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# Population Reports



Highlights Clinical trials assess effectiveness and safety of new contraceptives . 3 New low-dose DMPA formulation 10 More long-term choices for men....19

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## New Contraceptive Choices

Family planning users and providers have been calling for more choices. They want contraceptive methods that provide highly effective protection and at the same time cause fewer side effects, cost less, and are easier to use. In response, researchers are improving existing contraceptives and developing new ways to deliver hormones.

Offering a wide range of safe, effective, and convenient family planning methods encourages more people to use contraception. Having more choices helps ensure that users are satisfied with their family planning method. Most new methods reaching the market today result from investments made years ago. Virtually all methods undergo a long process of research and rigorous testing for safety and effectiveness and must obtain regulatory approvals before becoming available.

### **Key Developments**

This report focuses on selected innovations in contraceptives that are more effective, have fewer side effects, are less costly to manufacture, and are easier to deliver than many current options. A few of the new contraceptives discussed in this report are already available in some countries, others are on the brink of introduction, and still others are several years away from reaching the market. Among the improved contra-

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ceptives that have recently become available or are under development are the following:

**Vaginal rings.** Vaginal rings are a new way to deliver contraceptive hormones to the bloodstream. They are controlled by the user. Rings are easier to use correctly than oral contraceptives (OCs). Combined estrogen and progestin rings contain lower doses of hormones and cause fewer bleeding disturbances than combined OCs.

**Transdermal patches.** The contraceptive patch works by slowly releasing a combination of progestin and estrogen through the skin. The patch is safe, highly effective at preventing pregnancy, controlled by the user, and requires attention just once a week.

**Implants.** New research on implants has focused on different progestins that make it possible to reduce the number of rods or capsules from six to one or two. Also, the new implants produce fewer bleeding disturbances and ensure safety for use while breastfeeding.

**Combined injectables.** Combined injectables, compared with progestin-only injectables, disturb vaginal bleeding patterns less and allow earlier return to ovulation after women discontinue their use. Most combined injectables are injected once a month compared with once every two or three months for progestin-only injectables.

**Condoms.** New male condoms are being developed from nonlatex materials, while new female condoms are being developed in latex. Manufacturing condoms in different materials will expand variety, reduce cost, avoid allergic reactions, and so encourage condom use.

**Fertility awareness-based methods.** Two new fertility awarenessbased family planning approaches—the Standard Days Method and the TwoDay Method—simplify older fertility awareness-based methods, making it easier for couples to track the woman's fertile days and know when to avoid unprotected sexual intercourse.

**Oral contraceptives.** Pharmaceutical companies are introducing new hormonal formulations of OCs designed to reduce side effects, and thus encourage continuation.

**IUDs.** New IUDs in development contain hormones or are frameless. They may make insertion and removal easier and reduce expulsion, pain, and bleeding—innovations that could lead to greater acceptability and use.

**Transcervical sterilization.** Transcervical methods for women are nonsurgical. They result in contraceptive protection comparable to surgical sterilization but are safer and easier to provide. They reach the fallopian tubes through the vagina and uterus.

Male hormonal contraceptives. Hormonal contraception for men that could be as effective as OCs for women is in the clinical trial stages of development. Male hormonal contraception would offer men a reversible and convenient method to control their fertility. This report was prepared by Ushma D. Upadhyay, MPH. Indu Adhikary, MPH, and Catherine Richey provided research assistance. Bryant Robey, Editor. Richard D. Blackburn, Senior Research Analyst. Design by Linda D. Sadler. Production by John R. Fiege, Deborah Hall, Peter Hammerer, and Mónica Jiménez.

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### **Fertility Awareness-Based** Methods

Two new variations on fertility awareness-based approaches—the Standard Days Method<sup>™</sup> and the TwoDay Method<sup>TM</sup>—help women track their fertile days. Incorporating these or other fertility awareness-based methods into family planning services can appeal particularly to couples who do not want to use supply or clinical methods because of personal beliefs, financial constraints, lack of access to other contraceptives, or other reasons (161, 233). Both methods have been developed by the Institute for Reproductive Health (IRH) at Georgetown University, with support from USAID.

Family planning methods based on fertility awareness depend on commitment from and cooperation of both partners to avoid unprotected sex during the woman's fertile times. Male involvement is crucial to effective use of these methods (121, 165). Thus they are impractical for couples who cannot communicate about sex. Also, women who lack the power to choose when to have sex are not good candidates for these methods (99).

### The Standard Days Method

Couples can use the Standard Days Method to identify their likely fertile days and limit unprotected sex to days on which the woman is not likely to be fertile. To help women keep track of their fertile days, the developers of the method have created a string of color-coded beads called CycleBeads<sup>™</sup> that represent a woman's menstrual

cycle. To use CycleBeads, a woman moves a rubber ring to the next bead each day to identify where she is in her cycle. The colorcoded beads indicate whether she is on a fertile or infertile day. When the rubber ring is on a white bead, it signifies a fertile day, and thus the couple should avoid unprotected sex.

The Standard Days Method is based on the timing of the "fertile window" during the woman's menstrual cycleseveral days before ovulation and a few hours afterwhen she can become pregnant. The timing of ovulation varies among women and across cycles for the same woman. The developers of the Standard Days Method used a computer simulation that took into account this variation to determine how to provide maximum protection from pregnancy, while minimizing the number of days that users must avoid unprotected sex. Their analyses concluded that the fertile period most likely occurs between days 8 and 19 of the menstrual cycle (16, 260).

The Standard Days Method works best for women who usually (in at least 10 of every 12 cycles) have menstrual cycles between 26 and 32 days long (16). The Standard Days Method is not effective for women who have shorter or longer cycles, because they may ovulate outside of days 8 through 19. Some women may think they have regular cycles but do not. Through screening and monitoring, family planning providers can help identify women for whom this method will be most effective (213).

Effectiveness. For women who have regular cycles (between 26 and 32 days long) the Standard Days Method is about as effective as barrier methods. In a clinical trial in Bolivia, Peru, and the Philippines, which included only women who have regular cycles, typical use of the Standard Days Method resulted in 12 pregnancies per 100 women in one year of use. Typical use includes abstaining or using condoms, withdrawal, or no method at all on fertile days. Among those who used the method

Georgetown University, Institute for Reproductive Health

### **New Fertility Awareness-Based Methods**

Description: Tracking one's fertility and avoiding unprotected sex on fertile days.



Stage of development: Included in some programs.

Effectiveness: Standard Days Method—12 pregnancies per 100 women per year as typically used.

TwoDay Method—14 pregnancies per 100 women per year as typically used.

How they work: Avoiding unprotected intercourse during days identified as probably fertile.

What's new? Provide simplified ways to track fertile days with the use of colored beads or secretion diary.



To use the Standard Days Method, a woman avoids unprotected sex on days 8 through 19 of her cycle. Color-coded CycleBeads help track the woman's fertile days. Male involvement is crucial to effective use.

correctly (abstaining from sex during the fertile days), 5 of every 100 women became pregnant in one year (16).

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### The TwoDay Method

The TwoDay Method helps women determine whether they are fertile on any given day based on the presence or absence of cervical secretions. The method is based on the fact that a woman's cervical secretions are key to her fertility. Without cervical secretions, sperm have difficulty traveling to the egg (37, 176).

The TwoDay Method is appropriate for women with cycles of any length, regardless of regularity (15). Couples who can use the TwoDay Method successfully are those who can avoid unprotected sex for about 10–15 days per cycle.

To use the TwoDay Method, a woman asks herself two questions each day: (1) "Did I notice secretions today?" and (2) "Did I notice secretions yesterday?" If she noticed secretions of any type either today or yesterday, she would consider herself fertile and avoid unprotected sex. If she did not notice cervical secretions for two days consecutively, she would be unlikely to get pregnant from sex taking place today (15, 274).

The TwoDay Method was developed to provide a simpler approach to identifying the fertile days than either the Billings Ovulation Method or the Symptothermal Method, which also involve observations of cervical secretions (109). Users of these other two methods must differentiate among multiple characteristics of their cervical secretions (color, texture, and general appearance), correctly interpret changes in secretion patterns, or also observe changes in basal body temperature.

Effectiveness. In a clinical trial of the TwoDay Method in Guatemala, Peru, and the Philippines, typical use of the method resulted in 14 pregnancies per 100 women in one vear. Of women using the method correctly (abstaining from sex on fertile days), 4 of every 100 became pregnant in one year (15). After initial counseling, most participants (over 96%) were able to detect the presence or absence of cervical secretions. Continuation rates at the end of one year were only about 53%, however. Of those not completing the study, the largest group, about 16% of participants, was asked to leave the study because they either had cycles that were too long for study requirements, or they could not follow the protocol. Another 10% of participants dropped out because they became pregnant, and the remainder left the study for other reasons (15).