

Adding the Standard Days Method[®] to the contraceptive method mix in a high-prevalence setting in Peru

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Suggested citation

Arévalo M, Yeager B, Sinai I, Panfichi R, Jennings V. Adding the Standard Days Method[®] to the contraceptive method mix in a high prevalence setting in Peru. *Rev Panam Salud Publica*. 2010;28(2):80–5.

ABSTRACT

Objective. To determine what contribution the Standard Days Method[®] (SDM) makes to the contraceptive mix offered by regular health services in areas of Peru where contraceptive prevalence rates (CPR) are already high.

Methods. SDM was added to the family planning methods offered by the Ministry of Health in two provinces in Peru in September 2002. Retrospective interviews were conducted in March–June 2004 with 1 200 women who had chosen SDM as their contraceptive method and had used it for 2–20 months. Data were also obtained from the databases of the participating health services. The evaluation covered SDM demand, whether or not clients were switching to SDM from other modern methods, and SDM continuation and effectiveness.

Results. Demand for SDM stabilized at 6% of all new family planning users. Most users had not been using any reliable contraception at the time they started using SDM. About 89% of those who began using SDM at least 6 months before the interview were still using it at 6 months. The 12-month typical use pregnancy rate was estimated to be around 10.0 per 100 women years.

Conclusions. Adding SDM to a program's existing contraceptive method mix can increase coverage even in an already high-CPR setting. Most women who choose SDM do not switch from any other modern family planning method. Continuation compares well with other modern user-directed methods. SDM effectiveness, when offered in regular service delivery circumstances, compares well to efficacy trial findings.

Key words

Contraception; natural family planning methods; contraception behavior; Peru.

Adding a new family planning method to the contraceptive method mix often results in an increase in prevalence. Evi-

dence from several countries shows that users do not switch from established methods, but that the new method attracts new clientele (1, 2); however, these studies have been conducted in settings with relatively low contraceptive prevalence.

The present study sought to determine the impact of introducing a new method—Standard Days Method[®] (SDM) (Institute for Reproductive Health, Georgetown University Medical Center,

Washington, D.C., United States)—into the existing mix offered by health services facilities in San Martín, Peru, an area where contraceptive prevalence is relatively high. SDM is a fertility awareness-based method of family planning. To prevent or delay pregnancy, users avoid unprotected intercourse on the days that the method identifies as fertile (days 8–19 of the cycle). SDM works best for women with cycles that usually

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range from 26–32 days (3). It is often provided with CycleBeads®, (Institute for Reproductive Health, Georgetown University Medical Center, Washington, DC, United States) a color-coded set of beads that helps users track their cycles.

Although SDM uses the same basic approach to family planning as traditional periodic abstinence (avoiding unprotected sex on the days the user identifies as fertile), it is a modern method with proven effectiveness (4). An efficacy trial in Bolivia, Peru, and the Philippines, followed 478 women for up to 1 year of SDM use and showed a failure rate of 4.8 with perfect use (i.e., < 5 women became pregnant per 100 women using SDM correctly for 1 year) and 12.0 with typical use. It also showed that SDM is easy to teach, learn, and use, and is acceptable to couples from a wide range of cultural backgrounds (4). These failure rates compare well to those of other user-directed methods of family planning, including other natural methods, such as the Billings Ovulation Method and the Symptothermal Method (5). In addition, SDM is considered a modern family planning method by international organizations, such as the World Health Organization (6, 7) and USAID (8). It is increasingly included in national demographic and health surveys, such as the 2008 survey in the Philippines (9), where it is classified as a modern method and its users are considered to be modern contraceptive users.

Policymakers in countries that are considering adding SDM to the contraceptive mix want to know how its impact may differ in various settings. Though aware of its efficacy from the SDM efficacy trial (4), policymakers want to know how the method performs in “every-day” health services delivery settings. Although previous studies in seven countries in Asia, Africa, and Latin America (10) have documented the positive impact of adding SDM to the contraceptive mix in a variety of service delivery situations—public and private, urban and rural, and using providers with a range of education levels and backgrounds—these studies took place in settings with low or very-low contraceptive prevalence rates (CPR). Also, the information was collected in a research context, where research personnel periodically followed-up and monitored clients and service providers.

When policymakers in Peru considered SDM, they wanted to know that SDM

findings from countries with lower CPR would apply to their own higher prevalence setting. They requested evidence of its “real world” performance prior to committing to this method. Peru is considered a high contraceptive prevalence setting because almost 70% of married women of reproductive age use a family planning method (11); however, only about half of married Peruvian women report use of a modern method: injectables, 14.6%; tubal ligation, 10.3%; oral contraceptives, 7.1%; and intrauterine device (IUD), 5.6% (11). In Peru, “periodic abstinence” (predominantly unspecified versions of calendar rhythm) is the most frequently used family planning “method,” with 17.5% of women in a union reporting it as their current method. The high failure rate of these contraceptive practices (25 women becoming pregnant per 100 women in 1 year (5)) has important implications for actual contraceptive coverage, unmet need, healthy timing and spacing of pregnancies, abortion rates, and maternal and child morbidity and mortality. Therefore, evaluating the performance of SDM when it is delivered through regular health services in a high-prevalence setting, such as Peru’s, was a logical next step in the research-to-practice continuum.

MATERIALS AND METHODS

The study was specifically designed to address the following questions posed by policymakers in Peru, but may be relevant to other areas with high CPR:

- (a) Would there be a significant demand for SDM?
- (b) Would SDM users be switching away from other modern methods?
- (c) Would pregnancy rates be within the same range as those of the efficacy trial?
- (d) Would continuation rates be within the same range as those observed in the efficacy trial?

This was a retrospective study conducted in two provinces in the Department of San Martín situated in the Amazonian area of Peru. Department-level contraceptive prevalence was almost 70%, with a modern method prevalence of 49%. Injectables were the most prevalent method (17%), followed by tubal ligation (15%), and oral contraceptives (12%). About 18% of women in a union used traditional methods (11).

SDM was added to the method mix offered at Ministry of Health facilities in the two provinces. Provider and client materials were distributed to the facilities, and providers were trained in SDM counseling. Supervision systems were put into place and providers received refresher training as needed. CycleBeads® were added to the contraceptive supplies logistic and procurement systems, and SDM was added to the facility registers.

Demand for SDM was generated using strategies that were proven effective in previous projects and studies (10), such as community health talks, posters, and brochures. Women requesting family planning services were offered all the methods available, including SDM. Those who were interested in SDM and met its eligibility criteria received SDM counseling and CycleBeads®.

Providers recorded the same general demographic and clinical information routinely entered for all family planning clients, and SDM clients were recorded in the facility registers. No study-specific information was collected at this point.

To measure demand for SDM and other family planning methods, service statistics from these health facilities were collected and evaluated, beginning with provider training in SDM counseling (when SDM was first offered to clients) and continuing forward for a period of almost 4 years. These were the same data routinely collected as part of regular service delivery.

In addition, about 20 months after SDM was made available through these facilities, their records were used to identify all clients who chose SDM. Those identified as SDM users were located by the service providers and interviewed after giving their informed consent to participate in the study. The interview focused on clients’ experience using SDM (including pregnancy status), method continuation, any method used prior to SDM, and other related issues. This was the first time that these women had been contacted regarding SDM usage since choosing the method 2–20 months earlier.

Records indicated that 1 254 women had chosen SDM at participating health services sites prior to the study’s data collection effort. Of these, 1 200 could be located. All 1 200 signed the informed consent form and were interviewed in March–June 2004. In total, the study participants contributed more than 9 400

months of data pertaining to their first year of SDM use. The study was approved by the Institutional Review Board of Georgetown University (Washington, D.C., United States).

Interviews took place during a 2-month period, starting approximately 20 months after SDM first became available to clients in the area. Because clients began using SDM at different times during these 20 months, the length of their experience with SDM at the time of the interview varied as well (mean = 10.2 months; range < 1–20 months).

Since data were collected retrospectively, efficacy calculations could only be approximated. This was done using life tables. The same life table was used to determine 6-month continuation rate. Respondents who were still using SDM, but who were interviewed less than 6 months after they had adopted the method, were excluded from the life-table calculations because they had not been exposed to the risk of pregnancy long enough to measure failure. The exception to this was women who became pregnant, or stopped using the method. All pregnancies reported by the 1 200 participants were included in the efficacy calculations, including pregnancies of women who had been using the method for less than 6 months. Therefore, the following respondents were included in

the life-table calculations: (a) all women who became pregnant after they first started using SDM, regardless of how long they had used SDM before becoming pregnant; (b) all women who stopped using SDM, regardless of how long they had used it before discontinuation; and (c) women who were using SDM at the time of the interview and had been using it for at least 6 months prior.

In all, 886 women were included in the analysis. Note that all pregnancies were included in the analysis, including those reported as “planned.” This was necessary because the data were collected retrospectively. Justifying a pregnancy as “wanted” or “planned” after a woman becomes pregnant is a known phenomenon (12), and therefore attempting to distinguish between pregnancies that were planned and those that *became* wanted was not possible. Instead all pregnancies were included, producing more conservative results.

RESULTS

Among the 1 200 women interviewed, the median age was 28, with 59.5% being 20–30 years of age. The mean number of children per woman was 2.1 with a range of 0–7. The study results are presented according to the questions posed by the policymakers in Peru.

Would there be a significant demand for the Standard Days Method®?

Data on demand was obtained from Ministry of Health service statistics collected at participating facilities. Results are presented in Figure 1. Some clients chose SDM immediately after it first became available in September 2002. The number of clients selecting SDM increased gradually during the first few months, and then stabilized for several months. Subsequent increases reflect the training of additional providers and availability of SDM at additional facilities, as well as a reminder from the managers of the information systems to the providers to record SDM clients as such, rather than as “other.” Data were collected for 47 months, starting immediately after provider training. By the end of the study period, SDM users represented approximately 6% of the total demand for family planning.

Would Standard Days Method® users be switching away from other modern methods?

Very few respondents (1.5%) reported never before having used any form of contraception, but the majority of clients starting SDM had not been using any reliable form of contraception at the time.

FIGURE 1. New Standard Days® method acceptors in two provinces with high contraceptive prevalence rates in Peru, September 2002–July 2006

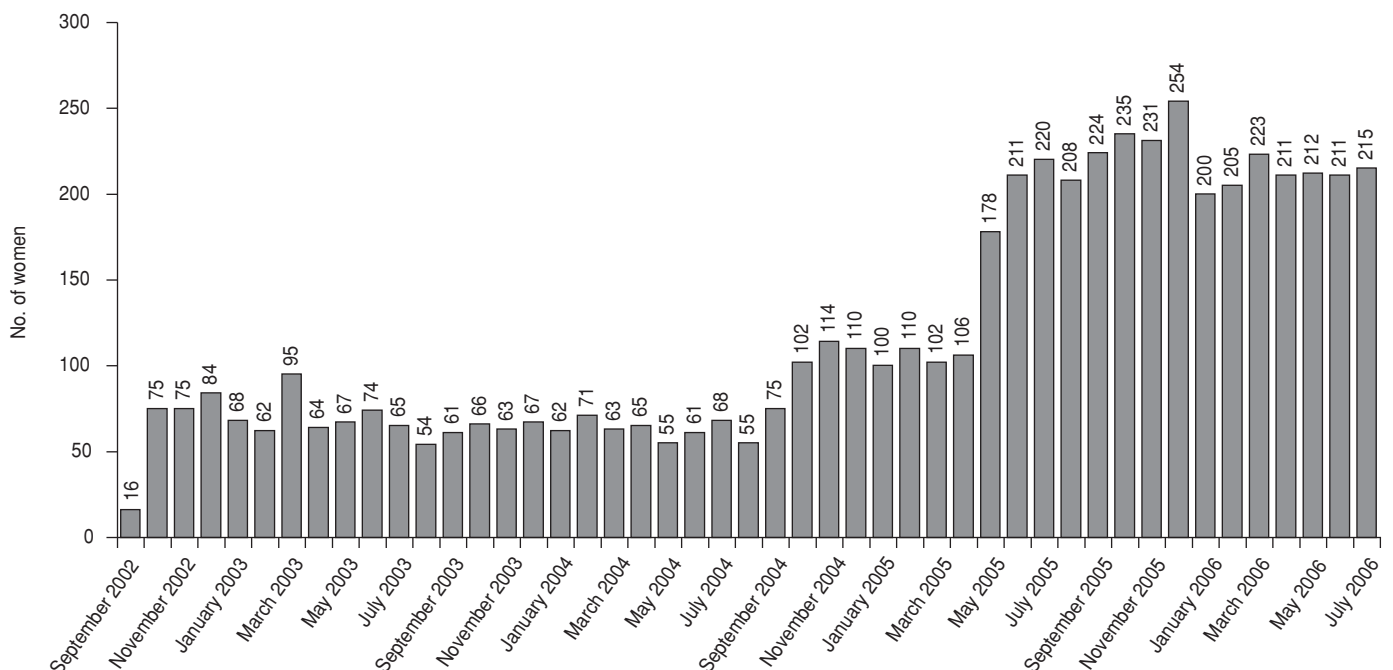


TABLE 1. Life table of pregnancies when introducing the Standard Days-Method® into existing services in San Martín, Peru, based on interviews conducted in March–June 2004

Month of use	Pregnancy rate	95% confidence interval
1	0.2	0.0 – 5.4
2	0.9	0.3 – 1.5
3	1.7	0.8 – 2.5
4	2.7	1.7 – 3.8
5	3.1	2.0 – 4.4
6	4.7	3.3 – 6.1
7	5.4	3.9 – 7.0
8	6.6	4.9 – 8.2
9	7.2	5.5 – 9.0
10	7.9	6.0 – 9.7
11	9.1	7.1 – 11.1
12	10.0	7.9 – 12.0

Note: Because sexual behavior was not recorded, it was not possible to calculate the correct-use failure rate; however, typical-use failure rate does not require information on sexual behavior. Due to the retrospective nature of the study, results are approximations.

Users of unspecified variations of calendar rhythm were the largest group (33%) choosing SDM, followed by former oral contraceptive (28.7%) and injectables (17.7%) users. Most users of these hormonal methods had stopped use 1–3 months prior to selecting SDM, and since SDM eligibility criteria includes having recent cycles within the 26–32 day range, these women could only adopt SDM if cycle regularity had been reestablished.

Of the 13.4% reporting condoms as their most recent method, most (130 of 161) continued using condoms with SDM to avoid unprotected intercourse on days identified by the method as fertile. Interestingly, all of the 161 condom users acknowledged that their previous condom use had been inconsistent.

Would pregnancy rates be in the same range as those seen in the efficacy trial?

Of 1 200 SDM users located and interviewed, 105 (8.75%) had become pregnant while using SDM. The 12-month pregnancy rate calculated by life-table analysis (Table 1) was 10.0 pregnancies per 100 woman-years of SDM use. This rate was calculated using all pregnancies (including those in the first cycles of method use); however continuing users were included in the analysis only if the interview took place at least 6 months after SDM was adopted. Given the retrospective nature of the data, specific dates of pregnancy could not be obtained. These rates are, therefore, approximations. On the other hand, the results are conservative, as women who said their

pregnancies were planned were included in the pregnancy rate analysis.

On average, pregnancies had occurred after 6.4 months (median) of method use. These pregnancy figures are in the same range as the total pregnancy figures established in the efficacy trial (12-month pregnancy rate of 12.0, or 8.9% of all users becoming pregnant during the first year of method use).

Some interesting phenomena were observed in the chronological distribution of pregnancies: there were significantly fewer pregnancies in the first 6 months of SDM use (41 pregnancies) than in the latter 6 months (64 pregnancies). Under-reporting of pregnancies is a possibility, more marked for months further away from the interview (so earlier in method use). Also, there was a cluster of pregnancies right at the 6th month of use. This could be partially attributed to users choosing to delay pregnancy for 6 months (see pregnancy breakdown in Table 1), although some heaping cannot be ruled out (although participants were asked about dates of pregnancy, not duration of method use).

Of the 105 SDM users (9%) who had become pregnant at some point in their first 12 months of method use, the largest groups (42 and 41 women, respectively) reported it had been a “wanted pregnancy,” i.e., they intentionally had unprotected intercourse on the days identified as fertile in order to become pregnant, and using the method incorrectly (having unprotected intercourse on fertile days, forgetting what cycle day they were on, or continuing to use the method despite having cycles

outside the recommended 26–32 day range). There were only eight planned pregnancies in the first 6 months of method use, and 33 planned pregnancies in the latter 6 months, suggesting that some women opted for SDM as a way to delay a pregnancy they were planning. Of 105 women who had become pregnant, 78 were pregnant at the time of the interview. No questions were asked about pregnancy outcomes.

Would continuation figures be in the same range as those observed in the efficacy trial?

Of the 886 clients interviewed at least 6 months after choosing SDM, 785 (89%) were still using this method 6 months after adopting it. The 101 (11%) respondents that were classified as non-continuing were the 60 women who had decided to stop using SDM and the 41 who had become pregnant. This continuation rate is higher than figures from closely monitored studies, including the efficacy trial (4). A possible explanation for this may be that some women continued using SDM despite no longer meeting eligibility criteria. About 28% of efficacy trial participants were encouraged to switch to another method because of cycles outside the SDM recommended range of 26–32 days (4); users in San Martín were given similar instructions during initial counseling, but only 7.4% reported stopping SDM use because of out-of-range cycles.

DISCUSSION

The study showed that, under regular service delivery circumstances and in a setting with a pre-existing high contraceptive prevalence, SDM was efficacious and continuation rates were high. One-third of acceptors were previous calendar rhythm users who were using untested “rules” to determine the days to avoid unprotected intercourse; over one-third had recently used hormonal methods, but discontinued; and more than 10% were inconsistent condom users who continued to use condoms on fertile days. This demonstrates that SDM contributed to the prevalence of modern, efficacious, family planning method use.

Regarding effectiveness, SDM performance, when delivered through regular health services, was comparable to that seen in the clinical trial, even assuming a

10%–15% underreporting of pregnancies due to very early and thus unnoticed, loss (13) and other pregnancy terminations (during the clinical trial, close follow-up of clients and availability of pregnancy tests allowed for detection of probably close to 100% of pregnancies).

This study had methodological limitations. Although key policymakers were aware that a study was necessary, it was important that neither SDM clients nor service providers have any contact with research personnel (except for the retrospective interview), in order to avoid influencing their behavior, and consequently, the study results. This significantly restricted the type of information collected. In addition, the accuracy of information provided in the client interviews regarding pregnancy, discontinuation, and other relevant events may have been affected by recall. However, any resulting inaccuracies were random and would not have created any overall bias.

Although there are no standards by which to measure strong demand for a new family planning method, policymakers in Peru acknowledged that if 6% of all new family planning clients choose SDM, and most of them had not been using a reliable form of contraception previously, then addition of SDM to the mix is a good investment.

Still, some program managers may be concerned that SDM may take clients away from other more, effective or longer-acting, methods. In this study, the vast majority (over 98%) of clients choosing SDM reported previous life-time use of other methods—to be expected where contraception has been readily available for many years and prevalence is 73%. Any concerns were allayed, however, as

very few clients requesting SDM were switching away from other effective methods; this remained true even after word about SDM had spread throughout the community. New SDM users tended to be women switching from less-reliable, traditional practices, such as calendar-based periodic abstinence; those who had already discontinued another modern method, mostly due to side effects; and inconsistent condom users. These were clients at risk of pregnancy, seeking a different family planning alternative. These observations seem to indicate that SDM does not compete with other modern methods and that the respective users of other methods seem to have different needs and preferences. A possible explanation for these differences may be that these clients are at different stages of their reproductive lives. As is true for any other family planning method, SDM should be offered in a context of free and informed choice, where clients can choose any method, regardless of what they have used in the past or are currently using.

As mentioned, this study was carried out in two provinces in San Martín Department in 2005; however, prior to completion, health officials from neighboring provinces within the San Martín Department requested technical assistance to offer SDM as part of their services. This assistance was provided by staff from the Ministry of Health with experience in the two initial provinces, and by the end of the 36 months covered by this study, SDM was available in most of the San Martín Department.

After results from the San Martín project were shared with policymakers, the decision was made to encourage other areas of the country to add SDM to their

contraceptive mix. SDM was gradually included by the regular health services in other departments, reaching an estimated 5–6 million individuals in Arequipa, Callao, Lima, Piura, and Tumbes departments.

Although this study was conducted in a discrete geographic area of Peru, the experience provides important insights for any program considering the addition of SDM to its contraceptive mix. Programs that do not yet offer a full menu of contraceptive options, particularly those that serve populations where use of traditional practices is high, should consider adding this modern, effective fertility awareness-based method, even if current CPR is already moderate or high.

Acknowledgements. The authors wish to thank Mary del Castillo who was instrumental in getting the Standard Days Method® integrated into the services offered by the Ministry of Health of Peru. We also thank Marco Basualdo and the staff of the Regional Health Directorate of San Martín for their help in providing the Standard Days Method® and facilitating the study.

The Institute for Reproductive Health, Department of Obstetrics and Gynecology, Georgetown University (Washington, D.C., United States) supported this study under cooperative agreement #HRN-00-A-97-00011-00 with USAID; the preparation of this article was supported under cooperative agreement #GPO-A-00-07-00003-00 with USAID.

Disclaimer. The views expressed by the authors do not necessarily reflect the views or policies of USAID or Georgetown University.

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Manuscript received on 4 December 2009. Revised version accepted for publication on 28 June 2010.

RESUMEN

Adición del Método de Días Fijos® a la combinación de métodos anticonceptivos en un entorno de alta prevalencia de anticoncepción en el Perú

Objetivo. Definir la contribución del Método de Días Fijos® (MDF) a la combinación de métodos anticonceptivos que ofrecen los servicios de salud en dos provincias del Perú, donde las tasas de prevalencia de anticoncepción ya son altas.

Métodos. El MDF se agregó a los métodos de planificación familiar ofrecidos por el Ministerio de Salud en dos provincias en el Perú en septiembre del 2002. Entre marzo y junio del 2004, se llevaron a cabo entrevistas retrospectivas a 1 200 mujeres que habían escogido este método anticonceptivo y lo habían usado durante un periodo de 2 a 20 meses. Se obtuvo también información a partir de las bases de datos de los servicios de salud que participaron en el estudio. Se recogieron datos para determinar la demanda del MDF, si las usuarias hicieron la transición del MDF a otros métodos modernos por el de los días fijos y con la continuidad del uso del método y su eficacia.

Resultados. La demanda del MDF se estabilizó en 6% de todas las nuevas usuarias de planificación familiar. La mayoría de ellas no estaba utilizando otro método de anticoncepción en el momento de comenzar a usar este método. Cerca de 89% de las mujeres que habían empezado a usar el MDF al menos 6 meses antes de la entrevista, todavía lo estaban usando 6 meses después. Se calculó que la tasa de embarazo con un uso típico del método durante 12 meses fue alrededor de 10,0 por 100 años-mujer.

Conclusiones. La adición del MDF a las opciones de métodos anticonceptivos propuestos por un programa puede aumentar la cobertura, incluso en entornos que ya cuentan con una alta tasa de prevalencia de anticoncepción. La mayoría de las mujeres que eligieron el MDF no había usado antes otro método moderno de planificación familiar. La continuación de su uso es comparable con la continuación de otros métodos modernos que dependen del usuario. La eficacia del MDF, cuando se ofrece en un contexto de prestación de servicios regulares es comparable con los resultados que se obtuvieron en el estudio de eficacia.

Palabras clave

Anticoncepción; métodos naturales de planificación familiar; conducta anticonceptiva; Perú.