each day of the fertile period and also result in the identification of a longer potential fertile period and number of abstinence days than more precise markers
- It is important to distinguish between the actual fertile period and the so-called unsafe days. The latter encompasses the former. The more accurately the day of ovulation is identified by NFP users, the closer the fertile period and unsafe days are to each other.
- More precise estimates of conception probabilities and the effect of co-variables (e.g. age of woman and man, parity) are needed
- More precise data are needed on the relationship between various reference points for ovulation used in NFP and the actual time of ovulation. Such a study would be best done in NFP users and should be large enough to permit pooled and separate analyses of volunteers based on important co-variables such as parity, age and whether NFP is used to avoid or achieve pregnancy. NFP reference points could then be used to obtain a more precise estimate of the conception probabilities on each day of the fertile period.

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- More precise estimates for modifying and standardizing the abstinence rules for the different NFP methods to decrease both the risk of unplanned pregnancy and the duration of abstinence should be established
  - New devices for predicting and determining the fertile time should include the capability to customize the rules for individuals depending on their particular circumstances, e.g. cycle length, parity, and motivation to avoid pregnancy versus desire for less abstinence. Additionally, this applies to potentially modifying electronic devices to permit the user to set the device to give a more or less precise detection of the onset and duration of the fertile period which, in turn, would either give greater effectiveness and more abstinence or less effectiveness and less abstinence
  - Current NFP methods, like the Billings ovulation/cervical mucus method and the sympto-thermal method, have perfect-use rates that range from as low as zero to about 3–4% and typical-use rates that range, on average, from 8% to 20%+, thus, it is unlikely that better estimates of conception probabilities will improve the perfect-use pregnancy rates
  - Obtaining precise data on conception probabilities and the co-variables influencing this may be helpful to better define the actual fertile period in NFP users. This could result in less abstinence and better compliance which would improve the typical-use pregnancy rates. This acceptance should make it easier for NFP acceptors to be a perfect users

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*Advances in Contraception* is the official organ of the Society for the Advancement of Contraception. The journal publishes peer-reviewed papers concerned with research in reproduction and clinical aspects of contraception. Its aim is to stimulate the knowledge of fertility regulation and family planning and to study new and existing methods of contraception.

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