

A PROSPECTIVE MULTICENTRE TRIAL OF THE OVULATION METHOD OF NATURAL FAMILY PLANNING. I. THE TEACHING PHASE*

WORLD HEALTH ORGANIZATION†

Task Force‡ on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland

The percentage of 869 women in five countries capable of being taught to recognize the periovulatory cervical mucus symptom of the fertile period was determined in a prospective multicentre trial of the ovulation method of natural family planning. The women were ovulating, of proven fertility, represented a spectrum of cultures and socioeconomic levels, and ranged from illiteracy to having postgraduate education. In the first of three standard teaching cycles, 93% recorded an interpretable ovulatory mucus pattern. Eighty-eight per cent of subjects successfully completed the teaching phase; 7% discontinued for reasons other than pregnancy, including 1.3% who failed to learn the method. Forty-five subjects (5%) became pregnant during the average 3.1-cycle teaching phase. The average number of days of abstinence required by the rules of the method was 17 in the third teaching cycle (58.2% of the average cycle length). To what extent the findings of this study can be extended to other couples remains to be demonstrated. Fertil Steril 36:152, 1981

Received December 15, 1980; revised and accepted March 13, 1981.

*Supported by the Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland.

†Reprint requests: Mr. J. M. Spieler, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research in Human Reproduction, WHO, 1211 Geneva 27, Switzerland.

‡The Task Force Investigators for this study were William Gibbons, M.D., and Francesca Kearns, R.N., Faculty of Health, San Lucas Centre, San Miguel, El Salvador; Marie-Mignon Mascarenhas, M.D., and Aloma Lobo, M.D., Family Welfare Centre, Bangalore, India; John Bonnar, M.D., and Esther Bradley, M.D., Department of Obstetrics and Gynaecology, University of Dublin, Rotunda Hospital, Dublin, Republic of Ireland; John France, Ph.D., and Margaret France, M.A., Postgraduate School of Obstetrics and Gynaecology, National Women's Hospital, Auckland, New Zealand; Vicente Rosales, M.D., and Bienvenido Angeles, M.D., Institute for the Study of Human Reproduction, University of Santo Tomas, Manila, Philippines; Henry Burger, M.D., Prince Henry's Hospital, Medical Research Centre, Melbourne, Australia; Jeffrey Spieler, M.Sc., Special Programme of Research in Human Reproduction, WHO, Geneva, Switzerland; and Hubert Campbell, M.D., Department of Medical Statistics, Welsh School of Medicine, Cardiff, United Kingdom.

The ovulation method (OM) of natural family planning is based on self-observation by the woman of a sequence of changes in the quality of cervical mucus that have been found to correlate with certain periovulatory hormonal changes.¹⁻³ In 1975, very little objective data were available on the ability of women to detect these changes and on the effectiveness of the OM.⁴ The present study was therefore initiated to determine the percentage of women who are capable of recognizing the changes in cervical mucus during the menstrual cycle, factors affecting this ability, and the effectiveness of this approach to family planning. The study was completed in June 1979. We describe here the design and methodology of the trial, the characteristics of the subjects, and the results of the teaching phase of the study.

METHODS

To permit a cross-cultural assessment, various centres with experience with the ovulation method and with qualified teachers were invited to participate. The five centres were in Auckland

(New Zealand), Bangalore (India), Dublin (Ireland), Manila (Philippines), and San Miguel (El Salvador). A principal investigator and a principal teacher with administrative and supervisory responsibilities were designated in each centre. They in turn chose a number of subcentres and selected a number of teachers who assisted in recruitment of subjects and who had primary responsibility for teaching and completing the follow-up forms for the study.

The individual centres enlisted 2 to 12 subcentres and appointed 3 to 39 teachers. In Auckland, volunteers were recruited from predominantly urban areas; in San Miguel, from predominantly rural areas. In Bangalore, Dublin, and Manila, volunteers were recruited from both urban and rural areas.

Design of the Study. The study was divided into two phases: a teaching phase, in which the percentage of women who were capable of recognizing the cervical mucus symptom of the fertile period was examined, and an effectiveness phase. A series of forms was designed to record the relevant data, including admission forms, teaching and effectiveness follow-up forms, and forms for reporting pregnancy and discontinuation. In general, after initial instruction, the first three completed cycles constituted the teaching phase. This phase was extended for up to three additional cycles if the teaching was considered to have been unsuccessful or if the subject was judged to require more time to master the method, to be anovulatory, to have cycles outside the range of 23 to 35 days, or to require time to discontinue a concurrent method.

The subject was given a chart on which data from three cycles could be recorded by means of daily written observations (or appropriate markings by illiterate subjects) and by use of colored stickers (stamps), one of which was used for each day of the cycle.⁵ All teachers were carefully instructed not to show the subjects typical OM charts and to stress the individual nature of the mucus secretion in an attempt to ensure that they did not merely reproduce patterns which they had seen during their instruction. Subjects were interviewed by a teacher at monthly intervals or occasionally during the first few cycles more frequently, at which time teaching was reinforced and data from the previous cycle were documented. Originals of all forms and charts were dispatched to the World Health Organization (WHO) at 3-month intervals.

OM Rules. The rules of the OM were those set out in *Atlas of the Ovulation Method*,⁵ with the exception that all days of mucus secretion during the preovulatory phase of the menstrual cycle were regarded as days of possible fertility. Briefly stated, subjects were instructed to abstain from intercourse during menstruation (because of possible early onset of the fertile period during the last days of menstrual bleeding), on alternative "dry days"¹ prior to the onset of the fertile period (to minimize difficulty in recognizing the onset of mucus secretion because of the presence of seminal fluid), and during the fertile period itself. The fertile period began with the onset of mucus secretion, or with a sensation of dampness or wetness, detectable at the vulva. The "peak day" was identified as the last day on which mucus of fertile type (resembling raw egg white)¹ was recognized or as the last day on which the wet or lubricative sensation was felt. The fertile period ended on the 3rd night past the peak, and intercourse could be resumed on the 4th night.

Data Processing and Analysis. All forms were checked by a statistical clerk at the WHO, who verified data items relating to the subjects' charts and corrected those items which had been coded incorrectly. The teachers and principal investigators were contacted whenever necessary to clarify problems or disagreements. All computer processing was carried out on an IBM 370 computer (model 158), and the statistical package for the social sciences was used for analysis.

Teachers. Advocates of natural family planning methods emphasize the importance of the quality of teaching in determining the success or failure of the method being practiced. Objective assessment of the competence of teachers of the OM to teach and to record the data required for the present trial has been difficult to achieve in every centre. Each teacher was asked to complete an OM questionnaire (devised by Billings) which was designed to test her knowledge and understanding of the method. The completed questionnaires were sent to the study coordinator for individual assessment. If the answers showed a deficiency in knowledge or understanding, the deficiency was immediately drawn to the attention of the principal investigator, who took the matter up with the teacher. In the majority of instances, the teachers were married women who were themselves using the method and had successfully completed the questionnaire.

Subject Selection Criteria. Selection criteria were chosen in a way to maximize the possibility

TABLE 1. *Education of Subjects*

Centre	No. of subjects (% of centre total)						
	Illiterate	Literate, self-taught	<6 yr of schooling	6-12 yr of schooling	Technical school	University	Postgraduate school
Auckland (N = 122)			1 (0.8)	76 (62.3)	29 (23.8)	13 (10.7)	3 (2.5)
Bangalore (N = 205)	38 (18.5)	5 (2.4)	49 (23.9)	90 (43.9)	7 (3.4)	15 (7.3)	1 (0.5)
Dublin (N = 234)			2 (0.9)	145 (62.0)	60 (25.6)	18 (7.7)	9 (3.8)
Manila (N = 146)			18 (12.2)	97 (66.4)	10 (6.8)	21 (14.3)	
San Miguel (N = 162)	78 (48.1)	20 (12.3)	52 (32.1)	11 (6.8)		1 (0.6)	
Total (N = 869)	116 (13.3)	25 (2.9)	122 (14.0)	419 (48.2)	106 (12.2)	68 (7.8)	13 (1.5)

that the study be undertaken in ovulatory women of proven fertility. Thus, the subjects were required to be less than 39 years of age, not lactating, to have a history of menstrual cycle intervals of 23 to 35 days, to have had at least one live birth (or stillbirth at term) within the preceding 5 years in the present union, to be cohabiting, not to have used hormonal contraceptives for at least three cycles prior to admission, and to agree not to use any other method of fertility regulation during the effectiveness phase of the study. In addition, the subject must not have practiced self-recognition of mucus changes for family planning, and was to be an informed volunteer willing to keep the necessary records.

RESULTS

Subject Characteristics. Altogether, 869 subjects were admitted to the teaching phase (Auckland, 122; Bangalore, 205; Dublin, 234; Manila, 146; and San Miguel, 162). The over-all mean age of the subjects was 30.1 years (range 28.5 in Manila to 31.0 in Dublin) and of their partners 34.5 (range 31.5 in Manila to 36.7 in San Miguel). Ninety-nine per cent of subjects were between 20 and 38 years of age.

Catholics constituted 83% of all subjects: 75% in Auckland, 55% in Bangalore, 99% in Dublin,

82% in Manila, and 99% in San Miguel. In Bangalore 32% were Hindu and in Auckland 12% were Protestant.

The educational status of the subjects is shown in Table 1. Eighty-three per cent of all subjects were housewives, and their partners had occupations varying widely between centres.

Couples had lived in their present unions for an average of 105 months, and subjects had had an average of 3.9 pregnancies (Auckland, 3.3; Bangalore, 3.7; Dublin, 3.3; Manila, 3.2; and San Miguel, 6.1). The last pregnancy had occurred within 6 months in 16% and within 7 to 18 months in 40%. In 23% this interval exceeded 31 months.

There was a wide variation in the frequency with which couples had previously used fertility-regulating methods (Table 2). Table 3 shows by centre the percentage of subjects for whom the indicated reason was their prime motivation for using the ovulation method.

Fifty-two per cent of subjects did not wish to have any more children ("limiters"), varying from 42% in Dublin and San Miguel to 70% in Bangalore. Eight per cent planned another pregnancy ("spacers") within 1 to 2 years (range 1% in Bangalore to 18.8% in San Miguel), 19% within 2 to 3 years, and 21% within three years or more.

TABLE 2. *Experience with Family Planning Methods*

Type ^a	No. of subjects (% of centre total)					
	Auckland (N = 122)	Bangalore (N = 205)	Dublin (N = 234)	Manila (N = 146)	San Miguel (N = 162)	Total (N = 869)
None	2 (1.6)	110 (53.7)	44 (18.8)	11 (7.5)	147 (90.7)	314 (36.1)
Pill	71 (58.2)	11 (5.4)	65 (27.8)	36 (24.7)	9 (5.6)	192 (22.1)
Intrauterine device	15 (12.3)	6 (2.9)	12 (5.1)	10 (6.8)	1 (0.6)	44 (5.1)
Diaphragm/cervical cap	9 (7.4)		6 (2.6)			15 (1.7)
Injectables	3 (2.5)			1 (0.7)	2 (1.2)	6 (0.7)
Spermicides	4 (3.3)	1 (0.5)	3 (1.3)			8 (0.9)
Periodic abstinence	90 (73.8)	34 (16.6)	150 (64.1)	69 (47.3)	5 (3.1)	349 (40.1)
Condom	28 (23.0)	36 (17.6)	31 (13.2)	51 (34.9)	1 (0.6)	147 (16.9)
Withdrawal	10 (8.2)	26 (12.7)	19 (8.1)	75 (51.4)		130 (14.9)
Other	7 (5.7)		3 (1.3)	1 (0.7)		11 (1.3)

^aMultiple methods could be indicated by the subjects, who were asked to specify all methods used previously.

TABLE 3. *Subject's Prime Motivation for Using the OM*

Centre	No. of subjects (% of centre total)				
	Religious reasons	Dissatisfaction or anticipated dissatisfaction with other methods	Recommendation of other OM user	Other methods contra-indicated in subject or partner	Other
Auckland (N = 122)	50 (41.0)	38 (31.1)	3 (2.5)	2 (1.6)	29 (23.8)
Bangalore (N = 199)	110 (55.3)	34 (17.1)	43 (21.6)	1 (0.5)	11 (5.5)
Dublin (N = 232)	96 (41.4)	75 (32.3)	30 (12.9)	6 (2.6)	25 (10.8)
Manila (N = 146)	33 (22.6)	47 (32.2)	46 (31.5)	3 (2.0)	17 (11.6)
San Miguel (N = 148)	55 (37.2)	8 (5.4)	13 (8.8)	15 (10.1)	57 (38.5)
Total (N = 848) ^a	344 (40.6)	202 (23.8)	135 (15.9)	27 (3.2)	139 (16.4)

^aMissing observations: 21.

Results of Teaching. In the first cycle following instruction, a mean of 93% of subjects showed an interpretable ovulatory mucus pattern, i.e., the subject's chart allowed the teacher to conclude that she was identifying her symptoms of ovulation correctly. Results of the second and third teaching cycles were similar, as is shown in Table 4. In those cycles not giving an interpretable ovulatory pattern, various descriptions were recorded, including "interpretable anovulatory," "cannot distinguish type of mucus," "infertile pattern." There were 60 subjects (6.9%) who did not have an interpretable pattern in the first cycle and, of these, 47 provided data in the second and third cycles: 30 (64%) had interpretable patterns in both of these cycles, 1 had an interpretable pattern in the second cycle but not in the third, 5 had an interpretable pattern in the third cycle but not in the second, and 11 continued to record noninterpretable patterns in both subsequent cycles. One hundred and seven women reported some vaginal discharge during the 6 months prior to admission to the study, but this did not affect the outcome of teaching.

The subject's understanding of the method following the first completed cycle in the teaching phase (Table 4) was assessed by the teacher as "excellent" or "good" in 91% of the subjects and

"poor" in 9%. These figures had increased to 94% and 97% assessed as "excellent" or "good" and decreased to 6% and 3% as "poor" in the second and third cycles, respectively. Of the 69 subjects whose understanding was "poor" in the first teaching cycle, and for whom data were available in the next two cycles, 52.2% had developed an "excellent" or "good" grasp of the method by the second cycle and 81.2% by the third. One hundred and seven subjects, including 53 (49.5%) from Dublin, entered an extended teaching period for the following reasons: method not fully learned and additional time required (36 women, 33.6%); one or no interpretable ovulatory patterns in the first three teaching cycles (17 women, 15.9%); still using a backup method (e.g., withdrawal, condom) and additional time required to discontinue this (12 women, 11.2%); additional time required to achieve two consecutive cycles in the range 23 to 35 days (8 women, 7.5%); and a variety of other reasons among 34 women (31.8%), including "irregular cycles due to stress," "assessment not possible, teacher or subject not available for interview," "change in mucus pattern because of treatment of cervical erosion," "motivation uncertain."

The over-all mean lengths of the first, second, and third teaching cycles were 29.4 (\pm 4.3 SD),

TABLE 4. *Cycles with an Interpretable Ovulatory Pattern and Women's Understanding of the OM*

Centre	1st Cycle		2nd Cycle		3rd Cycle	
	Interpretable pattern	Understanding excellent or good	Interpretable pattern	Understanding excellent or good	Interpretable pattern	Understanding excellent or good
	% of centre total					
Auckland	95.1	89.9	95.0	93.2	97.4	99.1
Bangalore	99.5	96.6	97.5	97.0	97.5	97.0
Dublin	88.9	88.9	92.4	93.7	93.1	97.2
Manila	87.7	95.5	88.7	98.4	89.6	98.4
San Miguel	94.4	82.7	94.3	88.2	92.8	94.6
Total	93.1	90.8	93.7	94.2	94.1	97.1

TABLE 5. *Outcome of Teaching by Cycle*

Teaching cycle	No. of subjects (% of total)			
	Subjects entering cycle	Subjects pregnant in cycle	Subjects withdrawn	Subjects entering effectiveness phase
1	869	8 (0.9)	17 (2.0)	
2	844	9 (1.1)	18 (2.1)	
3	817	16 (2.0)	41 (5.0)	653 (75.1)
4	107	8 (7.4)	9 (8.4)	45 (5.2)
5	45	2 (4.4)	7 (15.6)	17 (2.0)
6	19	2 (10.5)	7 (36.8)	10 (1.1)
All cycles	2701	45 (5.2)	99 (11.4)	725 (83.4)

29.3 (\pm 4.2) and 29.2 (\pm 4.0) days, respectively, and there was no significant difference between centres. Ninety-two per cent of these cycles were in the range 24 to 35 days. The fertile period (defined as the number of days from the onset of the mucus symptoms until and including the 3rd day after the peak) averaged 9.6 days in length for all centres, and was 10.8 days in Auckland, 9.7 in Bangalore, 10.5 in Dublin, 9.6 in Manila, and 7.3 in San Miguel. The figure for San Miguel was significantly lower than those for the other centres ($P < 0.01$). Furthermore, the fertile period in Auckland and Dublin was longer than that in the other three centres ($P < 0.05$). The number of days available for intercourse during the cycle, for subjects with only a single sequence of mucus days (88.5%), was made up of half the number of preovulatory dry days and the interval between the end of the fertile period and the following menses. Days of abstinence required included menses days (mean, 5.1 days), half the preovulatory dry days (average number of such days for the population, 3.5 days), and the fertile period as described. In the third teaching cycle, the number of days of abstinence required was 17 over-all, with individual means of 18.8 (\pm 4.6 SD) for

Auckland, 16.4 (\pm 4.2) for Bangalore, 19.8 (\pm 6.5) for Dublin, 16.1 (\pm 3.9) for Manila, and 13.2 (\pm 6.0) for San Miguel.

Discontinuations During Teaching. Of the 869 subjects who entered the teaching phase, 653 (75.1%) entered the effectiveness phase after the first three teaching cycles and an additional 72 (8.3%) after extended teaching for up to three more cycles (Table 5). A total of 45 subjects (5.2%) became pregnant during teaching, and 99 others withdrew from the study. Forty of the latter had successfully learned the method, giving a total of 88% who completed the teaching phase. Table 6 describes the outcome of the teaching phase and shows the reasons for discontinuation. Continuation rates varied from 75.3% in San Miguel to 93.2% in Bangalore.

The distribution of pregnancies between centres is shown in Table 6. Two pregnancies occurred even though all rules of the OM appeared to have been followed by the couples and a third may have been method-related. Thirty-two pregnancies occurred when couples chose to have intercourse during the fertile period and eleven more were judged to have resulted from inaccurate application of the instructions. The latter

TABLE 6. *Outcome of Teaching Phase by Centre*

Centre	No. of subjects (% of centre total)				
	Subjects admitted to teaching	No. of cycles	Subjects admitted to effectiveness phase	Pregnancies	Other discontinuation ^a
Auckland	122	377	102 (83.6)	7 (5.7)	13 (10.7)
Bangalore	205	618	191 (93.2)	8 (3.9)	6 (2.9)
Dublin	234	764	195 (83.3)	7 (3.0)	32 (13.7)
Manila	146	444	115 (78.8)	10 (6.8)	21 (14.4)
San Miguel	162	498	122 (75.3)	13 (8.0)	27 (16.7)
Total	869	2701	725 (83.4)	45 (5.2)	99 (11.4)

^aReasons for discontinuation other than pregnancy included the following: persistent rule-breaking or lack of motivation (9 subjects), moved away (28 subjects), dissatisfied (12 subjects), desire for other method (11 subjects), desire for pregnancy (8 subjects), failure of teaching (11 subjects), no further need (11 subjects), other (9 subjects).

resulted either from the couple's lack of complete comprehension of the method (e.g., lack of accurate interpretation of the "peak day") or from difficulty caused by stress or by the presence of continuous mucus discharge. For Bangalore, Manila, and San Miguel, 25 of 29 pregnancies resulted from a conscious departure from the rules, whereas this was so for only 7 of the 14 pregnancies in Auckland and Dublin.

A striking difference in discontinuations and pregnancy rates emerged when the results of the first three teaching cycles were compared with the results for subjects who required extended teaching. The former group was made up of 2530 cycles, in which there were 33 pregnancies (1.3% pregnancy cycles) whereas the latter group contained 171 cycles, with 12 pregnancies (7.0% pregnancy cycles). The relative discontinuation rates for other reasons between these two groups were 3.0% and 13.5%, respectively.

DISCUSSION

This study represents the first international multicentre evaluation of the OM. It was a pilot study in which a deliberate selection was made of fertile women. No attempt was made to assess the applicability of the method to an unselected group of couples or to special groups such as lactating women, those immediately postpill, or perimenopausal women. Therefore, the results can be applied only to women of the type investigated, i.e., regularly ovulating women of proven fertility who had not previously used the OM and who were motivated to volunteer for the study.

The most striking finding was the demonstration that 94% of women representing a wide range of cultural, educational, and socioeconomic characteristics were able to recognize and record the cervical mucus symptom which allows self-recognition of the fertile period.¹⁻³ A previous study⁶ of 1800 cycles of 166 British women who were instructed in these symptoms by correspondence showed that 75% of the subjects observed mucus symptoms in every cycle and an additional 21% in some cycles. It is noteworthy that self-recognition of cervical mucus was achieved equally well regardless of educational level: 94% of women in San Miguel produced an interpretable ovulatory mucus pattern, although 92.5% of them had had less than 6 years schooling and 48.1% were illiterate. The ability to observe the mucus symptom was also uninfluenced by a previous his-

tory of vaginal discharge or the finding of vaginal or cervical infection—for which treatment was offered at the initial examination. The study was designed to allow couples 3 months in which to learn the OM; in fact, understanding of the method was rated as "good" or "excellent" by the teacher in 90.8% of subjects after the first teaching cycle.

The question of the degree to which the subjects studied were representative of the general population in their respective countries cannot be answered easily because of lack of the necessary data regarding other women of comparable age and parity. With the exception of motivation, in the Dublin and San Miguel centres the subjects were probably very comparable to the population from which they were drawn; in Manila and Bangalore the educational status was higher than that of the general community, and in Auckland and Bangalore the percentage of Catholics was much higher than that in the general population.

Advocates of natural family planning methods emphasize the importance of the quality of teaching: review of the questionnaires completed by the teachers who participated in the present study revealed some unevenness in standard, although the preliminary data obtained during the teaching phase indicated that the majority of pregnancies occurred in couples who stated that they had consciously departed from the rules of the method. The psychosexual aspects of natural family planning and its teaching require much more attention. Thus, 47.3% of women who were "limiters" failed to abstain from intercourse in the first teaching cycle, compared with 44.6% of those who intended to have more children ("spacer"), whereas the percentages who actually became pregnant during the teaching phase were 3.8 and 6.8, respectively.

The fact that the overwhelming majority of subjects acquired an "excellent" or "good" grasp of the method after one teaching cycle and that half of these subjects did not in fact abstain from intercourse cast some doubt on the necessity to recommend complete abstinence from intercourse during the first cycle of instruction in the OM.⁵

A total of 5.2% of the subjects who entered the study became pregnant during the teaching phase, the rate being highest in San Miguel (8.0%) and lowest in Dublin (3.0%). Calculations of pregnancy rates by the Pearl index or by life-table analysis is not justifiable when the mean period of observation is 3.1 cycles/subject. It is noteworthy that the highest pregnancy rate (San

Miguel centre) occurred in a population in which only one in ten had previously used fertility-regulating methods and in which the subjects had previously had an average of six pregnancies and were of the lowest educational status among the five centres. Without the practice of any method, it could be anticipated that at least 25% of such highly fertile women would have become pregnant in the first month.⁷ Only two subjects (0.2%) became pregnant while apparently following the rules of the OM, and only one of these pregnancies could be firmly classified as a method-related pregnancy. A full analysis of the effectiveness of the OM will be published subsequently.

The discontinuation rate in the teaching phase of this study was relatively low, with 88% of those admitted completing the teaching phase and 83.4% going on to enter the effectiveness trial (range, 75.3% in San Miguel to 93.2% in Bangalore). In another recent study of the OM the continuation rate in a North American population was 77% after 3 ordinal months, with a 6.5% pregnancy rate at that interval.⁸ Over-all discontinuation rates will again be assessed at the conclusion of the study. An important aspect of the study was the observation that there were much higher pregnancy and discontinuation rates among subjects for whom teaching had to be extended for one or more cycles beyond the usual time (Table 5). It can be concluded that subjects who failed to learn the OM within three cycles are likely to have a high pregnancy rate and should be advised to adopt alternative methods if they wish to avoid pregnancy. In service programs these subjects require intensive follow-up and support.

Almost all women in the study, from five countries and of varying educational and socioeconom-

ic levels, were able to recognize the fertile period after one cycle of teaching. The ability to apply this knowledge to the regulation of fertility will be the subject of a later report, but the findings have important general implications not only to family planning but to the management of infertility.

Acknowledgments. The authors express their gratitude to the teachers and to the subjects who, by their voluntary efforts, made the study possible, and to the statistical clerk, Ms. Georgina Kainer, WHO, whose contribution was invaluable. The assistance of the Electronic Data Processing Unit and secretarial staff of the WHO is gratefully acknowledged.

REFERENCES

1. Billings EL, Billings JJ, Brown JB, Burger HG: Symptoms and hormonal changes accompanying ovulation. *Lancet* 1:282, 1972
2. Flynn AM, Lynch SS: Cervical mucus and identification of the fertile phase of the menstrual cycle. *Br J Obstet Gynaecol* 83:656, 1976
3. Hilgers TW, Abraham GE, Cavanagh D: Natural family planning. I. The peak symptom and estimated time of ovulation. *Obstet Gynecol* 52:575, 1978
4. Weissmann MC, Foliaki L, Billings EL, Billings JJ: A trial of the ovulation method of family planning in Tonga. *Lancet* 1:813, 1974
5. Billings EL, Billings JJ, Catarinich M: *Atlas of the Ovulation Method*, Second Edition. Melbourne, Advocate Press, 1974
6. Marshall J: The prevalence of mucous discharge as a symptom of ovulation. *J Biosoc Sci* 7:49, 1975
7. Behrman SJ, Kistner RW: A rational approach to the evaluation of infertility. In *Progress in Infertility*, Second Edition, Edited by SJ Behrman, RW Kistner. Boston, Little, Brown and Co, 1975, p 2
8. Wade ME, McCarthy P, Abernathy JR, Harris GS, Danzer HC, Uricchio WA: A randomized prospective study of the use-effectiveness of two methods of natural family planning: an interim report. *Am J Obstet Gynecol* 134: 628, 1979

A PROSPECTIVE MULTICENTRE TRIAL OF THE OVULATION METHOD OF NATURAL FAMILY PLANNING. II. THE EFFECTIVENESS PHASE*

WORLD HEALTH ORGANIZATION†

*Task Force on Methods for the Determination of the Fertile Period,
Special Programme of Research, Development and Research Training in Human Reproduction,
World Health Organization, Geneva, Switzerland*

*A five-country prospective study was undertaken to determine the effectiveness of the ovulation method of natural family planning. After successful completion of a teaching phase of three cycles, 725 subjects entered a 13-cycle effectiveness phase and contributed 7514 cycles of observation. The overall cumulative net probability of discontinuation for the effectiveness study after 13 cycles was 35.6%, 19.6% due to pregnancy. Pregnancy rates per 100 woman-years calculated using the modified Pearl index were as follows: conscious departure from the rules of the method, 15.4; inaccurate application of instructions, 3.5; method failure, 2.8; inadequate teaching, 0.4; and uncertain, 0.5. *Fertil Steril* 36:591, 1981*

Received April 10, 1981; revised and accepted July 17, 1981.

*Supported by the Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland.

†Reprint requests: Mr. J. Spieler, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research in Human Reproduction, WHO, 1211 Geneva 27, Switzerland.

‡The Task Force Investigators for this study were William Gibbons, M.D., and Francesca Kearns, R.N., Faculty of Health, San Lucas Centre, San Miguel, El Salvador; Marie-Mignon Mascarenhas, M.D., and Aloma Lobo, M.D., Family Welfare Centre, Bangalore, India; John Bonnar, M.D., and Esther Bradley, M.D., Department of Obstetrics and Gynaecology, University of Dublin, Rotunda Hospital, Dublin, Republic of Ireland; John France, Ph.D., and Margaret France, M.A., Postgraduate School of Obstetrics and Gynaecology, National Women's Hospital, Auckland, New Zealand; Vicente Rosales, M.D., and Bienvenido Angeles, M.D., Institute for the Study of Human Reproduction, University of Santo Tomas, Manila, Philippines; Henry Burger, M.D., Prince Henry's Hospital, Medical Research Centre, Melbourne, Australia; Jeffrey Spieler, M.Sc., Special Programme of Research in Human Reproduction, and Alain Pinol, D.E.S.T., Data and Text Processing Services unit, Division of Information Systems Support, WHO, Geneva, Switzerland; and Hubert Campbell, M.D., Department of Medical Statistics, Welsh School of Medicine, Cardiff, United Kingdom.

The ovulation method (OM) of natural family planning is based on self-observation by the woman of a sequence of changes in the quality of cervical mucus, which allow her to determine the fertile period.¹ In August 1976, the Special Programme of Research in Human Reproduction initiated a multicentre study of the OM, with the principal aims of determining the percentage of women of widely differing characteristics who could be taught successfully to recognize the mucus changes, and of assessing the effectiveness of the method in avoidance of pregnancy in such women. The study was, therefore, divided into two phases, teaching and effectiveness. A detailed report of the teaching phase has already been published.² The present report summarizes the results of that phase and the major findings of the effectiveness phase.

MATERIALS AND METHODS

Five centers, in Auckland, Bangalore, Dublin, Manila, and San Miguel (in New Zealand, India,

Ireland, the Philippines and El Salvador, respectively), were invited to participate and contributed a total of 869 subjects, who were admitted to a teaching phase of three to six cycles. Of these, 765 subjects (88%) successfully completed the teaching phase, and 725 entered the effectiveness phase. The remaining 40 withdrew from the study for various reasons, such as moving away, no further need for a method, dissatisfaction with the method, and desire for pregnancy.

The subject selection criteria were chosen so as to maximize the possibility that fertile women, with menses at intervals of 23 to 35 days, were admitted, and the only additional criterion for admission to the effectiveness study was evidence that the subject had successfully learned the OM, as judged by her teacher and the principal investigator in her center.

The rules of the OM were those set out in the *Atlas of the Ovulation Method*,¹ with the exception that all days of mucus secretion in the preovulatory phase of the menstrual cycle were regarded as days of possible fertility. In brief, subjects were instructed to abstain from intercourse during menstruation (because of possible early onset of the fertile period during the last days of bleeding), on alternate "dry days"¹ prior to the onset of the fertile period (to minimize difficulty in recognizing the onset of mucus secretion because of the presence of seminal fluid), and during the fertile period itself, leading to abstinence for approximately half of the total days of the cycle. The fertile period began with the onset of mucus secretion, or with a sensation of dampness or wetness, detectable at the vulva. The "peak day" was identified as the last day on which mucus of fertile type (resembling raw egg white)¹ was recognized or as the last day on which the wet or lubricative sensation was felt. Intercourse could be resumed with the ending of the fertile period on the evening of the 4th day past the "peak day."

Data-collecting forms were used for each cycle. The subject maintained a record of her symptoms; from this, and a monthly interview, the teacher transcribed cycle details and timing of the mucus symptoms, and noted the presence of any factors likely to disturb the cycle, occurrence of genital contact during the fertile period, observation of the OM rules, and details of the subject's comprehension of the method and attitude toward observation of the rules. Subjects were asked to record all acts of intercourse, but, at a minimum, the last act before the onset of the mucus symptoms, the

first act after the peak, and all acts during the fertile period were to be recorded.

The intentions of the couple to continue their use of the method were explored by means of questions including their wishes regarding further pregnancies, i.e., whether the couple were planning to space or limit their family. For subjects who became pregnant during the study, a pregnancy report form was used to record the method by which the diagnosis of pregnancy was established (pregnancy test or physical examination only), the details of the pregnancy cycle, the most likely time of conception, and the opinion of the couple and teacher on whether the pregnancy had resulted from method failure, inadequate teaching, and so forth.

Pregnancies occurring during the effectiveness phase were analyzed by inspection of the subject's own chart of the pregnancy cycle, by analysis of the data on the pregnancy report form, by review of previous charts for evidence regarding the standards of record keeping, and by apparent motivation as reflected in recording symptoms and rule-breaking. When available, an outcome of pregnancy report was reviewed to compare the date of birth and estimate of maturity with the calculated due date for delivery. Five categories were used in pregnancy classification, more than one category being applicable in some instances:

Method-Related Pregnancy. The data indicated that the couple had observed all rules of the method. Typically, such a chart would be characterized by a report of intercourse on or before the last dry day of the pre-peak period, and on or after the 4th day following the peak. Furthermore, the record indicated that the subject had correctly identified the peak day. The assumption was made that the couple had provided an accurate record of their acts of sexual intercourse in relation to the fertile period.

Pregnancy Resulting from Inadequate Teaching. The comments of the subject, teacher, or principal investigator, or the manner in which the forms were completed, indicated that the subject had been given inadequate or incorrect information.

Pregnancy Resulting from Inaccurate Application of Instructions. The record indicated that the subject did not fully understand the method or its application; e.g., she had difficulty in identifying the peak day or was confused as to which day following the peak was safe for resumption of intercourse. Alternatively, the record indicated that the couple had experienced difficulty in fol-

lowing the rules because of continuous mucus discharge, illness, or other circumstances that made it difficult for the subject to observe or chart the mucus.

Pregnancy Resulting from Conscious Departure from the Rules of the Method. The record indicated that the couple knowingly made a decision to have intercourse despite indications of fertility. Typically, such couples took a chance by having intercourse during the fertile period, or elected to abandon the rules because of, for example, a celebration or departure on or return from holidays or work.

Pregnancy, Classification Uncertain. In some instances of possible (though unlikely) method-related pregnancies, despite careful analysis of all the available data, no decision could be made regarding the correct classification. The final analysis of the pregnancies was undertaken by the study coordinator; points of disagreement with the relevant principal investigators were clarified by discussion.

The system of registering the subjects on admission to the trial and of recording data each month during the teaching period has been described.² Copies of all forms were checked for completeness and consistency in Geneva, and the data was entered into the computer (International Computing Centre). Errors, incomplete entries, and inconsistent entries were referred back to the centers, appropriate corrections were made, and an analysis file was created. Some of the tabulations were derived from the Statistical Package for Social Sciences (SPSS), others were programmed specifically for this study. Life table analysis^{3, 4} was undertaken with the use of menstrual cycle intervals rather than months of use as the time base, and the results were expressed as net probabilities (%) of discontinuation. Tests of statistical significance included the chi-square test, Student's *t*-test, Fisher's analysis of variance, and nonparametric tests, as appropriate.

RESULTS

Summary of Data from the Teaching Phase

The Study Population. The characteristics of the 869 subjects who entered the teaching phase of the study have been described in detail previously.² In brief, mean ages of subjects and partners were 30.1 (\pm 4.6 SD) and 34.5 (\pm 6.2 SD) years, respectively. Sixty percent had been in their present union for more than five years at

entry to the study, and the subjects had had an average of 3.9 pregnancies. Catholics constituted 83% of all subjects, and 32% of the subjects in Bangalore were Hindus. The educational status of subjects varied widely; 44% to 66% having had at least 6 to 12 years of schooling in four centers, whereas 92% in San Miguel had had less than six years, almost half of these being illiterate. Nearly all the subjects were housewives, while partners had a wide range of occupations. There was a wide range in the frequency with which couples had previously used fertility-regulating methods—98% in Auckland, 46% in Bangalore, 81% in Dublin, 93% in Manila, 9% in San Miguel—and in the methods used. Thirty-six percent of all subjects had never previously used any method. Reasons given for using the OM varied widely, religious reasons being described by 41%, dissatisfaction or anticipated dissatisfaction with other methods by 24%, and recommendation of another OM user by 16%.

Results of Teaching. In the first of the three standard teaching cycles, 93% of subjects recorded an interpretable ovulatory mucus pattern, and 91% were assessed as having an "excellent" or "good" grasp of the method. Ninety-two percent of the cycles were in the range of 24 to 35 days, and the mean cycle lengths of the three standard teaching cycles were 29.4, 29.3, and 29.2 days, respectively. Eighty-eight percent of the subjects successfully completed the teaching phase; 5.2% (45) became pregnant, and 11.4% (99) discontinued for a variety of other reasons. One pregnancy was classified as definitely method-related, 32 resulted from conscious departure from the rules of the method, 11 resulted from inaccurate application of instructions, and 1 was uncertain in nature. Inadequate teaching contributed to two of these pregnancies. Of the 451 subjects who stated they did not wish to have more children, 3.8% became pregnant, compared with 6.8% of the 410 who did. A noteworthy feature of the results was the difference in pregnancy rates for subjects who successfully learned the method in the three standard cycles of teaching (pregnancy occurred in 1.3% of all cycles) and those who required extended teaching (pregnancy in 7% of all cycles).

The Effectiveness Phase

The Study Population. The characteristics of the 725 subjects who entered this phase of the study did not differ significantly from those of the 869 originally admitted. Fifty-four percent were "limiters," i.e., they stated they had no wish for

TABLE 1. Cumulative Net Probabilities of Discontinuation from the Effectiveness Study after 13 Cycles, by Center and Overall

Reasons for discontinuation	Auckland	Bangalore	Dublin	Manila	San Miguel	All
No. entering	102	191	195	115	122	725
Dissatisfaction with method	0	0	1.2	0	2.2	0.7
Desire for another method ^a	6.9	0.6	3.1	0	1.0	2.1
Pregnancy	27.9	17.5	17.4	12.8	26.9	19.6
Desire for pregnancy	16.7	5.0	7.3	3.5	2.5	6.6
Separation of spouses	0	1.8	1.3	5.5	11.2	3.6
Discontinued by investigator	0	0	0.6	0	0	0.2
Moved away	4.0	2.3	1.4	14.7	7.4	5.2
Study too demanding	1.3	0	5.5	2.8	1.9	2.3
Other reasons ^b	2.1	0.6	0.6	1.8	0	0.9
Total net probability of discontinuation	48.2	25.8	33.3	35.3	44.3	35.6

^aPreferred other method or wished to combine with another method (calendar, intrauterine device, vasectomy, tubectomy, or combination with temperature, rhythm, condom, condom + temperature, diaphragm).

^bSurgery, hospitalization of subject, husband died, medical reasons (excessive bleeding).

further children. Sixty-nine percent of subjects had had three or more pregnancies, and 88% of couples had two or more living children.

Cycle Characteristics. Mean cycle length for all cycles analyzed during the effectiveness phase (7514) was 28.6 (\pm 3.5 SD) days, 96% of cycles being in the range of 23 to 35 days. The average duration of the fertile period (calculated from the day of onset of the mucus symptom to the third day after the peak, inclusive) was 9.6 days (Auckland, 10.8; Bangalore, 9.8; Dublin, 10.5; Manila, 9.1; San Miguel, 7.2). There was a mean of 13.5 days from the peak to the end of the cycle. The mean number of days of abstinence required by the rules of the method was 15.4 (\pm 1.8 SD), with individual values of 16.0 (Auckland), 15.6 (Ban-

galore), 16.0 (Dublin), 15.2 (Manila), and 13.8 (San Miguel); and the corresponding number of days during which intercourse was allowed by the method was 13.1 overall, with 12.5, 13.1, 12.2, 13.7, and 14.3 in the five centers, respectively.

Discontinuations. Table 1 presents the cumulative net discontinuation probabilities over 13 cycles of observation during the effectiveness phase, as calculated by life table analysis. The total net probability was 35.6%, with the major reason for discontinuation being the occurrence of pregnancy (19.6%). There was considerable variation between centers, with total net probabilities ranging from 25.8% in Bangalore to 48.2% in Auckland. Probabilities of pregnancy ranged from 12.8% in Manila to 27.9% in Auckland. Desire for

TABLE 2. Cumulative Net Probabilities of Discontinuation after 16 Cycles (Teaching and Effectiveness Phases) by Center and Overall

Reasons for discontinuation	Auckland	Bangalore	Dublin	Manila	San Miguel	All
No. entering	122	205	234	146	162	869
Dissatisfaction with method	2.8	0	2.6	0.7	5.9	2.2
Desire for another method ^a	10.3	0.6	5.8	0.8	1.0	3.5
Pregnancy	32.2	20.7	20.0	19.0	33.6	23.9
Desire for pregnancy	16.7	6.4	8.7	3.5	3.2	7.4
Separation of spouses	0.9	2.4	2.7	6.3	14.0	4.9
Discontinued by investigator	0	0	2.6	1.7	2.3	1.4
Moved away	4.8	2.8	3.6	21.7	12.0	8.2
Study too demanding	4.0	0	6.3	5.8	3.3	3.8
Other reasons ^b	3.0	0.6	2.8	1.8	0.7	1.8
Total net probability of discontinuation	56.7	30.4	44.2	48.7	57.4	45.9

^aPreferred other method or wished to combine with another method (calendar, intrauterine device, vasectomy, tubectomy, or combination with temperature, rhythm, condom, condom + temperature, diaphragm).

^bSurgery, hospitalization of subject, husband died, medical reasons (excessive bleeding).

TABLE 3. *Pregnancies During Study*

Basic data and reasons for pregnancy	Auckland	Bangalore	Dublin	Manila	San Miguel	All
Total no. of subjects admitted						
Teaching	122	205	234	146	162	869
Effectiveness	102	191	195	115	122	725
Number of cycles						
Teaching	377	618	764	444	498	2701
Effectiveness	964	2124	2044	1234	1148	7514
Total	1341	2742	2808	1678	1646	10215
Method-related pregnancies						
Teaching	0	1	0	0	0	1
Effectiveness	7	0	8	1	0	16
Subtotal	7	1	8	1	0	17
Inadequate teaching						
Teaching	0	0	0	0	0	0
Effectiveness	0	0	1	1	0	2
Subtotal	0	0	1	1	0	2
Inaccurate application of instructions						
Teaching	3	1	3	1	3	11
Effectiveness	10	5	5	0	0	20
Subtotal	13	6	8	1	3	31
Conscious departure from the rules of the method						
Teaching	3	6	4	9	10	32
Effectiveness	7	26	16	11	29	89
Subtotal	10	32	20	20	39	121
Uncertain						
Teaching	1	0	0	0	0	1
Effectiveness	1	1	1	0	0	3
Subtotal	2	1	1	0	0	4
Overall total						
Teaching	7	8	7	10	13	45
Effectiveness	25	32	31	13	29	130
Grand total	32	40	38	23	42	175
Percentage of subjects originally admitted	26.2	19.5	16.2	15.8	26.0	20.1

a further pregnancy as a reason for discontinuation had a probability of 16.7% in Auckland and 7.3% in Dublin, with lower figures from the remaining centers. Separation of spouses and departure from the study center had probabilities of 11.2% and 7.4%, respectively, in San Miguel, reflecting the nature of relationships (26% of couples were not formally married) and the pattern of agricultural work (requiring seasonal movement for harvest) in this rural community. Departure from the study center also had a high probability in Manila (14.7%).

Table 2 summarizes cumulative net probabilities of discontinuation, calculated over a 16-cycle interval corresponding to the standard three cy-

cles of teaching and 13 cycles of effectiveness. The total cumulative net probability of discontinuation was 45.9%, ranging from 30.4% in Bangalore to 56.7% in Auckland and 57.4% in San Miguel. Pregnancy probabilities ranged from 19.0 to 33.6%, with a mean of 23.9%. There was a low probability (2.2%) of discontinuation because of dissatisfaction with the method. The continuation rate for the entire study was 54.1% at 16 cycles and ranged from 69.6% in Bangalore to 43.3% in Auckland and 42.6% in San Miguel, where the pregnancy rates were greatest.

Details of the pregnancies occurring during the study are presented in Table 3, and modified Pearl rates (per 1300 cycles) for the effectiveness

TABLE 4. *Pregnancy Rates for Effectiveness Phase and for Entire Study (Modified Pearl Rates)^a*

Reasons for pregnancy	Auckland	Bangalore	Dublin	Manila	San Miguel	All
Effectiveness phase						
Method-related	9.4	0	5.1	1.1	0	2.8
Inadequate teaching	0	0	0.6	1.1	0	0.4
Inaccurate application of instructions	13.5	3.1	3.2	0	0	3.5
Conscious departure from rules	9.4	15.9	10.2	11.6	32.8	15.4
Uncertain	1.3	0.6	0.6	0	0	0.5
Total	33.6	19.6	19.7	13.8	32.8	22.5
Entire study						
Method-related	6.8	0.5	3.7	0.8	0	2.2
Inadequate teaching	0	0	0.5	0.8	0	0.3
Inaccurate application of instructions	12.6	2.8	3.7	0.8	2.4	3.9
Conscious departure from rules	9.7	15.2	9.3	15.5	30.8	15.4
Uncertain	1.9	0.5	0.5	0	0	0.5
Total Pearl rates	31.0	19.0	17.7	17.9	33.2	22.3

^aPer 1300 cycles.

phase and for the total study are shown in Table 4. Of 254 women who left the study during the effectiveness phase, 130 were pregnant. Overall, during the effectiveness study, 16 pregnancies classifiable as method-related occurred in a total of 7514 cycles of observation, giving a modified Pearl rate of 2.8 pregnancies per 100 woman-years (1300 cycles). Three pregnancies were classified as "uncertain," with the (unlikely) possibility of method-failure being present—a Pearl rate of 0.5. Of the remaining 111 user-related pregnancies during the effectiveness study, 89 resulted from conscious departure from the rules of the method and 20 from inaccurate application of instructions, giving a combined user-related Pearl rate of 18.9. Inadequate teaching was judged to be the major reason for pregnancy in two cases. A total of 175 pregnancies occurred over the 16-cycle interval (teaching and effectiveness combined, a total of 10,215 cycles), representing 20% of the subjects originally admitted, 2% of subjects becoming pregnant as a result of method failure. The modified Pearl rates for the 16 cycles of the teaching and effectiveness phases combined were 2.2 for method failure, 0.5 for "uncertain" causes, and 19.6 for user-related pregnancies. The most frequent reason for pregnancy was conscious departure from the rules of the method (15.4 pregnancies per 100 woman-years).

There were significant differences between centers in the reasons for pregnancy. Of the 16 definite method failures during the effectiveness phase, 7 occurred in Auckland (6.9% of subjects

entering this phase in that center), 8 in Dublin (4.1% of subjects), and 1 in Manila (0.9%). In contrast, all 29 pregnancies in San Miguel occurred as a result of conscious departure from the OM rules. A detailed analysis of differences between subjects who became pregnant and those who continued successful use of the method will be published subsequently. However, a comparison of couples who had no intention of undertaking another pregnancy with those who were spacing their families, calculated by life table analysis during the effectiveness phase, is shown in Table 5. It is noteworthy that the differences between the cumulative net probabilities of discontinuation because of pregnancy (22.2% for spacers, 17.1% for limiters) did not reach statistical significance ($P = 0.08$). However, if the data for spacers was broken down into groups who desired another child in 1 to 2 years, 2 to 3 years, or more than 3 years, probabilities for pregnancy of 26.2%, 24.6%, and 18.8% were found, the latter figure being similar to that for limiters. The overall cumulative discontinuation probability of 43.0% for spacers was significantly greater ($P < 0.001$) than that of 29.1% for limiters, largely because of the 12.8% probability of discontinuation to undertake another pregnancy among the spacers.

DISCUSSION

Although a number of studies of the OM have been published,⁵⁻⁹ this report is of the first inter-

TABLE 5. Cumulative Probabilities of Discontinuation from Effectiveness Study after 13 Cycles by Intention for More Children

Reasons for discontinuation	Spacers	Limiters
No. entering the analysis	332	389
Overall cumulative discontinuation probability	43.0 ^a	29.1
Dissatisfaction with method	1.2	0.3
Desire for another method	2.0	2.3
Pregnancy	22.2	17.1
Desire for pregnancy	12.8 ^b	1.6
Separation of spouses	4.2	3.1
Discontinued by investigator	0.4	0
Moved away	5.1	5.4
Study too demanding	3.9	1.3
Other reason	0.3	1.4

^aDifference between spacers and limiters statistically significant ($P < 0.0001$).

^bFour records excluded from analysis, where the couple were uncertain regarding their intentions.

national multicenter evaluation, involving an initial total of 869 subjects from five centers/countries. Subjects of proven fertility were selected deliberately. Analysis of the effectiveness of the method was based primarily on observations of 725 subjects who successfully completed a period of training in self-observation of cervical mucus and in the rules that are recommended if such symptoms are to be used to identify the fertile period and to prevent pregnancy.¹ The conclusions drawn from the study are applicable only to subjects of the type investigated, i.e., regularly ovulating women of proven fertility, who had not previously used the OM, who were motivated to volunteer for the study, who represented a wide range of cultural, educational, and socioeconomic characteristics, and who had shown themselves capable of self-recognition of cervical mucus changes and of understanding the ovulation method of natural family planning that is based on those changes. It should be noted that the intensity of follow-up (a requirement of the study) by the teachers, who, in all but the Indian center, were unpaid, was greater than that which could be provided in a national family planning program.

The most important results of the study relate to the number of pregnancies that occurred and to their classification. The variability between centers was striking, in particular, the relatively high method failure rates in the two most socioeconomically developed centers, Auckland and Dublin. Pearl rates for method failure during the effectiveness study ranged from 9.4 per 100 woman-years in Auckland and 5.1 in Dublin, to 1.1 in Manila and 0 in Bangalore and San Miguel. The

reasons for these large differences are not obvious but will be explored in a subsequent, more detailed analysis of the pregnancies. Such an analysis is of particular relevance to the results in Auckland. The method-related pregnancies have important implications for current concepts regarding sperm and ovum survival and fertilization capacity and will be analyzed from this point of view.

No previous study of the OM has attempted a cross-cultural assessment of the effectiveness of the OM, although a number of prospective studies have done so in individual countries.⁵⁻⁹ Method failure rates varied from 0.48 to 3.0 pregnancies per 100 woman-years, and total rates from 9.6 to 25.4.

Valid comparisons of the data reported here cannot be made with the results of studies of other methods of fertility regulation. Such comparisons would require proper prospective and comparative studies undertaken with subjects who are given equal opportunities to acquire the information necessary to select each method and who are given equivalent degrees of support while using it. Furthermore, adequate program criteria and adequate tools for evaluation of teaching have yet to be established for the provision of natural methods. The subjects in the present study were selected to maximize the probability that they were fertile; they were motivated to use natural family planning methods and had been screened through a teaching phase before entering the effectiveness study, although it must be noted that the rates of pregnancy did not differ significantly between the two phases. Although a high pregnancy rate was observed, continuation rates were also relatively high: 64% in the 13 cycles of the effectiveness phase, ranging from 52% (Auckland) to 74% (Bangalore).

Various conclusions might be drawn from these results. Advocates of natural family planning will be encouraged by the method failure and continuation rates, and may be stimulated to undertake further research into ways in which couples can be assisted to follow the rules of the OM. Skeptics of the OM of natural family planning may have their views reinforced by the use-effectiveness figures, although the relative success of the method in the three developing country centers may stimulate wider examination of its applicability. Perhaps the most unequivocal conclusion is that almost all the women entering the study were indeed able to identify the fertile period by self-observation of the cervical mucus symptom.

The characteristics of the large group of menstrual cycles observed, the details of pregnancies, with emphasis on the method failures and on the time relationships between intercourse and conception, the outcome of pregnancy, and the behavioral characteristics of the couples studied will be analyzed in future publications. From such data, it is hoped, a profile of potentially successful users of the OM can be provided.

Acknowledgments. The authors express their gratitude to the teachers and to the subjects, who by their voluntary effort made the study possible, and to the statistical clerk, Ms. Georgina Kainer, WHO, Geneva, Switzerland, whose contribution was invaluable. The assistance of the Data and Text Processing Services Unit and secretarial staff of the World Health Organization is gratefully acknowledged.

REFERENCES

1. Billings EL, Billings JJ, Catarinich M: Atlas of the ovulation method. Third Edition. Melbourne, Advocate Press, 1977
2. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development, and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. I. The teaching phase. *Fertil Steril* 36:152, 1981
3. Chiang CL: Introduction to Stochastic Processes in Biostatistics. New York, John Wiley, 1968
4. Azen SP, Roy S, Pike MC, Casagrande J: Some suggested improvements to current statistical methods of analyzing contraceptive efficacy. *J Chron Dis* 29:649, 1976
5. Weissmann MC, Foliaki L, Billings EL, Billings JJ: A trial of the ovulation method of family planning in Tonga. *Lancet* 1:813, 1972
6. Ball M: A prospective field trial of the "ovulation method" of avoiding conception. *Eur J Obstet Gynaecol Reprod Biol* 6:63, 1976
7. Dolack L: Study confirms values of ovulation method. *Hosp Prog* 59:64, 1978
8. Klaus H, Goebel JM, Muraski B, Egizio MT, Weitzel D, Taylor RS, Fagan MU, Ek K, Hobday K: Use-effectiveness and client satisfaction in six centers teaching the Billings ovulation method. *Contraception* 19:613, 1979
9. Wade ME, McCarthy P, Abernathy JR, Harris GS, Danzer HC, Uricchio WA: A randomized prospective study of the use-effectiveness of two methods of natural family planning: an interim report. *Am J Obstet Gynecol* 134: 628, 1979

A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase*

World Health Organization

*Task Force†‡ on Methods for the Determination of the Fertile Period,
Special Programme of Research, Development and Research Training in Human Reproduction,
World Health Organization, Geneva, Switzerland*

Seven hundred twenty-five women of proven fertility recorded the presence of cervical mucus at the vulva in 7514 menstrual cycles. The mean cycle length of the 6472 "normal" cycles was 28.5 days (standard deviation ± 3.18). The peak day of mucus discharge was the last day of slippery, raw-egg-white-like mucus and occurred on average on day 15 (± 2.6). The fertile period was defined as any day on which mucus was reported before the peak day until 3 days after the peak. Its mean length was 9.6 (± 2.6) days. The probability of pregnancy was maximal on the peak day and declined on the days before and after the peak. Fertil Steril 40:773, 1983

Received December 1, 1982; revised and accepted August 9, 1983.

*Supported by the Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland.

†Reprint requests: Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, 1211 Geneva 27, Switzerland.

‡The Task Force Investigators for this study were John France, Ph.D., and Margaret France, M.A., Postgraduate School of Obstetrics and Gynaecology, National Women's Hospital, Auckland, New Zealand; Marie-Mignon Mascarenhas, M.D., and Aloma Lobo, M.D., Family Welfare Centre, Bangalore, India; Hubert Campbell, M.D., Welsh National School of Medicine, Cardiff, United Kingdom; John Bonnar, M.D., and Esther Bradley, M.D., Department of Obstetrics and Gynaecology, University of Dublin, Rotunda Hospital, Dublin, Republic of Ireland; Vincente Rosales, M.D., and Bienvenido Angeles, M.D., Institute for the Study of Human Reproduction, University of Santo Tomas, Manila, Philippines; Henry Burger, M.D., Prince Henry's Hospital, Medical Research Centre, Melbourne, Australia; William Gibbons, M.D., and Francesca Kearns, R.N., Faculty of Health, San Lucas Centre, San Miguel, El Salvador; Jeffrey Spieler, M.Sc., and Alain Pinol, D.E.S.T., Special Programme of Research in Human Reproduction, World Health Organization, Geneva, Switzerland.

The results of the teaching and effectiveness phases of a prospective trial of the ovulation method of natural family planning in five countries have been published.^{1, 2} This study provided an opportunity to analyze the characteristics of the menstrual cycle in a large number of women whose cycles were not influenced by the use of hormonal or other forms of contraception. We now report the various phases of menstrual cycles in women who had successfully learned the ovulation method and pay particular attention to the length of the fertile phase and its variability as defined by self-recognition of mucus. We have examined the consequences of acts of sexual intercourse occurring within and outside the defined fertile phase.

MATERIALS AND METHODS

SUBJECTS

The data for the present analysis are derived from 725 women who entered the effectiveness phase of the multicenter study described in detail previously.^{1, 2} On the basis of the subjects' de-

Table 1. Length of Cycle by Center (6472 Cycles in Five Centers): Number of Cycles by Duration in Days

Duration	Dublin	Bangalore	Auckland	San Miguel	Manila	All centers	Cumulative percentage
<i>days</i>							
22 and under	15	30	7	11	10	73	1.1
23	35	40	5	14	10	104	2.7
24	72	75	29	24	28	228	6.3
25	135	133	49	56	64	437	13.0
26	209	205	75	83	109	681	23.5
27	260	243	125	177	126	931	37.9
28	279	327	124	245	166	1141	55.5
29	225	282	94	157	160	918	69.7
30	144	213	71	106	116	650	79.8
31	89	154	60	50	121	474	87.1
32	83	93	28	19	64	287	91.5
33	48	52	25	12	53	190	94.5
34	20	44	16	17	23	120	96.3
35	21	42	7	3	18	91	97.7
36 and over	28	63	23	10	23	147	100.0
All cycles	1663	1996	738	984	1091	6472	100.0
Median	27.4	27.8	27.6	27.6	28.2	27.7	
Mean	28.2	28.7	28.6	28.1	28.9	28.5	
SD	2.94	3.66	3.24	2.42	3.05	3.18	

scriptions, mucus was classified by the study coordinators in Geneva into two types: one was thick, sticky, tacky, and/or cloudy (here called sticky mucus and previously referred to as infertile-type mucus)^{3, 4}; and one which resembled raw egg white and was clear, stretchy, and/or lubricative (here called slippery mucus and previously referred to as fertile-type mucus)^{3, 4}. The last day on which slippery mucus was noticed or on which a wet or lubricative sensation was felt at the vulva was designated as the peak day (PD), whereas the fertile phase commenced on the first day of any recognizable mucus at the vulva, whether sticky or slippery, and ended on PD + 4. Because the PD is closely related to the estimated day of ovulation,⁵⁻⁷ we defined the follicular phase as extending from the first day of bleeding to the PD and the luteal phase from PD + 1 to the end of the cycle.

To estimate the variability within subjects and to compare it with the variability between subjects, we rejected those cycles in which there was a pregnancy, in which no PD was indicated, or in which two or more mucus patches were separated by > 1 dry day. We rejected all subjects who submitted data for only one cycle. For the remaining cycles, we calculated the mean and standard deviation (SD) of the lengths of the various phases of the cycles for all cycles, for cycles by center, and for cycles by subject. We calculated two types of SD: the overall, which is based upon all 6472 cycles, and the "pooled within subject" SD, which

is obtained by pooling the SD of the cycles for each individual about her own mean.

RESULTS

There were 725 women (mean age, 30.2 years) who recorded 7514 cycles. Among these, a pregnancy occurred in 130 cycles (1.8%); there was no identifiable PD in 200 (2.7%), there was a period of 2 or more dry days interrupting the mucus patch in 702 (9.3%), and 10 were excluded because the subjects reported only one cycle. There remained 6472 cycles (86.1%) recorded by 687 women which we designated "normal" cycles.

The number of cycles from each center by duration of cycle with the mean and median length and the SD are shown in Table 1. The mean length of the 6472 normal cycles was 28.5 days (SD ± 3.18), and the median was 27.7 days. Within-woman variability of cycle length was less than that between women: the SD between cycles within women was 2.61 days. This pooled SD was markedly influenced by the few women who had some irregular cycles of > 35 days. Ten percent of women had an SD about their own mean of < 1 day, over 50% had an SD of < 2 days, 80% had an SD of < 3 days, and 4.8% had an SD of 5 days or more.

CYCLE LENGTH BY AGE

The women were divided into four age groups: 18 to 22, 23 to 27, 28 to 32, and 33 to 39 years of

Table 2. Length of Phases of the Menstrual Cycle by Center (6472 Cycles in Five Centers): Mean Length in Days^a

Phases of cycle	Dublin	Bangalore	Auckland	San Miguel	Manila	All centers
Bleeding days	5.9 (1.3)	4.7 (1.1)	5.2 (1.3)	4.4 (1.0)	4.3 (1.0)	5.0 (1.3)
Dry days	1.5 (1.9)	3.7 (1.8)	2.8 (2.2)	4.9 (2.5)	5.1 (2.4)	3.5 (2.5)
Sticky mucus (infertile-type)	4.1 (2.6)	3.0 (1.4)	3.5 (2.7)	2.3 (1.6)	3.0 (2.3)	3.3 (2.2)
Slippery mucus (fertile-type)	3.4 (2.0)	3.8 (1.6)	4.3 (2.0)	1.9 (0.7)	3.1 (1.5)	3.3 (1.8)
Fertile	10.5 (2.8)	9.8 (1.8)	10.8 (2.7)	7.2 (1.9)	9.1 (2.6)	9.6 (2.6)
Follicular	15.0 (2.8)	15.2 (2.1)	15.8 (3.0)	13.6 (2.1)	15.6 (2.6)	15.0 (2.6)
Luteal	13.2 (2.1)	13.5 (3.5)	12.8 (2.2)	14.5 (1.8)	13.3 (3.0)	13.5 (2.8)

^aNumbers in parentheses are standard deviation. The PD is defined as the last day of slippery (fertile-type) mucus. The fertile phase is defined as the days of sticky mucus + slippery mucus + 3 days. The follicular phase is defined as from day 1 of the cycle up to and including the PD. The luteal phase is defined as from PD + 1 to the onset of the next cycle.

age. The mean cycle lengths were 29.2, 29.0, 28.6, and 27.9 days, respectively. There was no statistical difference between the under 23 years and 23 to 27 years groups, but all other differences were statistically significant ($P < 0.001$), and the trend toward shorter cycles with increasing age was also significant.

PATTERN OF THE CYCLE

The pattern of the cycle and the mean length (\pm SD) of the various phases at each center are tabulated in Table 2. Tables 3 and 4 show the frequency distributions for the different phases of the cycles in all 6472 cycles, and Figure 1 illustrates the cumulative frequency distributions. The mean length of *bleeding* was 5.0 days for all cycles, but this varied between 4.3 days in Manila and 5.9 days in Dublin; the two centers with the longest bleeding period were the centers in developed countries—Dublin and Auckland.

The mean length of *preovulatory dry days* was 3.5 days for all cycles, but this varied between 1.5 days in Dublin and 5.1 days in Manila. The mean duration of *sticky mucus* was 3.3 days, which varied from 2.3 days in San Miguel to 4.1 days in Dublin. The mean duration of *slippery mucus* was 3.3 days and ranged from 1.9 days in San Miguel to 4.3 days in Auckland.

Cycle length is divided into two major phases, the follicular phase and the luteal phase. The mean length of the *follicular phase* was 15.0 days; and only San Miguel, with 13.6 days, was significantly different from the other centers. The 90% frequency interval was 10.5 to 19.0 days.

The mean length of the *luteal phase* was 13.5 days. The mean length of 14.5 days in San Miguel was significantly longer than in the other four centers. The 90% frequency interval was 8.7 days to 17.2 days.

The mean length of the *fertile period* was 9.6 days, which varied between 7.2 days in San Miguel and 10.8 days in Auckland. The 90% frequency interval was 5.3 to 13.8 days.

Data on the relationship between the PD and the day of maximum mucus secretion were available in 6171 cycles. In 3328 (53.9%), these days were reported as being the same, but there were wide differences between centers: Bangalore, 81.8%; Dublin, 61.1%; Manila, 47.8%; Auckland, 31.5%; and San Miguel, 14.8%.

CORRELATIONS BETWEEN PHASES OF THE CYCLE

The correlation between follicular phase and cycle length was 0.55 and between luteal phase and cycle length, 0.62. The luteal phase was negatively correlated with the follicular phase ($r =$

Table 3. Duration of Phases Within the Follicular Phase in 6472 "Normal" Cycles: Number of Cycles by Duration in Days

Duration	Bleeding	Dry	Sticky mucus	Slippery mucus
<i>days</i>				
0	—	1124	370	—
1	3	417	777	690
2	47	702	1474	1696
3	599	1135	1549	1723
4	1775	1067	934	996
5	2178	781	524	625
6	1128	559	332	360
7	520	290	217	185
8	165	100	126	78
9	35	90	64	55
10 or more	22	127	105	64 ^a
Median	4.4	2.9	2.4	2.5
Mean	5.0	3.5	3.3	3.3
SD	1.28	2.52	2.19	1.80
SD (between cycles within women)	0.71	1.37	1.57	1.19

^aThree cycles were unspecified.

Table 4. Duration of Phases in the Menstrual Cycle in 6472 "Normal" Cycles: Number of Cycles by Duration in Days

Duration	Follicular phase	Luteal phase	Fertile period
<i>days</i>			
5 or less	1	26	168
6	3	20	479
7	1	59	649
8	20	103	1006
9	44	173	1180
10	130	328	1002
11	257	543	689
12	453	844	518
13	787	1212	301
14	1137	1192	194
15	1147	865	126
16	941	523	66
17	602	241	37
18	375	132	20
19	252	78	16
20	133	42	8
21	83	29	3
22 or more	106	62	10
Median	14.4	12.9	8.8
Mean	15.0	13.5	9.6
SD	2.61	2.79	2.60
SD (between cycles within women)	1.84	2.45	1.60

-0.31), which implies that a long follicular phase is followed by a short luteal phase and conversely. There was also a negative correlation ($r = -0.18$) between the luteal phase of one cycle and the follicular phase of the next. The length of the fertile phase was positively correlated with the follicular phase ($r = 0.62$) but negatively correlated with the length of the luteal phase ($r = -0.26$).

THE CHANGING PROBABILITY OF PREGNANCY DURING THE MENSTRUAL CYCLE

The concept of a fertile phase and of an infertile phase or "safe period" is essentially a probabilistic definition by which the probability of conception following intercourse is maximal during the fertile phase and minimal during the infertile phase. Data from this study allow us to make some estimates of the comparative probabilities, although this was not one of our primary objectives.

In the report of the effectiveness phase of this study, 130 pregnancies were recorded.²

We had information on whether intercourse occurred but not how frequently in the early "safe" phase (before the onset of mucus) or in the late "safe" phase (PD+4 or later); we asked only for

the day of the last and first act, respectively, in these phases. However, the day of every act of intercourse during the fertile phase was to be recorded. These details were assessed by the teacher and the subjects once every cycle. We had to assume that subjects honestly recorded all acts during the fertile phase. Since the women in San Miguel were reticent to disclose this information to the teachers, as we noted previously,¹ we excluded this center from the analysis.

As a first approximation to calculating the probability of pregnancy, the following criteria were observed: (1) In pregnancy cycles where there was a single act of intercourse recorded during the fertile phase and where the PD was indicated, that act was assumed to have led to the pregnancy even when there were acts at the boundaries of the fertile phase (i.e., on the last day before mucus or on PD+4). (2) In pregnancy cycles in which more than one act was recorded in the fertile phase, that act nearest to the PD was selected (this occurred on 14 occasions). If two acts were equally spaced around the PD, the act before PD was selected (on seven occasions). (3) In nonpregnancy cycles, each single act within the fertile phase was counted as "at risk." In 4 cycles, there were repeated acts in the same segment of the fertile period; in 14 cycles, there were acts both before and after the PD. (4) Pregnancy and nonpregnancy cycles were excluded from this analysis when the PD was not identifiable, when there was an inadequate description of the type of mucus, when the day of intercourse within the

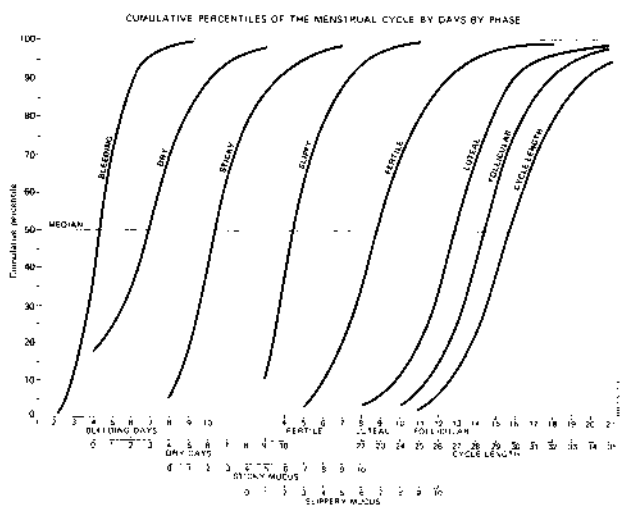


Figure 1 Cumulative percentiles of the menstrual cycle by days by phase.

Table 5. Probability of Pregnancy by Phase of Cycle and Days from PD^a

Phase of cycle	Relation to PD	Cycles with intercourse	No. of pregnancies	Probability of pregnancy
	<i>days</i>			
Sticky mucus	PD - 4 or earlier	81	2	0.024
Sticky mucus	PD - 3 to PD - 1	6	3	0.500
Slippery mucus	PD - 4 or earlier	17	6	0.353
Slippery mucus	PD - 3 to PD - 1	22	12	0.546
PD	PD 0	9	6	0.667
Post-peak	PD + 1	18	8	0.444
Post-peak	PD + 2	44	9	0.205
Post-peak	PD + 3	112	10	0.089
Outside fertile period	—	6158	22	0.004
All phases	—	6467	78	0.012

^aAll cycles and all pregnancies (29) from San Miguel were excluded. Twenty-three pregnancies from the other four centers were excluded: 18 provided inadequate data concerning the date of intercourse and 5 cases had intercourse using withdrawal or a condom. There were only 178 cycles in four centers in which no act of intercourse was recorded.

fertile phase was not stated, and when intercourse occurred using a condom or with withdrawal (five cycles). (5) When no act was recorded in the fertile phase but an act was recorded before or after this phase, the cycle was considered to be "at risk" irrespective of the frequency or timing of intercourse. The probability of pregnancy was calculated for each day relative to the PD and separately for both types (sticky and slippery) of mucus (Table 5).

The probability of pregnancy in the presence of sticky mucus was 0.024 on PD - 4 or earlier but rose to 0.500 on PD - 3 to PD - 1. In the presence of slippery mucus, the risk was 0.353 on PD - 4 or earlier and rose to 0.546 on PD - 3 to PD - 1. There were nine acts recorded on the PD out of the 7514 cycles, which resulted in six pregnancies, which gives a pregnancy probability of 0.667.

In the post-peak period, the probability declined from 0.444 on PD + 1, to 0.205 on PD + 2, to 0.089 on PD + 3.

Outside the fertile phase, the probability was 0.004 per cycle.

DISCUSSION

This report describes the first prospective international study of the characteristics of the

menstrual cycle and the fertile phase as defined by self-recognition of the cervical mucus discharge detected at the vulva. Billings et al.⁵ and Hilgers and Prebil⁴ reported the onset of mucus 6 days before the peak symptom; Hilgers et al.⁷ gave a mean interval of 6.3 days before the peak, and our study gives 5.6 days (sticky mucus + slippery mucus - 1). The general conclusion is that, on average, the duration of mucus that will be observed by women instructed in this method will be ~ 6 days before the PD. But it is important to note that in 18 cycles (0.3%) there was no mucus observed before the PD, in 149 cycles (2%) there was only 1 day of mucus before the PD, in 479 cycles (7%) there were 2 days of mucus, and in 649 cycles (10%) there were 3 days of mucus. Thus, in ~ 20% of all cycles, there are only 3 days of mucus or less before the PD.

Previous investigators^{8, 9} have reported an inverse correlation between the length of the follicular and luteal phases of the normal menstrual cycle when these have been defined by the basal body temperature or by luteinizing hormone peak measurements. Our study has confirmed that this negative correlation can be observed in selected cycles when the phases are defined by self-observation of cervical mucus.

Our series also confirms other reports^{8, 10} that the menstrual cycle length decreases slightly with increasing chronologic and gynecologic age until the approach of the menopause.

This study allowed us to evaluate whether the detection of mucus discharge at the vulva defines the fertile phase and whether the probability of pregnancy differs in the presence of sticky or slippery mucus. Our analysis indicates a probability of pregnancy per cycle of ~ 0.004 outside the fertile phase as defined by the ovulation method, which rises to a maximum of 0.667 on the PD and declines steeply during the following 3 days. Thus, the method does effectively define the fertile phase.

The difference in probability of pregnancy from intercourse in the presence of sticky or of slippery mucus is not great; in the 3 days before the PD (PD - 3 to PD - 1), the probability of pregnancy in the presence of sticky mucus was 0.500 and in the presence of slippery mucus, 0.546. Both these results are based upon small numbers, and the differences are not statistically significant. But it is important to note that there is a substantial probability of pregnancy if intercourse occurs in the presence of sticky (previously called infertile-

type) mucus, which has important implications in the teaching of the methods and which has been noted elsewhere.¹¹ It appears that proximity to the PD is a more reliable indicator of fertility than the characteristics of the mucus discharge before the PD as perceived by the woman.

Our maximum conception rate occurred on the PD; out of the 7514 cycles, there were only 9 cycles in which intercourse was reported on the PD, and these resulted in six pregnancies—for a pregnancy rate of 0.667. Using the day of rise (D) in basal body temperature as an index of ovulation, Barrett and Marshall¹² found a maximum probability on D-2 of 0.30, where a conceptus had to survive 6 weeks to be included in their study. Schwartz et al.¹³ found a maximum daily probability of conception alone of 0.65 and a maximum probability of fertilization, with pregnancy lasting at least 6 weeks, of 0.34, both on D-2. Royston¹⁴ also found a similar probability of conception leading to pregnancy for at least 6 weeks of 0.36 on D-2. Schwartz et al.¹³ estimated only 52% of eggs exposed to the possibility of fertilization gave a conceptus at at least 6 weeks' viability. Our method has not permitted us to make separate estimates of fertilization and 6-week pregnancy probabilities, but our very high conception rates suggest that, in our populations, losses of fertilized ova were lower than those reported by Schwartz et al.¹³ or by Leridon.¹⁵ In addition, it is likely that there was underreporting of intercourse during the fertile phase (rule-breaking); this would result in an upward bias in calculated conception probabilities.

It must be recalled that all these results are based upon the self-observation of mucus symptoms by women from Europe, Latin America, India, East Asia, and Australia varying in race, education, social status, and cultural background. These studies are not based upon any objective criteria of ovulation, but further studies are being organized to define correlations between the subjective symptoms of the fertile phase and the hormonal changes in luteinizing hormone, estrogen, and progesterone that may explain these observations and clarify some of the differences found.

The probability of pregnancy correlates very well with the self-identification of the PD. The interval which includes the days of mucus before the PD and the 3 post-peak days adequately distinguishes the fertile from the infertile phase of the menstrual cycle, and this has important im-

plications not only for family planning methods based upon periodic abstinence but also for the diagnosis and management of infertility.

Acknowledgments. The authors express their gratitude to the teachers and subjects who by their voluntary efforts over a period of more than 2 years made the study possible. They have relied heavily on the conscientious and invaluable work of the statistical clerk, Ms. Georgine Kainer, the HRP Data Processing Team, and the secretarial staff of the Human Reproduction Programme, World Health Organization, Geneva.

REFERENCES

1. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. I. The teaching phase. *Fertil Steril* 36:152, 1981
2. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. *Fertil Steril* 36:591, 1981
3. Billings EL, Billings JJ, Catarinich M: Atlas of the Ovulation Method, Second edition. Melbourne, Advocate Press, 1974
4. Hilgers TW, Prebil AM: The ovulation method: vulvar observations as an index of fertility/infertility. *Obstet Gynecol* 53:12, 1979
5. Billings EL, Billings JJ, Brown JB, Burger HG: Symptoms and hormonal changes accompanying ovulation. *Lancet* 1:282, 1972
6. Flynn AM, Lynch SS: Cervical mucus and identification of the fertile phase of the menstrual cycle. *Br J Obstet Gynaecol* 83:656, 1976
7. Hilgers TW, Abraham GE, Cavanagh D: Natural family planning. I. The peak symptom and estimated time of ovulation. *Obstet Gynecol* 52:575, 1978
8. Vollman RF: The Menstrual Cycle. Philadelphia, W. B. Saunders, 1977
9. Diczfalusy E, Landgren BM: How normal is the normal cycle? In *Endocrinology of Human Infertility: New Aspects*. London, Academic Press, 1981, p 1
10. Treloar EA, Boynton ER, Behn BG, Brown BW: Variation of the human menstrual cycle through reproductive life. *Int J Fertil* 12:77, 1967
11. Ball M: A prospective field trial of the ovulation method of avoiding conception. *Eur J Obstet Gynaecol Reprod Biol* 6:63, 1976
12. Barrett JC, Marshall J: The risk of conception on different days of the menstrual cycle. *Popul Stud (NY)* 23:455, 1969
13. Schwartz D, McDonald PDM, Heuchel V: Fecundability, coital frequency and viability of ova. *Popul Stud (NY)* 34:397, 1980
14. Royston JP: Basal body temperature, ovulation and the risk of conception with special reference to the life times of sperm and egg. *Biometrics* 38:397, 1982
15. Leridon H: *Human Fertility: The Basic Components*. Chicago, Chicago University Press, 1977

A prospective multicentre study of the ovulation method of natural family planning. IV. The outcome of pregnancy*

World Health Organization

Task Force† on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland

*In a prospective, five-country study of the ovulation method of natural family planning, 175 pregnancies occurred, with known outcome in 163. There were 140 live births (86% of known outcome); 2 congenital malformations (1.2%), including 1 stillbirth; 16 spontaneous abortions (9.8%); and 6 induced abortions (3.7%). The rates of congenital malformations, stillbirths, and spontaneous abortions do not differ from outcomes in the community or outcomes associated with other fertility-regulating methods. Among the live births, there were 81 males and 59 females, a male proportion of 0.58. There were no significant differences in sex ratio from varying intervals between the likely act leading to conception and the estimated day of ovulation. *Fertil Steril* 41:593, 1984*

Received July 26, 1983; revised and accepted December 20, 1983.

*Supported by the Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland.

†The Task Force Investigators for this study were John France, Ph.D., and Margaret France, M.D., Postgraduate School of Obstetrics and Gynaecology, National Women's Hospital, Auckland, New Zealand; Marie-Mignon Mascarenhas, M.D., and Aloma Lobo, M.D., Family Welfare Centre, Bangalore, India; Hubert Campbell, M.D., Welsh National School of Medicine, Cardiff, United Kingdom; Patrick Royston, Clinical Research Centre, Harrow, Middlesex, United Kingdom; John Bonnar, M.D., and Esther Bradley, M.D., Department of Obstetrics and Gynaecology, University of Dublin, Rotunda Hospital, Dublin, Republic of Ireland; Vincente Rosales, M.D., and Bienvenido Angeles, M.D., Institute for the Study of Human Reproduction, University of Santo Tomas, Manila, Philippines; Henry Burger, M.D., Prince Henry's Hospital, Medical Research Centre, Melbourne, Australia; William Gibbons, M.D., and Frances Kearns, R.N., Faculty of Health, San Lucas Center, San Miguel, El Salvador; Jeffrey Spieler, M.Sc., and Alain Pinol, D.E.S.T., Special Programme of Research in Human Reproduction, World Health Organization, Geneva, Switzerland.

‡Reprint requests: Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, 1211 Geneva 27, Switzerland.

Previous reports^{1, 2} have described the results of a prospective study of the ovulation method of natural family planning with respect to the ability of women to learn self-recognition of the fertile phase of the menstrual cycle, and to the effectiveness of the method in the prevention of unwanted pregnancy. We have also described the biology of the fertile period and the probability of pregnancy as a result of acts of intercourse within and outside that period.³ Earlier studies of family planning methods based on periodic abstinence have suggested that there may be an increased likelihood of spontaneous abortion⁴ and congenital abnormality⁵ among pregnancies occurring in users of these methods, due to fertilization involving overaged sperm and ova, although other studies have not confirmed such a relationship.⁶ Because our study was prospective and the subjects maintained detailed records of cycle characteristics, including the timing of acts of intercourse where they occurred during or at the boundaries of the fertile period, we have examined the outcome of the resulting pregnancies with regard to the occurrence of spontaneous abortions and congenital malformations. Pre-

vious authors^{7, 8} have claimed that sex ratios may vary with the timing of coitus with respect to the day of ovulation; according to Billings and Westmore,⁹ there is some evidence that intercourse early in the development of the slippery mucus, with no other act during that cycle, tends to result in a girl, and intercourse confined to the peak day (PD) tends to result in a boy. We have examined our data for such trends.

MATERIALS AND METHODS

SUBJECTS

The demographic characteristics of the subjects studied in five different centers (Auckland, New Zealand; Bangalore, India; Dublin, Ireland; Manila, Philippines; and San Miguel, El Salvador) have been described,^{1, 2} as have been the details of record-keeping of menstrual cycle characteristics.¹⁻³ The PD was defined as the last day on which subjects recorded the presence of slippery mucus or on which a wet or lubricative sensation was felt at the vulva. The PD is closely related to the estimated day of ovulation¹⁰⁻¹² and, as shown previously,³ is the cycle day on which the probability is highest that an act of intercourse will lead to conception.

The outcome of pregnancy was recorded on a standard form, completed shortly after delivery, on which the following data could be entered: date of birth, date of last menses, estimated duration of gestation, outcome (e.g., live birth, stillbirth, spontaneous abortion, induced abortion, minor and major congenital malformation, sex and weight of the child), and details of the pregnancy and delivery.

The subject's chart and the teacher's report form for the conception cycle were also available for analysis and included the description of the mucus symptoms, including the PD, and the recorded acts of intercourse, at least the last before the onset of the mucus symptoms, the first after the end of the fertile phase, and any during that time.

Records were analyzed as follows:

(1) If a single act of intercourse was recorded during the fertile phase, even when there were acts before and after that phase, it was assumed that it was the act during the fertile phase which resulted in conception—except where that act was 5 or more days prior to the peak, during sticky mucus, when another act had been re-

corded on the fourth day after the peak; these were classified as unknown.

(2) Where pregnancy was classified as resulting from method failure, it was regarded as inappropriate to attempt to relate a particular act occurring outside the fertile phase to the resulting conception. Only one exception was made, where no act was recorded prior to the PD and only a single act was recorded after the peak.

(3) Pregnancies were excluded from analysis where the data were inadequate to allow characterization of the PD, where the days of acts during the fertile phase were not recorded specifically, or where withdrawal coitus or condoms were used during the fertile phase. However, if withdrawal coitus occurred on the PD and there was no other act during the fertile phase, it was assumed that this had led to the pregnancy.

RESULTS

Table 1 summarizes the data. Of 175 pregnancies occurring during the teaching and effectiveness phases of the study, data on outcome were available for 163 (93%). There were 16 spontaneous abortions (9.8% of those with known outcome), with rates of 16.7% for Dublin and Manila being higher than for the other three centers, which experienced rates of 5.1%, 5.1%, and 9.7%, respectively. There were two congenital malformations, including one stillbirth, giving an overall rate of 1.25%.

Table 2 shows the relationship of maternal age (as recorded at admission to the study) to outcome of pregnancy. It is noteworthy that the spontaneous abortion rate of women < 35 years of age at admission was 7.9% if expressed as a percentage of the total births and spontaneous abortions (11 of 140); whereas in those aged 35 to 39, it was 29.4% (5 of 17). The mean age of women whose pregnancies ended in a live birth was 28.7 years, compared with 31.5 for those who had spontaneous abortions. The number of spontaneous abortions was too small for meaningful statistical analysis of this relationship within centers; however, there was a highly significant relation of spontaneous abortion rate to age (≤ 24 , 2 abortions for 33 live births; 25 to 29, 3 for 49; 30 to 34, 6 for 46; and 35 to 39, 5 for 12: $\chi^2 = 8.01$, $P = 0.005$). Of the two congenital abnormalities, one occurred in the 25- to 29-year age group (the stillbirth), the other (a female who had microcephaly

Table 1. Outcome of Pregnancy—By Center and Overall

Center	No. of pregnancies	No. where outcome known	No. of live births	No. of stillbirths	No. of spontaneous abortions	No. of induced abortions	Missing data
Auckland	32	31	27 (87%)	0	3 (9.7%)	1	1
Bangalore	40	39	33 (84.6%)	0	2 (5.1%)	4	1
Dublin	38	36 ^a	30 (83.3%)	0	6 (16.7%)	0	2
Manila	23	18	14 (77.7%)	0	3 (16.7%)	1	5
San Miguel	42	39 ^b	36 (92.3%)	1	2 (5.1%)	0	3
Total	175	163 (100%)	140 (85.9%)	1 (0.6%)	16 (9.8%)	6 (3.7%)	12

^aOne child with microcephaly and one absent kidney.

^bOne stillborn, anencephalic.

and absence of one kidney) in the 35- to 39-year age group, giving respective rates for those age groups of 2.0% and 8.3% as percentages of the numbers of live births and stillbirths.

Table 3 shows the sex of the child in relation to the likely time of conception. Overall, among the 140 live births, where the sex of the child was known, there were 81 males and 59 females, giving a male proportion (male to total) of 0.58. This does not differ significantly ($\chi^2 = 2.37, P = 0.12$) from the typical population value of 0.51.¹³ Among children conceived 2 to 5 days before the PD, there were 14 males and 9 females (male proportion, 0.61). For those conceived 2 to 4 days after the peak, there were 18 males and 9 females (male proportion, 0.67); and among those conceived within 1 day of the peak, there were 27 males and 22 females (male proportion, 0.55). These proportions do not differ statistically ($\chi^2 = 1.04, P = 0.3$). Among those where no assessment of the likely time of conception could be made, but where pregnancy was not considered to result from method failure, there were 16 males and 12 females (male proportion, 0.57); whereas for method failures, there were 6 males (0.46) and 7 females. In one of the method failures, the only recorded act was 4 days after the PD, and this child was included in the group where the likely

time of conception was known. Again, these proportions are not significantly different ($\chi^2 = 0.10, P = 0.8$).

Table 4 shows the data for spontaneous abortion in relation to the last before peak and first after peak acts of intercourse in order to address the question of whether "aged gametes" might lead to a higher rate of spontaneous abortion. For 9 of the 16, the likely time of conception was within ± 4 days of the PD (see also Table 3). Furthermore, in Table 3 it can be seen that for acts of intercourse on days -3 to -8, 3 spontaneous abortions were recorded from 15 pregnancies (excluding induced abortions). For acts on days +3 to +6, 1 spontaneous abortion resulted from 14 pregnancies. Combining these figures, there were 4 spontaneous abortions from 29 pregnancies (13.8%) in which coitus took place 3 or more days from the estimated time of ovulation, and 7 from 82 pregnancies (8.5%) where coitus took place within ± 2 days ($\chi^2 = 0.2, P = 0.7$). If method failures are included with the former group (giving 5 spontaneous abortions from 43 pregnancies, 11.6%) and cases where the day of conception was unknown with the latter (9 abortions, 114 pregnancies, 7.9%), there is again no statistically significant difference ($\chi^2 = 0.18, P = 0.7$).

Table 2. Relation of Maternal Age to Outcome of Pregnancy

Age	No. of live births	No. of stillbirths	No. of spontaneous abortions	No. of induced abortions	Total
yr					
< 20	2 (100%)	0	0	0	2
20-24	31 (88.6%)	0	2 (5.7%)	2 (5.7%)	35
25-29	49 (89.1%)	1 (1.8%)	3 (5.5%)	2 (3.6%)	55
30-34	46 (85.2%)	0	6 (11.1%)	2 (3.7%)	54
35-39	12 ^a (70.6%)	0	5 (29.4%)	0	17
Total	140	1	16	6	163

^aOne congenital abnormality.

Table 3. Outcome of Pregnancy by Day of Intercourse Relative to Peak Day

Day	Male	Female	Unknown sex	Spontaneous abortion	Induced abortion	Total
-8	—	—	—	1	—	1
-5	1	—	—	—	1	2
-4	1	5	—	1	—	7
-3	4	1	—	1	—	6
-2	8	3 ^a	—	3	—	14
-1	6	5	—	1	—	12
0	9	6	—	1	2	18
+1	12	11	—	2	1	26
+2	10	4	1 ^c	—	—	15
+3	8	4	—	—	—	12
+4	—	1 ^b	—	—	—	1
+6	—	—	—	1	—	1
Unknown (not method failure)	16	12	—	4	2	34
Method failure (coitus before and after peak)	6	7	—	1	—	14

^aOne congenital abnormality.

^bMethod failure.

^cStillborn, anencephalic.

DISCUSSION

This report provides the data on the outcome of pregnancy in the first major multicenter study of the ovulation method of natural family planning. It is important to note that the sample size of 163 pregnancies is limited, and that small differences in event rates would not be detected. Thus, the chi-square test would have a 90% chance of picking up a 5% malformation rate if the population rate was 1%. Nevertheless, the analysis undertaken provides additional information on the association between practice of the ovulation method and the incidence of birth defects and

spontaneous abortions. Of the 163 pregnancies where data on outcome were available, there were 140 live births (86%), and the overall rates for spontaneous abortion (10%) and for congenital malformation (1.2%) were similar to those reported in other series. Thus, in three cohort studies in which users of oral contraceptives before conception were compared with nonusers, rates of congenital malformation ranged from 17 to 46.8 per 1000 births in the nonusers, whereas rates for spontaneous abortion ranged from 8.6% to 11.9% in nonusers.¹⁴⁻¹⁶ Likewise, the rate is comparable to that reported following artificial insemination with donor semen (14%),¹⁷ where insemination is

Table 4. Outcome of Pregnancies—16 Spontaneous Abortions

Center	Subject no.	No. of days from intercourse to peak day		Comments
		Last before peak	First after peak	
Auckland	36	0	+6 ^a	Uncertain
	102	-2	+4	
	116	-2	+2	
Bangalore	66	0	+1	No peak identifiable
	247 (T)	-7 ^a	+9 ^a	
Dublin	72	-2	+4	All acts not recorded
	111	-3 ^a	+7 ^a	
	118	-4	0	
	123	-6 ^a	+5 ^a	
	137	-8 ^a	+5 ^a	
Manila	157	-8	+6	Method failure
	59	-2	+7	
	103	-1 ^b	+6	
San Miguel	91	-8 ^a	+4 ^a	Withdrawal on peak
	26	—	+1	
	127	No indication		Unclassifiable

^aUninterpretable with confidence.

^bWithdrawal coitus.

timed as closely as possible to ovulation. The numbers of births in our study do not allow valid comparisons to be made of the rates at each individual center, although higher rates were observed in Dublin and Manila than in the remaining centers. The spontaneous abortion rate was considerably higher in women between 35 and 39 years of age, as has been noted by other authors.¹⁷

The prospective nature of our study, which involved the subjects being interviewed each month, is likely to result in a higher rate of reporting of the occurrence of spontaneous abortion than in retrospective studies. Nevertheless, the rates of adverse outcome of pregnancy were well within the range reported in other series. The study does not therefore support the view that failures of methods based on periodic abstinence are likely to result in an increased number of abortions or congenital abnormalities.^{4, 5}

There was no evidence that spontaneous abortion or congenital malformation was related to the length of time from the likely act of intercourse leading to conception to the time of ovulation, as judged by the PD. Thus, the two congenital abnormalities resulted from acts within 2 days of the PD and 9 of the 16 spontaneous abortions resulted from acts within 4 days of the peak. The rate of spontaneous abortion was similar in pregnancies which resulted from intercourse > 3 days from the estimated time of ovulation and in those from acts within 3 days. These data do not therefore support a relationship between the incidence of abortion and congenital malformation and fertilization involving overaged sperm and ova.^{4, 5}

The ratio of male to female infants (overall male proportion, 0.58) is higher (although not statistically significantly) than the generally accepted ratio of 0.51¹³ and resembles the ratio of 0.57 reported from rhythm method failures.¹⁸ Meaningful conclusions cannot be drawn from the ratios for different days in relation to the presumed day of ovulation, although the trend to a slightly lower male proportion in those conceived within 1 day of the PD, as compared with those conceived 2 to 5 days before or 2 to 4 days after, can be noted and resembles that of previous reports.^{7, 8} The lowest proportion of male births (0.46) was seen among method failures, where it is likely that the coital act leading to conception was relatively far removed from the day of ovulation. This contrasts with the excess of male births and of spontaneous abortions reported in other

studies.^{4, 7, 8} Our results also raise questions about the findings quoted by Billings and Westmore,⁹ who reported > 98% success rates in achieving female and male offspring by timing intercourse in relation to the onset of the slippery mucus and the PD, respectively.

Although the number of observations is relatively small, we can conclude that unplanned pregnancies following the use of the ovulation method of natural family planning are unlikely to result in a rate of spontaneous abortion or congenital malformation any higher than expected in the general community and/or in relation to the use of other family planning methods. This study does not support the proposal that the timing of intercourse in relation to the likely day of ovulation has a significant effect on the sex of the child.

Acknowledgments. The authors express their gratitude to the teachers and subjects who by their voluntary efforts over a period of 2 years made the study possible. They have relied heavily on the conscientious and invaluable work of the statistical clerk, Ms. Georgina Kainer, World Health Organization, and on the work of M. Alain Pinol of the Electronic Data Processing Unit, and of the secretarial staff of the Human Reproduction Programme, World Health Organization, Geneva.

REFERENCES

1. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. I. The teaching phase. *Fertil Steril* 36:152, 1981
2. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. *Fertil Steril* 36:591, 1981
3. World Health Organization, Task Force on Methods for the Determination of the Fertile Period, Special Programme of Research, Development and Research Training in Human Reproduction: A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase. *Fertil Steril* 40:773, 1983
4. Guerrero R, Rojas OI: Spontaneous abortion and ageing of human ova and spermatozoa. *N Engl J Med* 292:573, 1975
5. Jongbloet PH: The intriguing phenomenon of gametopathy and its disastrous effects on the human progeny. *Maandschr Kindergeneesk* 37:261, 1969
6. Marshall J: Congenital defects and the age of spermatozoa. *Int J Fertil* 13:110, 1968

7. Guerrero R: Association of the type and time of insemination within the menstrual cycle with the human sex ratio at birth. *N Engl J Med* 291:1056, 1974
8. Harlap S: Gender of infants conceived on different days of the menstrual cycle. *N Engl J Med* 300:1445, 1979
9. Billings E, Westmore A: *The Billings Method*. Melbourne, Anne O'Donovan Pty. Ltd., 1980, p 70
10. Billings EL, Billings JJ, Brown JB, Burger HG: Symptoms and hormonal changes accompanying ovulation. *Lancet* 1:282, 1972
11. Flynn AM, Lynch SS: Cervical mucus and identification of the fertile phase of the menstrual cycle. *Br J Obstet Gynaecol* 83:656, 1976
12. Hilgers TW, Abraham GE, Cavanagh D: Natural family planning. I. The peak symptom and estimated time of ovulation. *Obstet Gynecol* 52:575, 1978
13. Hytten FE, Leitch I: *The Physiology of Human Pregnancy*, Second edition. Oxford, Blackwells Scientific Publications, 1971
14. Pederson WF: Pregnancy following oral contraceptive therapy. *Obstet Gynecol* 34:363, 1969
15. Royal College of General Practitioners: The outcome of pregnancy in former oral contraceptive users. *Br J Obstet Gynaecol* 83:608, 1976
16. Vessey M, Messler L, Flavel R, Yeates D: Outcome of pregnancy in women using different methods of contraception. *Br J Obstet Gynaecol* 86:548, 1979
17. Jansen RPS: Spontaneous abortion incidence in the treatment of infertility. *Am J Obstet Gynecol* 143:451, 1982
18. Shiono PH, Harlap S, Ramcharan S: Sex of offspring of women using oral contraceptives, rhythm, and other methods of birth control around the time of conception. *Fertil Steril* 37:367, 1982

A prospective multicenter trial of the ovulation method of natural family planning. V. Psychosexual aspects*

World Health Organization††

World Health Organization Task Force§ on Methods for the Natural Regulation of Fertility,
Special Programme of Research, Development and Research Training in Human Reproduction,
World Health Organization, Geneva, Switzerland

During the 13-cycle effectiveness phase of a five-center study of the ovulation method of natural family planning, there were substantial differences, particularly between the two developed and the three developing countries, in the stated degree of satisfaction with the frequency of intercourse (most couples were satisfied in Bangalore, Manila, and San Miguel, whereas one-third of the subjects and half of their partners would have preferred more frequent intercourse in Auckland and Dublin) and in expressed difficulties associated with abstinence (e.g., 62% had occasional difficulty in Auckland, 14% in Bangalore, 55% in Dublin, 28% in Manila, and 5% in San Miguel). Cumulative net probabilities of discontinuation due to pregnancy were 1.8%, 18.6%, and 54.7% for couples in whom the male partner's degree of satisfaction was described as "no difficulty," "occasional difficulty," and "always some difficulty," respectively. Fertil Steril 47:765, 1987

In 1976, the World Health Organization Special Programme on Human Reproduction undertook a five-country study of the ovulation method (OM) of natural family planning. The centers were in Auckland, New Zealand; Bangalore, India; Dublin, Ireland; Manila, the Philippines; and San Miguel, El Salvador. The major objectives of the study were to determine if the method could

be taught to women of widely differing educational and socioeconomic status (the teaching phase of 3 cycles) and to document its effectiveness as a fertility-regulating method (the subsequent 13 cycles). The major results of the study have been published.¹⁻⁴ In brief, during the teaching phase, 97% of the subjects learned the method to the satisfaction of their teachers. Among those who

*Received July 7, 1986; revised and accepted January 8, 1987.

†Supported by the Special Programme of Research Development and Research Training in Human Reproduction, World Health Organization, Geneva, Switzerland.

‡Reprint requests: Paul Van Look, M.D., World Health Organization, 1211 Geneva 27, Switzerland.

§This report was prepared by Henry G. Burger, M.D., F.R.A.C.P., Medical Research Centre, Prince Henry's Hospital, Melbourne, Australia.

¶The Task Force Investigators for this study were William Gibbons, M.D., and Francesca Kearns, R.N., Faculty of Health, San Lucas Centre, San Miguel, El Salvador; Marie-Mignon Mascarenhas, M.D., and Aloma Lobo, M.D., Family

Welfare Centre, Bangalore, India; John Bonnar, M.D., and Esther Bradley, M.D., Department of Obstetrics and Gynaecology, University of Dublin, Rotunda Hospital, Dublin, Republic of Ireland; John France, Ph.D., and Margaret France, M.A., Postgraduate School of Obstetrics and Gynaecology, National Women's Hospital, Auckland, New Zealand; Vicente Rosales, M.D., and Bienvenido Angeles, M.D., Institute for the Study of Human Reproduction, University of Santo Tomas, Manila, Philippines; Henry Burger, M.D., Prince Henry's Hospital, Medical Research Centre, Melbourne, Australia; Hubert Campbell, M.D., Department of Medical Statistics, Welsh School of Medicine, Cardiff, United Kingdom; Jeffrey Spieler, M.Sc., and Alain Pinol, D.E.S.T., Special Programme of Research in Human Reproduction, WHO, Geneva, Switzerland.

had learned the method satisfactorily and who entered the 13-cycle effectiveness phase of the study, 130 pregnancies occurred, giving a pregnancy rate (modified Pearl formula) of 22.5/100 woman-years: the rates for individual centers were Auckland, 33.6; Bangalore, 19.6; Dublin, 19.7; Manila, 13.8; and San Miguel, 32.8. Rates of method failure were 2.8 pregnancies/100 woman-years overall with individual center figures of Auckland, 9.4; Bangalore, 0; Dublin, 5.1; Manila, 1.1; and San Miguel, 0. The rate of pregnancy resulting from "conscious departure from the rules of the method" (i.e., the couple knowingly having intercourse during the fertile period) was 15.4 overall; in addition, 3.5 pregnancies/100 woman-years occurred because of inaccurate application of the instructions, and 0.5 pregnancies/100 woman-years could not be satisfactorily classified. Definitions of each type of pregnancy have been given previously.² The net probability of discontinuation from the study for all reasons was 35.6% overall with individual center figures of Auckland, 48.2; Bangalore, 25.8; Dublin, 33.3; Manila, 35.3; and San Miguel, 44.3.²

When the OM is used to avoid an unplanned pregnancy, several rules designed to ensure that no sexual contact occurs during the fertile days of the cycle must be observed.⁵ In the course of the five-country study, the subjects (and their partners when possible) were asked a number of questions to determine the degree of their adherence to the OM rules and to assess the relationship between the outcome of the study and the overall degree of difficulty experienced by the couple in practicing the OM. The current report summarizes the data obtained. Although it is open to a number of methodologic criticisms, it appears to demonstrate important trends and to provide a basis for further investigations designed to identify those couples best suited to practice this method of natural family planning.

MATERIALS AND METHODS

Eight hundred sixty-nine subjects were admitted to the teaching phase of the study. Their overall mean age was 30.1 years and that of their partners 34.5 years. Subjects were required to have been of proven fertility in their current

union and had had an average of 3.9 pregnancies (in San Miguel, 6.1). They had agreed not to use any other method of fertility regulation during the study; there was a wide variation in previous use of fertility-regulating methods: 58% in Auckland had used oral contraceptives; 54% in Bangalore and 91% in San Miguel had never used any method. Periodic abstinence had been used by 74% in Auckland, 17% in Bangalore, 64% in Dublin, 47% in Manila, and 3% in San Miguel. The subjects came from a wide range of educational and socioeconomic backgrounds.¹ Thus, more than 60% of subjects in Auckland, Dublin, and Manila had had 6 to 12 years of schooling, whereas 48% in San Miguel were illiterate. By the third cycle of teaching, 97% of subjects were judged to have an excellent or good understanding of the method. Seven hundred twenty-five subjects who had learned the OM to the satisfaction of their teachers entered the 13-cycle effectiveness study during which the data presented in this report were obtained.

The subjects were seen by their teachers at monthly intervals. In addition to recording basic information regarding the preceding cycle, such as cycle length, number of days of bleeding, day of onset, and duration of the fertile period, the teachers asked the subjects a series of questions aimed at assessing whether the couple had observed the OM rules and at determining the couples' degree of satisfaction with practice of the OM. The information was recorded by the teacher on a standard form. Although the teachers were experienced in imparting knowledge about the OM, they had not been trained specifically in interviewing techniques, nor had the questionnaires been subject to independent validation. Because of the nature of the questions asked, there was no possibility of evaluating the truthfulness of the replies. Subjects in San Miguel (where all pregnancies were the result of conscious departure from the OM rules) were unwilling to answer many of the questions. Despite these limitations, the investigators were of the opinion that the data collected would still be of some interest to natural family-planning programs.

Information was sought regarding the pattern of genital contact during the cycle (e.g., normal vaginal intercourse, coitus interruptus). A discontinuation form was completed for any subject who were discontinued from the study before the intended 13 cycles of observation.

RESULTS

SEXUAL BEHAVIOR PATTERNS AND ATTITUDES TO THE PRACTICE OF THE OM DURING THE INFERTILE PHASES OF THE MENSTRUAL CYCLE

In the context of the OM, the cycle is divided into four segments: (1) days of menstrual bleeding, (2) "early safe days" (the relatively infertile phase before ovulation), (3) the fertile phase, and (4) the "late safe days" (the infertile phase that follows ovulation). For acquisition of data for the analysis of subsequent pregnancies, couples were requested to record the last act of intercourse before the onset of the fertile phase and the first act after its completion and were encouraged to record all acts of intercourse during the cycle. A total of 7514 cycles was recorded during the effectiveness phase. Of the 7485 cycles for which the relevant records were available, intercourse was reported in both the early and late safe days in 46%, in the late safe days only in 26.6%, in the early safe days only in 1.9%, and not at all in 25.5%. There was a significant difference between Dublin and the other centers in this respect (possibly as a result of previous natural family-planning teaching patterns); intercourse was confined to the late safe days in 55% of the cycles in that center and in only 12% to 23% in the other four. Intercourse was reported in 40% of cycles in both the early and late safe days in Dublin, whereas the corresponding frequency in the other centers varied from 72% to 84%. The mean number of recorded acts/cycle was 4.8 ± 2.4 (standard deviation) with individual center values of 4.6, 5.8, 4.8, and 2.0 in Auckland, Bangalore, Dublin, Manila, and San Miguel, respectively. Couples were asked to state the average frequency of intercourse/week, and teachers were asked to record the best answer that could be elicited, especially those who marked only the last act before the fertile period and the first afterward. The average weekly frequency of intercourse for the four centers at which subjects were willing to provide this information is shown in Table 1. The investigation in San Miguel informed us that subjects in that center have a culturally based aversion to disclosure of information regarding their sexual behavior, and much of the data from this center in this respect is lacking.

In 7388 cycles, the women expressed their degree of satisfaction with the frequency of intercourse, and in 7324 the partner also responded to the question. The results are shown in Table 2.

Table 1. Stated Average Weekly Frequency of Intercourse by Center and Overall

No. of acts/week	Percent of cycles*				
	Auckland	Bangalore	Dublin	Manila	All
1	54.9	27.2	52.8	65.3	46.5
2	32.7	68.8	35.8	30.2	45.2
3	8.0	2.2	7.6	0.6	4.5

*n = 6269; information not provided in San Miguel.

There were substantial differences between centers, with most subjects stating that they were satisfied in Manila and San Miguel, while their partners were to a lesser degree. More than one-third of subjects and about one-half of their partners would have preferred more frequent intercourse in Auckland and Dublin.

ATTITUDES ABOUT THE REQUIREMENTS FOR ABSTINENCE DURING THE FERTILE PERIOD AND ABOUT THE RULES OF THE OM

In Table 3, we summarize the responses of the couples to a question concerning the difficulties associated with the requirement for abstinence during the fertile period. They were asked, separately when possible, whether any difficulties of abstinence had been observed; the choice of answers was "no difficulty," "occasionally some difficulty," "always some difficulty," "occasionally great difficulty," "always great difficulty," and "no comment." In Bangalore, Manila, and San Miguel, most cycles were characterized by "no difficulty" for the women, but in about one-third of cycles in Auckland and Dublin, "occasional difficulty" was described. "Difficulty" was most frequently described by partners, particularly in Auckland, Manila, and San Miguel.

Table 4 shows that 45% of the couples overall had admitted to breaking one or more rules of the OM during one or more cycles of the study. There were substantial differences between centers in this regard, with 82% of couples in Auckland admitting to rule breaking and less than 50% in all other centers. When individual cycles of the effectiveness study are examined (cycles 1, 7, and 13 were chosen, because they represent the beginning, middle, and end of this study; Table 4), a similar pattern is evident with 41% of subjects in Auckland breaking rules in cycles 1 and 7, and 33% in cycle 13, whereas less than 18% did so during any of these cycles in the other centers. There was a tendency for the percent of subjects

Table 2. Stated Satisfaction of Subjects and Partners with Current Frequency of Intercourse by Center and Overall

Stated opinion	Percent of cycles ^a					
	Auckland	Bangalore	Dublin	Manila	San Miguel	All
Satisfied						
Subject	64.8	97.0	63.1	96.2	97.6	83.7
Partner	46.4	90.6	54.8	58.5	67.8	66.6
Prefer more						
Subject	35.2	2.0	36.8	3.8	2.4	16.0
Partner	53.6	9.4	45.2	41.5	32.2	33.4
Prefer less						
Subject	0	1.0	0	0	0	0.3
Partner	0	0	0	0	0	0

^an = 7388 for subjects; n = 7324 for partners.

breaking rules to fall as the study progressed, with the overall percentage of those breaking rules in cycles 1, 7, and 13 being 14.8%, 10.3%, and 7.9%, respectively. This fall resulted mostly from the loss to the study because of pregnancy of couples who broke the rules.

There was considerable between-center variation in the reasons given by the couple for nonobservance of the rules: the most common reason was "unwillingness to follow them" (95, 56, 87, 89, and 100%, respectively, for Auckland, Bangalore, Dublin, Manila, and San Miguel), while in 29.1% of cases in Bangalore the couple gave "improper instruction" as the reason. In 8.4% of cycles in which rules were broken (0.9% of cycles overall), inability to comprehend the rules was given as the reason. Table 5 lists by center the percent of cycles in which specific rules were reported not to have been observed. The most frequently broken rules overall and particularly in

Auckland were "to avoid intercourse during bleeding and spotting," "to avoid intercourse on consecutive early dry days," and "to avoid intercourse until the fourth night after the peak day."

SATISFACTION OF COUPLES WITH PRACTICE OF THE METHOD

Couples were asked whether any marital-domestic friction had occurred as a result of requirements of the method. Again, when possible women and their partners were questioned separately, and the possible answers were "no friction," "moderate friction," "considerable friction," "intolerable friction," and "no comment." Teachers were instructed that we were trying to determine whether or not practicing the method had caused any problems not usually experienced by the couple. Such marital friction was uncommon—in 88% to 99% of cycles, the woman said that no friction was occurring, and the same opi-

Table 3. Stated Difficulties of Abstinence from Intercourse for Subjects and Partners by Center and Overall

Degree of difficulty	Percent of cycles ^a					
	Auckland	Bangalore	Dublin	Manila	San Miguel	All
None						
Subject	56.9	94.1	67.7	89.5	95.7	81.7
Partner	28.5	79.8	59.5	45.4	18.4	52.7
Occasional difficulty						
Subject	36.3	4.9	28.7	10.5	4.2	16.2
Partner	60.4	16.2	34.7	54.6	81.1	43.1
Always difficulty						
Subject	3.1	0	2.3	0	0	1.0
Partner	5.5	0.2	4.2	0	0.4	1.9
Occasional great difficulty						
Subject	3.4	0.3	1.0	0	0	0.8
Partner	4.6	2.4	1.2	0	0	1.6
Always great difficulty						
Subject	0.3	0	0	0	0	0.1
Partner	0.8	0.1	0.2	0	0	0.2
No comment						
Subject	0	0.7	0.2	0	0.1	0.3
Partner	0.2	1.2	0.3	0	0.1	0.5

^an = 7424 for subjects; n = 7350 for partners.

Table 4. Number (%) of Couples Who Broke One or More Rules During any Cycle, and in Cycles 1, 7, and 13

Center (no. entering study)	Whole study		Cycle 1		Cycle 7		Cycle 13	
	No.	% entering study	No.	% completing cycle	No.	% completing cycle	No.	% completing cycle
Auckland (102)	84	82.3	42	41	30	40.5	18	32.7
Bangalore (191)	66	34.6	18	9.4	6	3.7	1	0.7
Dublin (195)	89	45.6	21	10.8	10	6.6	10	7.8
Manila (115)	57	49.6	20	17.4	12	12.6	7	10.4
San Miguel (122)	31	25.4	6	4.9	0	0	0	0
All centers	327	45.1	107	14.8	58	10.3	36	7.9

The total number of cycles for which data were available was 7502. Rules were stated to have been followed in 89.3%; this table therefore gives data for rules broken in 10.7% of all cycles.

ion was expressed by partners in 81% to 99%. Ten percent of women in Auckland and 7% in Manila reported "moderate friction," and 17% of partners in Auckland and 14% in Manila made the same response.

Subjects and partners were asked to describe their overall satisfaction with the method (Table 6) and were given a choice of "excellent," "good," "poor," or "nil" as possible replies. In Bangalore and Manila, the investigators reported that superstitions were frequently associated with the descriptive use of superlatives (e.g., "excellent") and that in these centers the reply "good" would be employed by couples who were satisfied. The most common rating for all centers was "good," and satisfaction was described as "good" or "excellent" by women in 98.2% of cycles and by partners in 96.7%.

RELATION BETWEEN COUPLES' ATTITUDES TO AND EFFECTIVENESS OF THE METHOD

In order to define the influence of attitudes on outcome, life-table analyses were undertaken to compare the net probabilities of discontinuation

because of pregnancy, and for all other reasons, by subjects' and partners' stated difficulties with abstinence and overall satisfaction with the method. The results are shown in Table 7. It is noteworthy that the cumulative net probability of discontinuation rates because of pregnancy are lower for those couples in which the subject or partner described their level of satisfaction with the method as "excellent," compared with those who stated that it was "good," whereas the rates for those who stated it was "poor" were markedly higher.

CORRELATION OF RULE BREAKING WITH PREGNANCY DURING THE EFFECTIVENESS STUDY

An overall comparison of method-related pregnancy rates (i.e., pregnancies occurring with all the rules of the method appearing to have been observed) with rates of nonobservance of the rules shows that in Auckland the method failure rate was 9.4 pregnancies/100 woman-years with a rule breaking rate of 82%—this is discussed further subsequently. In Dublin, respective rates were 5.1% and 45.6%, in Manila 1.1% and 49.6%, and

Table 5. Specific Rules Broken by Center and Overall

	Percent of cycles*					
	Auckland	Bangalore	Dublin	Manila	San Miguel	All
Intercourse during bleeding or spotting	14.5	0.1	2.4	3.7	0.3	3.2
Intercourse on consecutive early dry days	7.9	1.9	1.9	5.7	0.2	3.0
Intercourse within 3 days after the peak day	7.3	0.8	2.2	4.8	1.6	2.8
Intercourse on days of mucus or wetness	5.7	1.4	2.7	1.9	1.5	2.4
Genital contact during mucus days	5.4	0.1	2.0	1.0	0	1.4
Intercourse during situations of stress, illness, etc.	0.7	0.3	0.5	0.8	0.7	0.6
Use of other fertility-regulating methods	0.7	0.2	0.5	0.8	0	0.4

*n = 7479.

Table 6. Stated Satisfaction with the OM by Subjects and Partners by Center and Overall Percent of Cycles^a

Degree of satisfaction	Auckland	Bangalore	Dublin	Manila	San Miguel	All
Excellent						
Subject	20.8	8.4	41.5	15.6	48.2	26.3
Partner	20.1	6.1	39.9	14.6	30.7	22.2
Good						
Subject	74.4	91.6	54.5	84.0	51.8	71.9
Partner	69.1	93.6	55.9	83.3	66.8	74.5
Poor						
Subject	4.6	0	4.0	0.4	0	1.8
Partner	10.7	0.3	4.2	2.1	2.0	3.2

^an = 7404 for subjects; n = 7313 for patients.

in Bangalore 0% and 34.6%. In view of the reticence among subjects in San Miguel to discuss their sexual behavior, the reliability of the data from that center in regard to rule breaking was not analyzed.

DISCUSSION

This report describes the sexual behavior patterns of couples who volunteered to learn and practice the OM. Such information has not been reported previously from a multinational study. It must be emphasized that although the teachers were experienced in imparting knowledge about the OM, they had not been trained specifically in

interviewing techniques, nor had the questionnaires been subject to independent validation. Because of the nature of the questions asked, there was no possibility of evaluating the truthfulness of the replies. Thus, the data must be interpreted with caution.

From the general viewpoint of the characteristics of the five centers, it can be stated that subjects and their partners in the two centers in developed countries (Auckland and Dublin) had reached the highest level of education.¹ Subjects in these two centers also had the longest periods of menstrual flow, the smallest numbers of pre-ovulatory dry days, longer fertile periods, smaller numbers of days from the peak to the end of the

Table 7. Life-Table Analyses of Discontinuations (%) in Terms of Subjects' and Partners' Difficulties with Abstinence and Satisfaction with the OM, by Center and Overall

Reason for discontinuation	Total population	No difficulty	Occasional difficulty	Always some difficulty	Occasional great difficulty
	%	%	%	%	%
Subjects' difficulty with abstinence					
All	32.6	28.9	45.3		
Pregnancy	15.7	13.6	24.7		
Other	20.1	17.8	27.4		
n	692	564	111	5	9
Partners' difficulty with abstinence					
All	32.4	21.4	42.4	40.4	
Pregnancy	15.5	7.6	23.7	22.9	
Other	20.0	14.9	24.5	22.7	
n	681	355	291	20	
		Excellent	Good	Poor	Nil
Subjects' satisfaction with method					
All	33.1	17.9	37.4	84.2	
Pregnancy	16.1	3.7	20.5	50.0	
Other	20.3	14.8	21.3	67.1	
n	695	204	471	19	1
Partners' satisfaction with method					
All	32.7	16.4	34.7	78.6	
Pregnancy	15.9	1.8	18.6	54.7	
Other	20.0	14.9	19.8	52.7	
n	687	180	464	42	1

cycle, longer required periods of abstinence, and lower numbers of days available for intercourse than the subjects in the centers in less developed countries.³ As noted in the current report, the couples from Auckland and Dublin exhibited a relatively high incidence of persistent rule breaking (seen also in Manila), a lower degree of satisfaction with their current frequency of intercourse, and higher levels of difficulty with abstinence. These two centers also had the highest method failure rates, and the highest rates of pregnancy due to "inaccurate application of instructions" (definition: The record indicated that the subject did not fully understand the method or its application; e.g., she had difficulty in identifying the peak day or was confused about which day following the peak was safe for resumption of intercourse. Alternatively, the record indicated that the couple had experienced difficulty in following the rules because of continuous mucus discharge, illness, or other circumstances that made it difficult for the subject to observe or chart the mucus), whereas they had the lowest rate of pregnancy due to "conscious departure from the rules of the method" (definition: The record indicated that the couple knowingly made a decision to have intercourse during the fertile period or elected to abandon the rules because of, for example, a celebration or departure on or return from holidays or work), despite their relatively high rates of rule breaking.² In contrast, the pregnancy rate due to "conscious departure from the rules" was much higher in San Miguel than in the other centers.^{2, 3} This occurred in a center in which the women had relatively short periods of menstrual flow, a large number of preovulatory dry days, a short fertile period, and a relatively large number of days available for intercourse as compared with the more developed centers.^{2, 3} The relative frequency of intercourse during the fertile period may be a reflection of the social characteristics of the predominantly rural/agricultural central American population studied. They are people of high fertility, without prior experience with fertility-regulating methods, and were described by the investigators in San Miguel as having a personality unaccustomed to making long-term decisions. Although we have no firm data on which to base a conclusion, it would appear that the lives of these people are dominated by their environment; favorable weather conditions and good crops could readily lead to the abandonment of previous plans to limit family

size. The work pattern of many partners was such that they were frequently absent from home, in order to work in neighboring or distant districts, with consequent demands for the exercise of their marital rights on returning home, regardless of whether this was during the fertile period.

Results in Bangalore and Manila were similar and were intermediate between those in San Miguel on the one hand and Auckland and Dublin on the other. In both centers, couples showed a similar distribution in education and cycle characteristics.³ Most subjects and partners expressed "good" satisfaction with their practice of the OM, and pregnancy rates were comparable between the centers and less than those in the other three. Only a single method-related pregnancy occurred during the effectiveness study in Manila and one in Bangalore during the teaching phase. Again, "conscious departure from the rules" was the major category of pregnancy in both centers.

Other differences between the centers were noteworthy. The reluctance to use early safe days for intercourse in Dublin may reflect conservatism in the teaching of the method in that center, in which 23% of subjects were given an extended period of teaching, as compared with 8% to 13% in the other four centers.¹ We have no data on the average frequency of intercourse in the general population of the five centers and cannot therefore make valid comparative comments regarding intercourse frequency. We observed that dissatisfaction with this frequency was more commonly expressed by subjects in Auckland and Dublin than in the other three centers. Of particular note, however, was the fact that partners in all centers except Bangalore frequently indicated a preference for more frequent intercourse and more frequently experienced occasional difficulty with abstinence; despite this, both subjects and partners stated general satisfaction with the OM. Somewhat similar findings were reported⁶ for a group of British couples following the basal body temperature method of regulating births; 53% of husbands and 56% of wives found abstinence to be difficult sometimes, although 66% of husbands and 75% of wives found the temperature method satisfactory in general. Klaus et al.⁷ also noted high levels of patient satisfaction with the OM, both in successful users and those who became pregnant as a result of user failure. Our observations suggest that in the further improvement of the OM, particular attention should be given to the development of approaches that will render

the period of abstinence from intercourse more acceptable to the couple, particularly to the male partner. Nevertheless, the couples stated that the practice of the OM appeared to induce little marital-domestic friction.

A particularly striking feature of the study was the high rate of reported nonobservance of the method rules in Auckland. We have no definite explanation—possibilities include a higher level of willingness to admit rule breaking in that center, lower motivation toward the practice of the method, or a difference in the quality of teaching. Despite the sociocultural similarities between Auckland and Dublin, the frequency of rule breaking was significantly different, a difference that became more marked as the study progressed.

We have no ready explanation for the apparent association between rule breaking and the rates of method failure. Possibilities include the fact that couples who frequently break rules may not have admitted such rule breaking when it led to pregnancy or may not be highly motivated to make careful observations of the mucus symptom. The association has led us to suspect that some of the pregnancies apparently resulting from failure of the method may have been misclassified, although the circumstances surrounding each pregnancy were investigated very carefully by the subject's teacher and the principal investigator in the centers.

The current report has dealt superficially with many of the psychosexual aspects of the OM. For national authorities to make decisions about the applicability of the method in national family-planning programs, much more information about the factors that affect demand, choice, and use of these methods is required, together with information on their impact on fertility rates. The major challenge to advocates of natural methods is to find means by which couples can be encouraged to observe the rules of the method and to cope with the difficulties associated with periodic abstinence from sexual intercourse.

ADDENDUM

In response to a referee's suggestion to analyze possible relationships between the degree of satisfaction with the use of the ovulation method (OM) and the amount of abstinence required, the average lengths of the fertile and infertile phases of the cycle and average number of days of abstinence required were calculated for each subject

and compared to her and her partner's mean satisfaction score (fair, good, very good, or excellent) during the course of the study.

Analysis of variance with a linear contrast indicated significant correlations between increasing satisfaction score of the women and (1) shorter length of the fertile phases ($P < 0.001$), (2) longer length of the infertile phase ($P = 0.02$), and (3) fewer days of abstinence required ($P < 0.001$). These trends were evident in women who completed the whole study (13 cycles) as well as in those who completed cycles 1 through 6 or cycles 7 through 12 only. The partners' satisfaction scores also increased with decreasing length of the fertile phase ($P = 0.03$) and fewer days of abstinence required ($P = 0.03$) but not with increasing length of the infertile phase. However, the trends were less marked and the correlations were not significant in the subgroup of couples who completed cycles 1 to 6, 7 to 12, or all 13 study cycles.

To explore possible relationships between length of the fertile and infertile phases of the cycle and use-effectiveness of the method, the average length of the fertile and infertile periods and the average number of days of abstinence required were calculated for women who (1) became pregnant as a result of rule-breaking, (2) became pregnant for other reasons, and (3) did not become pregnant during the course of the study. This analysis revealed no difference between the three groups of women.

REFERENCES

1. World Health Organization: A prospective multicentre trial of the ovulation method of natural family planning. I. The teaching phase. *Fertil Steril* 36:152, 1981
2. World Health Organization: A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. *Fertil Steril* 36:591, 1981
3. World Health Organization: A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase. *Fertil Steril* 40:773, 1983
4. World Health Organization: A prospective multicentre trial of the ovulation method of natural family planning. IV. The outcome of pregnancy. *Fertil Steril* 41:593, 1984
5. Billings EL, Billings JJ, Catarinich M: Atlas of the Ovulation Method, Second edition. Melbourne, Advocate Press, 1974
6. Marshall J, Rowe B: Psychologic aspects of the basal body temperature method of regulating births. *Fertil Steril* 21:14, 1970
7. Klaus H, Goebel JM, Muraski B, Egizio MT, Weitzel D, Taylor RS, Fagan MU, Ek K, Hobday K: Use-effectiveness and client satisfaction in six centres teaching the Billings ovulation method. *Contraception* 19:613, 1979