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The importance of screening and monitoring: the Standard Days Method☆ and cycle regularity

Irit Sinai*, Victoria Jennings, Marcos Arévalo

Institute for Reproductive Health, Georgetown University, 4301 Connecticut Avenue, NW, Suite 310, Washington, DC 20008, USA

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Abstract

The Standard Days Method™ is a simple fertility awareness-based method of family planning with a correct-use pregnancy rate of 4.8 at 1 year and a typical-use pregnancy rate of 12. The protocol for providing the method includes guidelines for screening potential users for cycle regularity. There also are guidelines for monitoring users to determine continued method eligibility. This article explores the importance of these screening and monitoring procedures. A large existing dataset from a World Health Organization study of the Ovulation Method was used to estimate the theoretical probability of pregnancy using the Standard Days Method, with and without screening and monitoring. We used data from the efficacy study of the Standard Days Method to examine the effectiveness of current screening and monitoring procedures. Results suggest that current screening and monitoring procedures are useful in identifying women for whom the Standard Days Method is less effective. Strict adherence to these procedures is ideal, but even women who do not meet the cycle-regularity guidelines would have a relatively low probability of pregnancy.

Keywords: Standard Days Method; Screening; Monitoring

1. Introduction

When potential users contact a family-planning service provider, they often have a specific method in mind. Receiving that method is a good predictor of continued use [1]. Ideally, the method the woman selects would be appropriate for her. However, not all family-planning methods are suitable for all potential users. Some family-planning methods are more appropriate than others for individual women. It is important that the woman gets a method that she can use correctly, and that would not harm her health. Other requirements for correct method use also need to be considered, particularly for user-dependent methods.

Initial screening is essential to help providers and women choose suitable methods. Screening guidelines should strike a balance between being sufficiently selective and as inclusive as possible, to allow the greatest number of clients to access the method. For most methods, a degree of ongoing monitoring is desirable to assess whether the method continues to be appropriate for the woman [2,3]. Specific guidelines have been developed for each method to assist clients and providers in making appropriate decisions on which method to offer [4,5]. This article examines initial screening and monitoring for the Standard Days Method™—a fertility awareness-based method of family planning focusing on cycle regularity.

The Standard Days Method was developed by the Institute for Reproductive Health, Georgetown University (IRH), to help fill the need for simple, effective, fertility awareness-based methods of family planning. A significant number of women worldwide use periodic abstinence as their method of family planning [6]. Research indicates that many of these women do not know how to correctly determine when they are fertile, which accounts for many unplanned pregnancies. For women who desire to use fertility awareness-based methods of family planning, one of the barriers to achieving their family-planning goals is the relative complexity of established effective methods, such as the Ovulation Method and the Symptothermal Method, which require a substantial investment of time in teaching and follow-up. In many developing countries, therefore, there is a high demand for an effective fertility awareness-

* Corresponding author. Tel.: +1-202-687-1392; fax: +1-202-537-7450.

E-mail address: irhinfo@georgetown.edu (I. Sinai).

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based method, such as the Standard Days Method, that is easy for providers to teach and for users to learn and use. One of the main attributes of the Standard Days Method is its inherent simplicity.

The Standard Days Method requires simply that women whose cycles usually range from 26 to 32 days long should avoid unprotected intercourse on days 8–19 (inclusive) of their cycle if they do not want to become pregnant. The method can be offered with CycleBeads™, a string of color-coded beads, to help users keep track of which cycle day they are on and monitor their cycle lengths. An analysis of the theoretical effectiveness of the Standard Days Method showed that the method would be extremely effective for women with cycles of 26–32 days, and would substantially reduce the probability of pregnancy for women who occasionally have a cycle that is shorter or longer [7]. Therefore, the current protocol for Standard Days Method use recommends that users who have a second out-of-range cycle in a year switch to another method.

An efficacy trial of the Standard Days Method, following 478 women for up to 13 cycles of method use in five sites in Bolivia, Peru and the Philippines, resulted in a 4.8 1-year pregnancy rate with self-reported correct use of the method. A 1-year pregnancy rate of 12 was calculated when taking into account all cycles and all pregnancies, including pregnancies that occurred in cycles in which users had unprotected intercourse on days identified as fertile [8].

Since the method works best for women whose cycles usually range from 26 to 32 days, study participants were screened for habitual cycle length prior to admission, and were monitored for cycle length throughout the study. But is this screening and monitoring necessary? If so, is it sufficient? This article addresses these questions, which have important programmatic implications.

2. Data and methodology

We compare patterns of cycle length of participants in two studies—the efficacy study of the Standard Days Method, in which women were screened for cycle regularity and monitored for cycle length, and a study of Ovulation Method users conducted by the World Health Organization (WHO), where screening was less stringent and there was no monitoring for continued cycle regularity. We use the WHO data also to examine the impact of not screening and monitoring on the theoretical effectiveness of the Standard Days Method.

2.1. Standard Days Method data (IRH)

The efficacy study of the Standard Days Method was conducted in five sites in Bolivia, Peru and the Philippines during 1999–2000. Some 478 women were admitted to the study after screening for cycle regularity, subfecundity, risk of sexually transmitted diseases and contraindications of pregnancy. They contributed to the study 4035 cycles of method use. Information about cycle length is available for most cycles [8].

Since women in these communities do not usually keep menstrual histories, we relied on their recall. During the screening interview women were asked:

> "Have your last three periods come approximately when you were expecting them?"
> "When was the first day of your most recent menstrual period?"
> "When do you expect your next period to start?"

Providers used calendars to assist prospective study participants in establishing the date of the most recent and next expected period. The providers then calculated the expected cycle length. If the woman stated that her last three periods had occurred when expected, and if her current cycle was expected to be 26–32 days long, she was admitted to the study.

Study participants were interviewed monthly and monitored for continuing cycle regularity. Since the analysis of the theoretical effectiveness of the Standard Days Method established that the method works well for women who have up to two cycles out of the 26–32-day range in a year [7], women who had a second cycle out of range during the study period were advised to use another method and were withdrawn from the study.

2.2. Ovulation Method data (WHO)

We compare data from the Standard Days Method efficacy trial with data from a study of the effectiveness of the Ovulation Method conducted by the WHO in the late 1970s in El Salvador, India, Ireland, New Zealand and the Philippines.

Some 726 study participants in the WHO study were followed for up to 18 cycles in some study sites and up to 13 cycles in others, resulting in over 8000 cycles. Information on cycle length is available for most cycles. Women were admitted to the study if they recalled having cycles ranging from 23–35 days in the previous 6 months—a much broader cycle range than the 26–32-day range recommended for the Standard Days Method [9]. There was no monitoring for cycle length during the study period.

2.3. Analysis

We begin by establishing the need for screening and monitoring. To do so, we examine the theoretical efficacy of the Standard Days Method for several groups of women, using the WHO data. The data include information on various characteristics of the cycle that allow us to review how effective the Standard Days Method would have been had the women been using it. See Arévalo et al. [7] for a detailed description of the mode of calculation.

We then examine the effect of the Standard Days

Table 1
Estimated daily probabilities of pregnancy (clinically detected 6 weeks from last menstrual period) from unprotected intercourse on different days relative to Peak day, for women theoretically observing the rules of the Standard Days Method (applied to WHO study data)

	Women with all cycles within the 26–32-day range	Women with no more than two cycles out of the 26–32-day range in a year	All women admitted to the WHO study	
	All cycles of these women	All cycles of these women	Only cycles up to and inclusive of the second out-of-range cycle (for women with less then two cycles out of the 26–32-day range, this includes all cycles)	Only cycles after a second out-of-range cycle (based on current guidelines the woman is no longer eligible to use the method after a second cycle out of the 26–32-day range)
	25.7% of women (n = 1,377 cycles) (A)	51.4% of women (n = 4,072 cycles) (B)	100% of women (n = 4,803 cycles) (C)	49.7% of women (n = 2,789 cycles) (D)
Peak − 8	0.000	0.000	0.000	0.000
Peak − 7	0.004	0.004	0.004	0.004
Peak − 6	0.007	0.007	0.008	0.010
Peak − 5	0.005	0.006	0.008	0.012
Peak − 4	0.004	0.006	0.009	0.014
Peak − 3	0.003	0.004	0.007	0.009
Peak − 2	0.003	0.004	0.007	0.008
Peak − 1	0.003	0.004	0.006	0.007
Peak day	0.003	0.003	0.005	0.005
Peak + 1	0.002	0.002	0.003	0.003
Peak + 2	0.001	0.001	0.001	0.001
Peak + 3	0.000	0.000	0.001	0.000

Peak denotes Peak day − a proxy for day of ovulation.

Method study screening and monitoring procedures by comparing patterns of cycle length of participants in the two studies. To make the data comparable, we use only the first 13 cycles of method use in the WHO study in this part of the analysis.

3. Results

3.1. Are screening and monitoring necessary?

The ideal methodology for studying the benefit of screening for cycle regularity of potential Standard Days Method users is to examine the number of pregnancies among women who were screened or not screened, and compare the number of pregnancies for women who had a cycle out of range to those who did not. However, our data do not allow us to do so because there were too few pregnancies during the efficacy trial of the Standard Days Method. Only 43 of the 478 women became pregnant during their participation in the study. Twenty-eight of these pregnancies occurred in cycles where women reported unprotected intercourse during their fertile days. Of the remaining 15 pregnancies, 3 occurred during the first two cycles; of the 12 pregnancies occurring later in the study, only 3 had experienced an out-of-range cycle earlier. Two of these three got pregnant on their third cycle in the study, and one on cycle 13 (her out-of-range cycle was cycle 5).

Since pregnancies in the Standard Days Method study were too few to allow for meaningful statistical analysis, we rely on theoretical failure rates instead. Table 1 presents the theoretical effectiveness of the Standard Days Method for four groups of women in the WHO study. It shows the estimated daily probability of pregnancy (clinically detected 6 weeks from last menstrual period) from unprotected intercourse on different days of the cycle relative to Peak day (used here as a proxy for ovulation), for women observing the rules of the Standard Days Method. These figures answer the question: if the women in the WHO study were using the Standard Days Method during the reported cycles, what would have been their probability of pregnancy? (Given the probability of pregnancy relative to ovulation [10], the relationship between ovulation and Peak day [11] and the information included in the WHO data about their Peak day.)

In column (A) we show the theoretical effectiveness of the Standard Days Method for women in the WHO study with all cycles ranging 26–32 days [7]. All the cycles these women contributed to the study were within this range.

In column (B) we show the theoretical effectiveness of the Standard Days Method for women who had up to two cycles out of the 26–32 day range in a year. The analysis includes all of their cycles in the study—with cycle lengths in and out of the 26–32-day range.

In column (C) we include cycles from all the women admitted to the WHO study. If they had less than two cycles out of the 26–32 day range, then all of their cycles are included in the analysis. If they had two or more cycles out

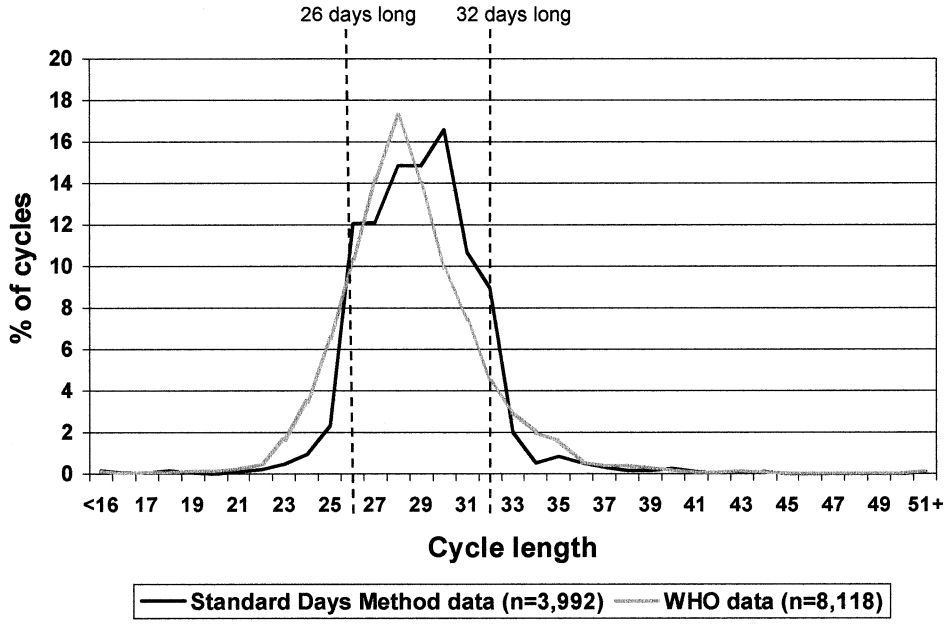

Fig. 1. Cycle length in days.

of the 26–32 day range, then only their cycles up to and inclusive of the second out-of-range cycle are included. Therefore, this column does not include cycles where monitoring would have identified that the woman should no longer use the method.

Finally, in column (D) we look at the theoretical effectiveness of the method for women who are no longer eligible to use the method (based on current guidelines) because they had a second cycle out of the 26–32-day range. Only cycles after the second out-of-range cycle are included. This would be the theoretical efficacy of the Standard Days Method for these women if current guidelines for discontinuation of method use were not followed, and they continued to use the method. That is, they would continue to use the method after they had a second cycle out of the 26–32-day range in a year.

As Table 1 shows, the theoretical probability of pregnancy from unprotected intercourse for women using the Standard Days Method is only slightly higher if the woman had occasional cycles out of the 26–32-day range—up to two such cycles in a year (column B) than for women with cycles always within the range (column A). The highest probability of pregnancy from intercourse on any given day is still only 0.007.

In column (B) we show the theoretical effectiveness of the method for women with relatively regular cycles. In the entire study period they had no more than two cycles out of the 26–32-day range in a year. They were only broadly screened for the study, but we expect that most women who are screened would exhibit such pattern of cycle regularity. In column (C), on the other hand, we present the theoretical effectiveness of the method for all women in the study until they had a second cycle out of the 26–32-day range. This includes the women presented in column (B) (about half of women in the study), but also women who had less regular cycles, including some who usually had cycles out-of-range, who would have been detected in screening and not offered the Standard Days Method. The somewhat higher probabilities of pregnancy presented in column (C), therefore, suggest that screening is important.

The results presented in column (D) show that if women who had two cycles out of the 26–32-day range continue to use the method, they are much more likely to become pregnant (highest probability of pregnancy on any given day is 0.014). Clearly, then, continued monitoring affects method efficacy.

3.2. Is current screening for cycle regularity effective?

Over 90% of cycles in the Standard Days Method study were within the 26–32-day range, compared to 77.5% of cycles in the WHO data. The distribution of cycles by cycle length is presented in Fig. 1.

Clearly, most of the cycles in both studies are within the 26–32 days range, but much more so in the Standard Days Method study. This difference results from both the different screening protocol and the ongoing monitoring. The effect of the screening alone is most apparent when we compare the number of women who had no cycles out-of-range during the study period in the two studies. While 41.3% of Standard Days Method study participants had all their cycles in the study within the 26–32-day range, only 24.4% of WHO study participants were in this category.

A question derived from these analyses is whether women who have several out-of-range cycles are just “irregular” or whether they, in fact, have regular cycles but their habitual cycle length falls within a different range. The answer to this question has potential implications for devel-

Table 2
Second cycles out of range (within 6 months)

		Standard Days Method study (n = 188 women)	WHO study (n = 455 women)
% of women who had a cycle shorter than 26 days who then had a	2nd cycle shorter than 26 days	47.1	66.5
	2nd cycle longer than 32 days	12.6	12.7
% of women who had a cycle longer than 32 days who then had a	2nd cycle shorter than 26 days	7.9	13.3
	2nd cycle longer than 32 days	45.5	63.8

Values are percentages.

opment of an alternative method that would meet the needs of these women for whom the Standard Days Method is not appropriate.

To address this question, we explore the extent to which having one cycle out of the 26–32-day range is a predictor of having another cycle out-of-range, and whether that second cycle would be short or long. We examine only cycles that occurred after the woman had already had one cycle shorter than 26 days or longer than 32 days, to see if the woman had another such cycle within the next six cycles, in both data sets. We include in this analysis only women who contributed to the study at least six cycles beyond a first cycle out of range, unless they were withdrawn from the study during these six cycles because of cycle irregularity. Women who left the study during the first six cycles after a cycle out of range for any other reason are excluded from the analysis, as are women who had no cycles out of the 26–32-day range. Results are presented in Table 2.

Overall, 56.4% of women in the Standard Days Method study who had a cycle out-of-range had a second cycle out-of-range within six cycles, compared to 78.2% of women in the WHO study. This difference suggests that while our screening process does not completely prevent offering the method to women who will have cycles out of the 26–32-day range, it significantly reduces the likelihood of this event. If women who pass the screening do have a cycle out-of-range, they are less likely to have another such cycle within the next 6 months.

These results also indicate that most women have relatively regular patterns. Women who have a cycle shorter than 26 days are much more likely to have another such cycle than to have a cycle that is longer than 32 days, and vice versa.

3.3. Is current ongoing monitoring of cycle length effective?

To examine the effect of ongoing monitoring on excluding from method use women for whom the method is less effective, we divide the cycles in the WHO data into two groups, following the guidelines of the current monitoring protocol. In group A are cycles that were contributed by women who did not have two cycles out of the 26–32-day range and by women who had two cycles out-of-range until and inclusive of the second out-of-range cycle. In group B are the remaining cycles. These cycles were contributed by women after having a second cycle out-of-range. If these women were following the current monitoring protocol, they would not have used the Standard Days Method on these latter cycles. We find that 18.3% of cycles in group A are shorter than 26 days or longer than 32 days, compared to 29.1% of cycles in group B. This difference can be clearly attributed to the monitoring protocol.

4. Discussion

Our results clearly indicate the importance and effectiveness of screening and monitoring, and suggest that the screening and monitoring mechanisms used during the efficacy study significantly reduce the probability of Standard Days Method users having cycles out of the 26–32-day range. But is this sufficient?

4.1. Screening

The theoretical analysis of the efficacy of the Standard Days Method suggests that the method is most effective for cycles within the 26–32-day range. Even with screening, there is no way to guarantee that a woman using the method would not have a cycle that is shorter or longer in the early months of method use. However, screening protocols could be made more stringent than the one used during the Standard Days Method trial. For example, programs may decide to only offer the method to users after they compile a menstrual history, showing cycles within range for a determined period of time. While such procedures will not completely eliminate the possibility of cycles out-of-range and pregnancy, efficacy would be improved. On the other hand, this would greatly reduce the access of potential users to the method and increase the cost of method provision, because counseling sessions would be longer and providers would need additional training. And, most important, women may become pregnant while compiling their menstrual histories.

Family-planning and reproductive health programs that offer the Standard Days Method would face the tradeoff between inclusiveness (delivering the method to more women) and efficacy (a lower pregnancy rate for Standard

Days Method users) and would have to make a decision that is ethically, programmatically and politically correct for them.

4.2. Monitoring

We have shown that the ongoing monitoring protocol—allowing for continued method use until the woman has two cycles out of the 26–32-day range within a year—also reduces the probability that women with very irregular cycles continue using the method, therefore, improving method efficacy. Efficacy would likely be even higher than we found in the effectiveness study if women were asked to withdraw after just one cycle out of the 26–32-day range. Yet, a more stringent monitoring criterion would significantly reduce continued use of the method, and having one cycle out of range does not necessarily result in having another one.

Even having a second cycle out-of-range does not necessarily mean eventually getting pregnant. Women could be advised to continue using the method even if they have two or even three cycles out-of-range in a year. Efficacy might be somewhat reduced, but women would be able to continue benefiting from the method, and their probability of pregnancy while using the method would still be relatively low.

We believe that the current protocol—screening based on recall and continued monitoring, allowing up to two cycles out of the 26–32-day range in a year—offers a good balance between efficacy and inclusiveness. However, the ideal balance may differ by culture, social norms, individual preferences and the political climate in different settings.

Clients' and programs' perceptions and tolerance of the risk of pregnancy while using the Standard Days Method may differ depending on the context. In some settings, the Standard Days Method may be the only available method that is acceptable to a large proportion of couples, who, if excluded through initial screening or ongoing monitoring, might then opt for not using any method at all (with an 85% probability of pregnancy in a year of "non-use") [4]. In these settings, trying to minimize denying the method to couples who ask for it may be a better way to meet the needs of the population. In other settings, some or many couples who prefer the Standard Days Method may nevertheless accept another method if screening or monitoring suggests that the Standard Days Method is not appropriate for them. In these other settings, it may be better to provide the method only to couples not likely to experience pregnancy because of cycle irregularity.

While the method provides some protection from pregnancy for women who regularly have cycles shorter than 26 days or longer than 32 days, it is significantly less effective for them. Research continues to explore possible options for these women, including a simple method that relies on cervical secretions rather than cycle length [12,13], and a method appropriate for postpartum women, following the return of menses.

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