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Standard Days Method of contraception: Evidence on use, implementation, and scale up

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Standard Days Method of Contraception: Evidence on Use, Implementation, and Scale Up



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January 2015

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This working paper is part of a larger initiative of the Evidence Project to strengthen the evidence on expanding access to family planning and reproductive health programs. More information about the project can be found at: evidenceproject.popcouncil.org

Acronyms

CHW	Community Health Worker
COCs	Combined Oral Contraceptives
CPR	Contraceptive Prevalence Rate
DHS	Demographic Health Survey
DMPA	Depo-Provera
DRC	Democratic Republic Of Congo
FAM	Fertility Awareness-Based Methods Project
FGDs	Focus Group Discussions
FP/RH	Family Planning and Reproductive Health
HMIS	Health Management Information System
IDIs	In-Depth Interviews
IPPF	International Planned Parenthood Federation
IRH	Institute for Reproductive Health
IUD	Intrauterine Device
KIT	Knowledge Improvement Toolkit
LMIC	Low and Middle Income Countries
NGO	Non-governmental Organization
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MSC	Most Significant Change
OR	Operations Research
PSI	Population Services International
SDM	Standard Days Method
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

Since the early 2000s, the Standard Days Method (SDM) of family planning has been tested, introduced, and scaled up in countries around the world. SDM is a fertility awareness-based method for avoiding unprotected intercourse during the fertile period, days eight through 19 of a woman's menstrual cycle (for women whose cycles range from 26 to 32 days). Most SDM users utilize a visual aid—CycleBeads®—to assist their correct use of SDM. In a 2002 trial, the method's first year failure rate (5 per 100 woman years with correct use and 12 per 100 woman years for typical use) was established, commensurate with certain other modern methods of contraception; since then, SDM has been introduced as well as studied in a variety of low and middle income countries (LMIC), and has been scaled up in some.

This working paper summarizes the results of a structured review on SDM by the Evidence Project in 2014. This review utilized standardized search strings and systematic screening and abstracting criteria for reviewing available peer-reviewed and grey literature reports on SDM outcomes. Fifty-two reports and peer-reviewed articles were included and abstracted for data and information on client outcomes, provider outcomes, SDM service delivery characteristics, cost effectiveness, and implementation and scale up documentation. The included literature covered SDM implementation, scale up, social marketing, provider training, costing, and studies of most significant change in 23 countries from 1999 to 2014.

This structured evidence review found that SDM users tend to be women with unmet need who do not want to use hormonal contraceptive methods, either new family planning (FP) users or transitioning from less effective methods such as rhythm or withdrawal. SDM users tend to be slightly older than other FP users, with varied levels of education. This review found that SDM users have high levels of knowledge both about FP methods and their fertile periods, and evinced high levels of correct method use. Ever and current use of SDM, although relatively low, was commensurate with other more established FP methods such as female condoms, implants, IUDs, and male sterilization. SDM continuation falls within standard ranges (as reported in Demographic Health Surveys (DHS)), and discontinuation is primarily due to women's out-of-range menstrual cycles. Most SDM users report their satisfaction with the method, its ease of use, as well as abstinence or use of protection during their fertile periods. Some female SDM users reported difficulties with negotiating protected intercourse during fertile periods if faced with opposition from their husbands. Many female users report that using SDM enhanced communication with their partners, who were supportive of SDM use. Male involvement with SDM use is seen as an essential part of method success, and providers are trained to counsel SDM users on strategies to deal with intercourse during the fertile period, as well as gender-based violence and sexually transmitted infection (STI) prevention, and negotiating intercourse during alcohol consumption.

In all study sites measuring the contraceptive prevalence rate (CPR) preceding and following SDM interventions (measurement durations of 1 to 3 years), CPR increased. SDM as a proportion of all FP methods ranged from three to 19 percent at endline or cross-sectional measurements, which is commensurate with female condoms, implants, IUDs, and male sterilization in some countries, according to SDM measurements included in the DHS since 2003. Data from El Salvador and India indicate that SDM interventions can increase SDM use while contributing to an overall CPR increase—in other words, SDM use does not appear to diminish use of other methods and appears to have a positive influence on overall CPR.

Although some providers have initial biases against offering SDM due to distrust of a non-hormonal method and lack of confidence in client ability for correct use, these biases improve after training and

several months of service delivery. Provision of SDM is feasible by a variety of providers—concrete data demonstrate that community health workers (CHWs), male volunteers, and pharmacists can all successfully offer SDM. Providers generally report SDM’s addition to their FP repertoires added to their overall knowledge and quality of care, although some were concerned about cycle range eligibility criteria. Providers scored well on interpersonal skills evaluations but demonstrated low levels of comprehensive information exchange on FP methods, indicating need for routine supportive supervision and refresher trainings, with particular emphasis on eligibility criteria and counseling topics.

This working paper’s final section is dedicated to issues related to SDM scale up. The Institute for Reproductive Health (IRH) used the World Health Organization’s (WHO) ExpandNet model to guide scale up in five countries: Democratic Republic of Congo (DRC), Guatemala, India, Mali, and Rwanda. Findings from the scale up show that consistent government support and involvement facilitates scale up and that involving government and other partners from the beginning facilitated sustainable implementation. Early scale up successes included SDM’s inclusion in national norms, policies, guidelines, and training curricula, which promoted its vertical scale up and institutionalization. SDM scale up challenges included CycleBeads® procurement and SDM’s inclusion in health management information systems (HMIS) or existing monitoring and evaluation (M&E) or survey systems. CycleBeads® procurement proved difficult, particularly in non-USAID districts or areas in certain countries. One key finding from the scale up studies is that demand creation and targeted information, education and communication (IEC) campaigns are integral to promoting SDM uptake. Social marketing and ongoing subsidies were necessary in many scale up sites, and researchers predict they will continue to be necessary until large scale increases in CycleBeads® awareness and demand to facilitate SDM use. SDM was found to be more cost-effective than pills, condoms, and injectables—and this cost effectiveness increases with longer use.

This review of evidence on SDM tells us that the method appeals to a specific tranche of women—those with unmet need, who desire to use non-hormonal contraception, and who are new to the use of effective modern FP methods. SDM as a method has correct and typical failure rates on par with some other modern methods of contraception (diaphragms, female condoms, and male condoms) and its prevalence is similar to some other modern methods that have been around for longer periods of time (female condoms, implants, IUDs, and male sterilization). SDM is easy to use and satisfying to users, it increases knowledge about the fertile period among both women and men, and it promotes male engagement in FP. It can be offered by a range of public and private providers throughout the health system. Scale up of SDM use requires stakeholder buy in and participation, early introduction of SDM into policies, guidelines, norms and curricula, inclusion of SDM into HMIS, procurement, and training systems, supportive supervision and refresher training, and public-private partnerships. In order to facilitate sustainable and systematic scale-up, particular attention needs to be to the procurement and availability of CycleBeads®, agreement within the international community that SDM is a modern method, inclusion of SDM in national surveys, and the expansion of cadres providing SDM.

Introduction

In 2002, an article in *Contraception* reported on a trial for a new method of contraception, the Standard Days Method (SDM). Building on the World Health Organization's (WHO) large Ovulation Study dataset, the SDM is a fertility awareness-based family planning (FP) method that identifies the eighth (8) through nineteenth (19) days of a woman's menstrual cycle as the fertile window (Arévalo, Jennings and Sinai 2002). Normally offered in conjunction with CycleBeads®—a visual aid to help couples identify and track their fertile periods—SDM is most effective for women whose cycles range between 26 to 32 days, although it has some efficacy for women with cycles outside of this range (Dosajh, Ghosh and Lundgren 2006). SDM users abstain or use barrier methods during their fertile periods to prevent pregnancy (Dosajh, Ghosh and Lundgren 2006). The trial established a first year method failure rate of five per 100 woman years with correct use, and 12 per 100 women for typical use; these are on par with many other user-directed modern methods of contraception (Arévalo, Jennings and Sinai 2002).

Over the decade since the publication of the original efficacy trial, the Georgetown University Institute for Reproductive Health (IRH) and other organizations have worked to introduce and scale up SDM in a number of countries to expand women with unmet contraceptive need's method access and use. Under the USAID-funded AWARENESS Project from 1997 to 2007 and the USAID-funded FAM Project from 2007 to 2013, IRH, in conjunction with a wide array of partners, undertook a trial to establish SDM's efficacy and effectiveness, as well as method introduction studies, long-term follow up studies, and scale up studies to evaluate and understand the process of introducing SDM into a country's method mix. Most studies included national or local ministry of health (MoH) partners and private and NGO sector organizations. International organizations involved in SDM method introduction, scale up, and other activities include CARE, CEDPA, Catholic Relief Services, FHI360, JHPIEGO, Marie Stopes International, Mercy Corps, PATH, Pathfinder, Population Council, Population Reference Bureau, Population Services International, Project Concern International, Save the Children, University Research Co., UNFPA, WHO, World Vision, and local IPPF affiliates. Additionally the Futures Institute worked on costing estimations, and a variety of international and local university partners were involved in these SDM interventions and research.

This paper reviews the published peer-reviewed and grey literature on SDM from more than a decade of research. This evidence includes the perspectives of users, providers, and communities, in addition to information about service delivery. The evidence demonstrates the feasibility of integrating SDM into national or sub-national FP service delivery, and documents experiences of scaling up SDM in five countries: Democratic Republic of the Congo (DRC), Guatemala, India, Mali, and Rwanda. Data collected during the FAM project in these five scale up countries found that over 115,000 new SDM users in the study areas were registered in public sector service statistics or reported by partner organizations, and 461,000 CycleBeads® were procured for the five countries.

Expansion of the contraceptive method mix in low and middle-income countries has a well-established positive relationship with contraceptive use (Ross and Stover 2013). After more than a decade of research on SDM, a review of the evidence is important, for expanding access to a method with potential for filling an important niche in countries' method mixes.

Methods

SEARCH STRATEGY

This review included a structured search of peer-reviewed and grey literature on the Standard Days Method (SDM)¹ (see Appendix 1 for the search string, inclusion criteria, and data abstraction process).

A total of 52 references met the inclusion criteria and were abstracted for relevant data on interventions, study designs, intervention populations, provider types, implementing organizations, relevant implementation and scale up information, and key outcomes. All included studies report on at least one outcome measure related to method use among women or service provision, namely:

- Efficacy and effectiveness
- Acceptability
- Knowledge
- Demand for SDM
- Use of SDM
- Outcomes for Providers
- Service delivery characteristics for SDM
- Costs or cost effectiveness of SDM implementation

Given the diversity of indicators presented across studies, the authors did not establish specific indicators for inclusion at the outset of the data abstraction process.

The authors attempted to identify instances where data from the same studies were reported across different peer-reviewed articles or grey literature reports, but it was not possible to identify all unique studies as there were multi-staged operations research (OR) and scale-up studies of SDM in a number of countries. Many of these OR interventions were multi-phased and have various reports and peer-reviewed literature available for different sub-interventions or outcomes, both across and within countries.

¹ Study topics included efficacy trials for SDM, long-term follow up on efficacy and effectiveness, method introduction studies, scale-up evaluations, and various research evaluating SDM implementation, service delivery, provider knowledge and attitudes, social marketing, and others.

STUDY CHARACTERISTICS

Table 1 depicts the types of studies included in the analysis and the countries in which they were conducted. For studies conducted in multiple countries, data presented in this review are reported in aggregate or by individual country, depending on their presentation in the article. Throughout this analysis, studies and their location are noted when reporting results.

Table 1. Types of Studies on SDM, by Country

COUNTRY	IRH SDM Implementation and Scale up Studies					Special studies undertaken within IRH Implementation and Scale up Studies ²				Other ³
	Efficacy Trial	Method Introduction Study	Impact Study	Long-term Follow Up Study	Scale-Up Study	Social Marketing Study	Knowledge Improvement Toolkit (KIT) Study	Cost of Integration Study	Most Significant Change Study	
Albania										X
Benin				X		X				
Bolivia	X			X						
Brazil										X
Burkina Faso		X								
DRC					X	X				
Ecuador		X		X						
El Salvador		X								X
Ethiopia				X						X
Guatemala					X		X	X	X	
Honduras		X								
India		X	X	X	X			X	X	
Iran										X
Kenya										X
Madagascar						X				
Malawi										X
Mali		X			X	X			X	
Nigeria						X				
Pakistan										X
Peru	X		X	X						X
Philippines	X	X		X						
Rwanda			X		X			X	X	X
Turkey										X

Figure 1 shows the timeline and breadth of studies in one country, India, which span over a decade, starting with SDM efficacy research and progressing to introduction and scale up. Sub-studies were also conducted on provider behaviors and women's empowerment (Chhugani, Jha and Caine 2013; Das and Nandan 2004; Dosajh, Ghosh and Lundgren 2006; Gribble et al. 2008; Hossain et al. 2013;

² Studies throughout implementation and scale-up of SDM that employ specific methodologies to examine SDM implementation, investigate specific tools (like the KIT), or work with partners to examine demand issues (PSI Social marketing)

³ Other studies include research undertaken on SDM use, efficacy, and effectiveness not related to IRH introduction and scale-up of SDM (in Brazil, Albania, Turkey, Iran, Kenya, Nigeria, and Ethiopia, Guatemala, Malawi, Rwanda, Bolivia, and Peru); research where SDM was included and measured in an intervention but was not the main focus (Pakistan FALAH), and costing studies (Guatemala, India, Rwanda).

IRH 2008; IRH, 2013c; Johri, Panwar and Lundgren 2005; León et al. 2007a; León et al. 2014; Lundgren et al. 2012; Rosen, Winfrey and Adesina 2013; Simmons, Ghiron and Fajans 2012; Sinai, Jennings and Arevalo 2004; Sinai, Lundgren and Gribble 2012). Unique data from the SDM studies in India are included in 15 of the 52 peer-reviewed articles or grey literature reports and cover a wide range and mix of regions in India.

Figure 1. SDM Studies in India, by Type; 1999-2013⁴

	1999	2000	2001	2002	2003	2004	2005	2007	2008	2009	2010	2011	2012	2013
Operations Research	■	■	■	■	■									
Long-term Follow Up Study		■	■	■	■	■	■							
Cost of Integration Study			■	■	■	■	■	■	■	■	■	■	■	■
Simulated Client Study					■	■	■	■						
Integration Study in Jharkhand					■	■	■	■						
KIT Supervision Study					■	■	■	■	■	■	■	■	■	■
Impact Study						■	■	■						
Scale Up Study									■	■	■	■	■	■

Studies of SDM interventions and scale up employed a range of methods to investigate SDM use. Because many SDM studies were designed specifically as OR studies, a mix of quantitative and qualitative methods measured outcomes. Study dates ranged from 1999 to 2014, with most from 2000 to 2012. IRH characterizes its implementation and study timeline as: 2000—research on the method concept; 2002—efficacy study; 2000 to 2004—pilot introductions; 2003 to 2005—OR studies; 2005 to 2007—impact studies; and 2007 to 2012—scale up (Lundgren 2013). While the literature roughly corresponds to this timeline, allowing for publication delays, not all peer-reviewed articles or grey literature reports identify their study dates.

In most studies, SDM was offered as part of the standard FP and reproductive health (RH) service delivery in the study site catchment area: In 10 studies, SDM was offered alone, and in other studies it was compared to condoms, injectables, sterilization, Depo-Provera (DMPA), and pills (Arévalo et al. 2010b; Dosajh, Ghosh and Lundgren 2006; Gribble et al. 2008; Johri, Panwar and Lundgren 2005; Kavle, Eber and Lundgren 2012; León et al. 2006; León et al. 2007a; Lundgren et al. 2005; Mohammadpourasl 2007; Ram and Doracaj N.D.; Rosen, Winfrey and Adesina 2013). The typical population in SDM studies comprised women of reproductive age who use SDM; some studies included comparisons of SDM users to non-users. Partners of female SDM users and couples were also frequently included. Some studies included providers, facilities, or special populations such as postpartum women or married adolescent girls. Many SDM providers were community-based or linked to some method of community delivery of SDM. Some studies involved clinical providers or

⁴ Sources: Chhugani, Jha, & Caine, 2013; Das & Nandan, 2004; Dosajh, Ghosh & Lundgren, 2006; Gribble et al, 2008; Hossain et al, 2013; IRH, 2008; IRH, 2013c; Johri, Panwar, & Lundgren, 2005; León et al, 2007a; León et al, 2014; Lundgren et al, 2012; Rosen, Winfrey & Adesina, 2013; Simmons, Ghiron & Fajans, 2012; Sinai, Jennings & Arevalo, 2004; Sinai, Lundgren & Gribble, 2012

clinic-based SDM provision, and one study compared clinician and pharmacist provision of SDM (Kavle, Eber and Lundgren 2012).

Sample sizes of the surveys associated with SDM studies ranged from 170 to 15,051 (one study in Mali utilized service delivery data in which over 350,000 people were recorded in routine statistics). Sample sizes for focus group discussions (FGDs) and in-depth interviews (IDIs) with providers and users were much smaller. Sample size was not reported or was ambiguous in some peer-reviewed articles or grey literature.

STUDY LIMITATIONS

This was a systematic review with retrieval of data in a structured fashion. Some limitations were due to the structure of the review itself, namely that peer-reviewed and grey literature articles were retrieved only if they met the review's search string criteria. Because SDM and CycleBeads® are sometimes called by other names, particularly in other languages, there is a possibility some evidence was missed.

Some of the studies experienced methodological limitations common to OR—unexpected political or social events hindering data collection, including the inability to collect an endline survey in Mali due to a coup d'état, or self-selection for SDM studies, significant loss to follow up, retrospective and self-reporting biases, and biases related to internal and external validity (Gribble et al. 2008, Sinai, Lundgren and Gribble 2012). Additionally, how data were reported was occasionally difficult to interpret in the OR report, as denominators shifted over time with loss to follow up, or were not clearly reported. These issues are not unique to SDM studies—they represent challenges faced when implementing complicated mixed method research and scale up efforts in diverse and ever-shifting contexts.

Many, but not all, of the studies included in this review followed only women who continued using SDM throughout their research processes, which means that the knowledge, attitudes, and practices of women who dropped out prior to endline measurements may not be accurately reflected in the data shown here. Although some evidence suggests that women may use SDM as a spacing method between births or a bridging method between non-use and use of other methods, the evidence on long term use dynamics among clients who use SDM is scant.

Results

DESCRIPTION OF SDM USERS IN THE STUDIES

Data from method introduction and scale up studies indicate that SDM reaches primarily women with unmet need who do not want to use hormones or medical devices for contraception (Gribble et al. 2008). Some women use SDM as an introductory method and transition to other methods, to delay a planned pregnancy or as a way to return to fertility (Arévalo et al. 2010a, Kalaca et al. 2005, Ram and Doracaj N.D.).

In the reviewed studies, SDM users were reported as older than users of other methods—in 10 studies the mean age of SDM users ranged from 29 to 32 years (Arévalo, Jennings and Sinai 2002; Blair et al. 2007; Brunie et al. 2013; Capo-Chichi and Anastasi 2005; Johri, Panwar and Lundgren 2005; Kalaca et al. 2005; Kursun, Cali and Sakarya 2014; Rawlins et al. 2005). One study in Kenya examined SDM use among married adolescent girls (Undie et al. 2012). SDM users' generally older age might reflect the fact that the method is more effective with partner participation, which could be easier in more established partnerships. Women who accepted SDM at enrollment in a study in Istanbul were more likely to be older than women who chose other methods ($p < .001$), were more likely to have lower parity (chi square 10.4), were more likely to have a spouse who did not want any children (chi square 14.5), and were more likely to be better educated ($p < .001$) (Kursun, Cali and Sakarya 2014).

SDM users had varied levels of education and literacy, depending on the study site. Studies in Rwanda and India reported low levels of education (Blair et al. 2007, Brunie et al. 2013, Johri, Panwar and Lundgren 2005). Five other studies report the percent of women with primary education—in Rwanda, it was 60 percent of SDM users, while 64 percent of participants in one study site and 68 percent at another in Turkey were primary school graduates (Brunie et al. 2013, Kursun, Cali and Sakarya 2014, Kalaca et al. 2005). In Albania, SDM users had significantly higher levels of education (Ram and Doracaj N.D.).

Most women requesting SDM were either first time FP users or were switching from ineffective methods such as rhythm, periodic abstinence, or inconsistent condom use (Arévalo et al. 2010a, Blair et al. 2007, Gribble et al. 2008, Lundgren et al. 2012). Ten of the 52 peer-reviewed articles or grey literature included in this analysis report whether SDM users had ever previously used a FP method (Arévalo, Jennings and Sinai 2002; Bekele and Fantahun 2012; Blair et al. 2007; Capo-Chichi and Anastasi 2005; Gribble et al. 2008; Johri, Panwar and Lundgren 2005; Lundgren et al. 2012; Monroy, Lundgren and Montano 2003; Rawlins et al. 2005; Suchi and Batz 2006). Most studies state that SDM acceptors were either new to FP or were using less effective methods in the two months prior to SDM initiation (Arévalo, Jennings and Sinai 2002; Bekele and Fantahun 2012; Blair et al. 2007; Capo-Chichi and Anastasi 2005; Gribble et al. 2008; Lundgren et al. 2012; Monroy, Lundgren and Montano 2003; Rawlins et al. 2005; Suchi and Batz 2006). SDM seems to appeal to new users or users switching from less effective methods, but it should be noted that IRH's studies specifically targeted women with unmet need, so many of those women were not currently using an FP method. Additional research may help understand the use dynamics of women who adopt SDM. One study in Peru found that 33 percent of women accepting SDM had switched to SDM from the rhythm or calendar method, 29 percent had switched from oral contraceptives, and 18 percent had switched from injectables—most users of hormonal methods had stopped use one to three months prior to selecting SDM and could only use SDM if they met the 26 to 32 day menstrual cycle range criteria (Arévalo et al. 2010a). SDM users who had never used a FP method prior to accepting SDM ranged

from 10 percent in a multi-site study to 96 percent in Rwanda (Arévalo, Jennings and Sinai 2002, Blair et al. 2007).

OUTCOMES FOR WOMEN

Efficacy of Correct Use of SDM and Effectiveness of Typical Use of SDM

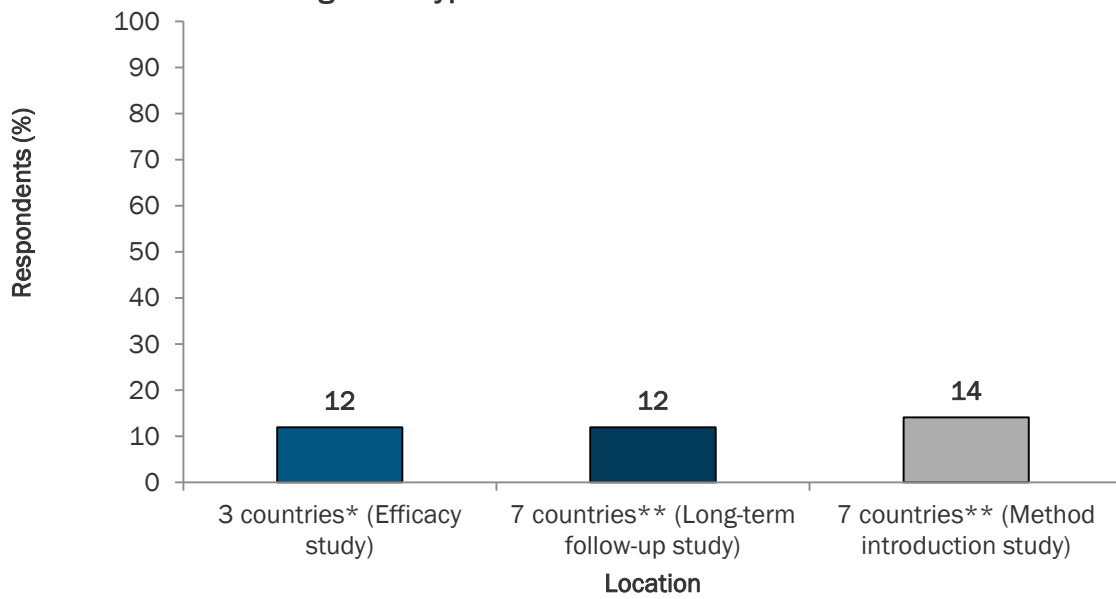
Efficacy with Correct Use

SDM's efficacy was established in a 1992 to 2001 trial in Bolivia, Peru, and the Philippines that measured its correct use. The trial followed women, aged 18 to 39, with self-reported cycles of 26 to 32 days, who desired to delay pregnancy. These women and their partners were counseled to abstain during the fertile period while being followed up (later studies did not have this requirement)—92 percent of women abstained during the fertile period and five percent used an alternate method during intercourse on fertile days. The data from this trial was evaluated using a single decrement multi-censoring life table calculating a cumulative probability of pregnancy for SDM use (Arévalo, Jennings and Sinai 2002). That trial measured a failure rate of five per 100 woman years for correct SDM use among women who abstained from intercourse during the fertile period (Arévalo, Jennings and Sinai 2002). Women reporting intercourse during the fertile period, with use of a condom or withdrawal, had a first year pregnancy rate of six per 100 woman years (Arévalo, Jennings and Sinai 2002). Two later studies reported on the percentage of women who became pregnant with correct use—in India a method introduction study found four percent of rural users and three percent of urban users were pregnant at a six month follow up visit, similar to three percent of rural users in a study in Burkina Faso (Hossain et al. 2013, Rawlins et al. 2005). These failure rates with correct use are comparable to correct use with other user-dependent methods such as female condoms (5%), male condoms (2%), Two Day Method (4%), Ovulation method (3%), diaphragms (6%), and withdrawal (4%) (Trussell 2011).

Effectiveness with Typical Use

In three studies covering seven countries, typical use method failure rates varied from 12 to 14 per 100 woman years (see Figure 2) (Gribble et al. 2008, Arévalo, Jennings and Sinai 2002). This typical use method failure rate is comparable to other user-dependent methods such as the male condom (18%) and diaphragm (12%), and is only slightly higher than user-dependent hormonal methods such as pills (9%) and NuvaRing (9%) (Trussell 2011).

Figure 2. Typical Use Method Failure Rate



*Bolivia, Peru, Philippines

**Benin, Bolivia, Ecuador, Honduras, India, Peru, Philippines
(Arévalo, Jennings & Sinai, 2002; Sinai, Lundgren & Gribble, 2012)

One study examining SDM's long term effectiveness found that its typical use method failure rate after one year of use was 14 per 100 woman years; this rate substantially decreased in the second year to four per 100 woman years, and slightly increased to six in the third year of follow up (Sinai, Lundgren and Gribble 2012). The confidence intervals widen significantly for each subsequent year of use due to decreases in the study population. Studies with more acceptors may be necessary for ascertaining long term method failure rates of SDM (Sinai, Lundgren and Gribble 2012).

Study results from India show that SDM is significantly more effective after the fourth month of use among women with some level of primary education compared to women with no formal education (Johri, Panwar and Lundgren 2005). A multi-site study examining long term SDM use in Benin, Ecuador, Honduras, and India found that the proportion of women becoming pregnant or with a second out-of-range cycle (less than 26 or more than 32 days) was significantly smaller in the study's second and third years, which means that most pregnancies were in the first year of SDM use, and women who passed initial eligibility screening were less likely to become pregnant and more likely to continue to experience in-range cycles (IRH 2008).

Experience with Out-of-range Cycles

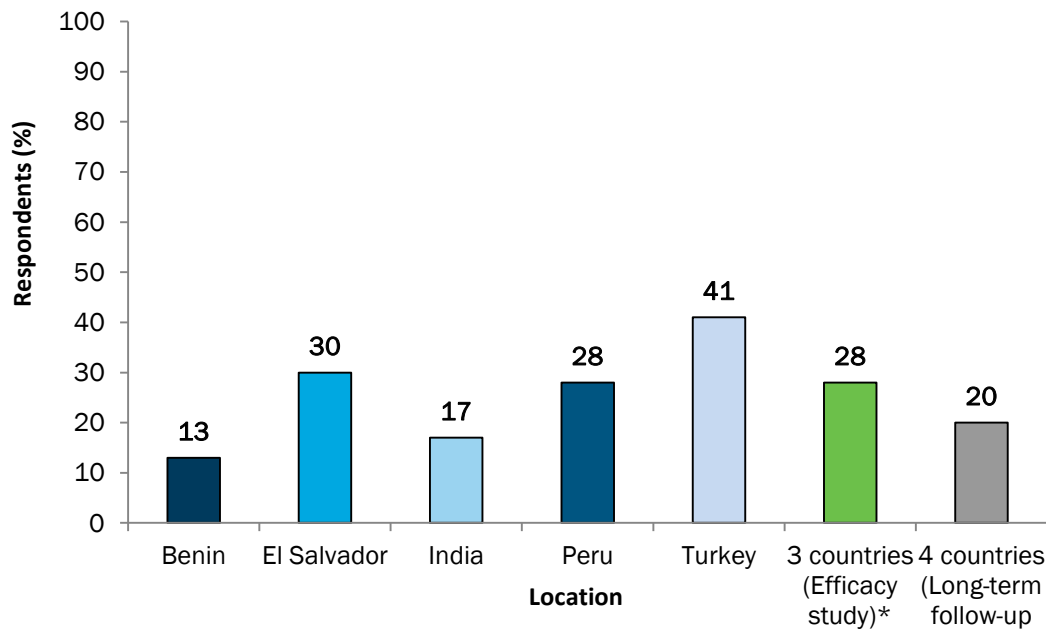
The SDM screening protocol originally required service providers to calculate a woman's cycle length based on the dates of her prior menstrual periods. In 2009, this protocol was revised to reflect the results of an SDM screening study that simplified provider counseling to only ask women if their periods were about a month apart (IRH 2013f). The revised screening protocol allows women who do not track or know the timing of their cycles to utilize SDM, but still requires a regular monthly cycle (Monroy, Lundgren and Montano 2003; Sinai and Arévalo 2006). Around one third of women have out-of-range cycles—this eligibility criterion was frequently reported as an inhibitor of SDM uptake and use, as not all women are able to use it (Gribble et al. 2008, Muramutsa 2004). Ensuring that women and their partners understand that cycle length eligibility criteria are central to SDM use, and that acceptors are willing to switch to other methods if ineligible for SDM, is essential for continuing to meet unmet need (Gribble et al. 2008). Women eligible at initial SDM screenings tend

to continue to be eligible for it (i.e. they don't have out of cycle ranges), which makes SDM a viable long term solution (Sinai, Lundgren and Gribble 2012).

Women with two or more cycles out of the 26 to 32 day range had a higher probability of becoming pregnant, but were still offered some protection from pregnancy by SDM (Sinai, Jennings and Arevalo 2004). Figure 3 provides an overview of women in different study sites who were ineligible for SDM use due *only* to out-of-range cycles—from 13 percent of women in Benin to 41 percent of women at health facility sites in Turkey. A publication reporting aggregated data from SDM pilot studies found that 65 percent of female FP acceptors interested in SDM in six countries (Benin, Ecuador, El Salvador, Honduras, India, the Philippines) were ineligible for SDM according to three criteria: out-of-range cycles, postpartum amenorrhea, and partner opposition (Gribble et al. 2008).

Women who pass initial eligibility screening who then have out-of-range cycles are unlikely to have another out-of-range cycle in the following six months: In a long term follow up study in Bolivia, Peru, and the Philippines, only four percent of women completing 13 SDM cycles had two or more out-of-range cycles (Arévalo and Sinai 2005, Sinai, Jennings and Arevalo 2004). In a method introduction study in India, many more rural than urban women were discontinued due to out-of-range cycles (Hossain et al. 2013).

Figure 3. Women with Out of Range Cycles



* Bolivia, Peru, Philippines

** Benin, Ecuador, Honduras, India

(Arévalo et al, 2010a; Arévalo, Jennings & Sinai, 2002; Capo-Chichi & Anastasi, 2005; IRH, 2008; Johri, Panwar, & Lundgren, 2005; Kalaca et al, 2005; Monroy, Lundgren & Montano, 2003)

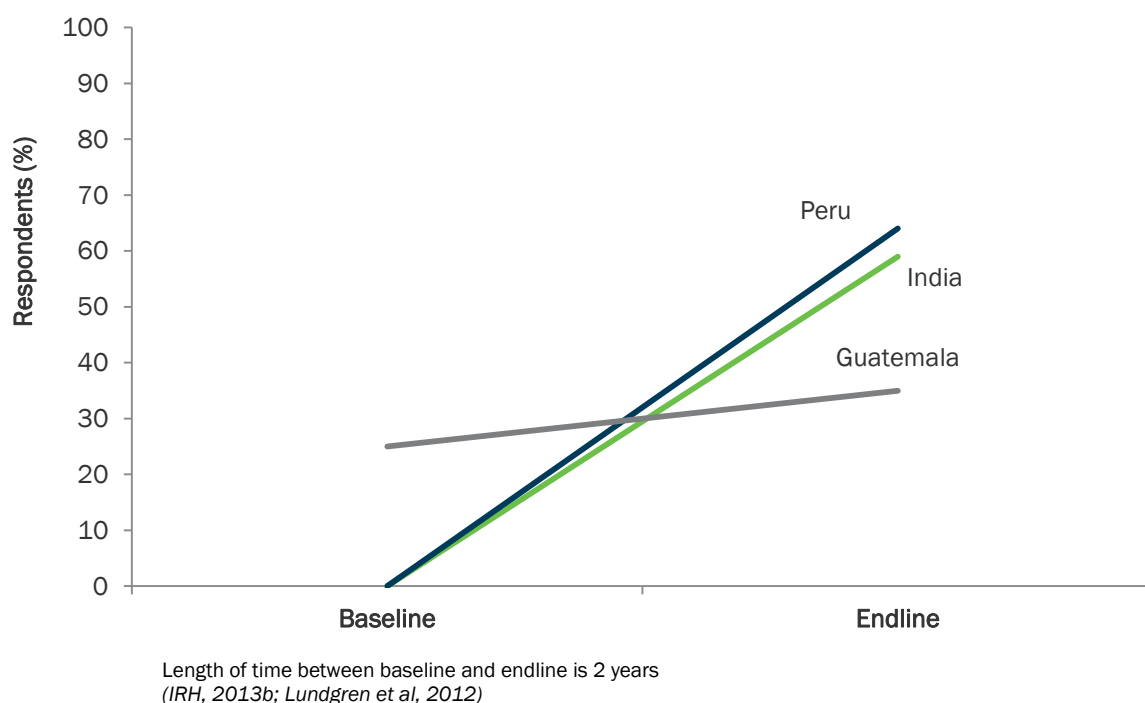
A study using retrospective data in Brazil that examined the potential for SDM use following discontinuation of combined oral contraceptives (COCs) showed that 53 percent of women discontinuing COCs had out-of-range cycles compared to 27 percent in the control group (Arévalo et al. 2010b), suggesting that SDM may not be an appropriate method immediately following discontinuation of hormonal methods, and that potential users should have three consecutive cycles within the 26 to 32 day range for eligibility criteria (Arévalo et al. 2010b).

Knowledge of SDM and other Contraceptive Methods

Ever heard of SDM

Studies measuring changes within communities of those ever hearing of SDM, before and after interventions, found significant increases. In method introduction studies, those who had ever heard of SDM increased from zero to 59 percent at endline in India and from zero to 64 percent at endline in Peru; baseline and endline measurements for scale up studies in Guatemala and India found that ever hearing of SDM increased from 25 percent to 35 percent and from three percent to 49 percent, respectively (see Figure 4) (IRH 2013b, IRH 2013f, Lundgren et al. 2012). The SDM integration study in El Salvador found that many more participants in the intervention area knew about SDM (45% of women and 30% of men) compared to those in the control area (8% of women and 7% of men) (IRH 2013b, Lundgren et al. 2005, Lundgren et al. 2012).

Figure 4. Ever Heard of SDM



Multi-site method introduction studies in India, Peru, and Rwanda found that literate respondents were 1.5 to three times more likely to have heard of SDM than non-literate respondents ($p < .01$) (Lundgren et al. 2012). The same study associated with knowledge of SDM in India and Peru, and that women who worked for money in India and Rwanda were more likely to have heard of SDM ($p < .01$) (Lundgren et al. 2012). SDM knowledge was positively associated with the level of women's education and exposure to the intervention in an OR project testing integration of FP education and community-based SDM services into a water and sanitation project in El Salvador (Lundgren et al. 2005).

In a scale up study in Guatemala, women had greater overall awareness of FP methods following the intervention, and significantly greater awareness of SDM (IRH 2013b). Although SDM awareness increased, it was still lower than other methods, and men's SDM awareness did not increase during scale up (IRH 2013b).

Knowledge of the Fertile Period and Knowledge of Correct Use of SDM

The most common methods for assessing user knowledge of SDM involve identifying how many of six key SDM knowledge items users can name, and asking participants to correctly identify their fertile period using CycleBeads®. The six knowledge items include where to place the ring on CycleBeads® for the first day of menses, marking calendars for menses, moving the ring one bead every day, refraining from unprotected intercourse when the marker is on the white beads, the possibility of unprotected sex when the marker is on colored CycleBeads®, and monitoring cycle length (whether their periods started between darker brown bead and the last bead) (IRH 2013a).

A scale up study in the DRC found that 77 percent of women correctly mentioned at least five of the six required elements for SDM use, while 90 percent of users during the first follow up visit in Benin mentioned at least four (Capo-Chichi and Anastasi 2005, IRH 2013a). Users in Burkina Faso had a mean score of five out of six items spontaneously recalled at a six month follow up; knowledge of how to use SDM exhibited an upward trend among continuing users between follow up interviews (Rawlins et al. 2005).

Using SDM increases knowledge of the reproductive cycle, specifically the fertile period. Knowledge of the fertile period among most women, as measured in the DHS, is low. Among the most recent surveys in countries where SDM was introduced, correct knowledge of the fertile period among periodic abstinence users ranged from four percent in Pakistan to 50 percent in Madagascar, with an average of 25 percent for 21 countries (Measure DHS 2014). In countries where SDM was not introduced, correct knowledge of the fertile period ranged from three percent in Mozambique to 64 percent in Ukraine, with the average among 60 countries at 24 percent (Measure DHS 2014). The SDM introduction study in India shows an increase in the percentage of women understanding the fertile period, from baseline to endline, from zero to 91 percent in the rural setting and from two percent to 67 percent in the urban slum setting (Hossain et al. 2013, Johri, Panwar and Lundgren 2005). A water and sanitation and SDM integration study in El Salvador found that knowledge of the fertile period increased among both men and women due to the SDM intervention, and in a cross-sectional survey in Ethiopia examining SDM's introduction at the community level, 83 percent of women exhibited correct knowledge of the fertile period (Bekele and Fantahun 2012, Monroy, Lundgren and Montano 2003). One DRC study found that current SDM users were better able to identify their fertile period than previous users (IRH 2013a). A SDM study in Albania found that clients demonstrated a high degree of knowledge about use at both first and second follow up visits, but was not significant (Ram and Doracaj N.D.). Data from SDM introduction in Rwanda show that 99 percent of female users and 88 percent of male users could correctly identify the fertile period on CycleBeads® (Blair et al. 2007). Three quarters (75%) of acceptors in Ethiopia could demonstrate what each section of the color coded beads on CycleBeads® represent (Bekele and Fantahun 2012). The scale up study in Mali demonstrated that 75 percent of users could correctly use SDM in that country (IRH 2013d).

Method Use

Reasons for Choosing SDM

Women offered a range of reasons for choosing SDM. Most SDM users cited its lack of health risks or side effects (Bekele and Fantahun 2012; IRH 2013e, Gribble et al. 2008, Kursun, Cali and Sakarya 2014, Rawlins et al. 2005). In studies in Rwanda, India, and Benin, most users said they chose SDM to avoid side effects or health risks. Other reasons for choosing SDM include perceptions that it is effective, simple to use, affordable, does not involve medication, involves partners in FP, and because partners opposed other methods (Blair et al. 2007, Capo-Chichi and Anastasi 2005, Johri,

Panwar and Lundgren 2005). Few women reported religious considerations for choosing SDM (Rawlins et al. 2005). In an SDM scale up study in Guatemala, at endline significantly fewer females in the community, versus at baseline, thought SDM had side effects or caused health problems (IRH 2013b). In Guatemala the percentage of the community who thought SDM was effective increased from 41 to 50 percent at endline, and the percentage who thought SDM was economical increased from 67 to 77 percent by endline (IRH 2013b).

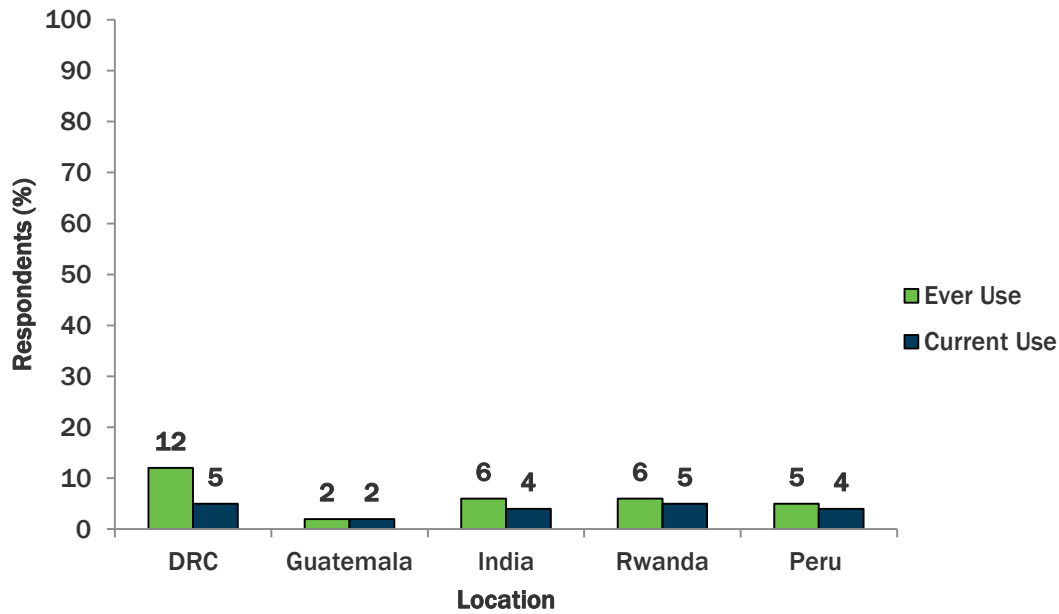
Ever and Current Use

The percentages of women choosing SDM (measured by health facility or service statistics) varied according to intervention sites. In Albania, 30 percent of women at intake health facilities chose SDM, in Guatemala 32 percent of new users chose SDM, and in Rwanda 23 percent of FP acceptors chose SDM during a six month period (compared to 46% choosing injectables and 27% choosing oral contraceptives) (Blair et al. 2007, Ram and Doracaj N.D., Suchi and Batz 2006). In Burkina Faso, 10 percent of new acceptors chose SDM during the enrollment period (Rawlins et al. 2005). In a study with postpartum women in Kenya, those choosing SDM increased from 61 percent at baseline to 67 percent at endline (not significant) (Undie et al. 2012). Method introduction studies in India, Peru, and Rwanda found that new SDM users increased in both experimental and control blocks, in both urban India and Rwanda, while new SDM users increased more in the experimental blocks in rural India and Peru compared to the control groups, while in Rwanda and urban India increases were similar in both groups (Lundgren et al. 2012).

Two studies reported on SDM users as a percentage of total FP acceptors. In Peru, SDM users represented six percent of all FP acceptors, and in a study in Turkey, SDM acceptors represented three percent of all acceptors (Arévalo et al. 2010a, Kursun, Cali and Sakarya 2014). In both studies, SDM was provided through government clinics, and FP acceptors were measured by service statistics (Arévalo et al. 2010a, Kursun, Cali and Sakarya 2014).

Ever having used SDM, at endline or cross-sectional measurements, ranged from six percent of women surveyed in Rwanda and India to 12 percent of all respondents surveyed in the DRC (IRH 2013a, IRH 2013f, Lundgren et al. 2012, Mahmood 2012). All reports of ever using SDM were under 12 percent, with most above five percent (see Figure 5) (Gribble et al. 2008, IRH 2013a, IRH 2013f, Lundgren et al. 2012, Mahmood 2012; Monroy, Lundgren and Montano 2003, Undie et al. 2012). A scale up study in India reported on increases in ever using SDM from baseline to endline, with females surveyed in India (Jharkhand) reporting an increase from zero to six percent at endline (IRH 2013f).

Figure 5. Ever Used and Currently Using SDM*



(IRH, 2013a; IRH, 2013f; Lundgren et al, 2012; Monroy, Lundgren & Montano, 2003)

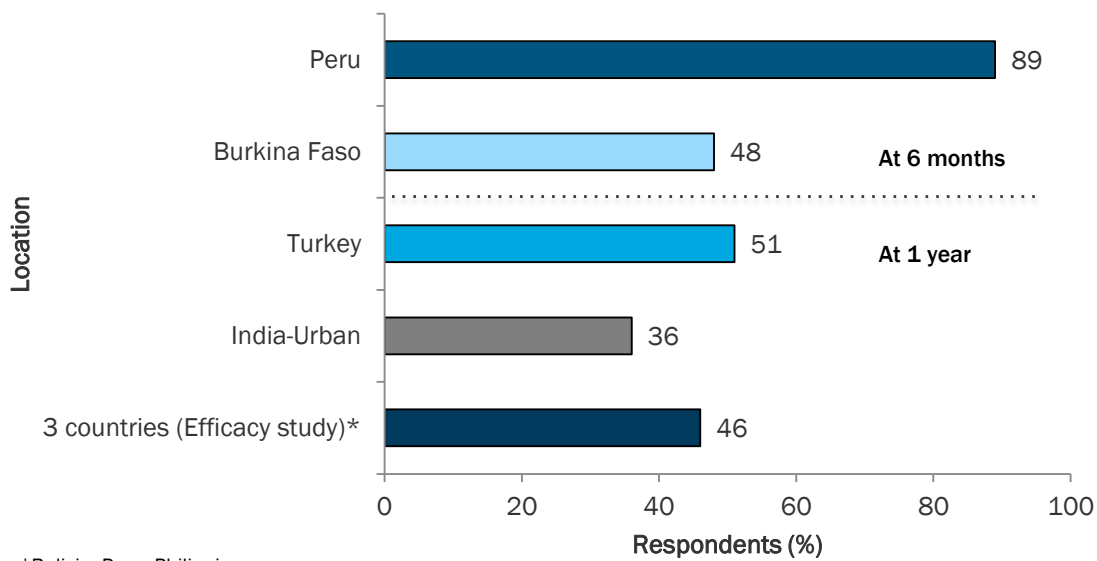
*Data reported in Figure 5 includes most representative sample from each country/study. All data shown here are for female respondents only. Data on current and ever use is additionally available for Kenya (not shown in Figure 5 because only post-partum and married adolescent girls were sampled), Mali (not included here because only baseline data was available), and Pakistan (not included here because LAMA and SDM were measured together. Additionally, a measurement of current use is available for El Salvador (but no ever use).

More studies report current SDM use than ever having used SDM—for example current use was reported in 8 separate sites or samples in India throughout the SDM literature, while ever use was reported in only 4 samples. Figure 5. Current use at endline or cross-sectional measurements ranged from two percent in Guatemala to five percent in Rwanda and the DRC (see Figure 5) (Dosajh, Ghosh and Lundgren 2006, Gribble et al. 2008, Hossain et al. 2013, IRH 2013f, Lundgren et al. 2012, Johri, Panwar and Lundgren 2005). Scale up studies in Guatemala and India reported increases in current use of SDM from zero at both baselines to two percent and four percent, respectively, at endline measurements (IRH 2013f).

Method Continuation

Multi-site and country specific studies on SDM efficacy, effectiveness, method introduction, and long term follow up find that the percentage of SDM acceptors continuing use at six months and one year following initiation range from 36 percent in India to 89 percent in Peru (5 studies other than those shown in Figure 6 report continuation but not measurement duration) (see Figure 6) (Arévalo, Jennings and Sinai 2002; Arévalo and Sinai 2005; Arévalo et al. 2010a; Blair et al. 2007; Dosajh, Ghosh and Lundgren 2006; IRH 2008; Kursun, Cali and Sakarya 2014; Muramutsa 2004; Rawlins et al. 2005; Sinai, Lundgren and Gribble 2012).

Figure 6. SDM Acceptors Continuing Use



*Bolivia, Peru, Philippines
 (Arévalo et al, 2010a; Arévalo, Jennings & Sinai, 2002; Dosajh, Ghosh & Lundgren, 2006; Kursun, Cali & Sakarya, 2014; Rawlins et al, 2005)

In a method introduction study in India continuation was significantly associated with users with more children, over 25 years of age, with prior contraceptive use, and higher levels of male involvement ($p < .05$) (Dosajh, Ghosh and Lundgren 2006, Johri, Panwar and Lundgren 2005).

Separate studies in India, Benin, Rwanda, Turkey, and Ethiopia found that SDM users report high levels of intention to continue SDM for the next year (85% to 100% range with most over 94%) (Bekele and Fantahun 2012, Blair et al. 2007, Capo-Chichi and Anastasi 2005, Dosajh, Ghosh and Lundgren 2006; Johri, Panwar and Lundgren 2005; Kalaca et al. 2005). A large percentage of male SDM users (94%) in Rwanda also reported their intention to continue SDM use for the next year (Blair et al. 2007). Research in Albania was the main outlier, with just 57 percent of SDM users reporting their intention to continue using the method (Ram and Doracaj N.D.).

Reasons for Discontinuation

Women who discontinued SDM provided a range of reasons. Discontinuation or removal from studies was primarily due to out-of-range cycles, although some women continued to use the method regardless of cycle length due to misunderstanding or disregard of instructions (Bekele and Fantahun 2012, Dosajh, Ghosh and Lundgren 2006, Rawlins et al. 2005). Other reported reasons for discontinuation include pregnancy, loss of CycleBeads® or calendars, change in fertility intentions, method distrust, too long duration of fertile period, and spousal dissatisfaction with SDM (IRH 2013a, IRH 2013b, Kursun, Cali and Sakarya 2014, Kalaca et al. 2005, Muramutsa 2004, Sinai, Lundgren and Gribble 2012).

Ease of Use

Studies also found that clients consider the method easy to use. In the SDM method introduction study in Benin 65 percent of early exiters from the study thought that marking their cycle on a calendar and moving the ring on the CycleBeads® was easy (Capo-Chichi and Anastasi 2005). OR in urban and rural sites in India found that 98 percent of couples found the method easy to use (Dosajh, Ghosh and Lundgren 2006). In the method introduction study in Rwanda, 95 percent of

female and 90 percent of male SDM users reported the method easy to use (Muramutsa 2004). Female continuing users in Burkina Faso reported increases in ease of method use between the first and sixth cycles (Rawlins et al. 2005). Data from an SDM method introduction study in Rwanda found that SDM is easy for providers to teach and for clients to learn and correctly use (Blair et al. 2007). Community survey data from the scale up of SDM provision in Guatemala (which included non-users) indicated that 54 percent of women at both baseline and endline—no change—thought SDM was difficult to use (IRH 2013b).

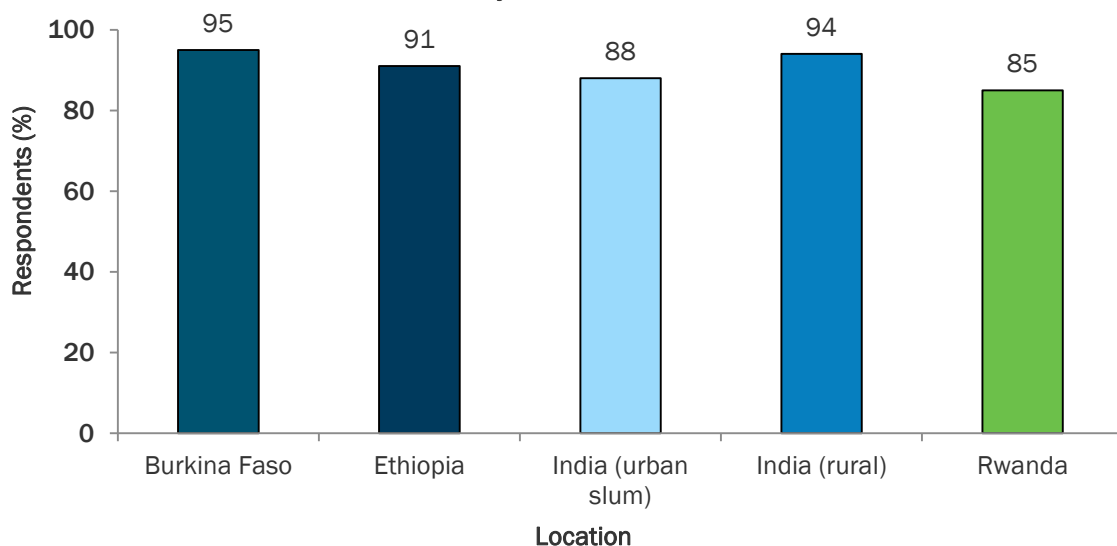
User satisfaction

Most SDM users report high levels of satisfaction, including 93 percent of current and former SDM users in the SDM scale up in the DRC, 90 percent of exiters from the method introduction study in Benin, over 90 percent of OR participants in Burkina Faso, and 47 percent of users in a study in Turkey reported satisfaction with SDM (Capo-Chichi and Anastasi 2005, IRH 2013a, Kalaca et al. 2005, Rawlins et al. 2005). Other studies in El Salvador, Rwanda, and India report high user and couple satisfaction citing ease of use, lack of side effects or health risks, and cost effectiveness (Blair et al. 2007, Das and Nandan 2004, Monroy, Lundgren and Montano 2003). The study in India also found that a reduction in condom use, only necessary during the fertile period, was a source of satisfaction due to condom disposal and storage issues (Das and Nandan 2004).

Correct Use

Overall, correct use of SDM by users was high—correct use was measured by correct placement of the black ring on users’ CycleBeads® at follow up interviews during SDM introduction studies. All studies with information on correct SDM use reported over 85 percent correct use (see Figure 7) (Arévalo, Jennings and Sinai 2002; Bekele and Fantahun 2012; Dosajh, Ghosh and Lundgren 2006; IRH 2008; Johri, Panwar and Lundgren 2005; Rawlins et al. 2005).

Figure 7. SDM Users with Correct Placement of Black Ring on CycleBeads®



(Bekele & Fantahun, 2012; Blair et al, 2007; Capo-Chichi & Anastasi, 2005; Dosajh, Ghosh & Lundgren, 2006; Johri, Panwar, & Lundgren, 2005; Rawlins et al, 2005)

A method introduction study in Benin reports increased correct use, from 84 percent at the first follow up visit to 95 percent at the third (Capo-Chichi and Anastasi 2005). Multiple measurements of

correct use at set intervals may not, however, reflect the fact that users who found SDM difficult may have discontinued prior to subsequent measurements. Social marketing studies in Benin, the DRC, Madagascar, Mali, and Nigeria found that female acceptors of SDM from pharmacists were likely to demonstrate equally high levels of correct use of SDM (92% of pharmacist acceptors and 88% of clinician acceptors) (Kavle, Eber and Lundgren 2012).

In research in Bolivia, Peru, and the Philippines, correct SDM use is associated with prior contraceptive use as well as study location (Sinai et al. 2006). Participants in Peru and the Philippines were significantly less likely to use SDM correctly than participants in Bolivia (significance not reported) (Sinai et al. 2006).

Data from efficacy trials in in Bolivia, Peru, India, and the Philippines reveal that three percent of SDM users had unprotected sex during their fertile periods (Arévalo, Jennings and Sinai 2002; Johri, Panwar and Lundgren 2005; Sinai et al. 2006; Sinai and Arévalo 2006). In Rwanda five percent of female SDM users and 10 percent of male SDM users reported unprotected sex during the fertile period, while one percent had unprotected sex in Ethiopia (Bekele and Fantahun 2012, Blair et al. 2007). A study comparing users obtaining SDM from clinicians to those obtaining it from pharmacists found that 14 percent of clinician-provided SDM users and seven percent of pharmacist-provided SDM users had unprotected sex during the fertile period (Kavle, Eber and Lundgren 2012).

Abstinence or use of barrier methods during the fertile period varied by study site, with intercourse at varying rates throughout fertile periods; most intercourse during the fertile period occurred on the eighth and nineteenth days of women's cycles, days women may perceive as less fertile than other fertile period days (Sinai and Arévalo 2006). Around five percent of couples had protected sex during the fertile period (Arévalo, Jennings and Sinai 2002, Sinai and Arévalo 2006). Long term follow up studies in Bolivia, Peru, and the Philippines found that a decrease in abstinence during the fertile period, from the first follow up to the last follow up visit, coincided with an increase in condom use during the fertile period (Arévalo and Sinai 2005).

Data from efficacy studies in Bolivia, Peru, and the Philippines show that SDM users choosing abstinence during the fertile period are less likely to be literate or have ever used a FP method (Sinai et al. 2006). Women with incomes were less likely to abstain during the fertile period (OR .7), and women with higher housing quality were more likely to abstain than have unprotected intercourse (OR 1.5) (Sinai et al. 2006). Previous contraceptive use significantly increased the odds for using an alternate method during the fertile period (OR 1.98 for previous use of a barrier method and OR 2.03 for withdrawal) (Sinai et al. 2006).

In interviews and FGDs, women reported that it can be difficult to abstain or use protection during their fertile periods if husbands insist on intercourse, and if either has consumed alcohol (Bekele and Fantahun 2012, Blair et al. 2007, Das and Nandan 2004). SDM counseling protocol includes screening for couple communication and support to identify strategies for handling sex during the fertile period. Providers are prompted to also provide counseling on gender-based violence and alcohol consumption, as well as strategies for dealing with these issues during the fertile period, such as sleeping in separate rooms, avoiding alcohol during the fertile period, or having women keep condoms around the house (Blair et al. 2007).

FGD participants in Rwanda discussed strategies for correctly using SDM—placing CycleBeads® in a visible location, working with their partners to make moving the ring collaborative and part of their daily habit, and marking the first day of menstruation on the calendar (Blair et al. 2007). In Rwanda community health workers (CHWs) and users thought that including condoms in the SDM package would help ensure protected intercourse during the fertile period (Muramutsa 2004). Some women do not own a calendar—this issue was resolved during implementation by including a calendar in the

SDM package (a one year calendar was later increased to a four year calendar so clients did not need to return to a facility to continue SDM use) (Bekele and Fantahun 2012, Blair et al. 2007, IRH 2013f).

Partner Participation

SDM use involves both men and women, as active management of the fertile period is essential for method success (IRH 2013a). Many male partners of female acceptors took an active role in helping their partners with using the method, including reminding them to move the ring on CycleBeads®, marking the calendar, and engaging partners in active discussions of avoiding unprotected intercourse on fertile days (Blair et al. 2007, Gribble et al. 2008, Hossain et al. 2013, IRH 2013f, Johri, Panwar and Lundgren 2005, Lundgren et al. 2005). Male involvement varied by country and study sites within countries. In areas where men were given information about SDM, couples were more likely to successfully use SDM, with better cooperation, and better understanding of the fertile period (Das and Nandan 2004, Ujuju et al. 2011). Research in the DRC found that male involvement was essential for successful SDM use (IRH 2013a).

Female SDM users reporting partner participation increased from 42 percent at baseline to 69 percent at endline in the DRC scale up, and from 48 percent at the first follow up visit to 92 percent at the fourth during method introduction in India (decreases in sample size could have skewed the results) (IRH 2013a, Johri, Panwar and Lundgren 2005). In Burkina Faso, however, partner involvement decreased slightly from the first to second follow up, dropping from 90 to 87 percent (Rawlins et al. 2005). In the method introduction study in Benin, 26 percent of couples reported relationship improvements (Capo-Chichi and Anastasi 2005). The El Salvador integration study found that couples discussing FP topics increased significantly following the intervention ($p < .05$) (Monroy, Lundgren and Montano 2003).

From 2001 to 2006, four IRH studies—in El Salvador, Guatemala, India, and the Philippines—specifically tested male engagement strategies for SDM introduction (Lundgren, Cachan and Jennings 2012). In El Salvador, IRH collaborated with Project Concern International (PCI) to include FP content in a water and sanitation program considered “male friendly.” PCI staff and volunteers included men trained to provide counseling and education to groups and in home visits. Men who participated in the intervention had significantly higher levels of knowledge for FP and male fertility (Lundgren, Cachan and Jennings 2012). In Guatemala, SDM was introduced in behavior change communication (BCC) activities designed with male input, to encourage men to support birth spacing, FP use, and participate in SDM with condom use or abstinence. Counselors in this intervention organized male-only educational talks, and female health providers sometimes brought male family members to their health visits (Lundgren, Cachan and Jennings 2012). In India’s Uttar Pradesh, IRH implemented an OR study with CARE that compared a control group in which female volunteers provided FP information to an experimental group in which male and female volunteers both provided counseling and led monthly educational meetings. Both blocks provided counseling to women, men, and couples, and conducted home visits. In the experimental block, incorrect SDM use was lower compared to the control block (.3% versus 2.6%) and pregnancy rates were lower (11.9% versus 18.8%) (Lundgren, Cachan and Jennings 2012). In the Philippines’ Bukidnon province, SDM was introduced to an agricultural group’s ongoing activities, and the feasibility of teaching male group members to use SDM, with supply side interventions, was measured. Utilizing couples and men as SDM counselors was found to be effective, with over 90 percent of SDM users able to correctly explain how to use the method (Lundgren, Cachan and Jennings 2012).

In an extension of the analysis data from the 2004 to 2007 SDM introduction study in India, researchers looked at women’s empowerment measures and a found significant association with the SDM intervention and increased female empowerment—illiterate women in the intervention areas demonstrated significantly more power to decide whether to have children ($p < .001$); all women’s

ability to make decisions about use of their earnings and making visits to relatives and friends significantly increased in the intervention area ($p < .001$); women with CHW visits about FP showed significant increases in decision-making for visits to family or friends and having children compared to women who visited health facilities, who demonstrated no increases in decision-making ($p < .05$) (León et al. 2014).

As part of their evaluation of SDM scale up, IRH employed the Most Significant Change (MSC) method, which employs storytelling and narratives to understand MSCs (positive or negative) associated with an intervention. The MSC method was employed in Guatemala, India, Mali, and Rwanda, and SDM users from its introduction cited their husbands' or partners' FP involvement and their increased communication as MSCs (IRH 2013e).

Users Stating They Would Recommend SDM to Others

Over 90 percent of women in method introduction studies in Benin, El Salvador, and India, and over 70 percent of men in El Salvador and India, stated they would recommend SDM to others (Capo-Chichi and Anastasi 2005, Das and Nandan 2004, Gribble et al. 2008, Johri, Panwar and Lundgren 2005). In India, men reached by a male provider were more likely to say they would recommend the method to others; in the India study an experimental block had both male and female SDM providers, while a control block had only female SDM providers—almost twice as many men in the experimental block reported potentially recommending SDM compared to the control block (Johri, Panwar and Lundgren 2005).

Acceptability of SDM

SDM was generally very acceptable to users and their partners. One study in the DRC found that more than half of SDM users thought the method was effective and acceptable to their partners (IRH 2013a). In a study in Nigeria, researchers found no religious or cultural opposition to SDM use in communities, and users found the method acceptable and effective, particularly when male partners were involved (Ujuju et al. 2011).

The El Salvador study incorporating SDM into water and sanitation programs found significant changes in positive attitudes towards SDM in an endline measurement compared to baseline (significance value not reported) (Lundgren et al. 2005). The increase in positive SDM attitudes over time was greater when compared to the control group, suggesting that the intervention had a significant effect across both experimental and control groups (Lundgren et al. 2005).

Demand for SDM

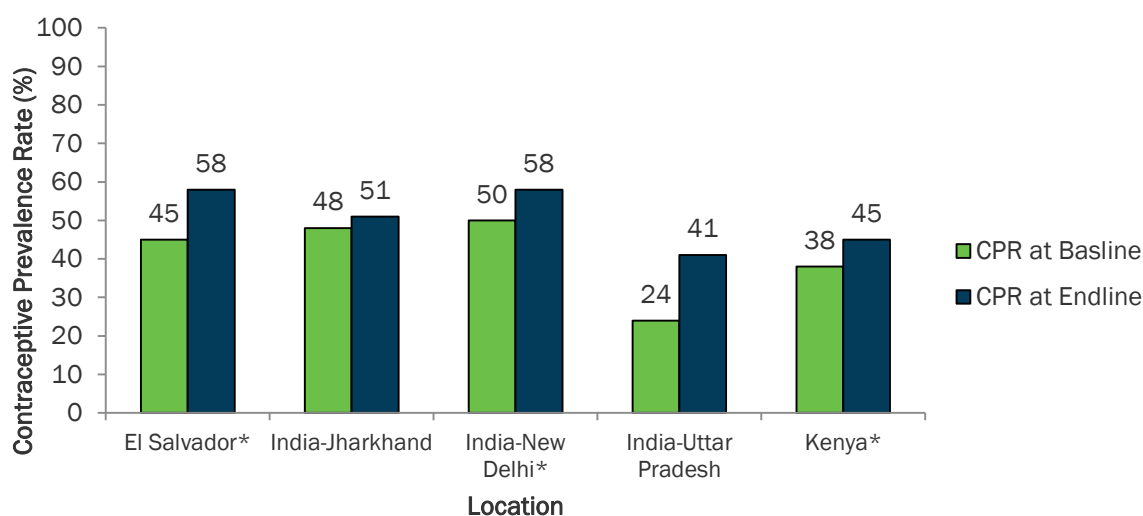
SDM demand was measured in a few countries. Data from SDM's introduction in India, Peru, and Rwanda suggest that SDM demand exists and can increase over time as availability and awareness increase (Lundgren et al. 2012). In Turkey, researchers found that demand for condoms, pills, and intrauterine devices (IUDs) was greater than SDM demand, which was comparable to demand for injectables (Kursun, Cali and Sakarya 2014). The same researchers also found that women were switching from pills and condoms more rapidly than from SDM (Kursun, Cali and Sakarya 2014). Another study in Turkey found that potential SDM demand among women not using any FP method, or using ineffective methods, was as high as 80 percent (Kalaca et al. 2005).

SDM'S EFFECT ON CONTRACEPTIVE PREVALENCE RATE

All SDM study sites measuring and reporting the Contraceptive Prevalence Rate (CPR), at both baseline and endline, showed CPR increases for one to three year periods (not all sites reported measurement durations) (Arévalo et al. 2010a; Brunie et al. 2013; Dosajh, Ghosh and Lundgren 2006; Gribble et al. 2008; Hossain et al. 2013; IRH 2013a; Lundgren et al. 2005; Lundgren et al. 2012; Johri, Panwar and Lundgren 2005; Monroy, Lundgren and Montano 2003; Undie et al. 2012). Three of these sites reported significant CPR increases between measurements (Jharkhand, India; Uttar Pradesh, India; El Salvador) (Gribble et al. 2008, Hossain et al. 2013, Lundgren et al. 2005, Lundgren et al. 2012). Lundgren et al.'s method introduction studies indicate that the SDM intervention may have contributed to Peru's overall FP increase (Lundgren et al. 2012). In India and Rwanda, SDM introduction had no overall effect on new users at clinics, but community results from India show a possible positive effect on CPR (Lundgren et al. 2012).

Method introduction studies in India, Peru, and Rwanda found significant increases in CPR at endline—in the India experimental group (no significant change in control group) and a significant increase in both the experimental and control groups in Peru (significance level not reported) (see Figure 8) (Lundgren et al. 2012). A SDM integration study by PCI in El Salvador experienced a significant increase in CPR following the intervention—from 45 percent at baseline to 58 percent at endline (Lundgren et al. 2005).

Figure 8. CPR Change in SDM Study Sites



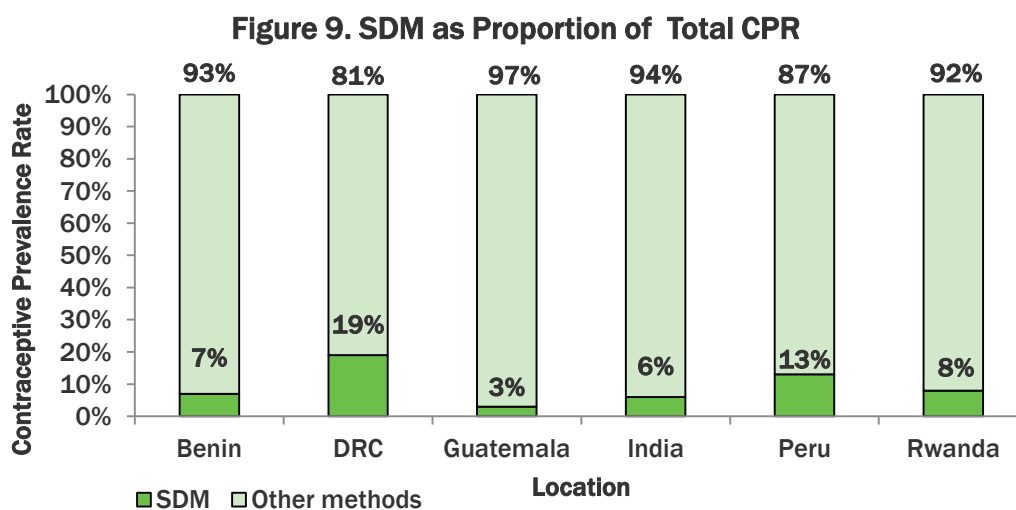
*Indicates significant increase
(Gribble et al, 2008; Lundgren et al, 2012; Monroy, Lundgren & Montano, 2003; Undie et al, 2012)

SDM as a proportion of all methods ranged from three percent in Guatemala to 20 percent in the DRC, when measured cross-sectionally or at endline in the seven study sites reporting on this measure (see Figure 9; note that method introduction research in Rwanda found that SDM accounted for 23% of CPR, however this sample purposively included SDM users) (Brunie et al. 2013, Capo-Chichi and Anastasi 2005, IRH 2013a, IRH 2013b, IRH 2013d, Lundgren et al. 2012, Muramutsa 2004). Scale up studies in Guatemala and India report changes in SDM as a proportion of all methods from baseline to endline: In Guatemala SDM accounted for one percent of all method use at baseline and three percent at endline; in India it accounted for one percent at baseline and six percent at endline (IRH 2013f). Most publications included in this analysis concur that users adopting SDM either switched from less effective methods or had never previously used a FP method;

therefore, SDM introduction does not diminish use of other modern methods (Arévalo et al. 2010a). Table 2 shows pre- and post-SDM intervention FP data from El Salvador and India, which demonstrate that SDM acceptors do not detract from acceptance of other methods—in both India and El Salvador, use of all methods increased following the SDM interventions. Additional studies on contraceptive use dynamics, including SDM, are needed to more fully understand the reasons women choose, discontinue, and switch methods.

Table 2. CPR in El Salvador and India, Pre and Post-SDM Intervention		
	Pre-SDM Intervention	18 Months Post-SDM Introduction
El Salvador, Rural		
CPR	45%	58%
Permanent methods	16%	19%
Birth Spacing Methods	28%	39%
SDM	0%	4%
India, Urban Slums		
CPR	49%	58%
Tubal Ligation	20%	24%
DMPA	<1%	1%
Condom	15%	17%
IUD	5%	5%
SDM	0%	1%
(Project Concern International, 2002; TNS MODE, 2004)		

Figure 9 provides SDM data, as a proportion of CPR, as reported in the reviewed SDM studies. In addition to these studies, beginning in 2003 the DHS began including SDM as a modern method in some national surveys. Table 3 shows SDM ever and current use for all women in selected countries with other modern methods (Measure DHS 2014). SDM use is comparable to female condoms, implants, IUDs, and male sterilization in most countries (Measure DHS 2014). Ever having used SDM was highest in Rwanda in both 2005 and 2007, at one percent, and SDM's current use was highest in Rwanda in 2007, at .3 percent (Measure DHS 2014). The values of SDM as a proportion of total CPRs are lower in DHS data compared to data reported in SDM studies, which is likely due to interventions' effects on SDM uptake in study areas.



Capo-Chichi & Anastasi, 2005; IRH 2013f; Lundgren et al, 2012

Table 3. SDM Use Reported in Demographic Health Surveys, 2003-2013, All Women

	Country	Year	MCPR	Modern Method % Use										Traditional Method % Use
				Female sterilization	Male Sterilization	Pill	IUD	Injectables	Implants	Male Condoms	Female Condoms	SDM	Other**	Traditional Methods
Ever Use	Ethiopia	2005	17.4	0.2	-	8.9	0.4	12.7	0.2	0.9	-	0	0.3	1.9
	Rwanda	2005	15.2	0.3	0	5.6		8		2.6		1	2.7	10.5
	Rwanda	2007	28.5	0.5	0.1	9.7	0.5	16.5	1.2	4.9	0.1	1	3.6	18.7
	Madagascar	2008	40.8	0.9	0.1	17.4	0.7	26	1.6	9	0.1	0.1	9.5	23.9
	Philippines	2003	38.5	6.9	-	25.8	6.4	7.5	-	9.9	-	0.2	4.2	27.3
	Philippines	2008	41.5	6	0.1	28.5	6.1	8.8	-	11.2	0.1	0.3	3	31.3
	Pakistan	2012	47	8.5	0.3	10.5	9.3	13.6	0.2	21.8	-	0.1	10.2	22.8
Current Use	Honduras*	2005	37.7	15	0.1	7.1	4.4	8.6	-	2.3	-	0.1	0.1	5.5
	Rwanda	2005	5.6	0.3	-	1.3	-	2.4	-	0.8	-	0.2	0.6	3.9
	Rwanda	2007	16.3	0.5	0	3.6	0.1	9	0.9	1.4	0	0.2	0.6	7.7
	Rwanda	2010	25.2	0.5	0	3.9	0.2	14.6	3.6	1.8	-	0.3	0.3	3.4
	Madagascar	2008	23	0.9	0.1	4.8	0.3	14.1	1.2	1	0	0	0.8	8.7
	Mali*	2012	9.6	0.1	0	2.6	0.3	3.8	2.4	0.2	0	0.1	0	0.4
	DRC	2013	8.1	0.5	0	0.7	0.1	0.9	0.5	4.6	0.1	0.2	0.4	11.1
	Nigeria	2013	11.1	0.3	-	1.9	0.8	2.5	0.3	4.5	-	0.1	0.8	4.8
	Philippines	2013	23.5	5.4	0.1	11.8	2.2	2.3	-	1.4	-	0.1	0.3	11

*SDM counted as traditional method in DHS in these countries.

** SDM may be recorded in DHS “Other” category on a country-by-country basis.

(Measure DHS, 2014)

OUTCOMES FOR PROVIDERS

Provider's Views on SDM

SDM's acceptance by providers has also been studied. Data from pilot sites in Benin, Ecuador, El Salvador, Honduras, India, and the Philippines indicate that providers have initial biases against fertility awareness methods, but their attitudes toward SDM improved following training and several months of service delivery (Gribble et al. 2008). In FGDs in Rwanda, CHWs stated that they found SDM easy to teach and that it added to their overall knowledge and improved quality of care (Blair et al. 2007). In the same study, CHWs voiced concerns that SDM added to their workloads without additional compensation, although they were interested in continuing to provide it to their communities (Blair et al. 2007). In Nigeria, discussions with providers found that they thought SDM was well accepted as a method with minimal reports of method failure (Ujuju et al. 2011). Comments from providers also reflected dissatisfaction with the restrictions of the eligibility criteria (i.e. cycle length requirement), and some providers refused to provide the method unless acceptors' partners participated in the consultation (20% of providers in Rwanda would not provide SDM without the partner present) (Blair et al. 2007, León et al. 2006). Additionally, some providers expressed concerns about SDM's effectiveness, which underscores the need to emphasize the evidence base during provider training (Kavle et al. 2009). Other providers resisted SDM because they thought clients wouldn't understand the method and that counseling would take too long, despite evidence that clients exhibit high levels of correct use in SDM studies (Kursun, Cali and Sakarya 2014).

SDM Knowledge Among Providers

The most common method for assessing providers' SDM knowledge was evaluating their information exchanges with simulated clients or their knowledge of six core SDM counseling elements. Provider information exchanges were compared—for providers offering pills versus SDM to simulated clients—and clients receiving SDM in Rwanda had an average provider score of 70 percent for information exchange items, while pill clients had an average provider score of 49 percent (León et al. 2006). In Peru SDM information exchange by clinical providers was greater than for the pill or DMPA (León et al. 2007b). Providers in Peru demonstrated acceptable interpersonal skills with SDM clients, and the information exchanged with these clients included most of the essentials of SDM counseling, but provider information exchanges were scored lower than provider interpersonal scores—only 53 percent of relevant knowledge items were addressed by 80 percent or more of providers (León et al. 2007b).

Providers in India and Guatemala exhibited increased knowledge of core SDM knowledge items and CycleBeads® demonstration abilities from baseline to endline (from 80% to 100% in Guatemala on 6 SDM elements, from 61% to 94% on knowledge of screening criteria in India, and from 70% to 92% in India for ability to demonstrate CycleBeads®) (Chhugani, Jha and Caine 2013, Suchi and Batz 2006). A Knowledge Improvement Tool (KIT) evaluation during scale up studies in Guatemala and India found that 88 percent of all providers demonstrated correct CycleBeads® use, 89 percent screened for user eligibility based on in-range cycle length, and 60 percent screened users for their ability to abstain with their partners on fertile days (IRH 2013f).

A method introduction study in Rwanda found that providers had some difficulty providing SDM and had variable correct knowledge of women's eligibility criteria (Muramutsa 2004). Scale up research in Mali showed that 70 percent of all providers correctly instructed women on CycleBeads® use, while 82 percent of midwives provided correct instructions on use (IRH 2013d). Data from Rwanda, India, and Peru demonstrate that provider communications on FP provision was higher for

SDM than the pill (and lower than sterilization), but provider scores on all methods were relatively low (León 2007a). Providers surveyed during IRH’s MSC inquiry reported that SDM increased their FP knowledge and improved their understanding of the menstrual cycle (IRH 2013e).

One study in India revealed that nurses’ knowledge of key SDM counseling points is high, and that nurses represent an essential bridge to community and rural SDM provision in addition to public and private sector provision (Chhugani, Jha and Caine 2013).

Data from method introduction studies in India, Peru, and Rwanda show providers significantly less likely to respond to questions about SDM than to questions about sterilization or pills, but significantly more likely to treat SDM users respectfully compared to pill users ($p < .05$) (Lundgren et al. 2012).

Evidence from multiple sites in east, west, and central Africa reveal trained pharmacists less likely than clinicians to provide spontaneous information on SDM, less likely to tell women when they are ineligible for SDM, while equally likely to show clients the SDM instructional insert (Kavle, Eber and Lundgren 2012).

CHWs in El Salvador were found to be effective in delivering SDM, although they scored lower on SDM knowledge than clinical providers and required more refresher training (Monroy, Lundgren and Montano 2003). CHWs in the method introduction study in Rwanda could name 10 of 23 eligibility requirements for SDM use (Blair et al. 2007).

EVIDENCE ON EXPERIENCES WITH SDM SCALE UP

IRH used the WHO-developed ExpandNet model to guide its scale up in five countries: the DRC, Guatemala, India, Mali, and Rwanda (IRH 2013f). Rwanda and Mali both had the potential for near-national provision of SDM, but Mali’s 2012 military coup truncated scale up activities (IRH 2013f). In the DRC, scale up was limited by poor infrastructure and human resource deficits (IRH 2013f). In Guatemala, SDM was scaled up in USAID’s three focus regions, and in India SDM was scaled up to 50 percent of Jharkhand’s districts with greatest FP need (IRH 2013f). During the course of scale up, several lessons emerged.

MoH and Partner Participation and Support

Consistent government support and involvement facilitated scale up where it occurred (IRH 2013f). In IRH’s five scale up countries, the degree of government interest and involvement was an important factor in explaining the relative success of scale up in each country (Simmons, Ghiron and Fajans 2012).

IRH found that national political support for FP as a development strategy promoted SDM scale up, and mandates for scale up from Ministry of Health (MoH) partners provided scale up initiatives legitimacy (IRH 2013f). Changes in national infrastructure or MoH organization affected SDM integration and provision. In Guatemala, the national social security group incorporated the FP unit within MoH into the maternal and child health unit, diluting FP focus (IRH 2013b). In Mali, the MoH showed consistent, strong support for SDM following their spontaneous adoption of the method—they supported inclusion of SDM in large projects with major institutional partners (IRH 2013d).

To facilitate scale up, the MoH and other key FP stakeholders should be involved in defining and designing the implementation and scale up strategy—this will facilitate strategic planning for scale up later (IRH 2013b). Including the MoH and other key stakeholders early fosters shared values between stakeholders, which can facilitate scale up and generate strong champions who can advocate for SDM scale up and inclusion of the method in national norms, policies, and guidelines (IRH 2013f, IRH 2013a). Planning dissemination and utilization activities with key partners and the MoH can additionally result in acceptance of the method or its evidence by partners, resource leveraging, and strategic implementation and research partnerships (Salguero, Mendoza and Vernon 2005).

IRH's scale up studies found that national government contributions to SDM scale up are vital for creating a commitment to its sustainability, and managing threats and opportunities from shifting policy environments are necessary for managing the scale up process (IRH 2013f). Additionally, supporting public-private partnerships and leveraging them for alternative funding support, implementation partnerships, advocacy, and research support is essential for sustainable scale up (IRH 2013a, IRH 2013f).

Policy Change

SDM's inclusion in norms, policies, guidelines, and training curricula were early gains in vertical scale up in the DRC, Guatemala, India, Mali, and Rwanda (IRH 2013f). In all five countries, the MoH led scale up, which provided legitimacy to activities. In Guatemala, SDM implementers leveraged a re-emergence of FP legislation discussions to promote SDM's inclusion in national guidelines and policies (IRH 2013b). This process relied heavily on key stakeholders' investments in specific interventions and advocacy initiatives (IRH 2013b).

Health System Needs for SDM

A major success from the SDM scale up studies was the use of SDM scale up for strengthening existing health systems. Many of the countries in which IRH worked had weak monitoring and evaluation (M&E), procurement or HMIS systems, non-standardized national protocols, and weak service provision and MoH capacities (Bwazi et al. 201, IRH 2013f, IRH 2013c). By using SDM scale up as an opportunity for strengthening existing health system weaknesses, IRH helped promote SDM while strengthening service delivery, building capacity, and gaining trust and support from country stakeholders (IRH 2013f).

Results from the scale up studies recommend, to achieve sustainable scale up, that implementers need to incorporate SDM into national or regional training curricula, norms, guidelines and policies, as well as expanding the geographic coverage of SDM provision, incorporating it into standard social services programs, and utilizing existing M&E and procurement systems to ensure accurate data and supplies (Das and Nandan 2004, IRH 2013b, IRH 2013c, IRH 2013f, Rawlins et al. 2005). Factors contributing to improved health system readiness for SDM integration include national or decentralized health authorities' involvement in SDM planning and implementation, participatory supervision, ongoing institutional collaboration, and clear definitions of the studies' goals, which all improved SDM uptake and integration (Capo-Chichi and Anastasi 2005).

Procurement and Stock Outs

Procurement of CycleBeads® proved challenging during scale up, with sustainable inclusion of SDM and CycleBeads® in donor procurements a challenge in multiple countries. Although USAID was generally supportive of procuring CycleBeads®—it is included among the commodities its missions

order through the DELIVER mechanism—UNFPA, the other major contraceptive commodity procurement agency, was resistant, as CycleBeads® are not on the list of essential medicines issued by WHO (CycleBeads® are now part of the AccessRH mechanism, and UNFPA will procure them on behalf of a country if it will use its own funds) (IRH 2013a, IRH 2013b). In the DRC, SDM implementers found that raising SDM demand was counter-productive in non-USAID focus zones, where CycleBeads® could not be procured (IRH 2013a). In India, SDM was included in the Jharkhand state registry and procurement systems, but because it was not incorporated in the national procurement and health management information systems (HMIS), CycleBeads® had to be produced by a local organization, to bypass national procurement processes (IRH 2013c). Procurement of essential supplies, such as IEC materials and CycleBeads®, should be integrated into the existing supply chain to ensure aligned procurement models (Igras et al. 2014).

In Guatemala, IRH tested the feasibility of using a paper-based image of CycleBeads® for providing SDM to interested clients. Although findings from this study confirmed that a paper image is acceptable to providers and potential users, with no differences in correct use among CycleBead® users than paper image users, users and providers both prefer CycleBeads® (Kavle and Lundgren 2010). In settings where CycleBeads® are not available or are not affordable, a paper image adapted to the local context appears to be a viable option for providing SDM to interested clients. Initial research testing the feasibility and acceptability of CycleTel™, an mHealth service using text messaging to facilitate SDM use, is underway in India, but evaluation results are not yet available (Puleio and Ettinger 2013).

Few peer-reviewed articles or grey literature report on stock outs of CycleBeads®. Sixteen percent of facilities in the DRC, 80 percent of facilities surveyed in Bolivia, 75 percent of facilities surveyed in Mali, and 38 percent of facilities in Guatemala had CycleBeads® stock outs when interviewed (IRH 2013a, IRH 2013d, Salguero, Mendoza and Vernon 2005, Suchi et al. N.D.). Additional data from a service delivery assessment of SDM scale up in Rwanda found that 88 percent of its facilities had stock outs of CycleBeads®. In 2008, IRH and Rwanda's MoH tackled CycleBeads® stock outs by tasking the DELIVER Project to review existing procurement procedures, institute new procedures to ensure regular supplies, and train health centers and pharmacists on contraceptive re-supply processes. This reorganization and prioritization of procurement processes led to stock outs in only eight percent of facilities during a second service delivery assessment (Igras et al. 2014).

Advocacy is still needed for SDM commodity security and expansion of public-private partnerships—particularly for exemptions for CycleBeads® from commercial VAT or import duties (IRH 2013a, Kavle, Eber and Lundgren 2012).

M&E, HMIS, National Surveys

Routine use of M&E data is essential to understand whether innovations work at scale or allow for triangulation, as well as revealing service provision or supply chain issues that can be corrected (Igras et al. 2014, IRH 2013f, Lundgren et al. 2012). These data allow implementers to understand service delivery experiences and refine and improve its constituencies including trainings, protocols, and materials (IRH 2008). Where possible, SDM should be incorporated into existing M&E systems so data collection efforts are not duplicated.

Scale up studies in the DRC, Guatemala, India, Mali, and Rwanda reveal that integration of SDM in HMIS and national surveys (such as the DHS) proved challenging (IRH 2013f). As seen in Table 2, Rwanda is the only one of the five countries consistently including SDM in its DHS surveys, despite extensive method introduction and scale up in all five. When it is included in the DHS, SDM is not consistently listed as a modern method (such as in Mali and Honduras), which creates a significant

barrier not only to scale up but initial introduction, as FP agendas are based on expanding “modern method” use.

Only one study quantitatively reports provider recording of SDM in the HMIS—in the DRC at midline 78 percent of providers recorded SDM in their registers (IRH 2013a). In the method introduction study in Jharkhand, India, SDM was recorded in local registers but was not included in the national HMIS due to national regulations, and was therefore left out of national reporting (IRH 2013c).

Training

One recurring theme throughout SDM scale up studies was the need for ongoing refresher trainings for providers (Kavle et al. 2009, IRH 2013b, León et al. 2006, Muramutsa 2004, Naik, Suchi and Lundgren 2010, Ram and Doracaj N.D.). Without refresher trainings, provider knowledge dropped below the minimally acceptable 60 percent in Guatemala during an evaluation of the Knowledge Improvement Toolkit (KIT) (Suchi et al. 2008.). Many of the studies also simplified and adapted provider training materials for decentralized or non-clinical providers—this was both to make it easier to train lower level providers and to make it easier for clients to understand the method (Ram and Doracaj N.D., Simmons, Ghiron and Fajans 2012). The KIT developed by IRH was regularly employed by supervisors to ensure high levels of provider competence and counseling quality (Simmons, Ghiron and Fajans 2012, Suchi et al. 2008).

Method introduction and scale up research in India experienced delays in publication of FP curricula including SDM, which was exacerbated by an absence of national prioritization of birth spacing, lack of incentives for SDM integration, and negative attitudes by providers and leaders towards SDM (IRH 2013c). In Mali, IRH and its partners engaged with educational institutions and developed a FP curriculum including SDM intended for implementation in 38 schools in 2012, but which was interrupted by the military coup (IRH 2013d).

Demand Creation and IEC

Multiple studies found that IEC and demand creation activities are integral to promoting SDM uptake (Kavle et al. 2009, Lundgren et al. 2012, Ujuju et al. 2011). During social marketing promotion and training from 2008 to 2010 by Population Services International (PSI) in the DRC, Madagascar, and Mali, demand for CycleBeads® in these three countries rose, while demand decreased in Benin and Nigeria, where promotion and training were not carried out (Kavle, Eber and Lundgren 2012). In Mali, PSI reported that CycleBeads® sales varied from 2007 to 2012 depending on intensity of product promotion; PSI suggested that SDM needs to be introduced in the private sector at the beginning of implementation (IRH 2013d).

In Nigeria, awareness created by district heads and religious leaders in Katsina and Enugu states was essential for SDM’s acceptance within local communities (Ujuju et al. 2011). One of the most successful examples of awareness-raising is a social diffusion activity with leaders of women’s savings and loan groups in Mali (IRH 2013d). This demand creation was supplemented by training networks of religious leaders, encouraging men to support FP use, and providing educational sessions to students (IRH 2013d). Another successful demand creation activity in Rwanda adapted the “Each one invites three” strategy from SanteNet Project’s work in Madagascar, providing FP users with an invitation card to reach non-user friends and neighbors—this outreach showed a 39 percent increase in FP after the campaign, with a slight decrease in the control area (IRH 2013f). In Guatemala, researchers found that using interpersonal communications was the most effective way to recruit new

SDM users, but that the cost associated with maintaining a network of volunteer community promoters was high (Suchi and Batz 2006).

A key recommendation from the scale up studies is promotion of SDM demand and awareness through targeted IEC activities pre-tested with user audiences (IRH 2013b, IRH 2013f). Low SDM awareness outside of implementation areas and differential outcomes of awareness raising campaigns strengthened the conclusion that IEC channels need to be diversified, advocacy and messaging needs to be targeted as well as country-specific, and that shifting to scale up requires heightened demand creation strategies (Das and Nandan 2004, IRH 2013f, Simmons, Ghiron and Fajans 2012).

Counseling and Interpersonal Relations

Effective counseling is a crucial part of SDM provision, as it addresses issues couples may face during the fertile period. Counseling is especially important because learning to use SDM and modifying sexual behaviors does not occur instantaneously (Sinai and Arévalo 2006). Method introduction and scale up studies in seven countries in Africa, Asia, and Latin America found that including condom counseling along with training providers to address gender-based violence, alcohol use, and STI risks improved SDM method use and contributed to better quality of care (Gribble et al. 2008). A study in Turkey found that 15 percent of women selecting SDM did not actually start the method due to partner opposition (Kursun, Cali and Sakarya 2014). It is important to include male partners in counseling where possible, but should not be a requirement for method provision.

Multiple studies found that providers report that the time required for counseling clients on SDM was too long (Bekele and Fantahun 2012, León et al. 2007b, Rawlins et al. 2005, Ram and Doracaj N.D.). In Peru, the average SDM counseling session was 23 minutes, in Rwanda the average was 43 minutes (versus 38 minutes for pill counseling on average), and in Albania and Ethiopia researchers found that individual counseling sessions for SDM users required somewhat more time than other methods (León et al. 2006, León et al. 2007b). Although SDM counseling generally seems to fall into allotted timeframes for counseling within service delivery guidelines, concern about the length of counseling sessions was frequently raised by providers (Dosajh, Ghosh and Lundgren 2006, Gribble et al. 2008, IRH 2013a, León et al. 2007b, Ram and Doracaj N.D., Rawlins et al. 2005).

Cultural and Religious Context

Some studies included religious leaders in SDM outreach activities or asked women whether they had religious motivations for choosing SDM. Most women did not report choosing SDM for religious reasons, and one study in Nigeria found that involving religious leaders contributed significantly to method acceptance (Ujuju et al. 2011). A study in Guatemala, however, found that certain sectors of the Catholic Church opposed SDM because it is not based on checking physical fertility signs and includes the option of barrier method use during fertile days (IRH 2013b). This demonstrates the effect that implementation contexts can have on the success of method introduction—in some study sites religious leaders from various denominations promoted SDM success and uptake, while in other places it hindered its integration (Kavle et al. 2009, Ujuju et al. 2011).

Scale up research in Mali found that strong pro-natalist traditions, relatively low levels of formal education, gender norms limiting discussion of birth spacing, normative gerontocracies, and rumors and myths about contraceptive use inhibited uptake of SDM and other FP methods (IRH 2013d).

Use of Community Health Workers and Male Volunteers

In Guatemala the SDM intervention reached couples unlikely to visit a public sector facility or receive follow up visits and support needed to continue method use (Suchi and Batz 2006). By providing high quality, low cost SDM services at the community level in the local language, this intervention reached women with unmet need who may not have been reached otherwise. Multiple studies in India, Guatemala, Rwanda, and El Salvador found that CHWs, including male outreach workers, were competent and able to provide SDM to their community clients (Blair et al. 2007, Dosajh, Ghosh and Lundgren 2006, IRH 2013c, León et al. 2014, Suchi and Batz 2006). The participation of male volunteers or outreach workers facilitated male community members' involvement and willingness to use FP and SDM in India, and women receiving CHW visits had a significant increase in decision making compared to women who visited health facilities (Johri, Panwar and Lundgren 2005, León et al. 2014). PCI's El Salvador integration project was able to involve male staff who had worked on water and sanitation issues in promoting male FP engagement (Lundgren et al. 2005). Some studies report that CHWs require more supervision and refresher training than their counterparts, however, and two studies report that CHWs felt SDM's addition to their repertoire increased their workload to the point they requested additional compensation (although stating their intention to continue to provide the method regardless) (Dosajh, Ghosh and Lundgren 2006, Muramutsa 2004). Method introduction research in Rwanda found that some CHWs tended to exaggerate SDM's benefits while opposing other FP methods—reinforcing the need to integrate SDM into the existing method mix while providing trainings that incorporate the principles of voluntarism and women's empowerment (Muramutsa 2004).

Role of the Private Sector

A long term follow up study in Benin on SDM's implementation found that private NGO providers were much more successful in recruiting new users than government partners, due to public sector infrastructure and institutional instability including personnel reassignment, administrative barriers, and lack of flexibility and leadership (Capo-Chichi and Anastasi 2005).

A key issue in implementing SDM with private sector partners is providing a business case for SDM's inclusion in the method mix. For example, APROFAM, a private, non-profit service provider in Guatemala, was originally reluctant to integrate SDM within its services because the organization is dependent on fees-for-services, and local awareness and sales were low. APROFAM changed its position following outreach activities, however, and in 2012 included SDM a method offered (IRH 2013b). Disparate evidence exists on the feasibility of pharmacist provision of SDM, from both the financial and quality of care perspectives (IRH 2013a, Kavle, Eber and Lundgren 2012, Muramutsa 2004). Clients and pharmacists in multiple study locations feel that pharmacies are inappropriate venues for SDM provision due to the in-depth counseling required as well as potentially low profit margins for pharmacists (IRH 2013a, Kavle, Eber and Lundgren 2012, Muramutsa 2004). Data comparing pharmacist and clinical provider SDM provision show that pharmacist clients are equally competent with correct use, and women purchasing CycleBeads® at pharmacies are able to understand and use the method as well as their counterparts receiving the method from FP counselors (Kavle, Eber and Lundgren 2012). High levels of correct use among women purchasing CycleBeads® at pharmacies, combined with the finding that there is demand for CycleBeads®, and its affordability compared with oral contraceptives, suggests that pharmacists may be a viable option for expanding service delivery (Kavle, Eber and Lundgren 2012).

Integration with Non-health Programs

One study in El Salvador reveals that SDM and FP could be effectively integrated into water and sanitation service provision. By the project's end, MoH health promoters reported changes in how FP information diffused through communities—it was no longer a taboo topic, and local water boards had included FP meetings in their future work plans (Lundgren et al. 2005). In communities where FP and SDM were introduced in conjunction with water and sanitation issues, community members were much more amenable to FP discussion and involvement (Lundgren et al. 2005).

Research in the Philippines' Bukidnon province demonstrates SDM's effective inclusion within ongoing activities of a local NGO working with subsistence farmers and agrarian reform beneficiaries. This study found that there were positive changes in RH attitudes and intra-spousal communications (Lundgren, Cachan and Jennings 2012).

Cost of Scale Up

Scale up studies found that costs are lower in the initial years of SDM integration, gradually increasing as the method is scaled up (IRH 2013f), with some costs are specifically tied to scale up. The top expenditure categories for SDM scale up include communications, research, M&E, and training (IRH 2013f). While spending varied by country, spending by project partners ranged from 20 to 28 percent, and fixed costs comprised 50 to 60 percent of costs in all countries (IRH 2013f). Variable costs related to communications and training, and depended on contexts and existing health systems where scale up occurred (Rosen, Winfrey and Adesina 2013). Analysis by the Futures Institute found that the cost of scaling up SDM was US \$671,000 in half of India's Jharkhand state over six years, US \$916,000 over 11 years in Guatemala, and US \$2,718,000 USD in Rwanda, over 11 years (Rosen, Winfrey and Adesina 2013). This analysis included direct and indirect costs (Rosen, Winfrey and Adesina 2013).

A cost analysis by the Futures Institute found that the cost per birth averted for SDM (US \$13) was much lower than for other methods (condoms were US \$32, injectables were US \$43, and pills were US \$53) (Kavle, Eber and Lundgren 2012). Cost measures for SDM use decreased the longer the method is used due to the single initial cost of CycleBeads® and single initial counseling session, compared with recurring costs for other methods (Rosen, Winfrey and Adesina 2013).

Training providers is a significant cost with SDM introduction and scale up. To assess the cost-effectiveness of different types of refresher training, providers in a SDM study in Guatemala were randomly assigned to four groups—the groups received individual, group, traditional, or no refresher training, using the Knowledge Improvement Tool (KIT) developed by IRH. Costs for each type of refresher training were assessed per provider—individual KIT refresher training cost was much higher than the group or traditional refresher trainings (\$141 versus \$28 versus \$24) (Naik, Suchi and Lundgren 2010, Suchi et al. 2008). The group with no refresher training scored significantly lower on a test of six core SDM knowledge elements than the other three groups ($p < .01$), and the individual KIT group scored significantly higher compared to the group that received group refresher training ($p < .05$) (Naik, Suchi and Lundgren 2010, Suchi et al. 2008).

Donor Support

Some SDM studies, particularly those conducted during the scale up phase, reported resource constraints related to donor issues and priorities (IRH 2013b). USAID has been the only major donor supporting SDM (although the Bill and Melinda Gates Foundation recently provided initial support for pilot efforts in two countries). IRH reports that global donor focus on long-acting methods and emphasis on increasing CPR send mixed messages about prioritizing SDM scale up and inhibits its integration and scale up (IRH 2013d). Ongoing commodity procurement will also likely require donor support in most countries, at least until countries have sufficient experience with SDM to include CycleBeads® in their own procurement systems (Kavle, Eber and Lundgren 2012).

Conclusions

SDM has been well studied, and its use has expanded considerably given it was established as a modern method in 2000 and its efficacy trial results were published in 2002. As the method moves from projects directly supporting its scale up to general method mixes supported by numerous countries, donors, and organizations, it is important to explore the evidence generated about the method. The SDM evidence base spanning a decade and a half provides ample data on topics ranging from its efficacy and effectiveness to its scale up. The review of this evidence results in the following conclusions:

SDM is established in some countries with its use commensurate with FP methods available for much longer. Where introduced, SDM use, while still low, is commensurate with methods available in those countries for decades. Constraints appear to result from policies and systems than from lack of demand.

SDM appeals to distinct groups of women with unmet FP need. Women who are new to FP use, those who desire non-hormonal methods without side effects, and those transitioning from less effective methods are those who are most likely to use SDM. The expansion of SDM into FP programs presents an opportunity to meet these women's needs.

SDM's correct use efficacy rates and typical use effectiveness rates are similar to other modern methods of contraception. Several studies demonstrate a rate of 95 percent for SDM with its correct use, and effectiveness of 88 percent with typical use. These rates are comparable with other modern, user-dependent FP methods.

Most women who use SDM find it fairly easy to use and are satisfied with the method, and rates of correct use of SDM by users are high.

SDM increases general knowledge of women's fertile period of ovulation. Given the very low knowledge most people have about women's fertile period, this aspect of SDM is highly appealing. Expansion of the method to younger adults could provide young women with the information they need to understand their menstrual cycles and fertility, while providing them with a lifelong alternative method of contraception.

SDM promotes male engagement in family planning. SDM involves both men and women, as active management of the fertile period is essential for method success. While male engagement varies by country, men tend to be active partners in SDM use.

SDM can be offered by a range of public, private, and NGO providers who are trained in its provision. Community health workers and male volunteers were both found competent and effective at providing SDM. Women who purchased CycleBeads® from pharmacists exhibited high levels of correct use. Expansion of community-based provision as well as the cadres of providers offering SDM will allow greater accessibility for the method.

Recommendations

Scale up of SDM requires attention to a number of issues:

- Establishing stakeholder investment, particularly by governments and Ministries of Health, is critical to the success of SDM scale up.
- Early introduction of SDM within policies, guidelines, norms, and curricula, can help to ensure its scale up is strategic and sustainable. It is essential to incorporate SDM into national or sub-national HMIS, procurement, and training systems as early as possible.
- Regular supportive supervision and refresher trainings for providers should address issues related to the understanding eligibility criteria and provider biases against SDM.
- Incorporation of private-public partnerships early in the scale up process will leverage resources, build demand creation, and enhance service delivery.

In addition to the factors related to scale up, particular attention is needed to address:

Procurement and availability of CycleBeads®. Procurement has remained an issue both globally and in specific countries. In scale up countries, not all donors included SDM in their procurement lists, making it difficult to provide SDM in all countries. At least one scale up country, India, has not included SDM on the national procurement list, making state level scale up extremely difficult.

Agreement that SDM is a modern method of contraception. The efficacy trial of SDM established it as a modern method of contraception, but not all organizations and countries recognize it. Given the current FP2020 emphasis on the modern contraceptive prevalence rate (MCPR), it is important for the global community to agree on SDM's designation as a modern method of contraception. SDM meets numerous criteria for a modern method: it is based on a thorough understanding of reproductive biology, has criteria and protocols for correct use, and has been rigorously tested to assess efficacy and effectiveness in various conditions (IRH 2012). Global consensus on what constitutes a modern method has not been achieved, and additional work will be needed to resolve this definitional issue. Without the “modern” designation, SDM will fail to be included in national family planning strategies as countries work to achieve increases in MCPR.

Measurement of SDM in HMIS and national surveys. Currently, SDM is not included in most HMIS or many national surveys. To measure the use of this method, it is crucial that HMIS and national surveys include SDM. In addition, it is critical that SDM be identified as a “modern method.” Failure will continue countries' decisions to not to include it in their programming as they focus on increasing modern method use.

Expanding the cadres of SDM providers. To continue sustainable introduction and scale up of SDM, improving existing evidence that CHWs can effectively provide the method to clients is necessary. Expanding community outreach, including male outreach workers, will encourage uptake of SDM and reach couples who may not be reached by the traditional health system.

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Appendix 1: Search String and Data Abstraction for Structured Review of SDM

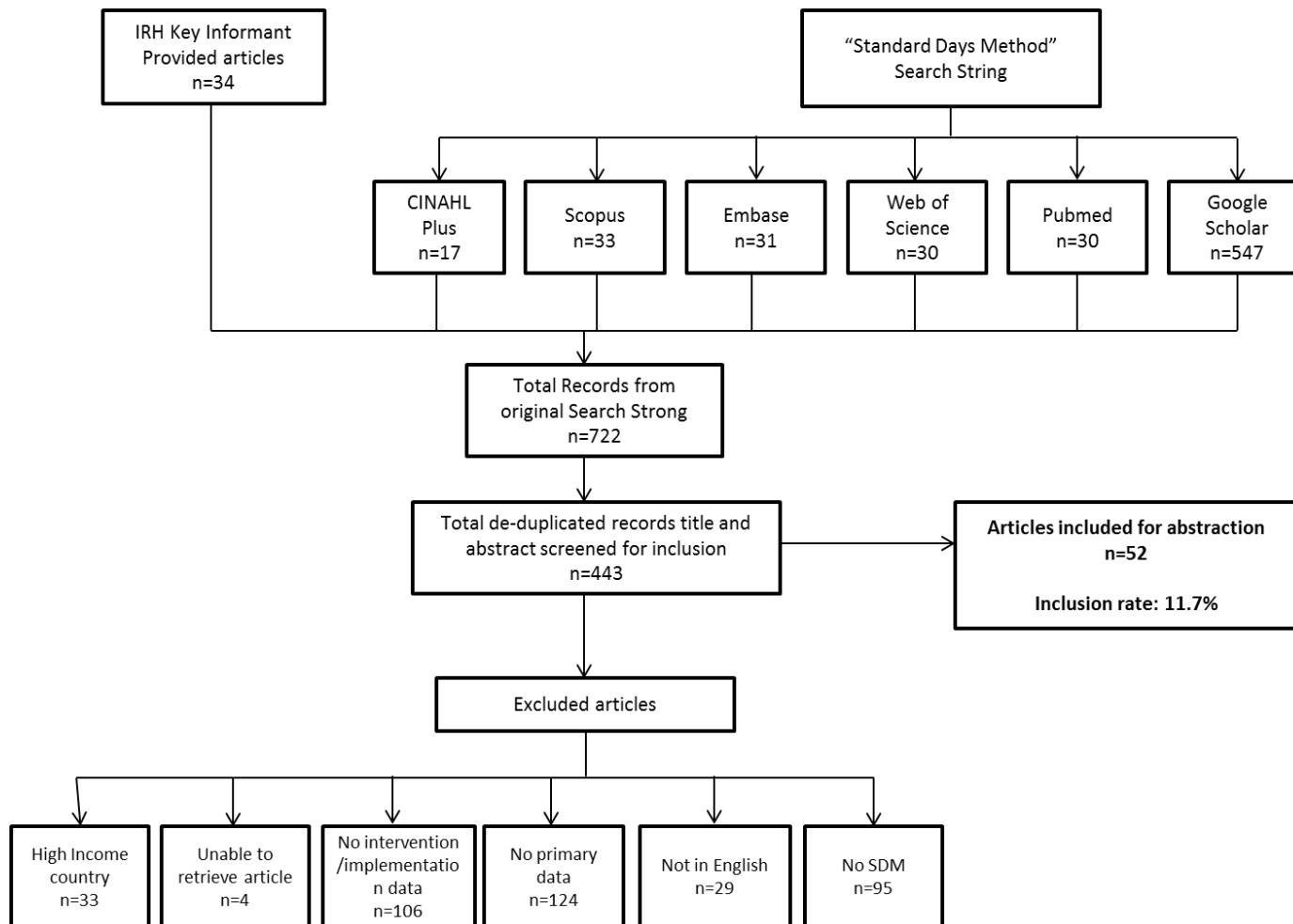
A structured search of peer-reviewed literature on the Standard Days Method (SDM) was undertaken in five databases (CINAHL, Embase, Pubmed, SCOPUS, and Web of Science). An additional search for grey literature was undertaken using Google Scholar and additional literature was provided by the Institute for Reproductive Health (IRH), the key implementing organization for SDM studies. The search strategy consisted of the phrase “Standard Days Method”, as this contraceptive method is trademarked and rarely occurs in the literature under an alternative name. To test this assumption, the search term “CycleBeads®”(the main commodity associated with SDM) was also searched, with all of the search hits being duplicates of the original “Standard Days Method” search string.

The initial search yielded 443 unique references. Title and abstract screening were conducted on these peer-reviewed articles or grey literature reports and literature was included where all of the following criteria were met: 1) peer-reviewed articles or grey literature reports were in English, 2) SDM interventions, studies or evaluations were located in low or middle income countries (LMIC) 3) SDM was included in the intervention or study, 4) the study or intervention referenced primary data, and 5) the intervention or study had to be a study (i.e. not an op ed.) and had to report on outcomes or scale-up processes. Based on these criteria, 52 of the 443 references were included in this structured review of SDM. Approximately half of the included studies were peer reviewed (52%) and half were grey literature (48%), consisting primarily of project and operations research reports.

The 52 references included were abstracted for relevant data related to the intervention, study design, intervention population, provider type, implementing organizations, relevant implementation and scale-up information, and for key outcomes. All study designs were included—no restrictions were placed on the methods or rigor utilized in the included studies. Studies that mentioned outcomes related to Natural Family Planning (NFP) methods, the Two Days Method (TDM), or other family planning methods without explicit mention or disaggregation of SDM in the reported outcomes were not included. The breakdown of literature/interventions by study design can be seen in Appendix N. All included studies reported on at least one of the following outcome measures:

- Efficacy and effectiveness of SDM
- Acceptability about SDM
- Knowledge of SDM
- Demand for SDM
- Use of SDM
- Provider outcomes
- Service delivery characteristics for SDM
- Costs or cost effectiveness of SDM implementation

SDM SEARCH STRING AND REVIEW STRUCTURE



Appendix 2: Table of Included Studies

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
The acceptability and feasibility of introducing the Standard Days Method (SDM) of family planning in reproductive health clinics in Burkina Faso West Africa. Final report	A. Bicaba, B. Rawlins, R. Dineen and B. Ouedraogo	2005	Burkina Faso	Grey Literature	May 2003-January 2004	SDM users (n=79) Male partners (n=17) Trained health care providers (n=14) New FP clients who declined the SDM (n=30)
Adding the Standard Days Method® to the contraceptive method mix in a high-prevalence setting in Peru	M. Arévalo, B. Yeager, I. Sinai, R. Panfichi and V. Jennings	2010	Peru	Peer reviewed	March 2004 –June 2004	n=1200 n=866 for life table analysis of effectiveness
Assessing the effect of introducing a new method into family planning programs in India, Peru, and Rwanda	R. Lundgren, I. Sinai, P. Jha, M. Mukabatsinda, L. Sacieta and F. R. León	2012	India, Peru, Rwanda	Peer reviewed	Baseline: India: December 2004 Peru: January-March 2005 Rwanda: n/a Endline: India: Nov 2006-January 2007; October-November 2007 Peru: November 2006-February 2007 Rwanda: October 2006	n > 3400 women at endline
Being strategic about contraceptive introduction: the experience of the Standard Days Method®	J. N. Gribble, R. I. Lundgren, C. Velasquez and E. E. Anastasi	2008	Benin, Ecuador, El Salvador, Honduras, India, Philippines	Peer reviewed	not stated	SDM acceptors (n=1646)
Birth spacing and family planning uptake in Pakistan: evidence from FALAH	A. Mahmood	2012	Pakistan	Grey Literature	Baseline: 2008–09 Endline: 2011–12	Baseline: 10,604 MWRA, 2,784 married men Endline: 12,402 MWRA, 2,649 married men

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
Challenging the courtesy bias interpretation of favorable clients' perceptions of family planning delivery	F. R. León, R. Lundgren, A. Huapaya, I. Sinai and V. Jennings	2007	India, Peru, Rwanda	Peer reviewed	October 2004-January 2005	Average number of visits by simulated clients ranged from 18.3 to 30
Continued use of the Standard Days Method	I. Sinai, R. I. Lundgren and J. N. Gribble	2012	Benin, Bolivia, Ecuador, Honduras, India (two sites) Peru Philippines,	Peer reviewed	2000-2006	Efficacy Study (n=478) Method Introduction studies (n=1181)
The cost effectiveness of Standard Days Method refresher trainings using the Knowledge Improvement Tool in Guatemala	T. Suchi, F. Karim, J. Marcus and S. Naik	2008	Guatemala	Grey Literature	2004	Providers (n=80)
Costing the Standard Days Method: The cost of integrating the Standard Days Method (SDM) into family planning programs at scale and of providing the SDM in routine service delivery in Guatemala India and Rwanda	J. Rosen, B. Winfrey and A. Adesina	2013	Guatemala, India, Rwanda	Grey Literature	Guatemala: 2003-2013 India (Jharkhand): 2007-2013 Rwanda: 2003-2013	N/A
Cultivating men's interest in family planning in rural El Salvador	R. I. Lundgren, J. N. Gribble, M. E. Greene, G. E. Emrick and M. de Monroy	2005	El Salvador	Peer reviewed	2001-2002	Baseline (n=341 (men and women)) Follow-up (n=364 (men and women))
Efficacy of a new method of family planning: the Standard Days Method	M. Arevalo, V. Jennings and I. Sinai	2002	Bolivia, Peru, Philippines	Peer reviewed	Not Reported	n=478
Expanding family planning options: offering the Standard Days Method to women in Istanbul	S. Kalaca, D. Cebeci, S. Cali, I. Sinai, M. Karavus and V. Jennings	2005	Turkey	Peer reviewed	May and June 2001	Couples offered SDM (n=657) Eligible women (n=346) Female Acceptors (n=132)

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
Feasibility of incorporating the standard days method into CASP family planning services in urban slums of India	U. Dosajh, I. Ghosh and R. Lundgren	2006	India (Sangam Vihar-urban slum in New Delhi)	Grey Literature	April 2001-September 2003	Household survey of in-union women, 13-49, baseline (n=15,437) Household survey of in-union women, 13-49, endline (n=14,826) Baseline: unclear sample size Providers at baseline (n=66) Providers at endline (n=28) SDM Acceptors (n=230)
Fertility awareness-based methods of family planning: predictors of correct use	I. Sinai, R. Lundgren, M. Arevalo and V. Jennings	2006	Bolivia, Peru, Philippines	Peer reviewed	Not Reported	SDM Acceptors (n=478) TDM Acceptors (n=450)
A fixed formula to define the fertile window of the menstrual cycle as the basis of a simple method of natural family planning	M. Arévalo, I. Sinai and V. Jennings	1999	Global	Peer reviewed	Not Reported	Menstrual Cycles (n=7600)
Four criteria to evaluate providers' service-delivery response to new contraceptive introduction	F. R. León, M. Arevalo, R. Lundgren, V. Jennings, A. Huapaya and R. Panfichi	2007	Peru	Peer reviewed	2004-2005	Facilities (n=62)
Implications of cycle length immediately after discontinuation of combined oral contraceptives on use of the Standard Days Method	M. Arévalo, I. Sinai, B. Olivotti and L. Bahamondes	2010	Brazil	Peer reviewed	1979-2006	Women (n=2,845)
The importance of screening and monitoring: the Standard Days Method and cycle regularity	I. Sinai, V. Jennings and M. Arevalo	2004	Global	Peer reviewed	Not Reported	WHO Ovulation Trial (n=726) SDM Acceptors (n=478)

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
India: Introducing the Standard Days Method in urban and rural sites	M. Hossain, J. Fullerton, N. Piet-Pelon, W. Trayfors, S. Wilcox, T. Osteria, A. Martin, R. Vernon, D. Mansour and M. Mueller	2013	India	Grey Literature	2001-2003	Rural (n=482) Urban (n=285)
Introducing a natural family planning method in Albania	S. Ram and D. Doracaj	N.D.	Albania	Grey Literature	2003-2008	Clients (n=254)
El Salvador: Introducing the Standard Days Method into Community-Based Programs	M. Monroy, R. Lundgren and G. Montano	2003	El Salvador	Grey Literature	2001-2002	SDM Acceptors, 18-35 (n=143) Baseline survey (men and women) (n=341) Endline survey (men and women), (n=364)
Introducing the standard days method: expanding family planning options in Rwanda	C. Blair, I. Sinai, M. Mukabatsinda and F. Muramutsa	2007	Rwanda	Peer Reviewed	2002-2003	SDM Users (n=121) Partners of SDM users (n=51)
Introduction of the Standard Days Method in CARE-Indias community-based reproductive health programs	L. Johri, D. Panwar and R. Lundgren	2005	India	Grey Literature	May 2001-August 2003	SDM Acceptors (n=482) Baseline Community Census (n=1,009) Eendline Community Census (n=1,000)
Introduction of the Standard Days Method of family planning into reproductive health programs in Benin West Africa	V. Capo-Chichi and E. Anastasi	2005	Benin	Grey Literature	2002-2003	Couples (n=219)
It's all in the timing: coital frequency and fertility awareness-based methods of family planning	I. Sinai and M. Arévalo	2006	Bolivia, Peru, Philippines	Peer Reviewed	Not Reported	SDM Acceptors (n=478) TDM Acceptors (n=450)
Long-term use of the SDM following the efficacy study. Final report	M. Arevalo and I. Sinai	2005	Bolivia, Peru, Philippines	Grey Literature	Not Reported	n=197
Nurses bring new family planning methods to communities: Standard Days Method and Lactational Amenorrhea Method	M. Chugani, P. Jha and K. L. Caine	2013	India	Peer Reviewed	Not Reported	n=170

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
Options for maintaining quality family planning counseling: strategies for refresher training	S. Naik, T. Suchi and R. Lundgren	2010	Guatemala	Peer Reviewed	2004	Providers (n=80)
The Potential for Social Marketing a Knowledge-Based Family Planning Method	J. Kavle, M. Eber and R. Lundgren	2012	Benin, DRC, Madagascar, Mali, Nigeria	Peer Reviewed	Not Reported	Clinicians (n=82) Pharmacists (n=84) SDM acceptors (n=212)
Qualitative assessment of the incorporation of the Standard Days Method into a community-based program in Sitapur: a focus on male involvement	U. Das and D. Nandan	2004	India	Grey Literature	April 2004	FGDs (n=8) IDIs (n=26)
Quality of delivery of the Standard Days Method as compared with contraceptive pills in Rwanda	F. R. León, C. Blair, A. Huapaya, R. Lundgren, M. Mukabatsinda, F. Muramutsa and V. Jennings	2006	Rwanda	Peer Reviewed	2005	SDM Users, men and women: (n=113) Providers (n=12)
Religion, culture and male involvement in the use of the Standard Days Method: evidence from Enugu and Katsina states of Nigeria*	C. Ujuju, J. Anyanti, S. Adebayo, F. Muhammad, O. Oluigbo and A. Gofwan	2011	Nigeria	Peer Reviewed	Not Reported	FGDs (n=113) IDIs (n=12)
Scaling Up the Standard Days Method® of Family Planning in Five Countries	R. Simmons, L. Ghiron and P. Fajans	2012	DRC, Guatemala, India, Mali, Rwanda	Grey Literature	2007-2013	Sample Size Unclear
Social Marketing CycleBeads®: An Innovative Solution to Unmet Need in the Philippines	J. Kavle, C. Blair, J. S. Dacanay III, R. Lundgren and V. Jennings	2009	Philippines	Grey Literature	2000	SDM Acceptors (n=78) Couple Educators (n=12) Male Educators (n=12) Information Campaign Study (n=1,016)
The Standard Days Method((R)): efficacy, satisfaction and demand at regular family planning service delivery settings in Turkey	Z. Kursun, S. Cali and S. Sakarya	2014	Turkey	Peer Reviewed	2006-2008	FP Acceptors (n=993)

Title	Author	Year of publication	Country/ Countries	Peer reviewed/ Grey Lit	Research dates	Sample Size
The Standard Days Method: an addition to the arsenal of family planning method choice in Ethiopia	B. Bekele and M. Fantahun	2012	Ethiopia	Peer Reviewed	December 2007 to June 2008	n=184
Strengthening services and increasing access to the Standard Days Method in the Guatemala Highlands. Washington, DC: Georgetown University	T. Suchi and B. Batz	2006	Guatemala	Grey Literature	2002	Standard service delivery statistics; Sample size not reported
Utilization of Postpartum Family Planning Services between Six and Twelve Months of Delivery at Ntchisi District Hospital, Malawi	C. Bwazi, A. Maluwa, A. Chimwaza and M. Pindani	2014	Malawi	Peer Reviewed	2011	Women (n=383)
Long-Term Use of Standard Days Method®: Experience of Operations Research Study Participants	IRH	2008	Benin, Ecuador, Honduras, India	Grey Literature	Not Reported	SDM Acceptors (n=1181)
Systems approach to monitoring and evaluation guides scale-up of the Standard Days Method of Family planning in Rwanda	S. Igras, I. Sinai, M. Mukabatsinda, F. Ngabo, V. Jennings and R. Lundgren	2014	Rwanda	Peer Reviewed	Not Reported	Sample size unclear
The Use-Effectiveness of the Combined Contraceptive methods: Standard Days Method, Condom, and Emergency Contraceptive Pills	A. Mohammadpourasl	2007	Iran	Peer Reviewed	Not Reported	Women (n=240)
Scale-Up of the Standard Days Method® (SDM) in DR Congo	IRH	2013	DRC	Grey Literature	2003-2012	Midterm survey, providers (n=154) Endline household survey (n=2,397)
Scale-Up of the Standard Days Method® (SDM) in Guatemala	IRH	2013	Guatemala	Grey Literature	2002-2012	Baseline women (n=504) Endline women (n=477) Baseline Facilities (n=32) Endline Facilities (n=52)
Scale-Up of the Standard Days Method® (SDM) in India	IRH	2013	India	Grey Literature	2001-2013	Baseline, women and men (n=2,245) Endline, women and men (n=3,441) Baseline, facilities (n=109) Endline, facilities (n=176) Providers (n=2,500) KIT Evaluation (Providers) (n=81)

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Scale-Up of the Standard Days Method® (SDM) in Mali	IRH	2013	Mali	Grey Literature	2007-2012	IDIs (n=9) Service Statistics (n>350,000) Household surveys (n not reported)
Using Most Significant Change Methodology to Evaluate Impact of a Health Innovation in Four Countries	IRH	2013	Guatemala, Mali, Rwanda, India (Jharkhand)	Grey Literature	2010-2011	MSC Interviews (n=155)
Promising Practices for Scale-Up: A Prospective Case Study of Standard Days Method® Integration	IRH	2013	DRC, Guatemala, India, Mali, Rwanda	Grey Literature	2007-2012	DRC (n=1,200) Guatemala (n=504) India, Jharkhand (n=1,809) Rwanda (n=400)
Getting to 70%: Barriers to modern contraceptive use for women in Rwanda	A. Brunie, E. E. Tolley, F. Ngabo, J. Wesson and M. Chen	2013	Rwanda	Peer reviewed	2009-2010	Survey (n=637) IDIs (n=81)
Expanding access to comprehensive reproductive health and HIV information and services for married adolescent girls in Nyanza Province	C.C. Undie, H. Birungi, F. Obare, B. Ochieng, W. Liambila, E. Oweya, I. Askew, R. Burnet, B. Deacon and A. Mohamed	2012	Kenya	Grey Literature	2009-2011	Baseline, married adolescent girls (n=472) Baseline, partners of married adolescent girls (n=235) Endline, married adolescent girls (n=485) Endline, partners of married adolescent girls (n=202)
Cross-cultural Adaptation of Reproductive Health Services in Bolivia	M. A. M. F. G. Salguero, R. P. Mendoza and R. Vernon	2005	Bolivia	Grey Literature	2004	15 Service providers, 46 observed consultations, Exit interviews with clients (n not given)
Mid-term Assessment of the Standard Days Method (SDM) Introduction in Rwanda	F. Muramutsa	2004	Rwanda	Grey Literature	2002-2004	FGDs (n=275) IDIs (n=233)
Increasing literate and illiterate women's met need for contraception via empowerment: a quasi-experiment in rural India	F. León, R. Lundgren, I. Sinai, R. Sinha, and V. Jennings	2014	India	Peer reviewed	2004-2007	n=1755