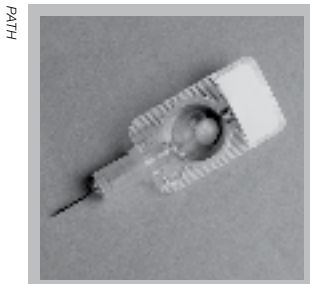




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## EXPANDING CONTRACEPTIVE CHOICE: FIVE PROMISING INNOVATIONS



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Contraception is a “best buy” for development.<sup>1</sup> By helping individuals to choose when to have children, family planning saves lives; it prevents unintended pregnancies, averts maternal and child deaths, and prevents abortions.<sup>2</sup> Family planning also saves public sector resources; for \$1 a government spends on family planning service delivery, \$2 to \$6 can be saved in providing other interventions, including basic health and education for fewer children, maternal health services, and improvements in water and sanitation.<sup>3</sup>

of use, and to provide users with options that are more within their control. This policy brief highlights five “next generation” contraceptives, each of which offers one or more advantages over similar earlier methods (see table). These innovations are among those expected to enter the market within five years and can assist country programs to make contraception more accessible and attractive to women and couples.

### Sino-Implant (II): A Much Lower Cost Implant

Contraceptive implants are flexible, hormone-releasing rods made of medical-grade silicon. These matchstick-sized rods are placed under the skin of a woman’s upper arm, inserted and later removed in a quick, minor surgical procedure by a trained provider. Depending on the product, implants provide protection against pregnancy for three to five years. Although implants were developed more than 25 years ago, they remain one of the least widely available methods; more women want implants than are able to obtain them.<sup>7</sup> In Kenya, where implants are the most popular of the long-acting and permanent methods (LAPM), demand continually exceeds supply.<sup>8</sup>

Half of married women worldwide now use a modern method of contraception, but globally 200 million women still have an “unmet need” — they would like either to stop having children or delay their next birth for at least two years, but are not using an effective contraceptive method.<sup>4</sup> Unmet need is fueled by lack of information, fear of social disapproval or a husband’s opposition, and concern for contraceptive side-effects or impacts on health.<sup>5</sup> Unmet need can be considerably reduced by expanding access to methods that are currently under-utilized and by assuring clients that a variety of modern methods are available to meet their diverse needs.<sup>6</sup> Unmet need is also being addressed through ongoing contraceptive research, which aims to improve affordability and ease

200 MILLION

The number of women with an “unmet need” for family planning services worldwide.



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### Selected Next Generation Contraceptives

PRODUCT	METHOD TYPE	INNOVATION	TIMELINE
Sino-Implant (II)	Hormonal	Significantly lower cost than comparable implants.	Widely distributed in China and Indonesia. Currently registered in Kenya and Sierra Leone; under review by national drug regulatory authorities in eight countries, with 10 more reviews expected by mid-2010.
Depo-SubQ Provera 104 in Uniject Syringe	Hormonal	New formulation for injection under the skin rather than into the muscle; packaged in a single-use syringe to permit broader access.	Depo-SQ is approved by the U.S. Food and Drug Administration (FDA); approval for Depo SubQ in Uniject syringe is expected from the European Medicines Agency (EMA) by mid-2010*. Anticipated rollout in 2011-2012.
NES-EE Vaginal Ring	Hormonal	Longer duration (12 month vs. one month) protection. Does not require refrigeration before insertion. Potential for use as emergency contraception.	Anticipated rollout in 2012, pending FDA approval.
SILCS Diaphragm	Barrier	One size eliminates need for fitting by a provider; user-friendly design eases insertion and removal.	Anticipated rollout in 2011, pending FDA approval.
Standard Days Method With Cell Phone Alerts	Fertility awareness	Users reminded of fertile period and need to abstain or use barrier method via cell phone short message service (SMS).	Concept being tested in India (2009).

\*EMA serves a similar function in Europe in terms of the scientific evaluation of medicinal products, as does the FDA in the U.S.

Often, only physicians are permitted to insert and remove implants, a requirement that increases cost and decreases access. However, in some areas nurses and other health professionals have been trained in insertion and removal.<sup>9</sup> Implants are highly effective, with an annual pregnancy rate of less than 1 percent, and a higher continuation rate than for any method other than sterilization.<sup>10</sup> Implant rods contain a hormone that acts primarily by thickening cervical mucus and suppressing ovulation. Because implants do not contain estrogen, the method is safe for breastfeeding women (when inserted six weeks postpartum), and can be used by women with cardiovascular risk factors such as high blood pressure, as well as by women who smoke cigarettes. For women who desire to become pregnant, an implant has the advantage of an immediate reversal of the contraceptive effect upon removal.

Sino-Implant (II), a two-rod system manufactured since 1994 by Shanghai Dahua Pharmaceutical Company Ltd., provides four years of protection against pregnancy at about 30 percent to 40 percent of the cost (based on the comparison product and volume purchased by international donors) of existing implants. The lower price will enable programs to serve more clients per dollar investment in contraceptive commodities. To date, 7 million units of Sino-Implant (II) have been distributed in China and Indonesia. Most recently, the product has been registered in Kenya and Sierra Leone under the trade name Zarin. Currently, the method is under review by national drug regulatory authorities in eight countries and is expected to be under review in 10 additional countries by June 2010. Family Health International (FHI) has funding through 2013 to ensure product quality and to assist local partners in registering the product.

## Depo-SubQ Provera 104: For Improved Access and Greater User Control

Injectables containing the hormone DMPA first became available in 1971 in Thailand, and are now registered in 179 countries.<sup>11</sup> Depending on the specific product, injectables provide one to three months of contraceptive protection by suppressing ovulation. Injectables are highly effective; if women return within the required timeframe for an injection, less than three in 1,000 will become pregnant. In actual use, the failure rate of injectables is about three per 100 users, less than half that of the oral pill.<sup>12</sup>

DMPA is inexpensive and can be used by breastfeeding women as early as six weeks postpartum.<sup>13</sup> In recent years, injectables have become the most widely used method in a number of sub-Saharan African countries, and surveys indicate that between 6 percent and 20 percent of use may be without the knowledge of others.<sup>14</sup> A new generation DMPA injectable, the three-month Depo-SubQ Provera 104 (Depo-SQ), is already available in the United States and several European countries. It has been reformulated to be administered subcutaneously (under the skin), using a much shorter needle than is required for intramuscular injection. This makes it easier for trained pharmacists and community-based health care workers to provide the injections.<sup>15</sup>

An additional innovation now being assessed by PATH is to provide Depo-SQ in a prefilled Uniject single-use syringe (see top-left photo, page 1). This mode of delivery will allow community-based access to be scaled up, and opens up greater possibilities for at-home and even self-administration. In surveys FHI conducted among both new and long-term Depo users, one in four said they would prefer to inject at home, while a similar

percentage preferred to receive the injection from a community-based health worker.<sup>16</sup> PATH expects to conduct preintroduction operations research on Depo-SQ in Uniject in 2010, with initial introduction activities beginning in 2011-2012. When it becomes available, Depo-SQ in a single-use Uniject syringe should provide women with a user-controlled method that offers privacy and a high level of protection at a public-sector cost expected to be comparable to the currently available product.

## NES-EE: A Long-Acting Vaginal Ring

The NES-EE One-Year Contraceptive Ring developed by the Population Council is a user-controlled method that will be available by prescription.<sup>17</sup> A silicone ring with a circumference of approximately 2 inches (5 centimeters) is inserted by the woman into her vagina. Because the exact placement of the ring is not critical, the ring does not require fitting by a provider. The ring continuously releases a low-dose combination of a new progestin (nestorone) and an estrogen that act to suppress ovulation. After three weeks, the user removes the ring to allow a week for bleeding, and then reinserts it. A single NES-EE ring can be reinserted monthly for one year. The vaginal ring is not appropriate for breastfeeding women or women over age 35 who smoke.<sup>18</sup>

Worldwide studies of the contraceptive efficacy and acceptability of the NES-EE ring were recently completed by the Population Council and the U.S. National Institutes of Health. Preliminary results indicate that women are very satisfied with the method and would recommend it to others. Women found it easy to use and were not concerned about reusing a single ring for a year. Research suggests that the vaginal ring may be somewhat more effective in actual use than the oral pill, which has a 7 percent failure rate. The NES-EE ring has also been shown to have potential as an emergency contraceptive when inserted shortly after unprotected intercourse.<sup>19</sup>

The Population Council estimates that following approval by the U.S. Food and Drug Administration (FDA), the NES-EE Ring will be ready to market in 2012. The U.S. Agency for International Development (USAID) anticipates that the cost of the long-acting vaginal ring in the public sector will be less than \$10 for a year of contraceptive protection. Unlike NuvaRing, a monthly ring not currently distributed in public-sector programs in developing countries, the NES-EE 12-month ring does not require refrigeration before use and may be attractive to women with limited access to health facilities.<sup>20</sup>

## The SILCS Diaphragm: One Size Fits Most

The diaphragm, a cervical barrier made of latex or silicone that prevents pregnancy by blocking sperm from entering the uterus, is the oldest manufactured contraceptive for women. The diaphragm is used only during intercourse, has no method-related side effects, and can be used by some women without the knowledge of a male partner. It can be put in place several hours in advance so that insertion does not interrupt sex, and should be left in place for six to eight hours afterward. The diaphragm is suitable for women who are breastfeeding. A diaphragm is relatively inexpensive to produce and the cost can be distributed over several years of use. However, currently available diaphragms come in multiple sizes and the required fitting by a provider adds considerably to the expense.

Interest in a female-controlled, dual-protection barrier method that could help women protect themselves from both unintended pregnancies and sexually transmitted infections (STIs) has fueled renewed interest in the diaphragm. The SILCS diaphragm (see bottom-left photo on page 1), designed by PATH with the input of women in a wide variety of settings, is made of a durable silicone capable of withstanding the commonly encountered heat and poor storage conditions in developing countries.<sup>21</sup> A single size fits most women, eliminating the need for fitting by a provider. Special design features include an elongated shape that is easier to fold in half for insertion, a fingertip “dome” to ease removal, and silicone “dimples” to help maintain grip.<sup>22</sup> With these characteristics, the SILCS diaphragm should require much less provider support than a standard fitted diaphragm.

A contraceptive effectiveness study is underway (in 2009) after which FDA approval will be sought. PATH aims to begin international and U.S. marketing as early as 2011 and is seeking regional partners. PATH continues to investigate the feasibility of the SILCS diaphragm for delivering a controlled-release microbicide that would prevent HIV. A combined physical and chemical barrier method would be an important new option for meeting women’s sexual and reproductive health needs.

## Standard Days Method With Cell Phone Alerts

The Standard Days Method (SDM) is a fertility awareness-based method of family planning developed by the Institute for Reproductive Health (IRH) of Georgetown University. IRH’s scientific analysis of the fertile period established that more than 80 percent of women’s menstrual cycles are between 26 days and 32 days long, and women are fertile for all or part of the period from day 8 through day 19 of the cycle. Efficacy studies showed that when most of a woman’s cycles fall within this 26 to 32 day range, pregnancy can be prevented up to 95 percent of the time by avoiding unprotected intercourse during days 8 to 19.

The SDM has been integrated into family planning programs in more than 25 countries. Most SDM users rely on CycleBeads, a color-coded string of beads to help them keep track of where they are in their cycle and which days they are potentially fertile. Each day of the cycle, a rubber ring is moved from one bead to the next. When the ring is on a white bead, the woman knows she is in her fertile period and must avoid unprotected intercourse. The SDM requires the cooperation of the male partner, providing an entre for couple communication and encouraging men to think of family planning as a joint responsibility. Some couples choose to abstain on fertile days while others rely on condoms. Because the method does not require resupply and the only cost is a one-time expense for CycleBeads (U.S.\$1 in the public sector), the SDM can help reduce unmet need and improve contraceptive security.<sup>23</sup> In addition to its low cost and lack of side effects, the SDM is popular because of its convenience and the ease with which it can be incorporated into multi-method programs. For more than half of users in some studies, the SDM is the first contraceptive method ever tried. Many women who use the SDM subsequently switch to another modern method, demonstrating that the SDM can bring new users to family planning.<sup>24</sup>

Building on global trends, IRH is now piloting an effort to use cell phone technology to remind women and couples of the fertile period and of the need to abstain or use a barrier method during that time. More than two-thirds of the 4.1 billion global cell phone users live in developing countries and the majority of them use text messaging or SMS to send and receive messages. IRH has developed CycleTel, an SMS application that has the potential to make the SDM more broadly available. Currently, IRH is testing this concept in India, where there is a demonstrated demand for the SDM. India is also one of the world’s fastest growing telecom markets and second only to China in number of cell phone users.<sup>25</sup> Results, to be available in the next six to nine months, will suggest whether CycleTel has the potential to improve awareness and consistent use of the SDM, facilitating continual access for women and couples to a method that prevents unintended pregnancy.

## ‘Next Generation’ Contraceptives

### USER NEEDS

User-controlled, community-based, and over-the-counter availability of next-generation contraceptives offers many advantages for women. With methods that do not require screening and follow-up by a health provider, women will be more dependent on pharmacies and community-based programs to meet their information needs, such as whether these methods provide protection against STIs and HIV. Higher quality of care leads to more consistent use, greater user confidence, satisfaction, and higher levels of continuation.<sup>26</sup> Therefore, attention must be given to ensuring that:

- Auxiliary health personnel are well-trained to provide information, screening, counseling, and, if needed, referral to a health provider.
- Product information, including brochures and package inserts, is comprehensible to low-literate women.
- Clients are advised to use a male or female condom to protect against STIs, including HIV.

### POLICY AND PROGRAM NEEDS

Next generation contraceptives improve upon the currently available options, and can help to reduce unmet need. To introduce and incorporate these contraceptive advances, national and community health programs will need to:

- Advocate and plan strategically to ensure an introduction and scaling-up process that responds to women’s needs.<sup>27</sup>
- Have guidance on managing the bureaucratic processes associated with introducing a new contraceptive method. Sino-Implant (II), for example, is presently licensed in only a few countries and governments have little experience in procuring it.
- Obtain approvals from drug regulatory agencies and ministries of health to expand the range of methods provided and, for example, to permit community-based or in-home-administration of injectables.<sup>28</sup>
- Expand access through training nurses and other health professionals, to insert and remove implants, for example.

- Phase out similar but less advantageous methods to prevent overload and confusion in the supply system.<sup>29</sup>
- Closely monitor and evaluate the process of integrating new generation methods into existing systems (such as training, supervision, and procurement).
- Ensure that products are obtained at low cost to the public sector.

## Conclusion

Nearly all countries have agreed on the rights of women and couples to decide on the number and spacing of their children, yet, especially in rural and remote areas of many countries, few contraceptive options are offered to make this right a reality.<sup>30</sup> A diverse contraceptive method mix increases the likelihood that individuals will find an appropriate product to meet their unique needs and circumstances.<sup>31</sup> While a compelling need continues for new contraceptives, particularly nonsurgical methods for male and female sterilization and a single method that provides dual protection against both pregnancy and HIV, there is little doubt that existing methods are underutilized. Much work remains to address factors contributing to this underutilization, including restrictive policies, tariffs, and provider biases.<sup>32</sup> But soon, programs can also take advantage of the innovations in contraceptive technology described above to diversify their programs, attract new users, ease logistical constraints, and reduce cost. By doing so, countries can reap more of the benefits family planning offers as a “best buy” for economic and social development.

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