

Original research article

Being strategic about contraceptive introduction: the experience of the Standard Days Method®

James N. Gribble^{a,*}, Rebecka I. Lundgren^b, Claudia Velasquez^b, Erin E. Anastasi^c

^aBRIDGE Project, Population Reference Bureau, Washington, DC 20009, USA

^bInstitute for Reproductive Health, Georgetown University, Washington, DC 20008, USA

^cLondon School of Hygiene and Tropical Medicine, Rockville, MD 20852, USA

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Abstract

Background: Many national and institutional family planning policies explicitly include fertility awareness-based methods among the method options that should be made available, but these methods are often not offered for a variety of reasons. After testing the efficacy of the Standard Days Method® (SDM), which is a fertility awareness-based method that identifies Days 8–19 of the menstrual cycle as fertile for women with cycles lasting between 26 and 32 days, pilot studies were conducted to introduce it into programs.

Study Design: Through 14 pilot studies around the world, ministries of health, family planning associations and community development organizations introduced the SDM. Follow-up interviews with users and other data collection methodologies were used to track user characteristics and experiences. Supervision data and simulated clients assessed the effects on service delivery.

Results: The SDM appeals to a broad range of women throughout the world. Clients report using abstinence or condoms to manage the fertile days. Both men and women report high levels of satisfaction with the method. The cross-study first-year failure rate of 14.1 pregnancies per 100 woman-years of use is similar to typical-use rates found in the SDM efficacy trial.

Conclusions: The results of the pilot studies offer guidance for scaling up service delivery of the SDM. Condom counseling can help many users manage the fertile window effectively. Because out-of-range cycles can lead to method failure, users must understand the importance of tracking cycle length and be willing to switch to another method when the SDM is contraindicated. Community providers can offer the method; within clinical settings, SDM counseling typically takes no more time than allowed in most program norms. Training providers to address alcohol use and gender-based violence improves SDM method use and contributes to better quality of care.

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1. Introduction

Successful introduction of a new family planning method must be done in a systematic and strategic way. According to the World Health Organization (WHO), the introduction of contraceptive methods should focus not on a technology-driven approach, but rather on how a new method responds to peoples' needs and rights, as well as on how it enhances overall quality of care and broadens the options available to clients [1]. The WHO strategic approach uses a client-centered systems framework to examine the acceptability and sustainability of innovations — such as a new family

planning method — as a function of three elements: (1) people and services, (2) technologies and (3) policies and institutional capacities [2]. This article uses elements of the client-centered systems framework to describe the Standard Days Method® (SDM) pilot studies, which assessed the feasibility and acceptability of introducing the method into different service delivery settings. These studies represent the first systematic introduction of the SDM into service delivery settings outside the context of the clinical trial.

2. Materials and methods

2.1. The SDM

Many national and institutional family planning policies explicitly include fertility awareness-based (FAB) methods

* Corresponding author. Tel.: +1 202 939 5403; fax: +1 202 328 3937.
E-mail address: jgribble@prb.org (J.N. Gribble).

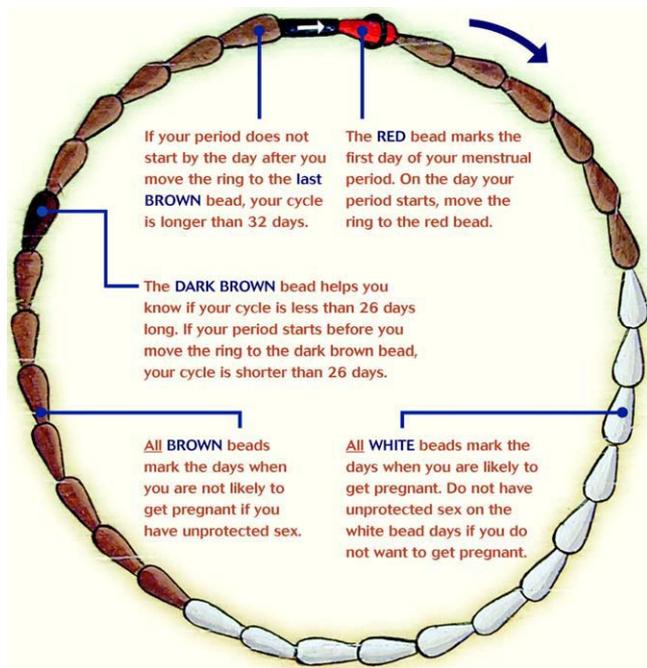


Fig. 1. CycleBeads illustration.

among the method options that should be made available.¹ Yet, programs rarely fully implement those policies, most often due to providers' concerns about the perceived difficulty of offering FAB methods and their effectiveness, providers' lack of training and a concern that if FAB methods are available, clients will discontinue use of other methods.

In response to the need for a simple FAB method, researchers at Georgetown University's Institute for Reproductive Health (IRH) developed the SDM using an existing WHO data set to identify the combination of days that provided an optimal balance between the length of the identified fertile period and the efficacy in avoiding unplanned pregnancy [3]. The formula that achieved this balance identified Days 8–19 of the menstrual cycle as the fertile window for women with menstrual cycles lasting between 26 and 32 days. The SDM was tested in a multisite efficacy study, which found a first-year pregnancy rate of 4.8 per 100 woman-years of correct use (95% confidence interval, 2.33–7.11); this rate compares favorably to other user-directed methods. A full description of the SDM efficacy study is provided in an article published in *Contraception* in 2002 [4]. To facilitate use of the SDM, the IRH also developed CycleBeads®, a mnemonic device consisting of a color-coded string of beads to help a woman track her cycle days, identify when she is fertile and monitor her cycle length (see Fig. 1). These results of the efficacy study helped to establish the SDM as a modern

¹ Fertility awareness-based methods of family planning depend on identifying the "fertile window" or the days during each menstrual cycle when intercourse is most likely to result in pregnancy. Users of FAB methods develop their own strategies for dealing with the fertile window.

method, facilitating its inclusion in WHO's *Medical Eligibility for Contraceptive Use and Selected Practice Recommendations for Contraception* as well as in *Contraceptive Technology and Family Planning: A Global Handbook for Providers* [5–8].

2.2. Developing and testing program innovations

The efficacy study suggested that the SDM could be provided by public and private sector family planning programs, as well as through community development organizations. However, while program managers were interested in the SDM, they required information on issues related to integrating the method into their programs, such as:

- People's perspectives and needs: who uses the SDM and why do they choose it. What is their experience with correct use and satisfaction? How are men involved in method use, and what strategies are used to avoid unprotected sex during the fertile window?
- Services: how does introducing the SDM affect aspects of quality of care?
- Outcome: how does introducing the SDM affect method mix and contraceptive prevalence?

At the time the studies began, relatively little was known about how to best offer the SDM. The studies provided answers to the above questions, as well as the opportunity to refine and improve the overall introduction of the SDM.

2.3. Selection of countries and partner organizations

To achieve a geographic and cultural balance, we conducted 14 pilot studies utilizing the public sector, private family planning associations (FPAs) and community-based organizations (CBOs) in six countries in Latin America, Asia and Africa (see Table 1).

Studies conducted with the public sector explored the value of adding the SDM to national family planning programs. In Honduras, the SDM was offered in Ministry of Health (MOH) primary care centers in Tegucigalpa; in Benin and the Philippines, the MOH sites were maternity hospitals that had dedicated family planning clinics (Homel and Fabella, respectively).

Five nongovernmental FPAs conducted studies: Centro Medico de Orientacion y Planificacion Familiar (CEMOPLAF) in Ecuador, Asociacion Hondurena de Planificacion Familiar (ASHONPLAFA) in Honduras, Friendly Care in the Philippines and Association Beninoise pour la Promotion de la Famille (ABPF) and Organization for Service and Life (OSV-Jordan) in Benin. CEMOPLAF, ABPF and OSV-Jordan also had community-based programs.

In addition, six CBOs tested the feasibility of introducing the SDM into a variety of community development programs, primarily in rural areas. Two of them had no previous experience with family planning services: the Kaanib Foundation, which is an agricultural cooperative in the Philippines, and the Project Concern International (PCI)

Table 1
Partner organization and study characteristics

Region	Country	Partner agency	Number of subjects	Target audience	Information contributed	
Africa	Benin	HOMEL	46	MOH maternity hospital	User profile and experiences	
		ABPF	54	FPA	Men as users	
		OSV-Jordan	119	NGO	Method mix	
LAC	Ecuador	CEMOPLAF	165	FPA clinics with outreach	User profile and experiences Two vs. one follow-up visits Method mix Provider performance	
		El Salvador	PCI CIRES	92	NGO rural community programs	User profile and experiences Pricing assessment Provider performance Men as providers Community effect Qualitative data from users and providers
	Honduras	ASHONPLAFA	32	FPA	User profile and experiences	
		CEVIFA/CRS	27	FBO	Method mix	
		MOH	50	Health center	Provider performance	
	Asia	India (New Delhi)	CASP Plan	230	NGO urban community program	User profile and experiences Pricing assessment Provider performance Men as providers Community effect
			India (Uttar Pradesh)	CARE	482	NGO rural community program
Philippines		Fabella Maternity Hospital	150	MOH hospital	User profile and experiences 2 v. 1 follow-up visit	
		Kaanib Foundation	78	NGO rural community program	User profile and experiences	
		Friendly Care	54	FPA	User profile and experiences Pricing assessment	

affiliate in El Salvador involved in water and sanitation. The remaining four CBOs already offered family planning services. Comite de Integracion y Reconstruccion para El Salvador (CIRES) in El Salvador had begun providing health services and infrastructure development after the 2001 earthquakes. CEVIFA is a faith-based organization and natural family planning program that collaborates with Catholic Relief Services and the MOH in Honduras. CARE operates a reproductive health program in rural villages of Uttar Pradesh, India. The Community Aid Sponsorship Program (CASP), in conjunction with Centre for Development and Population Activities (CEDPA), works in urban slums in Delhi, India.

2.4. Recruitment of SDM study participants

A total of 1646 SDM acceptors were enrolled in the 14 studies, with numbers of participants in each study ranging from 27 to 482. In addition to study participants, other women began using the SDM during the recruitment period but opted not to participate in follow-up interviews. All women accepting the SDM were counseled by providers

offering the SDM who were trained to (1) include the SDM in counseling on method choices, (2) screen women to ensure that the SDM would be suitable for them (i.e., cycles between 26 and 32 days in length and ability of the woman and her partner to avoid unprotected sex during the fertile days) and (3) counsel on correct use of the method, including CycleBeads. Only after a client had chosen the SDM and had been counseled in method use was she invited to participate in the study. All study participants signed a consent form prior to the first interview. Study protocols were approved by the Georgetown University Institutional Review Board.

2.5. Data collection and analysis

Several different types of data were collected to assess the feasibility of integrating the SDM into different types of service delivery models and explore user experiences; this report analyzes use of the following approaches:

- Structured interviews with SDM users about their sociodemographic characteristics and reproductive history, reasons for choosing SDM, attitudes about

the method, perspective on the male partner's role and couple communication, the instruction on method use she received and overall quality of care. Interviews were held within a week of enrollment and then after 1, 4, 7, 10 and 13 months of use (or whenever a woman exited the study). At follow-up interviews, women who had missed their period and who were uncertain about their pregnancy status were administered a pregnancy test. To determine if the pregnancy was due to method or user failure, participants were interviewed to find out if they had had unprotected intercourse during the fertile window. Pregnancy rates were calculated using life-table analysis.

- Structured interviews with male partners at the end of study, primarily about their satisfaction with the method, as well as their experience communicating with their wives about method use. Men and women were interviewed separately to avoid contamination of responses.
- Ongoing review of service statistics on numbers and percentage of new clients using each method to examine how SDM introduction affected method mix.
- Data from supervision interviews to assess how well providers understood and counseled clients about the SDM.

Some of the studies included additional data collection activities, including qualitative methodologies. [Table 1](#) presents the research topics addressed by each specific study. Pre- and postintervention community surveys were conducted by PCI in El Salvador and CARE and CASP in India. In El Salvador, cluster sampling was used to identify communities and households to be included in the interviews. To conduct the censuses in India, community health workers visited all households in the community to identify all women of reproductive age (15–49 years) and obtain information about their age, current pregnancy status, number of children and current and previous use of family planning methods. Simulated client studies were conducted by CEMOPLAF and ASHONPLAFA to assess providers' abilities to provide informed choice and SDM counseling. To conduct these studies, interviewers were trained to play the role of a woman seeking family planning services; the visits were conducted without the providers knowing which women were simulated clients. After the visit, the interviewer completed a checklist assessing the counseling session on a number of dimensions, including duration of the session. Prior to beginning the simulated client study, all providers were informed of the upcoming study and signed a consent form to participate in it.

2.6. Study limitations

These studies were designed to observe trends and patterns across programs and assess strategies for providing the SDM. They were not designed as clinical trials in which people deciding to use family planning were randomized to a

specific method. Thus, the factors that affected the number of participants enrolling in each study were the population density of the program's catchment area and the method's acceptance rate.

These 14 studies were very heterogeneous, including diverse programs in a wide range of settings. Self-selection of SDM acceptors, loss to follow-up, self-reporting and the strengths and weaknesses of the programs themselves certainly affected some of the findings. Follow-up interviews may have improved client knowledge and motivation to use the method. In addition, some participating organizations and providers may have been more enthusiastic about the SDM than would have been the case outside of a research context.

3. Results

The WHO client-centered systems framework focuses on critical issues related to (1) people, services and technologies, (2) policy and (3) institutional capacities, and how these three elements affect the acceptability and sustainability of a new family planning method. The following discussion focuses on the elements of people and services.

3.1. People's perspectives and needs

The following results examine user characteristics and experiences in managing the fertile window; pregnancy rates are also presented.

The 14 studies included a total of 1646 women. It is difficult to characterize these women because the study populations were very diverse. However, some user characteristics are presented in [Table 2](#), and these characteristics are summarized below.

- Age. The most consistent characteristic was age. The mean age of women who initiated use of the SDM varied little across studies, ranging between 28 and 32 years. However, women as young as 18 years (the youngest age enrolled in the study based on informed consent requirements) and as old as 47 years obtained the method and used it successfully.
- Parity. Parity varied greatly by study site. For example, 41% of users in Benin's urban ABPF study had not yet had children; in contrast, 69% of users in the Philippines' rural Kaanib study had at least three children.
- Education. Fifty-one percent of users in a study in urban India (CASP) had never attended school at all, while 65% of women in the Friendly Care study conducted in an urban setting in the Philippines had attended college.
- Ever use of modern contraception. Previous use of modern methods was common in most of the studies (nine studies had 50% or more reporting previous use of a modern method). Among acceptors at Benin's ABPF clinic, only 13% had used a modern method. At the opposite end of the spectrum, 80% or more of acceptors

Table 2
Selected SDM acceptor characteristics by study site

Country	Study sites	<i>n</i>	Age (mean)	Parity (mean)	No more than primary education (%)	Ever use modern family planning (%)	Used no family planning or only traditional methods 2 months before SDM acceptance (%)
Benin	ABPF	54	31.2	2.9	50.0	13.0	92.6
	Homel	46	29.6	1.9	28.2	52.2	54.5
	OSV Jordan	119	28.1	1.7	48.8	31.9	81.5
Ecuador	CEMOPLAF	165	29.4	1.8	28.4	72.1	61.8
El Salvador	PCI	92	29.9	3.0	72.8	56.5	81.5
	CIRES	50	28.1	3.6	92.0	30.0	92.0
Honduras	ASHONPLAFA	32	28.8	1.9	15.6	81.3	53.1
	CEVIFA	27	27.3	2.0	29.6	44.4	66.6
	MOH	50	28.9	1.8	36.0	82.0	56.0
India	CASP	247	28.4	2.9	65.6	64.8	31.2
	CARE	482	28.8	3.3	72.4	49.6	66.7
Philippines	Fabella	150	30.6	2.5	7.3	68.0	54.6
	Kaanib	78	32.2	3.9	50.0	56.4	85.9
	Friendly Care	54	31.9	2.1	3.7	53.7	64.8

from ASHONPLAFA and the Honduran MOH reported previous use of a modern method.

- Contraceptive use immediately prior to SDM. Far fewer SDM acceptors switched from an effective method to begin using the SDM. In 13 of the studies, more than half of women reported either not using a method at all or using a traditional method in the 2 months prior to starting with use of the SDM. The one exception was CASP, where most acceptors reported using condoms during the preceding 2 months.

In general, the most common reason for choosing the SDM rather than a different method was that it does not have side effects nor does it affect women's health. An additional reason was its low cost. Although FAB methods are frequently associated with religious beliefs, relatively few women gave this response as reason for selecting the SDM. Only the studies with PCI and CEVIFA (an FBO) had a sizable proportion of women citing religion as a reason for acceptance (20% and 14%, respectively). In the other 12 studies, religion was mentioned by between 0.5% and 7.4% of participants as a reason for accepting the SDM.

Although many women were interested in using the SDM, not all of them were eligible at the time of initial screening. According to data from eight of the studies (CEMOPLAF, CARE, CASP, OSV Jordan, ABPF, HOMEL, PCI, CIRES), about 35% of women inquiring about the SDM met the eligibility criteria, with the major reasons for ineligibility being out-of-range cycles and postpartum amenorrhea; partner opposition was cited less frequently.

When new acceptors were asked how they would handle the 12-day fertile window, the most common initial response in 10 of the studies was abstinence. However, actual strategies for managing the fertile days varied widely across service delivery settings. Users from two studies — ASHONPLAFA and CASP — planned to use condoms

during the fertile days (65% and 87%, respectively); users from CEMOPLAF and the MOH in Benin were almost equally divided in their preference for condoms and abstinence. In contrast, no users from Kaanib and CEVIFA reported that they planned to use condoms during the fertile days. However, during the follow-up interviews, participants in most sites indicated that condom use during the fertile days was about 10% higher than was initially planned. For example, one quarter of Friendly Care users stated that they planned to use condoms during the fertile days during the admission interview, compared with 34% who reported condom use during the exit interview.

Men's interest and commitment to the SDM varied, but in general, male users were interested in the method. In Benin, for example, many men came to the clinic by themselves to be counseled in SDM use. To assess user satisfaction with the SDM, women in all studies were interviewed upon exit from the study. In four studies (CEMOPLAF, PCI, CIRES, CASP), men were also interviewed. Although men and women were interviewed separately, their answers were fairly concordant. Men and women did not necessarily find avoiding intercourse or using condoms during the fertile days easy, but about 90% of them reported that the SDM was simple to use and that they would recommend the method to others. Women tended to be somewhat more satisfied than men and found the method easier to use. In India, for example, 99% of women users and 70% of men users would recommend the SDM to others. In El Salvador, 96% of women users and 90% of men users would recommend the method.

Data from the follow-up interviews provided the opportunity to estimate typical-use pregnancy rates. Due to small sample sizes in many of the studies, data were consolidated to estimate a single first-year typical-use pregnancy rate of 14.1 pregnancies per 100 woman-years of use. This estimate is similar to the typical-use pregnancy rate of 12 pregnancies per 100 woman-years of use

calculated from the SDM multisite efficacy study [4]. The leading reason for method failure was that couples knowingly took the risk of having unprotected sex on fertile days. Many of these couples reported using condoms or withdrawal during these days. User failure accounted for one third of pregnancies, in general. The percentage of participants getting pregnant due to user failure varied from 1.6% (CASP) to 9.3% (Fabella). Other factors less frequently mentioned by study participants were pressure from male partners to have sex on fertile days and desire for pregnancy.

3.2. Services

According to the WHO systems framework, introducing a new family planning method should improve quality of care, which according to Bruce's [9] framework, includes provider competence, interpersonal skills and follow-up to ensure effective use.

3.2.1. Provider competence

Correct use of the SDM depends to a great extent on the ability of providers to screen clients effectively and teach them how to use the method successfully. SDM counseling requires working with clients to determine whether the method is appropriate for them and will suit their lifestyle. Providers must then teach women to track their cycles, identify fertile days and develop strategies for managing the fertile window. In the 14 studies, a total of 333 providers were trained: 15% professional (doctors, nurses and certified midwives), 14% paraclinical (auxiliary nurses, family planning counselors and social workers) and 71% volunteer and paid community health workers. The providers' level of education and previous experience in providing family planning were the primary determinants of the type of training needed. The professional and paraclinical providers tended to have fewer training and supervision needs because of their experience offering family planning. However, it was not unusual for these providers to have a bias against FAB methods that had to be addressed. Before training, half of the clinical providers at ASHONPLAFA, for example, did not consider FAB methods to be an acceptable option for their clients. However, supervision data indicated that attitudes toward the SDM improved after training and several months of service delivery.

Training for community providers was divided into shorter modules, with sufficient time between sessions to absorb information before going on to the next session. The total amount of training time for low-literacy community health workers varied from 2 to 3 days, depending on the need to include the basics of family planning counseling, informed choice and an overview of other methods. In contrast, clinical providers, once their concerns were addressed, could learn to offer the SDM in about half a day. All providers were taught to use counseling cue cards that outlined the screening criteria and the essential steps for correct use of CycleBeads [10].

A pictorial counseling cue card was especially valuable for community providers.

3.2.2. Interpersonal skills and informed choice

To ensure informed choice and correct use of the SDM, the provider must have sufficient knowledge and counseling skills to explore the couple's ability to manage the fertile days, including risks of alcohol use, sexually transmitted infections and partner violence. In the CASP study, the ability of providers to identify couple issues and partner opposition accounted for 27% of ineligibility. In addition, when women experienced out-of-range cycles and were counseled to discontinue SDM use, providers needed to help women choose an alternative method.

Results of a simulated client study conducted by ASHONPLAFA found that SDM introduction increased informed choice and improved quality of care, regardless of the method ultimately chosen, as shown in Table 3. After introducing the SDM, the percentage of simulated clients who chose their method freely increased as well as the percentage who reported receiving enough information to select a FAB method doubled from 38% to 75% in both ASHONPLAFA and the Honduran MOH. At the same time, the percentage of providers recommending against FAB methods decreased from 24% to 2%.

3.2.3. Follow-up mechanisms

Ensuring that clients are using a family planning method correctly with an understanding of related side effects requires appropriate follow-up. The protocols of most of the programs involved in the studies included a programmed follow-up visit for new users, regardless of the method selected. To test the effects of a programmed follow-up visit on correct use, two studies — Fabella Hospital and CEMOPLAF — randomized SDM users into two study arms: with and without a second formal counseling session. According to client reports, a follow-up visit does not significantly improve correct use of the SDM in these settings. At times, clients of clinical programs returned to providers when they had a question about method use, but overall findings indicate that a follow-up visit is not necessary.

Related to the demand placed on providers, the time needed to provide FAB methods was sometimes cited as a barrier to their inclusion in multimethod programs. The

Table 3
Effects of SDM introduction on informed choice counseling

Counseling characteristic	SDM introduction	
	before (%) (n=55)	After (%) (n=71)
Client selected method	38	75
Client received sufficient information to select a FAB method	38	75
Providers recommended against FAB methods	24	2

amount of time needed to counsel new SDM users typically did not exceed what is generally allocated in program norms for new family planning consultations. Simulated client studies in Ecuador found that the average amount of time for counseling was 20 min; similar studies in Honduras indicated 25 min. Moreover, SDM counseling regularly addresses STI risks, screens for partner violence and introduces condom use.

3.3. Outcomes

Although these pilot studies were not designed to measure the impact of SDM introduction at the community level, data collected in some of the study sites provide an indication of the possible effects of SDM introduction.

Baseline and end-line household surveys were conducted by CARE, CASP and PCI to assess the effect of SDM introduction on contraceptive prevalence. In India, community censuses conducted before and after SDM introduction showed increases in contraceptive prevalence. According to the CASP census in the catchment area in Delhi, contraceptive prevalence increased from 50% to 58% after introduction of the SDM. About 3% of the women interviewed were using the SDM. In the CARE study area, prevalence increased from 24% to 41%, with 7% of women using the SDM. The results in PCI were similar. According to the surveys, contraceptive prevalence increased over a 20-month period from 45% to 58%, with 4% of women using the SDM at end-line.

4. Discussion

The experience and results of these introduction studies provide insight into the feasibility and acceptability of the SDM in diverse service delivery settings and offer guidance for SDM expansion. Implications for the integration process, provider training and supervision, and service delivery protocols are discussed below.

Data on user characteristics from the 14 studies indicate that the SDM reached a group of women with unmet need but who did not want to use any kind of contraceptive hormones or devices. Although the characteristics of SDM users varied widely, their contraceptive history prior to initiating SDM use indicated that 55% had never used any family planning method and 37% reported using another method — often inconsistent use of condoms — during the 2 months before adopting the SDM.

In these diverse settings, the SDM appealed to women with different characteristics, which suggests that the method need not be targeted to any specific segment of the population. In some studies, most users indicated that their preferred strategy for managing the fertile days was condom use. Though not particularly surprising, the implication for scaling up is notable: couples interested in using the SDM will find a way of managing the fertile days; for many of them, that strategy involves condom use.

Men and women continuing to use the SDM at the end of the introduction study indicated that they were satisfied with the method. Women who had more than one out-of-range cycle or who were unable to manage the fertile days were advised to change to another effective method. This finding suggests that it is important that users understand the importance of cycle length and that programs provide a wide range of options to meet clients' needs.

An important finding was that many men were interested in the SDM and participated in method use by abstaining or using condoms during the fertile days, obtaining condoms and helping their wives keep track of the fertile days. Study organizations found that introducing the SDM provides a vehicle for programs to increase male involvement, even if men do not directly participate in counseling.

The results of these studies suggest that SDM introduction can improve client–provider interaction. Simulated client studies found that information provided on FAB methods and condom use improved after SDM introduction. Instructing clients to use the SDM involves exploring the couple's relationship; therefore, providers learn to screen for issues that might undermine successful method use, such as alcohol use, partner violence, and poor couple communication and negotiation. It also increases provider comfort in addressing these issues.

Community-based providers with little or no experience in family planning can provide the SDM effectively, with appropriate training and supervision. An important advantage of community providers is that with training, they can also refer women interested in using other methods, including those ineligible for the SDM, to another service delivery site, as was the case with CARE, CIRES, PCI and CEVIFA.

The amount of time needed to counsel new SDM users typically did not exceed what is generally allocated in norms for new family planning consultations. Moreover, SDM counseling regularly addresses STI risks, screens for partner violence and includes condom use instruction. In addition, the studies that systematically examined the effect of a programmed follow-up visit in clinic-based programs found that the second visit contributed to improved knowledge but had no significant effect on correct use.

The results of these 14 studies suggest that the SDM responds to people's needs, improves quality of care and can be introduced into a variety of settings. This evidence has been useful for guiding policy development and strategies to integrate the SDM into public- and private-sector family planning programs.

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