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Original research article

Does the evidence support global promotion of the calendar-based Standard Days Method[®] of contraception?

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Abstract

Objectives: To scrutinise claims about the effectiveness of the Standard Days Method[®] (SDM). The SDM is a calendar method with similarities to the rhythm method that has now been reclassified and is marketed as a modern contraceptive method. As promoted, it requires users to avoid unprotected intercourse on days 8–19 of the menstrual cycle. It is used in at least 100 countries. SDM has been researched, developed, and is marketed by the Institute of Reproductive Health (IRH) at Georgetown University, USA, and a for-profit company Cycle Technologies. SDM proponents say it is a major advance on traditional periodic abstinence, claiming that it is 95% effective when used correctly — rivalling pills and condoms. The effectiveness claim is repeated in recent documents from the World Health Organization.

Study design: Evaluation of evidence obtained via literature review of published and unpublished reports.

Results: Claims made for SDM effectiveness appear to rely on a single efficacy study where “correct use” of SDM was defined as total abstinence from intercourse in cycle days 8–19. It may therefore be misleading to apply a 95% effectiveness figure from the study to SDM as promoted, where abstinence is not required. Moreover, “typical use” effectiveness figures, cited as 88%, are based on an unrepresentative sample of women using SDM in ways likely to vary from how SDM is used in practice.

Conclusion: Existing evidence does not support claims that the effectiveness of SDM as promoted is comparable to the best short-acting modern contraceptive methods. SDM is promoted in ways that may mislead users, by quoting overestimates of effectiveness and providing efficacy comparisons only with selected methods of contraception. Users should be provided with full and accurate information to make contraceptive choices.

Implications: Use, delivery and promotion of SDM should be reevaluated. Meanwhile, SDM should only be offered to family planning clients as an adaptation of traditional periodic abstinence methods, requiring total abstinence in fertile days — reflecting “correct use” in the efficacy study — to achieve high effectiveness. Delivery of any form of SDM should include presentation of the full range of other contraceptive methods, including the most effective options.

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Keywords: Standard days method; Rhythm method; Periodic abstinence; Efficacy; Effectiveness

1. Introduction

The Standard Days Method[®] (SDM) is a calendar method with similarities to the rhythm method that is marketed as a modern contraceptive method. It is used in at least 100 predominantly low- and middle-income countries [1,13]. Claims for the method are eye catching: its proponents claim

95% effectiveness when used correctly [1,2], rivalling better-known, short-acting contraceptives such as oral pills or condoms [3], and representing “a major improvement” over traditional periodic abstinence methods (p.13) [2]. Periodic abstinence is estimated to be between 76 and 83% effective with typical use [4,5].

The SDM as promoted uses a proprietary CycleBeads[®] necklace of coloured beads to help women track their menstrual cycles, with white beads representing days to avoid coitus or use back-up methods (Fig. 1). Women who have cycles of 26 to 32 days use it by passing a rubber ring

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Fig. 1. Cyclebeads®.

over one bead each day, with white beads representing predicted fertile days 8–19 (12 days).¹

The SDM has been researched, developed, promoted and marketed through the Institute of Reproductive Health (IRH) at Georgetown University, USA, and Cycle Technologies, a for-profit company, which sells CycleBeads® and CycleBeads® Online (web-based application), and produces iCycleBeads® and DOT™ (“Dynamic Optimal Timing”) (mobile phone applications) [7–9]. SDM introduction, scale up, and other activities have involved a wide range of international organisations,² largely funded by the United States Agency for International Development (USAID) [10,11]. The Bill and Melinda Gates Foundation has also provided support for pilot efforts in two countries [10].

Given that side effects are a major reason for contraceptive switching and discontinuation [5,12], the prospect of a method with few or no side effects but — unlike most natural methods — with high efficacy has obvious appeal for programmers and clients. In settings where choice is limited and good contraceptive counselling or support for switching

are nonexistent, stopping a method may mean stopping all family planning. In such cases, a less effective method requiring no follow-up may be preferable to no method at all.

The IRH promotes the Standard Days Method® as a “modern” method of contraception [1,14,15]. The SDM is now included in contraceptive guidance from the World Health Organization (WHO), including *Medical Eligibility Criteria for Contraceptive Use* [16]. The WHO recently reclassified SDM as a modern method [17] following a technical consultation on the classification of contraceptives, jointly organised with USAID. We were not able to obtain the consultation reports that might explain the rationale for this change.

The new “modern” designation of SDM contrasts with the “traditional” rhythm method. The term *modern*, rightly or wrongly, [18] implies “effective” and indeed, strong claims are made for SDM effectiveness, with the IRH and Cycle Technologies making frequent references to the method being over 95% effective and scientifically proven [1,2,19]. The IRH also promotes the method as simple to use and claims that it improves partner communication [3,19]. The SDM is proposed as a way to bring in new users of contraception, and to overcome religious or cultural concerns about family planning [3]. SDM may help users adhere to Catholic doctrine on contraception, although many countries where SDM is promoted, such as India, Mali or Madagascar, are not predominantly Catholic, and populations in predominantly Catholic countries have long used “artificial” methods.

The highest recorded national prevalence of SDM is low (0.3% of 15–49 year old women reported current use in the 2010 Rwanda DHS [10]), although 15–20% of women using family planning have been reported to use SDM in districts in the Democratic Republic of Congo where the method has been promoted [10,20,21].

The stakes are high: an ineffective family planning method may increase recourse to abortion. For instance, one 15-country study showed periodic abstinence failure contributed to one sixth of all foetal losses, most of which were likely to be illegal induced abortions [4]. Abortion remains a life-threatening procedure in many countries [22], including countries where SDM is being promoted, and children born from unwanted or unintended pregnancies may be at risk of poorer outcomes than children born from planned pregnancies [23].

The effectiveness claims made in SDM promotion have not previously been independently scrutinised. This paper provides a scientific review of the evidence so that family planning programme managers, policy makers and contraception users can make informed programming and method choices.

2. Material and methods

Eight databases were searched in July 2015 including Africa-wide Information, CINAHL Plus, EMBASE, Global

¹ The period of peak ovulation probability was modelled using datasets of menstrual cycles of women across the world, and the model suggested the probability of conception on any given day outside the peak 8–19 day time is 0.007 [6].

² These include CARE, Catholic Relief Services, Centre for Development and Population Activities (CEDPA), FHI360, JHPIEGO, Marie Stopes International, Mercy Corps, PATH, Pathfinder, Population Council, Population Reference Bureau, Population Services International, Project Concern International, Save the Children, the United Nations Population Fund (UNFPA), University Research Co., WHO, World Vision, and local affiliates of the International Planned Parenthood Federation [10].

Health, International Bibliography of the Social Sciences, MEDLINE, POPLINE, and Scopus. Databases were searched using the terms *standard days method* and *cyclebead**. In addition, we searched the resource library at Georgetown University's Institute for Reproductive Health [24], the Cycle Technologies|Brilliantly Simple™ website [25] and the WHO's Department of Reproductive Health and Research [26].

We reviewed titles and abstracts/executive summaries for relevance and retained any that contained technical information about SDM (e.g., effectiveness) or were promotional materials about SDM. We categorised reports according to their main themes and extracted summaries of key claims or findings into a thematic matrix. We examined in detail the technical information cited in support of SDM effectiveness claims.

3. Results

Our search yielded 137 unique items broadly covering the topic of SDM, with 111 from IRH, USAID and collaborating agencies. They covered research or implementation activities in 25 countries across five continents. We found 34 peer-reviewed journal articles, 10 websites (including news reports), and 93 other items including reports, summaries, guidance on SDM use/implementation, commentaries, and letters. One item was an online toolkit containing multiple SDM educational and promotional materials. Eighteen reports presented data on pregnancies during SDM use (tally includes reviews containing duplicate data). For other items, the primary themes were general information about SDM (N=50), method development (N=7), acceptability and use (N=29), and implementation (N=33).

One of the 18 reports with data on pregnancies was an efficacy study of SDM use [6]. All the others were either implementation studies, often with very small sample sizes, and/or had designs that precluded robust effectiveness calculations.

Claims about SDM effectiveness rely on the efficacy study, published in this journal in 2002, by Arévalo et al. among 478 women in Bolivia, Peru, and the Philippines [6]. In line with recommended practice [27] the Arévalo et al. study analysed data from complete menstrual cycles from the women, plus the first cycle where any pregnancy had occurred, up to 13 months' worth per woman. Women who became pregnant stopped contributing cycle data. Calculations of "correct use" (seemingly similar to perfect use i.e. how effective methods can be, where perfect use is defined as following the directions for use [28, p. 397]) used data from the number of cycles contributed with and without pregnancy. The study recorded 95% correct use effectiveness where correct use was defined as "no intercourse on days 8-19" p.336 [6].

The study recorded 88% effectiveness (i.e. 12% failure) under what the authors describe as "typical use" conditions [6]. Typical use is generally defined as "how effective the different methods are during actual use (including inconsistent or

incorrect use)" [28, p. 397]. While 12% failure may apply to typical use within the study, the SDM study participants were few in number (N=478), nonrandomly selected and atypical of the general population (e.g., almost all had children, most were literate) and so are subject to multiple biases and therefore not a representative sample of the general population. Yet the IRH has criticised a suggestion to use a 24% typical use failure rate estimate for SDM based on population rates for other fertility awareness methods saying that its 12% figure should be quoted [28–30].³

3.1. Accuracy of effectiveness claims

There are further problems with the estimates provided by IRH, both in terms of the direct claim that SDM as promoted is highly effective in preventing pregnancy and with the implicit claim that SDM itself is a single, nonvarying entity.

A crucial point is that the SDM in the Arévalo et al. study that provides the figure of 95% effectiveness was different to SDM as it is being promoted worldwide. The SDM as promoted requires women to *avoid unprotected intercourse*, including permitting the use of barrier methods, in days 8–19 of the cycle [3]. Cycles contributing to the 95% effectiveness figure in the study, on the other hand, involved participants *abstaining completely* from coitus in those days. The authors explain that cycles during which there was protected coitus on days 8–19 were excluded "because it is not possible to determine whether the woman was protected from pregnancy by the SDM only or by the other method" (p.335) [6]. The SDM as promoted, however, does not rely solely on abstinence during days 8-19 and includes other methods.

When the 5% of efficacy study cycles that included use of condoms and withdrawal (and so were excluded from "correct use" figures) are included in the analysis, one year SDM failure increased by around a fifth (5.7% vs. 4.8% SDM failure with abstinence in days 8–19). This suggests an effectiveness of SDM as promoted of less than the +95% that has been claimed [1,19] — even when the promoted method is used correctly — because substituting abstinence with condoms or other methods inevitably raises the risk of pregnancy.

Another key difference between the SDM in the study and SDM as promoted is that women in the efficacy study were required to use a paper calendar record of menstruation as well as CycleBeads® [6]. Yet SDM as promoted does not require a calendar. While a written calendar need only be updated once per cycle (to record first day of menses), CycleBeads® require women to remember to move the rubber band along the beads each day and only once on each day. Literate women with both beads and calendar can check band position against the calendar. Yet CycleBeads® are promoted using the high correct use effectiveness rates from a study where calendars were used alongside them [13,19].

³ Publicity materials such as the front page of www.cyclebeads.com prominently feature the figure of "95% effective"

The efficacy of SDM in typical use is quoted as 88% based on the efficacy study, yet the differences above suggest typical use in the study may well be different to typical use of the method as promoted. Moreover, Arévalo et al. state that women's use of multiple record systems likely improved the accurate tracking of days. They also point out that the monthly follow-up for data collection may further have increased correct use of the method [6].

All effectiveness figures were calculated based on cycles in the range 26–32 days. Women were withdrawn from the study if their cycles fell outside this range for two consecutive cycles. The presence of two or more cycles outside the 26–32-day range is a contraindication for SDM [32], presumably because the peak fertile days are more likely to fall outside cycle days 8–19 once cycles themselves are too short or long. In the efficacy study, women were also excluded after a single >42 day cycle. IRH guidance, however, also appears to suggest that women may be deemed eligible without exact knowledge of cycle length if their periods usually come “when expected” or “about a month apart” [33].

“Out-of-range” cycles are common. Among study participants, 28% had two consecutive out-of-range cycles over the 13-month period and were withdrawn from the study [6]. It appears that the out-of-range cycles contributed by women before they were withdrawn are included in the calculations of correct and typical use. However, there is a danger that those ineligible women who start with an in-range cycle length will continue to use the method, as happened within the efficacy study, where “many” (p.338) of the women withdrawn from the study after two out-of-range cycles ignored advice to stop using SDM [6]. Presumably, the effectiveness of the method is reduced when used by women with out-of-range cycles.

3.2. Presentation of effectiveness claims

In IRH materials, SDM effectiveness is compared only with that of selected short-acting methods. The materials we found [3,31,32,34–37] — with one exception published by USAID [38] — omit comparisons with any of the most effective contraceptive methods, including injectables, the intrauterine device, and implants.

The impression that scientific studies support 95% effectiveness of SDM as promoted permeates most materials on SDM, often without reference to typical use effectiveness. For instance, the WHO advisory note on procurement of CycleBeads[®], which references the Arévalo et al. study, states that, “[r]esearch has shown that SDM used with CycleBeads[®] is more than 95% effective” [39]. The CycleBeads[®] webpage states that, “[i]t's over 95% effective as shown in efficacy trials (note the use of the plural ‘trials’ — yet only one citation is provided on the website, to Arévalo et al. [6]) and used by millions of women around the world” [19].

The SDM website [3] provides both 95% and 88% figures but in large letters states: “When used correctly and

consistently — and most users do so — SDM is 95% effective”.

It may be difficult for users and providers to compare SDM adequately with other methods because many sources, including WHO guidance, present only the “correct use” figure for SDM (95% effectiveness) with no typical use effectiveness figures [1,2,39], even in places where other methods are presented with their typical use effectiveness figures [16,42].

4. Discussion

The SDM has been successfully promoted over the past 15 years, but the strong claims made for it do not stand up to scrutiny. Effectiveness figures may mislead and seem overoptimistic; promotional materials for SDM seem to put the method in an artificially favourable light.

To assess SDM as promoted, additional trial data would be needed to examine the effects of using methods other than abstinence during days 8–19, as well as the effects of guidance on estimating cycle length to determine eligibility [33]. To understand use in situ, it would be helpful, too, to investigate the extent to which use of CycleBeads[®] alone leads to errors in cycle tracking compared with CycleBeads[®] plus calendars. Overall typical use effectiveness should be carefully investigated in a sample representative of the general population.

It would also be useful to understand better the proportion of users who manage to use SDM perfectly — which requires them not only to avoid unprotected intercourse at certain times, but also to keep track of their cycle length and discontinue the method if they become ineligible. Trussell notes the proportion of perfect users as one of four key pieces of information that would help couples to make an informed decision about their contraceptive method, saying: “The percentage of perfect users or percentage of months during which a method is used perfectly reveals how hard it is to use a method correctly and consistently.” [28 p.397]. Perfect use of SDM may also be easier or more difficult for some groups — for instance those with access to a smartphone app — and this deserves further investigation.

It is possible that promotion of SDM might help improve knowledge and reduce failure rates for women using periodic abstinence incorrectly. One study showed that only 62% of self-reported periodic abstinence users in 15 DHS surveys had a reasonably correct knowledge of the fertile period, although the failure rate of those with correct knowledge was only slightly better than among those women with incorrect knowledge [4].

Users of short-acting methods already overestimate the effectiveness of their method and underestimate the effectiveness of long-acting methods [40]. Providing incorrect information in this context is therefore particularly problematic, as well as working against the principle that clients are entitled to correct information to help inform their

health choices [41]. Some WHO family planning guidance [16,42] quoting 5% failure rates for SDM defines the method as requiring abstinence in days 8–19 of the cycle, however at least two documents [17,39] appear to repeat the effectiveness claims from IRH and the CycleBeads® manufacturer without this qualification. In the absence of robust evidence of the effectiveness of SDM as promoted, SDM should only be offered to family planning clients with in-range cycles as an adaptation of traditional periodic abstinence methods, requiring total abstinence in fertile days and careful monitoring of cycle length — reflecting “correct use” in the efficacy study — to achieve high effectiveness. Delivery of any form of SDM should include presentation of the full range of other contraceptive methods, including the most effective options.

Women and couples must receive full and accurate information about the methods they use. Existing evidence does not support claims that the effectiveness of SDM as promoted is comparable to the best short-acting modern methods. We therefore suggest that the use, delivery, and promotion of the SDM should be reevaluated.

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