LONG-TERM USE OF THE TWODAY METHOD FOLLOWING THE EFFICACY STUDY

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ABBREVIATIONS AND ACRONYMS

ABPF	Association Beninoise pour la Promotion de la Famille (Beninese association for the promotion of the family)
CBD	Community Based Distribution
DHS	Demographic and Health Survey
DSF	Direction de la Sante Familiale (Department of Family Health)
HOMEL	Hôpital Maternité Lagune (Lagune Maternity Hospital)
IEC	Information Education and Communication
IPPF	International Planned Parenthood Federation
IRH	Institute for Reproductive Health
LEADD	Laboratoire D'Etudes Appliquées aux Dynamique de Développement (Laboratory of Applied studies to the Dynamics of Development)
MOH	Ministry of Health
MSP	Ministere de la Sante Public (Ministry of Public Health)
NFP	Natural Family Planning
OSV/ JORDAN	Organisation pour la Santé et Vie (Organization for Service and Life)
SDM	Standard Days Method
UNFPA	United Nations Fund for Population Assistance
USAID	United States Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

At the conclusion of the one-year efficacy study of the TwoDay Method participants were invited to participate in an additional two years of follow up. The purpose of the long-term follow-up study was to examine long-term efficacy and continuation of the method.

Some 185 women in Guatemala and Peru participated in the long-term follow-up study. Efficacy study participants from the Philippines sites were not invited to participate in the long-term follow-up study because IRH had concluded its work in that country. Participants were followed for two additional years, and interviewed at 6, 12, 18, and 25 months. At each interview they were administered a standard follow-up form to determine if they were still using the TwoDay Method, and elicit information about satisfaction with the method and any problems with method use. The interviews were administered by the same providers who counseled the women in method use at the beginning of the TwoDay Method efficacy study, and who had interviewed them monthly during that study.

Only 21 participants reported that they became pregnant while using the TwoDay Method in the second and third years of use. Life tables were calculated to establish long-term failure rates of the TwoDay Method. The typical use pregnancy rate for year 2 was 7.9; for year 3 it was 5.1. These results show that the method continues to be effective for long term users.

Of the 185 participants, 61% were still using the method two years later. This continuation rate is particularly high given that fertility preferences were not a condition for participation in the long-term follow up study. Some 17% of participants stopped using the method because they wanted to become pregnant Women who complete the first year of TwoDay Method use are likely to continue to be able to use the method successfully and effectively.

Long-Term Use of the TwoDay Method Following the Efficacy Study

I. INTRODUCTION

The purpose of this study was to examine the long term efficacy and acceptability of a simple fertility-awareness based method of family planning as a follow up to the method's 1-year efficacy trial. The TwoDay Method™ was developed to respond to the need for simple, accurate ways for women to recognize when they should avoid unprotected intercourse to prevent pregnancy. Women using the TwoDay Method rely on the presence or absence of cervical secretions to determine whether or not they are fertile each day. The woman asks herself two simple questions: (1) "Did I note secretions today?" and (2) "Did I note secretions yesterday?". She should consider herself fertile today if she notices cervical secretions of any type today or she noticed them yesterday. She avoids unprotected intercourse on these days to prevent pregnancy. If she noticed no cervical secretions of any type today and yesterday, her probability of getting pregnant from intercourse today is very low (Sinai et al., 1999).

A multi-site clinical trial of the TwoDay Method followed women in Guatemala, Peru, and the Philippines for up to 13 cycles of method use. The primary research question of the 1-year efficacy trial was to determine the first-year pregnancy rate of women who use the TwoDay Method as their only means of avoiding pregnancy. Results showed the method to be effective and acceptable. The failure rate was 3.5 with correct use and 13.7 when all pregnancies and cycles were included in the analysis, including cycles in which the couple had unprotected intercourse during the days the method identified as fertile (Arévalo et al., 2004).

1.1 Justification

Surveys conducted in countries around the world suggest that a substantial number of women in union who use a contraceptive method state that periodic abstinence is their method of family planning (Curtis and Neitzel, 1996). Many of these women use some type of calendar-based approach to determine when they should avoid unprotected intercourse to prevent pregnancy. However, survey data also indicate that a significant percentage of women who report using this approach, more than 90% in some populations, have incorrect knowledge about when during their menstrual cycles they are most likely to become pregnant (Che et al., 2004).

Another potential source of incorrect method use is the relative complexity of instructions that users of some existing fertility-awareness based methods, such as the Ovulation Method and the Symptothermal Method, are required to follow. Consider, for example, the Ovulation Method, which is based on self-observation and interpretation of changes in cervical secretions that occur as the woman approaches ovulation and when ovulation has occurred. To use the Ovulation Method effectively, women learn to differentiate between multiple characteristics of their cervical mucus (feel, color, texture, and general appearance), and to correctly interpret and chart their findings (Billings and Estmore, 1991). The Symptothermal Method involves additional monitoring of basal body temperature and, according to some instructions, characteristics of the cervics

itself, as well as other fertility signs (Kippley and Kippley, 1997). This requires hours of intensive teaching. Instructors need to follow users for several cycles, until users are able to correctly interpret their symptoms of fertility and to use the method independently (Jennings et al., 1998). Despite the high perfect-use effectiveness rates and the significant demand for methods based on periodic abstinence, tested methods such as the Ovulation Method and Symptothermal Method are not offered in most multi-method programs, in part because many providers do not have time to acquire the skills and engage in the extensive teaching process these methods require (Arévalo, 1997).

Women who currently use fertility awareness-based methods without correct knowledge of how to identify their fertile days could benefit from simple, effective instructions to help them know when they should avoid unprotected intercourse to prevent pregnancy. Other women who may be interested in a family planning method that involves identifying their fertile days and modifying their behavior to avoid pregnancy and/or does not require drugs, devices or surgical procedures, may also gain from these instructions.

The availability of a simple fertility-awareness based method that requires minimal training for providers and interaction for clients, would make it feasible for multi-method family planning programs, as well as educational and/or community based, and other programs, to incorporate these methods into their activities, thus meeting the family planning needs of a larger number of women, especially in under-served populations. Also, providing women with these methods could be their entry point into other reproductive health services (Arévalo, 1997).

The Institute for Reproductive Health, Georgetown University (IRH), has recently developed another fertility awareness-based methods – the Standard Days Method. The Standard Days Method identifies days 8-19 of the cycle (inclusive) as the fertile days for every user in every cycle. An efficacy study resulted in a pregnancy rate of 4.8 with correct use (Arévalo et al., 2002). The Standard Days Method can be successfully used after just one counseling session, and is easy for providers to teach and for users to learn and use. However, the Standard Days Method is only appropriate for women with cycles that usually range 26-32 days. Women who often have shorter or longer cycles, and women who have cycles with irregular length, cannot use it as effectively.

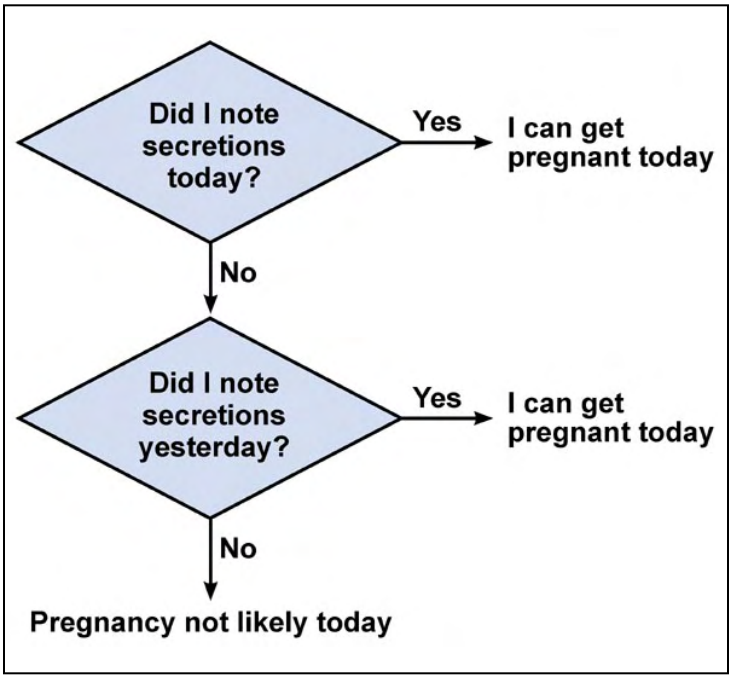
The TwoDay Method was designed to address this gap, and provide a simple but effective option for women regardless of cycle length and regularity. It appears to be easier for clients to learn and use and for providers to learn and teach. It is less time consuming and cheaper to provide than established fertility awareness-based methods such as the Ovulation Method and the Symptothermal Method, and it involves less provider follow-up of clients. Previous research shows that the theoretical effectiveness of the TwoDay method is high (Sinai et al., 1999; Jennnings et al., 2001, Dunson et al., 2001). The efficacy trial confirmed method effectiveness.

1.2 Developing the TwoDay algorithm

The TwoDay Method is based on a simple algorithm. Users note their secretions daily, by sensation or observation, and ask themselves two simple questions: (1) Do I note secretions today? And (2) did I note secretions yesterday. If the answer is ‘yes’ to either of these questions, the user should consider herself fertile today. If the answer is

'no' to both questions, the woman's risk of pregnancy from unprotected intercourse today is minimal. Figure 1 shows this algorithm.

Figure 1: Eligibility criteria for TwoDay Method use



IRH began developing the TwoDay algorithm in 1998, with the goal of creating a new fertility awareness-based method of family planning that would be easy for providers to teach and for users to learn and use, yet would be effective for avoiding unplanned pregnancy. The rigorous development and testing of the algorithm is described in this section.

1.2.1 The biological basis for the TwoDay algorithm

The physiological basis for fertility awareness-based methods is well established. There is evidence that conception only occurs near the time of ovulation. There is a fertile window during a woman's menstrual cycle – a few days when she can, with varying degrees of likelihood, become pregnant following unprotected intercourse. The probability that unprotected intercourse would result in a clinically detected pregnancy increases progressively from about 4% five days before ovulation to 29% two days and 27% one day before ovulation, and declines to 8% from intercourse occurring on the day of ovulation. Pregnancy from intercourse on any other day of the cycle is very unlikely (Wilcox et al., 1998). An older study (Barret and Marshall, 1969) and results from a multi-center European study (Colombo and Masorotto, 2002) suggest a similar pattern.

Also well documented is the relationship of hormonally-produced fertility signs to the fertile days (Hilgers et al., 1978; Vigil et al., 1992). One of the primary fertility signs is

cervical secretions, which can be felt or observed at the vulva. Typically, there are no noticeable cervical secretions right after menses. Several days before ovulation occurs, cervical secretions become progressively noticeable, until they are abundant and wet right before and during ovulation. After ovulation, some women have a few days of secretions while others have none. Then, there are again no noticeable secretions until the next menses. Unprotected intercourse cannot result in pregnancy without the presence of cervical secretions, even if it occurs close to ovulation (Odeblad, 1997). Methods that rely on cervical secretions, such as the Billings Ovulation Method, have been shown to be highly effective when used correctly (Guida et al., 1997; Trussel and Grummer-Strawn, 1990; World Health Organization, 1981).

Ideally, a woman using a fertility awareness-based method should be able to identify the six days of her fertile window with neither false positives (days identified as fertile that are actually infertile) nor false negatives (days identified as infertile that are actually fertile). However, the technology to precisely measure the fertile window is expensive and unavailable in many countries. IRH's goal in developing the TwoDay Method was to try and balance the need to provide effective protection from unplanned pregnancy while restricting the identified fertile period to as few days as possible. In essence, to determine what identified fertile window would include days with the highest probability of pregnancy for most women.

The Billings Ovulation Method, which is highly effective when used correctly (Guida et al., 1997) defines the fertile period as beginning with the onset of mucus secretions, or with a sensation of dampness or wetness, detectable at the vulva. The Peak day is the last day on which fertile-type mucus is recognized, or the last day on which the wet or lubricative sensation is felt. The fertile period ends on the fourth day after Peak day (World Health Organization, 1981). To develop the TwoDay Algorithm we examined 183 actual charts created by users of the Billings Ovulation Method and the Symptothermal Method. Women using these methods need to differentiate and interpret their cervical secretions. To assist them in their interpretation they usually chart their findings. We studied these charts to establish the TwoDay Alrogithm, which is a much simpler rule that appeared to provide as much protection from pregnancy as these established methods.

1.2.2 Theoretical efficacy of the TwoDay algorithm

We determined the theoretical efficacy of the TwoDay Algorithm by applying the algorithm to appropriate data sets from the World Health Organization and from the Ovulation Method center in Vicenza, Italy. These studies showed that for women using the TwoDay Method the highest theoretical probability of pregnancy from intercourse on any day relative to ovulation was only 0.025 (Sinai and Jennings, 1998; Jennings and Sinai, 2001). We also calculated the theoretical failure rate of the method based on day-specific intercourse information using data from a multi center European study. Results indicated that the theoretical first-year pregnancy rate compared favorably with reported rates of other widely used family planning methods (Dunson et al., 2001).

1.3 Developing the TwoDay Method

Before the TwoDay algorithm could be tested it was developed into a family planning method. IRH developed a protocol for method provision, and created a variety of teaching aids and method tools to assist providers in determining eligibility for method use and in providing the method.

1.3.1 Eligibility criteria for TwoDay Method use

The TwoDay method can be used by women of reproductive health, regardless of their history of cycle length or regularity. Table 1 summarizes eligibility criteria for method use.

Table 1: Eligibility criteria for TwoDay Method use

Who can use the TwoDay Method?

- Couples with stated desire to use a natural method; and
- who are willing and able to monitor daily the presence or absence or secretions; and
- who are willing to avoid unprotected intercourse during the days the method identifies as fertile.

Exceptions:

- Postpartum or breastfeeding women, unless they have completed three cycles since their child was born. Analysis of data from a study of breastfeeding women who were using the Symptothermal method suggests that the TwoDay Method would be effective for these women following the resumption of menstruation. However, because they may have more days of secretions than non-breastfeeding women the identified fertile window can be too long to be acceptable to most couples (Arévalo et al., 2003).
- Users of hormonal contraception or medication in the previous three months. This gives enough time for fertility and the appearance of cervical secretions to be restored following cessation of hormonal use.

1.3.2 Instructions for method use

TwoDay method users are instructed to monitor their secretions daily. Secretions can be detected in a variety of ways (i.e., by observing and touching them in underwear or toilet paper, by touching the genitals, or by the sensation of wetness in the genital area or on underwear), and users are advised to monitor their secretions in a way that works best for them. To avoid confusing cervical secretions with semen, it is recommended that women pay attention to their secretions in the afternoon and evening.

TwoDay Method users are taught that secretions may look or feel different on different days of the cycle, and that amounts of secretions vary, but that a woman should consider herself fertile if she notices secretions of any type, regardless of characteristics or amount. Users are also instructed that once secretions start, they should be continuous for several days of the cycle.

The TwoDay algorithm is then explained to users. They are taught that if they note secretions today or yesterday, they should consider themselves fertile today. If they noted no secretions today and yesterday, they are probably not fertile today.

TwoDay method users are also instructed to return to their provider if they have cycles with fewer than 5 days with noted secretions, with the assumption that they are either unable to learn how to detect secretions, or they are not ovulating. Similarly, women who have more than 14 consecutive days of secretions are advised to return to their provider, assuming that this might indicate infection or some hormonal disorders.

1.4 Key findings of the efficacy trial

A total of 450 women were admitted to the efficacy trial, with a mean age of 29.2. They contributed 3928 cycles to the study. Table 2 shows participant profile.

Table 2: Profile of participants (women) in the TwoDay Method efficacy study (n=450)

Characteristic	Percent of participants
Age at admission	
18-24	23.3
25-29	28.7
30-34	26.4
35-39	21.6
Parity	
No children	0
1-2 children	60.9
3-4 children	28.2
5 children or more	10.9
Education	
No education or some primary education	26.7
Completed primary education	20.2
Completed secondary education	19.6
Some technical or university	33.4
Occupation	
No income earning occupation	47.8
Agriculture	0.9
Sales (including also street vendors)	15.3
Blue collar job	25.5
White collar job	10.5

*Ever use of family planning methods**	
None	20.7
Rhythm	42.2
Withdrawal	31.8
LAM	6.4
Other traditional method	0.7
Barrier method	28.9
IUD	10.7
Hormonal method	41.8

* Figures sum to more than 100% because many respondents specified more than one method.

Only 47 pregnancies began during the study. As expected, most (53.2%) were in cycles in which women reported unprotected intercourse during the fertile days. Additional pregnancies happened when the couple was using withdrawal (12.8%) or condoms (8.5%) as backup during the fertile days. Only 12 pregnancies (25.5% of pregnancies) occurred in cycles where couples reported no intercourse during the fertile days.

In the efficacy trial the first-year pregnancy rate was 3.5% (95%; CI 1.44-5.52) with correct use of the method (pregnancies occurring in cycles in which participants reported no intercourse on the days the method identifies as fertile). When we included in the analysis cycles in which participants reported intercourse with use of condom or withdrawal as backup during their fertile days (and pregnancies occurring in such cycles) the first-year pregnancy rate is 6.3 (95%; CI 361-8.81). When we included all cycles and pregnancies in the analysis, the pregnancy rate was 13.7% (95%; CI 9.93-17.34). The single-decrement multi-censoring life table for correct use (including only cycles and pregnancies with no reported intercourse on the fertile days) is presented in Table 3. The life table including all cycles and all pregnancies is presented in Table 4.

Table 3: Life table pregnancy rates for correct use of the TwoDay Method in year 1 (efficacy study)

Cycle	Women exposed*	Pregnancies	Pregnancy rate	95% confidence interval
1	319	2	0.63	0.24 to 1.49
2	335	3	1.52	0.19 to 2.83
3	317	2	2.14	0.56 to 3.69
4	307	1	2.46	0.76 to 4.12
5	293	1	2.79	0.97 to 4.57
6	282	1	3.14	1.20 to 5.03
7	264	0	3.14	1.20 to 5.03
8	262	1	3.50	1.44 to 5.52
9	249	0	3.50	1.44 to 5.52
10	239	0	3.50	1.44 to 5.52
11	237	0	3.50	1.44 to 5.52
12	237	0	3.50	1.44 to 5.52
13	233	0	3.50	1.44 to 5.52

* Excluding censored cycles

Table 4: Life table pregnancy rates including correct and incorrect use of the TwoDay Method in year 1 (efficacy study)

Cycle	Women exposed*	Pregnancies	Pregnancy rate	95% confidence interval
1	411	11	2.68	1.10 to 4.22
2	380	7	4.47	2.43 to 6.47
3	347	5	5.85	3.49 to 8.14
4	319	4	7.03	4.42 to 9.56
5	305	4	8.25	5.41 to 11.00
6	289	4	9.52	6.44 to 12.49
7	272	1	9.85	6.71 to 12.88
8	269	3	10.85	7.54 to 14.04
9	257	2	11.55	8.12 to 14.85
10	246	2	12.27	8.72 to 15.68
11	243	2	12.99	9.32 to 16.51
12	240	2	13.71	9.93 to 17.34
13	234	0	13.71	9.93 to 17.34

* Excluding censored cycles

The mean number of days with secretions of participants in the efficacy study was 12.1 days (median 12 days, minimum 3 days, maximum 31 days). Most cycles had between 10 and 14 identified days with secretions. Women identified less than 10 days with secretions in only 4.5% of efficacy study cycles (women who identified less than five days were removed from the study). Women identified more than 14 days in only 4% of cycles. There were more than 16 days with secretions in only 1% of cycles (women who had more than 14 consecutive days with secretions were removed from the study).

Of the 450 participants who entered the study, 52.7% completed 13 cycles of method use. Some 99% of these women were planning to continue using the TwoDay Method.

1.5 Purpose of the long-term follow up study

The present study followed efficacy-study participants for two additional years, beyond the efficacy study period of one year.

The long-term follow-up study was designed to answer the following questions:
- What is the long-term continuation rates of TwoDay Method use?
- What is the long-term effectiveness of the TwoDay Method?
- How many women stop using the TwoDay Method because of cycle irregularity?
- Do women continue using the TwoDay Method as they were initially counseled?
- Why do women stop using the TwoDay Method?

II. METHODOLOGY OF THE LONG-TERM FOLLOW UP STUDY

Couples in Guatemala and Peru who had successfully used the TwoDay Method for one year during the efficacy study were invited to participate in the long-term follow up. Philippina clients were not invited to participate because IRH had closed its projects in the Philippines at the time. The study followed couples using the TwoDay Method for two additional years of method use.

2.1 Study population

The efficacy trial of the TwoDay Method followed 450 women in five economically and culturally diverse sites in Guatemala, Peru, and the Philippines for up to 13 cycles of method use. Participants in the efficacy trial had to meet the following criteria:

- Age 18 to 39 at the time of admission into the efficacy trial,
- No use of hormonal contraceptives in the three months prior to enrollment,
- Neither the woman nor her partner were sterilized,
- Male partner agreed to women's participation in the efficacy trial,
- No history of infertility,
- Not at high risk for STIs,
- Sexually active,
- Wished to avoid pregnancy for at least one year.

Breastfeeding women were admitted to the efficacy trial only if they met all the above criteria, including having regular cycles during the three months prior to enrolling in the trial.

These same women participated in the long-term follow up study. However they were a year older at admission (age 19-40), and their fertility preferences were not considered. Women continued into the long-term follow up study regardless of whether they wished to continue avoid pregnancy.

2.2 Survey instruments

Providers and clients continued to use the materials that were developed for the efficacy study. However a complete set of survey instruments was developed to reflect the different focus of the study. These instruments included:

- A Screening form was administered at the time of screening to screen potential clients for method and study eligibility. The form included questions related to the eligibility criteria and provided a full assessment of each woman's continued eligibility to use the TwoDay Method and participate in the study.
- An Informed consent form was signed by all clients prior to admission.
- A Follow-up form was administered at each follow-up visit to collect information about how the client was using the method each cycle, the couple's satisfaction with the method, and any problem they had;
- An Exit form was administered when clients left the study, either at completion of two additional years in the study or for any reason other than pregnancy. It collected information about overall use of the method and satisfaction with it.

- A Pregnancy form was administered to clients who became pregnant during the study period.
- A Lost to follow-up form was filled by providers for clients who were lost to follow up.

All study instruments were approved by the Georgetown University Medical Center Institutional Review Board. A copy of all study forms is attached as Appendix A.

2.3 Study procedures

During their participation in the efficacy trial women were interviewed monthly, and completed coital logs daily. At the end of the efficacy study, 185 of the women who had successfully completed 13 cycles of method use agreed to participate in the long-term follow-up study. They were followed for up to two additional years, and interviewed at 3, 6, 12, 18, and 24 months after starting their participation in the long-term follow-up phase of the study.

Participants did not complete coital logs, and were not asked whether they still wished to avoid pregnancy in the near future. All couples who successfully completed the efficacy study were eligible to be admitted to the long-term follow-up study, regardless of their fertility preferences. Table 5 shows the differences between the two studies – the efficacy study (the first year of method use), and the long-term study which followed it and is the focus of this report.

Table 5: Differences between the efficacy study and the long-term follow-up study

	Efficacy study	Long-term follow-up study
Year of TwoDay Method use	1st	2nd & 3rd
Number of participants at admission	450	185
Length of study	1 year	2 years
Frequency of interviews	Monthly	At 3, 6, 12, 18, 24 months
Use of coital logs	Yes	No
Use of pregnancy tests	Yes	No
Wish to avoid pregnancy at least 1 year	Yes	Not necessarily

In each long-term follow-up interview participants were administered a standard follow-up questionnaire to determine if they were still using the TwoDay Method, and elicit information about satisfaction with the method and any problems with method use. If the participant self-reported that she was pregnant, she was administered the pregnancy questionnaire to determine if the pregnancy was planned (if she had stopped using the TwoDay Method in advance of the pregnancy) or unplanned, and to establish how many months the woman contributed to the study before she stopped using the method in order to become pregnant, or before an unplanned pregnancy. If the woman

reported that she had stopped using the method during the interval between interviews (but was not pregnant), she was administered the exit questionnaire to determine the reason for discontinuation, and how many cycles the woman contributed to the study before she stopped using the method. If the interviewer was not able to locate a participant after three attempts, or if the participant has moved to an inaccessible location, the lost-to-follow-up form was completed.

These interviews were administered by the same providers who counseled the women in method use a year earlier, and had administered the monthly follow-up interviews during the efficacy trial. IRH staff, in conjunction with the local principal investigators, conducted a retraining workshop for the providers. During this training workshop they were instructed in the protocol for the long-term follow-up study, and were familiarized with the study instruments. The new instruments were much briefer then those used in the efficacy trial, but dealt with similar issues, so were easy for providers to learn and understand. The retraining included also discussion of informed consent issues.

Life-tables were calculated in the efficacy study to establish failure rates. Women were interviewed every cycle; we calculated survival per cycle; pregnancies were determined by pregnancy test; we knew exactly when women became pregnant, left the study, or were lost to follow-up; and women who had a second cycle out of the 26-32 day range were removed from the study.

Life-tables were calculated also in the long-term follow-up study. However we expect that results are less accurate, because women were interviewed periodically and we rely on their recollection to determine in which cycle they became pregnant. Also, pregnancy was self reported. It is possible that some women who became pregnant did not report it. Also, without coital logs we could not distinguish between correct or incorrect use of the method, and could only calculate typical use failure rates.

With these drawbacks in mind, life-tables were calculated to determine second and third year (unplanned) pregnancy rates. Participants in the long-term study did not complete a coital log, and were not asked whether they did or did not have unprotected intercourse during the days the method identifies as fertile. Therefore we could not calculate correct use failure rates. The rates we present here are typical use failure rates.

Use of the TwoDay Method requires either abstinence during the fertile days or use of a barrier method as backup on these days. However, to facilitate the study of method efficacy participants in the efficacy study were asked to abstain on days 8-19 of the cycle, but to report in their coital log if they had intercourse on the fertile days, with or without a back-up method. This requirement was lifted when participants moved on to the long-term follow-up study. The typical use rate reported here, therefore, more closely reflects real-life (not study setting) use of the method.

III. RESULTS

Participants in the long-term follow-up study represented a mix of socio-demographic characteristics. They resided in urban, mixed urban/rural, and rural sites. The educational level of participants in Guatemala was significantly lower than that of participants in the other sites. Some 76% of Guatemala participants did not complete primary education, compared with 2.6% in Peru. More than half of participants in Guatemala could not read or could only read with difficulty. In comparison, only 2% of participants in Peru could not read or could only read with difficulty, and 74.4% had completed secondary education or higher.

All study participants had children. The youngest child in the Peru sites (mean 4.6 and 4.1) was older than in the Guatemala site (mean 1.6). Participants in Guatemala were poorer than Peruvian participants.

3.1 Efficacy and correct use

Of the initial 185 participants, only 21 women reported that they became pregnant while using the TwoDay Method in the second and third years of use. We do not know if they used the method correctly in the pregnancy cycle, or if they had unprotected intercourse during the fertile days. This translates into very high typical use efficacy rate, as seen in the Table 6. The Table shows pregnancy rates for typical use of the TwoDay Method in the first, second, and third years of use.

Table 6: Typical use life table pregnancy rates

Period	Pregnancy rate	95% confidence interval
Year 1 (from the efficacy study)	13.71	9.33 to 17.34
Year 2	7.85	3.81 to 11.71
Year 3	5.10	1.34 to 8.72

Year 1 rates were calculated per 13 cycles
Years 2 and 3 rates were calculated per 12 calendar months each

As expected, the pregnancy rate for typical use declined with time. It is only 7.9 for the second year of use and 5.1 for the third year, compared to 13.7 for the first year of use. It is possible that some women who became pregnant during the long-term follow-up study period did not report the pregnancy to us. It is also possible that women who reported that they stopped using the method some months earlier because they wished to become pregnant were actually using the method until their pregnancy. Therefore these second and third year pregnancy rates are less exact than the first year rates. Clearly, however, the method continues to be effective for long-term users.

3.2 Continuation

Of the 185 women who entered the long-term follow-up study 112 (60.5%) were still using the method two years later. This is a very high continuation rate, particularly given that at the beginning of the long-term study period women's fertility preferences for the study period were varied – not all couples wanted to avoid pregnancy for the full study period. The following Table 7 shows reasons for discontinuation.

Table 7: Reason for exiting the TwoDay Method long-term follow up study (n=185)

Period	Percent of participants
Complete 2 additional years of method use	60.5%
Wished to become pregnant	16.8%
She or her husband did not like or trust the method	6.5%
Marital dissolution	5.9%
Lost to follow-up	1.6%
Unintended pregnancy	11.4%

Some 31 participants stopped using the method stating that they wished to become pregnant. Of these, 21 became pregnant before their next scheduled interview. Several women left the study because they no longer had need for contraception due to marital dissolution or a hysterectomy.

Only 12 women stopped using the method because they, or their partners, did not like or trust the method.

IV. CONCLUSION

These findings show that the TwoDay Method continues to be a highly effective family planning method in the second and third year of method use.

A weakness of the study is the retrospective nature of the interviews. Participants were interviewed at six-month intervals and asked about their use of the method in the preceding months. Another weakness is not using coital logs and pregnancy tests, relying instead of participant's answers about their correct and incorrect use of the method and about their pregnancy status.

Because of these weaknesses we posit that our results are less exact than those of the efficacy study. It is possible that more women had an unintended pregnancy during the study and did not report it. However the failure rates we present here for typical use are very low. Even if twice the women had become pregnant during the study period, the typical-use pregnancy rate would still compare favorably to that of other user directed methods.

In conclusion, the TwoDay Method is an effective and acceptable fertility awareness-based method of family planning. Women who complete the first year of TwoDay Method use are likely to continue to be able to use it successfully and effectively.

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