

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

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*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*

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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.<sup>1-3</sup> In 1975, very little objective data were available on the ability of women to detect these changes and on the effectiveness of the OM.<sup>4</sup> 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.<sup>5</sup> 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*,<sup>5</sup> 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"<sup>1</sup> 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)<sup>1</sup> 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 <sup>a</sup>	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)

<sup>a</sup>Multiple 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 ( <i>N</i> = 122)	50 (41.0)	38 (31.1)	3 (2.5)	2 (1.6)	29 (23.8)
Bangalore ( <i>N</i> = 199)	110 (55.3)	34 (17.1)	43 (21.6)	1 (0.5)	11 (5.5)
Dublin ( <i>N</i> = 232)	96 (41.4)	75 (32.3)	30 (12.9)	6 (2.6)	25 (10.8)
Manila ( <i>N</i> = 146)	33 (22.6)	47 (32.2)	46 (31.5)	3 (2.0)	17 (11.6)
San Miguel ( <i>N</i> = 148)	55 (37.2)	8 (5.4)	13 (8.8)	15 (10.1)	57 (38.5)
Total ( <i>N</i> = 848) <sup>a</sup>	344 (40.6)	202 (23.8)	135 (15.9)	27 (3.2)	139 (16.4)

<sup>a</sup>Missing 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 <sup>a</sup>
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)

<sup>a</sup>Reasons 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.<sup>1-3</sup> A previous study<sup>6</sup> 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.<sup>5</sup>

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.<sup>7</sup> 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.<sup>8</sup> 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.

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