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## Standard Days Method: Family planning option

For couples who want a contraceptive method that is user-controlled and free from side effects, a new fertility awareness-based form of family planning may be a suitable option for them.

Based on sophisticated computer modeling of reproductive physiology data, the Standard Days Method (SDM) identifies the 12-day "fertile window" of a woman's menstrual cycle. The 12 days take into account the life span of the woman's egg, the viable life of sperm, as well as the variation in the actual timing of ovulation from one cycle to the next.<sup>1-3</sup> The method calls for users to avoid unprotected intercourse during cycle days eight through 19, during which time they can protect against the risk of pregnancy through the use of contraception, such as condoms, or abstinence.

A two-year clinical trial evaluated the effectiveness of the method for 478 women in Bolivia, Peru, and the Philippines, all of whom were of childbearing age with menstrual cycles between 26 and 32 days long.<sup>4</sup> The study followed the women over 13 cycles. A life table analysis of the data indicates a cumulative probability of pregnancy of 4.75% over 13 cycles of correct use of the method, and an 11.96% probability of pregnancy under typical use.

The pregnancy prevention offered by the method and its acceptance by couples in a wide range of settings make it a viable option in family planning, says study co-author **Victoria Jennings**, PhD, director of the Institute for Reproductive Health and

### EXECUTIVE SUMMARY

A new fertility awareness-based form of family planning now is available: the Standard Days Method.

- Based on sophisticated computer modeling of reproductive physiology data, the method identifies the 12-day "fertile window" of a woman's menstrual cycle.
- The method calls for users to avoid unprotected intercourse during cycle days eight through 19, during which time they can protect against the risk of pregnancy through use of contraception, such as condoms, or abstinence. Researchers have developed CycleBeads, a string of 32 color-coded beads with each bead representing a day of the menstrual cycle. They help women keep track of which days to avoid unprotected intercourse.

professor of obstetrics and gynecology at Georgetown University, both in Washington, DC.

"While we are glad to see that there are some new delivery systems, such as the patch and the ring, for hormonal methods, as well as developments such as the female condom, we realize that most providers and programs do not offer a natural method," says Jennings. "We wanted to help fill that gap."

### Not rhythm method

Providers may look at the SDM as a form of the rhythm method, but there is a difference, explains Jennings. The rhythm method requires a woman to collect detailed information about the last six menstrual cycles and perform monthly calculations to figure out which days in the current cycle she is most likely to get pregnant, she notes. The SDM requires no such calculations by the user. In addition, no reliable, scientific effectiveness trial of the rhythm method has been reported.

To develop the SDM formula, researchers used a large data set from the Geneva-based World Health Organization, which includes information on more than 7,500 menstrual cycles from women in five countries.<sup>5</sup> Information about the variable probability of pregnancy on different cycle days relative to ovulation also was considered in the analysis.

The researchers found that women who usually have menstrual cycles between 26 and 32 days long have a significant probability of pregnancy if they have unprotected sex on days eight through 19 of their cycles, says Jennings. On other cycle days, the probability of pregnancy is extremely low.

To help women keep track of which days to avoid unprotected intercourse, the Institute for Reproductive Health developed CycleBeads, a string of 32 color-coded beads with each bead representing a day of the menstrual cycle. Beginning with the red bead, which represents the first day of her menstrual period, the woman moves a small rubber ring one bead each day. Brown beads designate the days when pregnancy is very unlikely, and glow-in-the dark white beads (beads eight through 19) represent fertile days. CycleBeads serve three primary functions, according to Jennings:

- The beads help keep track of a woman's cycle days. By moving the rubber ring one bead per day, beginning with the first day of her menstrual cycle, the user can see where she is in her cycle.
- The different colors of the beads help the woman determine the days pregnancy is likely if she has unprotected intercourse, and which days pregnancy is unlikely.
- By looking at the "darker" bead and the total number of beads, a woman can easily tell whether her cycle is between 26 and 32 days long, the optimal cycle range for using the SDM.

"CycleBeads are a critical tool for teaching, learning, and using the SDM," says **Marcos Arevalo**, MD, director of clinical trials at the Institute for Reproductive Health and assistant professor of obstetrics and gynecology at Georgetown University. "The fact that they are visual and easy to understand makes them ideal for clients and providers in a wide range of settings."

**Roberto Rivera**, MD, director of the Office of International Research Ethics at Family Health International in Research Triangle Park, NC, says he has seen the Standard Days Method presented in the field, and the CycleBeads necklace has facilitated the use of the method. It offers a practical way for the woman or for the couple to find out when the fertile days start (to avoid unprotected intercourse), and it indicates very clearly when the fertile days are finished, he observes.

In addition, CycleBeads are an excellent tool for promoting communication between the woman and her partner, not only about method use and how they choose to deal with the days in her cycle when pregnancy is likely, but also about family planning issues as well, notes Jennings.

### Correct use essential

Negotiation is a key factor in using any form of natural family planning, observes Rivera. Such methods are not woman-controlled; they involve the partner as well, he notes. If the partner does not cooperate, it is difficult to use the method correctly and consistently, he points out.

In discussing SDM along with other contraceptive options, providers will need to review the efficacy rates for each method, says Rivera. Couples who are seeking very reliable contraception but may have difficulty using SDM correctly all of the time should consider alternate methods. However, SDM may be an appropriate choice for couples motivated to use such a fertility awareness-based method.

"I'm a strong believer that there is no one method that is good for all couples, and that the secret of family planning is to be able to find for the woman, or the couple, the method that is best," Rivera notes.

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