

Original research article

# Does the evidence support global promotion of the calendar-based Standard Days Method<sup>®</sup> of contraception?

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## Abstract

**Objectives:** To scrutinise claims about the effectiveness of the Standard Days Method<sup>®</sup> (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**Study design:** Evaluation of evidence obtained via literature review of published and unpublished reports.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

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## 1. Introduction

The Standard Days Method<sup>®</sup> (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<sup>®</sup> 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).<sup>1</sup>

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,<sup>2</sup> 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

<sup>1</sup> 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].

<sup>2</sup> 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].

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