Continued use of the Standard Days Method®

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Abstract

Objective To examine the long-term effectiveness and continuation of the Standard Days Method (SDM)®, a fertility awareness-based method of family planning that identifies Days 8–19 (inclusive) of the cycle as the fertile window. On these days users avoid unprotected sexual intercourse to prevent pregnancy. The method works best for women with cycles that are usually in the range of 26–32 days, which is an important reason for method discontinuation in the first year of use. The authors determine if this continues to be an issue in the second and third years of method use.

Methods Participants in an earlier efficacy study (478 women in three countries) and method introduction studies (1181 women in four countries) were followed for 2 years beyond the original 1-year study period, to determine their continued use of the method, intended and unintended pregnancies, and reasons for discontinuation. Life-tables were used to approximate typical use pregnancy rates.

Results The method continues to be effective in the second and third years of use, and compares favourably to other user-directed family planning methods. Women with no more than two cycles outside the 26–32-day range within a year are likely to continue having cycles within this range.

Conclusions Women who complete the first year of SDM use are likely to continue to be able to use the method successfully and effectively. The method presents a viable longer-term option for women who prefer this approach to family planning.

Key message points

- The Standard Days Method® continues to be effective in the second and third years of use.
- The method presents a viable longer-term option for women who prefer this approach to family planning.

Introduction

For most family planning methods, studies of method effectiveness, acceptability and continuation focus on the first year of method use. The reason seems obvious. Women who use the method for a year clearly find the method acceptable. Side effects severe enough to cause discontinuation of method use usually occur in the first few months of use. Also, efficacy in the second and third year is likely to be better than in the first year because (1) women for whom the method is biologically less effective would tend to get pregnant earlier and (2) failure due to user error is more likely to occur in the first few months of method use while users learn to use the method correctly. These findings are confirmed in the studies that include efficacy or continuation figures for any family planning method beyond the first year of use, though these studies usually examine longer-acting methods, such as intrauterine devices and implants. [1–3]

The Standard Days Method (SDM)® is a fertility awareness-based method of family planning. The method identifies Days 8–19 (inclusive) of the cycle as the fertile window for every user in every cycle.[4] To prevent pregnancy, users avoid unprotected sexual intercourse on these days. The method works best for women with cycles that usually range between 26 and 32 days. Users are advised that the method may not be effective for them if they have a second cycle out of this range in a year. A multisite clinical trial of the SDM that followed women for up to 13 cycles of method use showed it to be effective and acceptable. The failure rate was 4.8 with correct and 12.0 with typical use.[5] The trial was followed by a series of 14 method introduction studies (following users for up to a year) that tested service delivery options in a variety of settings. Results showed that the method appeals to a wide range of women around the world. It is easy for providers of all levels to teach and for users to learn and use, and is acceptable to both men and women.[6]

Given the SDM's requirement for cycle regularity, it is important to study longer-term use of the method (beyond the first year). If it is the case that cycle regularity in the first year of use is a predictor of continued cycle regularity, then effectiveness and continuation rates may be higher

in subsequent years. Also, the SDM is a relatively new method. Family planning programmes wishing to add the SDM to their method mix need to weigh the cost of integrating a new method into services against the benefit of longer-term efficacy and continued use that it offers.

The purpose of the present study was to estimate the longer-term effectiveness and continuation rates of the SDM. Previous studies show that 25–30% of women have a second cycle outside the 26–32-day range in the first year of use. Out-of-range cycles are the most common reason for method discontinuation in the first year.[5,6] The present study examines continuation of method use beyond the first year, and the effect of cycle irregularity on continuation in the second and third years of method use.

Methods

Data were used from two sources. First, the Standard Days Method efficacy trial followed women for up to 13 cycles of method use. For the purpose of the present study, these women were followed for up to two additional years (for a total of 3 years). Second, participants in five of the method introduction studies were followed for up to 2 years beyond the initial study period. Data collection for the earliest study began in 2000, and for the latest study it ended in 2006. Figure 1 shows the flow of the studies.

Similar procedures were followed in all of these studies. Upon completion of the efficacy trial or the method introduction study, participants were invited to enrol in the follow-up study and were interviewed at 3, 6, 12, 18 and 24 months, for up to two additional years of method use.

In each follow-up interview participants were administered a standard follow-up questionnaire to determine if they were still using the SDM, and to obtain information about satisfaction with the method and any problems with method use. If the participant self-reported that she was pregnant, she was administered a pregnancy questionnaire to determine if the pregnancy was planned (if she had stopped using the SDM in advance of the pregnancy or even used the method to time a desired pregnancy) or unplanned, and to establish how many months had elapsed between her last interview and her becoming pregnant (or stopped using the method in order to become pregnant). If the woman reported that she had stopped using the method during the interval between interviews, she was administered an exit questionnaire to determine the reason for discontinuation, and how many cycles the woman contributed to the study before she stopped using the method.

Further follow-up of efficacy trial participants

The efficacy trial followed 478 women in five economically and culturally diverse sites in Bolivia, Peru and The Philippines for up to 13 cycles of method use. They were screened for eligibility to use the method before admission to the study. The SDM was integrated into services provided in public sector facilities where providers were trained to offer the method and in study procedures. These facilities were offering a variety of contraceptive methods, and the SDM was added to the method mix available to clients. Women enrolling in the study indicated that they wished to avoid pregnancy for at least a year. They were interviewed monthly and completed coital logs daily. Results of the efficacy study have been published elsewhere.[5]

At the end of the efficacy study the 218 participants who successfully completed 13 cycles of method use were invited to participate in this follow-up study. All couples who successfully completed the efficacy study were eligible to be admitted to the follow-up study, regardless of their fertility preferences. A total of 197 women agreed to participate.

Further follow-up of method introduction studies' participants

The initial 14 method introduction studies were designed to assess the feasibility of offering the SDM in diverse cultural and service delivery settings, and the acceptability of the method to clients offered the method in regular service delivery. A variety of service delivery situations

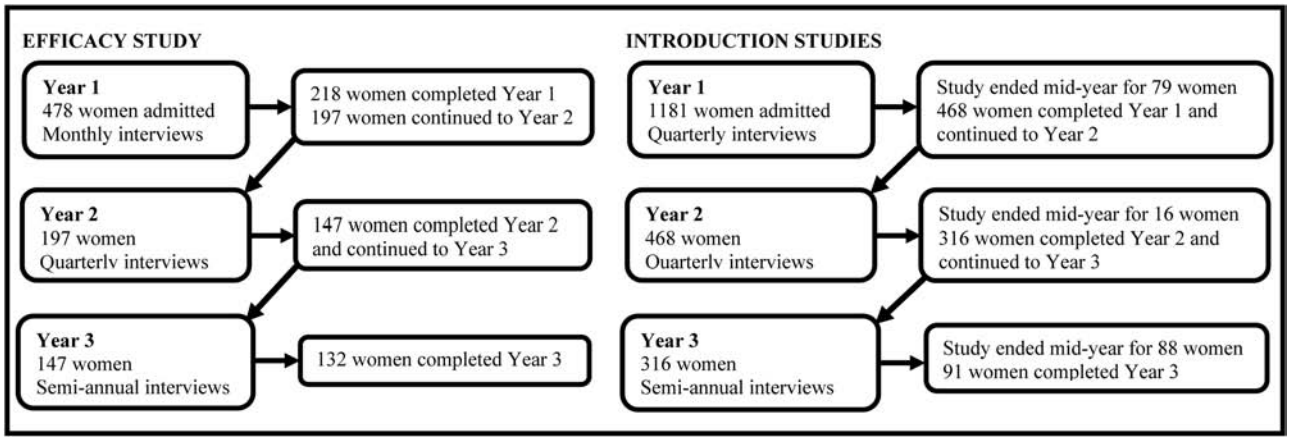

Figure 1 Participation in long-term follow-up studies. Participants were recruited from two sources.

were selected, including public, private and community-based, in urban, peri-urban and rural regions, to diverse populations. A detailed description of the sites, participants and the research question each was designed to answer has been published elsewhere.[6]

After the studies ended, participants in study sites in Benin, Ecuador, Honduras and two sites in India were asked to participate in the longer-term follow-up effort that is the focus of this article. The total number of introduction study participants in the five sites was 1181 (Benin 217, Ecuador 160, Honduras 108 and India 696 in two studies). They participated in the studies for varying durations because the method introduction studies varied in length. While some women completed a full year of method use in the method introduction studies, others were enrolled toward the end of the studies, and were only using the method for a month or two before their method introduction study ended and they were asked to participate in the longer-term follow-up study. Also, the longer-term follow-up effort was developed when the method introduction studies were already underway and in some instances participants had already completed the 13-cycle study. The results of these five studies are presented in the aggregate, and not by study, because grouping these diverse sites together would allow for greater generalisability of results.

Data management and analysis

Participants' use of the method is considered to start when they were counselled about the SDM and enrolled in the efficacy trial or method introduction study. For data management purposes, the initial studies have not been separated from the longer-term follow-up study. For example, a woman who left the efficacy study after 10 months is treated identically to a woman who entered an introduction study 4 months before it ended and who was enrolled in the follow-up study for 6 months, for a total of 10 months of method use. This approach provides information on up to 3 years of method use.

The efficacy study and the introduction studies used different approaches to data collection and monitoring in the first year (Table 1).[5,6] Participants in the efficacy trial were interviewed monthly by the same provider who counselled them in method use. They were also required to complete a coital log. Conversely, participants in the introduction studies were interviewed quarterly by an interviewer rather than a provider, and coital logs were not maintained.

In both the efficacy and introduction studies pregnancy was determined by means of a pregnancy test. In the efficacy study, participants were followed each cycle until they either menstruated or had a positive pregnancy test; in the introduction studies, pregnancy tests were administered 42 days after the last period. Both these studies treated all pregnancies occurring during the study as unintended, because planning to avoid pregnancy for a year was an eligibility criterion. However, when participants went on to the longer-term follow-up study they were eligible to participate regardless of their fertility intentions. Therefore the longer-term follow-up analysis allows for planned pregnancies, when women stopped using the SDM in order to become pregnant, or even used the method to time intercourse for a planned pregnancy.

In the efficacy study, providers kept track of participants' cycle length monthly and withdrew participants from the study who had two cycles outside the 26–32-day range during the 1-year study period. In the method introduction and longer-term follow-up studies, interviewers reviewed the calendars that study participants used to mark the first day of their menstrual period each month to determine whether or not they had out-of-range cycles during the previous 3 months. There is anecdotal information that demonstrates that some women who had a cycle out of range did not report it, and continued to use the method, but this was not documented or quantified.

Finally, the SDM does not require abstinence during the fertile days. Couples can use a barrier method on these days. However, to calculate the method's 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 backup method. This

Table 1 Differences in data collection between the efficacy study, the method introduction studies, and the longer-term follow-up study that succeeded them

Study characteristic	Earlier studies		Longer-term follow-up study
	Efficacy study	Method introduction studies	
Length of time women participated in study	1 year	2–13 months	2 additional years
Instructions for fertile days	Abstain	Abstain or use condom	Abstain or use condom
Frequency of interviews	Monthly	At 1, 4, 7, 10, 13 months	At 3, 6, 12, 18, 24 months
Use of coital logs	Yes	No	No
Use of pregnancy tests	Yes	Yes	No
Wish to avoid pregnancy for at least 1 year	Yes	Yes	Not necessarily
Sites	Bolivia Peru Philippines	Benin Ecuador Honduras India	All seven countries

requirement was lifted when participants moved on to the longer-term follow-up study in order to more closely approximate regular service delivery conditions. In the method introduction studies, participants were counselled from the start to avoid unprotected sexual intercourse during the fertile days. They were advised to use whichever strategy worked best for them – abstinence or a barrier method. The typical use failure rate reported for introduction study participants therefore more closely reflects real-life (not trial setting) use of the method.

Since these differences between the efficacy study and the introduction studies could potentially lead to different efficacy and continuation rates, the studies are analysed separately.

For the efficacy study data, life-table analysis was used to establish failure rate.[7] Women were interviewed every cycle; 'survival' (i.e. not becoming pregnant) was calculated per cycle; pregnancies were determined by pregnancy test; the researchers 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 also calculated in the method introduction studies and follow-up study. Data collection followed a less rigid methodology, with women being interviewed quarterly and relying on their memory to determine how many cycles they contributed to the study. Interviewers asked participants in each interview if they had cycles outside the 26–32-day range, and reminded participants that if they had a second such cycle in a year the method may not be as effective for them. However, the length of the menstrual cycle was calculated based on information recorded on the participant's calendar, and may be less precise than the information recorded in the coital logs of efficacy study participants, and some under-reporting of out-of-range cycles is to be expected.

Single-decrement multi-censoring life-tables were used to calculate failure rates.[7] The life-table methodology allows for the calculation of a failure rate for each time segment of the study (in the present case years), for a standard period of time (here 3 years), by considering the survival of a cohort of individuals for each time segment. That is, the table calculates the probability that women will 'survive' (i.e. still be using the method) at the end of each year of use, and these probabilities are cumulative.[8] Compared to traditional life-table analysis, which treats all exits from the study (pregnancy, exit for other reason, lost-to-follow-up) equally, multi-censoring life tables have the added advantage of allowing for more than one exit point from the study. That is, women who were not followed for several months were not censored from the rest of the study.[7] This was particularly important in the present context because for some women there was a gap between exiting the method introduction studies and enrollment in the longer-term follow-up study.

Results

The profile of clients participating in the efficacy study and the method introduction studies has been described in detail elsewhere.[5,6] Longer-term follow-up study participants met this general description. They resided in urban, mixed urban/rural and rural sites. More than 90% of participants who moved on from the efficacy trial had completed primary education and most were literate, but 51% of participants in one of the Indian sites had never attended school. Women participating in the method introduction studies from Benin and Ecuador were older, on average, than women in Honduras and India; parity was highest in India and lowest in Benin. Almost all participants had children, with at least one child younger than 2 years old when the woman was admitted to the efficacy or method introduction study, but ever use of family planning varied. Previous use of a modern contraceptive method ranged from 13% in the Benin method introduction study to 80% of participants in the Honduran site.

Longer-term effectiveness of the SDM

Few participants became pregnant in the second and third years of method use. It is not known if they used the method correctly in the cycle when pregnancy occurred, or if they had unprotected sexual intercourse during the fertile days. This low pregnancy rate translates into very high typical use efficacy, as seen in Tables 2 and 3. Table 2 shows the percentage of participants who became pregnant with typical use of the

Table 2 Unplanned pregnancies per year as a percentage of participants who were using the Standard Days Method® at the beginning of that year, by the study they participated in before continuing to the longer-term follow-up study

Unplanned pregnancies	From efficacy study (*n*=478)	From method introduction studies (*n*=1181)
Year 1		
Participants pregnant (%)	9.0	11.4
Participants at start of year (*n*)	478	1181
Year 2		
Participants pregnant (%)	5.1	2.8
Participants at start of year (*n*)	197	468
Year 3		
Participants pregnant (%)	3.4	4.7
Participants at start of year (*n*)	147	316

Table 3 Typical use life-table pregnancy rates by the study they participated in before continuing to the longer-term follow-up study

	From efficacy study (*n*=478)		From method introduction studies (*n*=1181)	
Period	Pregnancy rate (%)	95% CI	Pregnancy rate (%)	95% CI
Year 1*	12.0	8.5–15.3	14.1	11.8–16.4
Year 2	5.2	1.8–8.5	3.7	1.9–5.6
Year 3	3.4	0.4–6.3	5.9	3.0–8.8

* Year 1 rates from the efficacy study were calculated per 13 cycles; all other rates were calculated using calendar quarters.
CI, confidence interval.

SDM in the first, second and third years of use; Table 3 shows first, second and third year of use pregnancy rates.

As expected, the percentage of pregnancies during typical use was much lower in the second and third years of use than in the first one. These second- and third-year pregnancy figures are only approximations because under-reporting of pregnancy is possible, as is reporting of unplanned pregnancies as intended (i.e. stopped using the method in order to become pregnant). Nevertheless, these figures clearly demonstrate that the method continues to be effective over time.

Continuation

Of the 197 women who entered the follow-up study from the efficacy study, 132 (67.0%) were still using the method 2 years later. This is a relatively high continuation rate, particularly given that at the beginning of the longer-term study women's fertility preferences for the study period were varied. Because of the different study lengths for the method introduction studies, similar figures cannot be computed for women who entered the longer-term follow-up study from these. Nevertheless, continuation was clearly high, especially in the third year of use, as shown in Table 4. The table shows reason for discontinuation by year of method use. The percentage of women who left the study in the second year for reasons other than pregnancy or cycles out of range appears high, especially for women who came from the method introduction studies. Most (between half and two-thirds in the various sites) did so because of changed fertility intentions – they now desired a pregnancy.

A major reason for discontinuation in the first year of method use was having a second cycle out of range, as shown in Table 5. During the efficacy study participants completed coital logs in which they also marked the first day of each cycle. It can therefore be stated with certainty that 28% of participants had two out-of-range cycles in their first year of method use during that study. However, in the method introduction studies and in the longer-term follow-up study participants were asked every 3–6 months if they had a cycle out of range. It is to be expected that there was under-reporting of out-of-range cycles by women who wished to continue using the method. This would explain the significantly lower proportion of women with cycles out of range in these studies. However, the trend of fewer women with cycles out of the 26–32-day range is clear.

These results demonstrate that women who have almost all their cycles (i.e. fewer than two out-of-range cycles) within the 26–32-day range for a year are likely to continue having cycles within this range afterwards. As Table 4 shows, few women who discontinued use of the method in the second and third year of use did so because of out-of-range cycles.

Discussion

The SDM is appropriate for women who wish to space their pregnancies, and the present findings show that couples continue to use the method beyond the first year, and that it is an effective option for them. Effectiveness of the method in the first year of use compares well with the known effectiveness of other user-directed methods such as condoms (with typical use, if 100 women use condom for a year, about 14 become pregnant).[9] Effectiveness in the second and third years of method use is even better in comparison to other user-directed methods. Ranjit *et al.*[10] pooled data from the 1988 and 1995 National Survey of Family Growth to get a better picture of failure rates. They determined that 4.8% of oral contraceptive users experienced a pregnancy in the second year of use. In comparison, the present results demonstrate that 5.1% of participants who continued from the efficacy study, and 2.8% of participants who continued from the introduction studies, became pregnant during the second year of SDM use. These findings also suggest that cycle irregularity is not a problem for women who had no more than one cycle out of the 26–32-day range in the first year of method use.

A limitation of the study is the retrospective nature of the interviews. Participants were interviewed at 3-month intervals for the first 6 months and at 6-month intervals later in the study and asked about their use of the method in the preceding months. Another limitation is reliance on participant recall rather than coital logs and pregnancy tests. Conversely, this methodology more closely approximated regular service delivery conditions, without the intense follow-up of the efficacy study.

Table 4 Reasons for leaving the study by year and the study they participated in before continuing to the longer-term follow-up study (percentage of exits are given in parentheses)

Reason for leaving the study	From efficacy study (*n*=478)	From method introduction studies (*n*=1181)
Year 1		
Started the year (*n*)	478	1181
Study ended [*n* (%)]	0	79 (11.1)
Lost to follow-up	34 (12.1)	190 (26.6)*
Chose not to continue† [*n* (%)]	21 (7.5)	0
Cycles out of range [*n* (%)]	134 (47.7)	140 (19.6)
Pregnant (planned) [*n* (%)]	0	34 (4.8)
Pregnant (unplanned) [*n* (%)]	43 (15.3)	124 (17.4)
Left for other reason‡ [*n* (%)]	49 (17.4)	146 (20.5)
Exits (*n*)	281	713
Year 2		
Started the year (*n*)	197	468
Study ended [*n* (%)]	0	16 (10.5)
Lost to follow-up [*n* (%)]	6 (12.0)	24 (15.8)
Cycles out of range [*n* (%)]	5 (10.0)	9 (5.9)
Pregnant (planned) [*n* (%)]	11 (22.0)	24 (15.8)
Pregnant (unplanned) [*n* (%)]	9 (18.0)	13 (8.6)
Left for other reason‡ [*n* (%)]	19 (38.0)	66 (43.4)
Exits (*n*)	50	152
Year 3		
Started the year (*n*)	147	316
Completed 3 years§ [*n* (%)]	132 (89.8)	91 (28.7)
Study ended [*n* (%)]	0	88 (27.9)
Lost to follow-up [*n* (%)]	3 (2.0)	16 (5.0)
Cycles out of range [*n* (%)]	2 (1.4)	10 (3.1)
Pregnant (planned) [*n* (%)]	2 (1.4)	16 (5.0)
Pregnant (unplanned) [*n* (%)]	5 (3.4)	18 (5.8)
Left for other reason‡ [*n* (%)]	3 (2.0)	77 (24.4)
Exits (*n*)	147	316

*Including women who could not be found mid-year after their study ended to see if they would like to enrol in the longer-term follow-up study.
†Women who chose not to participate in the longer-term follow-up study after completing the efficacy study.
‡Including dissatisfaction or distrust of the method by the women or her partner, changed fertility preferences, and marital dissolution.
§Based on women who started Year 3 (147 and 316 women in the efficacy study and introduction studies, respectively).

The method introduction studies varied in length. Also, the need to collect longer-term follow-up information became apparent in the later stages of the introduction studies, and the decision to conduct the study was made after the introduction studies were already completed in some sites. In these sites, many participants had already exited the studies. As a result, the transition from the introduction studies to the longer-term follow-up was not automatic, and many participants did not have the opportunity to contribute 3 years to the study because of the need to censor the 'between studies' months.

Because of these methodological limitations these results are approximations. It is possible that more women had an unintended pregnancy during the study and did not report it. However, the failure rates presented here for typical use are low. Even if twice as many women had become pregnant during the study period, the typical-use pregnancy rate would still compare favourably with other user-directed methods.

The SDM is an effective and acceptable family planning option, but it requires cycle regularity, as it is most appropriate for women whose cycles usually are in the range 26–32 days. A study of the theoretical effectiveness of the method showed that women who continue using the SDM after a second out-of-range cycle during a 12-month period would still obtain some protection from pregnancy, but the method would not be as effective for them.[11]

If only the women who reported having a cycle out of range in the second and third years indeed had cycles outside of the 26–32-day range, then women who had regular cycles for a year are very likely to continue having regular cycles. Conversely, if more study participants had cycles out of range but did not report this fact and continued to use the method, then the method was still effective for them, despite their

Table 5 Participants who had a second out-of-range cycle per year, as a percentage of the number of participants who were using the method at the beginning of that year

Cycles out of range	From efficacy study (*n*=478)	From method introduction studies (*n*=1181)
Year 1		
Cycles out of range (%)	28.0	12.8
Participants (*n*)	478	1181
Year 2		
Cycles out of range (%)	2.5	1.9
Participants (*n*)	197	468
Year 3		
Cycles out of range (%)	1.4	2.5
Participants (*n*)	147	316

less regular cycles, suggesting that the cycle regularity requirement may be less important for women who have had regular cycles for a year.

The SDM is an effective and acceptable fertility awareness-based method of family planning. In recent years it has become a regular part of service delivery in over 30 countries, reaching users of varied education, socioeconomic and cultural backgrounds.[6] The present results suggest that couples can use the method effectively over a longer period of time. There is selection in the first year of SDM use: women with two cycles out of range, and women who dislike the method, or have problems using it correctly, generally discontinue method use in the first year. However, women who complete the first year of SDM use are likely to continue to be able to use it successfully.

The present findings are of interest to policymakers and programme managers who are considering the addition of the SDM to their services. Some programmes may decide to offer the SDM because it brings new couples to family planning, and provides a bridge to other modern family planning methods.[12,13] Other programmes may be reluctant to offer the method if they perceive that it will be used only for a short time, and therefore integration may not be worth the effort. Study results suggest that women can, and do, continue to use the SDM. Out-of-range cycles do not stop many women from using the method in the second and third years of method use, and many couples continue using the method for a longer term.

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