Contraceptive Implants

Description

Introduced more than 25 years ago, contraceptive implants are one of the most effective family planning methods available when used in accordance with approved prescribing information. Implants are thin, flexible rods that are inserted just under the skin of a woman's upper arm and provide sustained contraception ranging generally from three to five years.

The Population Council developed the first contraceptive implant—Norplant—which was approved in Finland, the country of manufacture, in 1983. Norplant consisted of six rods (2.4 mm × 34 mm), each containing 36 mg of levonorgestrel (a progestin). The second-generation system, Jadelle, was subsequently developed and approved by the U.S. Food and Drug Administration (USFDA) in 1996; Jadelle consists of two rods (2.5 mm × 43 mm), each containing 75 mg of levonorgestrel. In 1994, Sino-implant (II), a similar two-rod implant with the same amount of active ingredient as Jadelle, was introduced in China. This was followed by Implanon in 1997 and approved by USFDA in 2006, a single-rod contraceptive implant (2 mm × 40 mm) containing 68 mg etonogestrel, a synthetic female hormone resembling progesterone, which was developed in the Netherlands. Production of Norplant was discontinued in 2008.[1]

Contraceptive implants provide long-lasting contraception by suppressing ovulation, impeding sperm transit by thickening the cervical mucus, and altering the endometrial structure.[2] The duration of contraceptive protection varies by brand: Jadelle is registered to provide contraception for five years, Sino-implant (II) for four years, and Implanon for three years. Doctors may advise women who are overweight to replace the implant earlier. Insertion and removal of an implant must be conducted by a well-trained health care provider, and both insertion and removal are generally short, non-complicated procedures. After removal, return to fertility is usually rapid as the synthetic hormones in implants have a short half life, and there is no delayed return to fertility for implant users, as compared to women who do not use contraception.[3] A new implant can be inserted at the time of removal if continued contraception is desired.

Contraceptive implants can be used by almost all women. Implants are best suited for women who desire a user-independent contraceptive method for birth spacing and limiting. Implants should not be inserted in women during the first six weeks after childbirth if they are exclusively or partially breastfeeding; those with serious liver disease, problems with blood clots, or unusual vaginal bleeding; and women that have or have had breast cancer.[3] Contraceptive implants do not provide protection from sexually transmitted infections.

Efficacy

Contraceptive implants are one of the most effective contraceptive methods available. Annual pregnancy rates are less than 1 percent with all implants.[4,5] Continuation rates are often better than those for other hormonal contraceptives or intrauterine devices.[6] No significant differences are found in contraceptive effectiveness or continuation rates among users of various contraceptive implants.[4]

The major side effects associated with the use of contraceptive implants are changes in bleeding patterns (frequency, duration, and amount).[3,7] Other potential side effects include weight gain, headaches, abdominal pain, acne, dizziness, nausea, breast tenderness, and mood changes. Rarely, infection at the site of the implant will occur.[3] Ovarian cysts may also occur, but usually do not require treatment.[8]

Current programme/sector use

Because of implants' effectiveness and convenience, they are popular and in high demand when available in family planning programmes. However, the high upfront commodity cost can be a barrier to access especially in resource-constrained settings. Still, because they are effective for a number of years (i.e., three to five years), are independent of user's compliance, and do not require frequent resupply, implants are more reliable and more cost-effective compared to other shorter-acting contraceptive methods.[9]

Although use of implants—as a percent of the method mix—remains low worldwide, demand often exceeds supply. In many settings, potential implant users go on waiting lists or choose another method. This has led analysts to conclude that the true demand for implants is unknown because there are not enough supplies and services available to meet demand.[10] Significant increases in procurement of contraceptive implants have been

reported worldwide over the last four years. Data gathered by the RH Interchange show that in 2005 fewer than 100,000 implants were donated in sub-Saharan Africa. By 2010, donations rose 19-fold to more than 1.8 million.[11]

Contraceptive implants are a practical method for use in all settings as their insertion requires a short in-office procedure for a one-rod implant and a minor surgical intervention for the two-rod implant. An essential element of implant provision is ensuring excellent counselling before insertion so that women know what potential side effects to expect and how to reliably access removal services.[1]

Guidance for effective implant introduction and scale-up is available for providers and managers. An online toolkit on contraceptive implants provides up-to-date and accurate information on training, guidance on best practices, and resources and tools to help improve access to and quality of services: http://www.k4health.org/toolkits/implants.

Manufacturers

Jadelle is manufactured by Bayer Schering Pharma.

Sino-implant (II) is manufactured by Shanghai Dahua Pharmaceuticals Co., Ltd.

Implanon is manufactured by Merck/MSD.

Registration status/suppliers

Jadelle: Available with a disposable trocar, prequalified by the World Health Organization, and has been registered in more than 47 counties worldwide. This product is distributed commercially by Bayer Schering Pharma.

Sino-implant (II): Available with a disposable trocar, has been registered in 13 countries in Africa and Asia, and is under active review in ten additional countries as of January 2011. In addition to the manufacturer's name for the product (Sino-implant (II)), the product is marketed under a variety of names by distributors in different countries: as Zarin by Pharm Access Africa, Ltd., as TRUST by DKT Ethiopia, and as Femplant by Marie Stopes International.

Implanon: Available in a preloaded, disposable, sterile trocar; is prequalified by the World Health Organization; and has been registered in 80 countries. The product is distributed commercially by Merck/MSD.

Public-sector price agreements

Jadelle: Public-sector price agreements with organizations such as the US Agency for International Development (USAID), the United Nations Population Fund (UNFPA), PSI, and others have been established.

Sino-implant (II): Public-sector price agreements are established with distribution partners.

Implanon: Public-sector price agreements have been made through contracts with individual ministries of health, UNFPA, USAID, and nongovernmental organizations engaged in family planning.

References

1 Ramchandran D, Upadhyay UD. Implants: The Next Generation. *Population Reports. Series K: Injectables and Implants* 2007;7:1–19.

2 Croxatto HB. Mechanisms that explain the contraceptive action of progestin implants for women. *Contraception*. 2002;65(1):21–27.

3 World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), INFO Project. Family Planning: A Global Handbook for Providers. Baltimore and Geneva: CCP and WHO, 2007.

4 Glasier A. Implantable contraceptives for women: effectiveness, discontinuation rates, return to fertility, and outcome of pregnancies. *Contraception*. 2002;65(1):29–37.

5 Steiner M, Lopez M, Grimes D, et al. Sino-implant (II)—a levonorgestrel-releasing two-rod implant: systematic review of the randomized controlled trials. *Contraception*. 2010; 81(3)197–201.

6 Power J, French R, Cowan F. Subdermal implantable contraceptives versus other forms of reversible contraceptives or other implants as effective methods for preventing pregnancy. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.:CD001326. DOI:10.1002/14651858.CD001326.pub2.

7 Sivin I. Risks and benefits, advantages and disadvantages of levonorgestrel-releasing contraceptive implants. *Drug Safety*. 2003;26(5):303–35.

8 Hohmann H, Creinin MD. The contraceptive implant. *Clin Obstet Gynecol*. 2007;50(4):907–17.

9 Mavranezouli I. Health economics of contraception. *Best Pract Res Clin Obstet Gynaecol*. 2009;23(2):187–98.

10 Hubacher D, Kimani J, Steiner MJ, Solomon M, Ndugga MD. Contraceptive implants in Kenya: Current status and future prospects. *Contraception*. 2007;75(6):468–473.

11 Tumlinson K, Steiner M, Rademacher K, et al. The promise of affordable implants: is cost recovery possible in Kenya? *Contraception*. In press.

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This brief was last updated January 2011.

CycleBeads®

Description

CycleBeads® are a colour-coded string of beads that help a woman use the Standard Days Method®, a clinically tested natural method of family planning that enables women to manage their own fertility. CycleBeads® work for women with menstrual cycles 26 to 32 days long. Using CycleBeads®, a woman can track her menstrual cycle, identify the days when unprotected intercourse is likely to result in pregnancy, and monitor her cycle length. She either uses a barrier method or abstains on her potentially fertile days—identified as days 8–19 of the menstrual cycle—to avoid pregnancy.

A woman can use CycleBeads® by placing the rubber ring on the RED bead on the first day of her period. She moves the ring one bead each day, even on the days when she has her period. She abstains or uses a condom when the ring is on any WHITE bead if she does not want to become pregnant. She can have unprotected sex when the ring is on any BROWN bead, as she is not likely to get pregnant on those days. She needs to move the ring to the RED bead again when her next period starts, skipping over any remaining beads.

Efficacy

Research has shown that the Standard Days Method® is more than 95 percent effective with correct use (condoms or abstinence during days 8–19 of the menstrual cycle), and more than 88 percent effective in typical use,[1] similar to a number of other user-directed methods.[2] Similar levels of efficacy have been found when the method is offered in regular service delivery.[3] Further, studies of women who purchased CycleBeads® in the context of social marketing—and thus relied on the CycleBeads® instructional insert and point-of-sale materials for method use—showed that their ability to understand and use the method correctly was equal to that of women who received instruction from a trained provider.[4] The Standard Days Method® provides two couple-years of protection (CYPs).

Current programme/sector use

To date, the Standard Days Method® and CycleBeads® have been used in more than 50 countries and have been successfully integrated into many existing family planning programmes and community networks, resulting in approximately two million users worldwide.[5] The Standard Days Method® does not require special equipment, medical procedures, facilities, or costly commodities, and as a knowledge-based method, it is easy to teach and learn. Thus, it can be offered through a wide variety of programmes and by a range of providers—including physicians, nurses, auxiliary nurses, community volunteers, public- and private-sector reproductive health programmes, faith-based organizations, and social marketing programmes through pharmacies and other retailers—without significant additional resources. This method also addresses the needs of diverse populations with varied religious and ethical beliefs, education, and socioeconomic status. It has no side effects and can be used by women who want a pregnancy, as well as by those who do not.

Programmes in several countries have found that including the Standard Days Method® and CycleBeads® among the options they offer contributes to contraceptive prevalence, enhances the method mix, and brings first-time users to family planning.[6] Given the scientific and programmatic evidence, the Standard Days Method® and CycleBeads® are included in numerous documents of the World Health Organization, the US Agency for International Development (USAID), International Planned Parenthood Federation, and Contraceptive Technology.[7,8,9,10]

The primary impediment to expanded availability and use of this method is ensuring sufficient supply of CycleBeads®. Because the Standard Days Method® is a relatively new method, governments and implementing partners often do not have data about current use on which to forecast future demand and base estimations for CycleBeads® procurement. However, a toolkit is available to aid countries interested in procuring CycleBeads® by providing a step-by-step process for estimating the initial supply of CycleBeads® needed in their country. It is available electronically from the USAID | DELIVER PROJECT (email: askdeliver@jsi.com); individuals may also contact irhinfo@georgetown.edu. For additional information, see www.cyclebeads.com and www.irh.org. The fact that CycleBeads® require no special storage facilities, have an indefinite shelf-life, and are impervious to environmental conditions makes them an ideal product for low-resource settings.

Additionally, up-to-date data on CycleBeads® procurement by country and donor can be found on the Reproductive Health Supplies Coalition's online RHInterchange, which supports pipeline monitoring, commodity management, analysis, and planning for programme managers, donors, researchers, and advocates.

Manufacturer/supplier

Cycle Technologies (contact: 1+202-237-0662, info@cyclebeads.com) is the licensed manufacturer of CycleBeads®. CycleBeads® have been available since 2003 and are now offered through nongovernmental organizations, faith-based organizations, and public social-marketing programmes.

Public-sector price agreements

CycleBeads® are now offered as part of the contraceptive method mix available through the Central Contraceptive Procurement (CCP) Project of the Commodities Security and Logistics (CSL) Division at USAID, and can be ordered by USAID programmes alongside other contraceptive methods. Missions can provide funding requests for procurement of CycleBeads® to the CCP project either as field support or as a Modified Acquisition and Assistance Request Document. Orders should be forwarded to the CSL country backstopper.

Non USAID-funded groups interested in purchasing CycleBeads® should contact the manufacturer, Cycle Technologies, directly (see www.cyclebeads.com).

References

1 Arevalo M, Jennings V, Sinai I. Efficacy of a new method of family planning: the Standard Days Method. *Contraception*. 2002; 65:333–338.

2 Sinai I, Jennings V, Arevalo M. The two-day algorithm: A new algorithm to identify the fertile time of the menstrual cycle. *Contraception*. 1999; 60(2):65–70.

3 Gribble J, Lundgren R, Velasquez C, Anastasi E. Being Strategic about Contraceptive Introduction: The Experience of the Standard Days Method®. *Contraception,* 2008; 77: 147–154.

4 Kavle J, Foreit J, Eber M, Lundgren R, Jennings V. The Potential for Social Marketing a Knowledge-Based Family Planning Method. *Article pending publication*, 2011.

5 Data provided by Cycle Technologies, the licensed manufacturer and distributer of CycleBeads.

6 Gribble J, Lundgren R, Velasquez C, Anastasi E. Being Strategic about Contraceptive Introduction: The Experience of the Standard Days Method®. *Contraception,* 2008; 77: 147–154.

7 Medical Eligibility Criteria for Contraceptive Use 3rd Ed. Geneva: World Health Organization, 2004. Available at: www.who.int/reproductive-health/publications/mec/fab.html.

8 Jennings V, Lundgren R. Standard Days Method: A Simple Effective Natural Method. USAID Global Health Technical Briefs 2004. Available at: http://irh.org/sites/default/files/USAID%20SDM%20Technical%20Brief%202004.pdf

9 IPPF Medical and Service Delivery Guidelines for Sexual and Reproductive Health Services 3rd Ed. 2004. Available at: www.ippf.org/en/Resources/Medical/IPPF+Medical+and+Service+Delivery+Guidelines.htm.

10 Jennings V, Arevalo M. Chapter 15: Fertility Awareness-Based Methods. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart F, Kowal D, eds. Contraceptive Technology 19th Revised Edition. New York: Ardent Media Inc., 2007:343–349.

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Diaphragm

Description

The diaphragm is a barrier device that covers the cervix and part of the vaginal wall and prevents pregnancy by blocking sperm from entering the uterus (see below for a list of brand names). Traditionally diaphragms were made of latex, but now most are made of silicone. Diaphragms are made in different sizes (generally four to seven sizes depending on the brand), and a woman must be fitted for the correct size by a clinician. Diaphragms are durable and reusable, making them a low-cost contraceptive method.

The diaphragm is held in place by a flexible rim. To use it, a woman inserts the diaphragm with contraceptive gel before intercourse and leaves it in place for six hours afterwards. The diaphragm can be inserted before sex, but should not be kept in place for more than 24 hours without removing it to wash. Research evaluating the safety and acceptability of continuous use of the diaphragm (still removing once a day for cleaning) is ongoing.[1,2] Clinical guidelines recommend adding additional contraceptive gel before further acts of intercourse. In addition, women who use the diaphragm must be able to wash and store the device.[3]

Since it is worn internally, diaphragms offer more discreet protection than female or male condoms. As a female-initiated method, the diaphragm provides contraceptive protection without requiring male partner involvement. Although some men report not being aware of the diaphragm during sex, women may choose to discuss this method with their partner depending on the communication and expectations in their relationship. Diaphragms are appropriate for women who cannot or choose not to use hormonal or other long-term contraceptive methods, and for women who want protection only around the time they have sex. Diaphragms are also an appropriate back-up method in case a woman has missed taking oral contraceptive pills or her other method is out-of-stock at the family planning clinic. There are no age or parity restrictions on use, and a woman can use a diaphragm throughout her reproductive life (although the size may need to be checked). Return to fertility is immediate after use. Diaphragms are best suited for women who find using a method near or at the time of intercourse acceptable, can learn the insertion technique, and feel that they have sufficient privacy for insertion and removal.

Efficacy

Contraceptive effectiveness depends on correct and consistent use. The diaphragm used with spermicide is 84–94 percent effective in preventing pregnancy during the first year of use.[4]

Use of a spermicide containing Nonoxynol-9 (N-9) is not recommended for women at high risk of HIV infection.[5] Definitive information on the contraceptive efficacy of the diaphragm without spermicide is not available.

Current programme/sector use

Challenges

There are a number of obstacles to expanded use of traditional-sized diaphragms. One is the requirement for a clinician fitting; another is the complexity of supplying product in multiple sizes. A reanalysis of fitting data from previous barrier-method clinical trials suggests that many women could be correctly fitted with a one-size diaphragm.[6] There are currently two single-sized products under evaluation; at least one is expected to be available in late 2011.

Effective use also is dependent upon a continued supply of contraceptive gel. Given concern about increased risk of HIV, many family planning programmes in regions with HIV prevalence have stopped supplying products containing Nonoxynol-9 (N-9). Efforts are under way to identify contraceptive gel alternatives that do not use N-9. Even when an alternative gel is identified and validated, supply and cost issues will remain.

Opportunities

When women receive information from providers and support from their partners, they find diaphragms very acceptable and successful as a method of family planning. Over the past decade, clinical studies in 13 countries have found diaphragms can be used successfully by women in low-resource settings. One report from India emphasized that women can use diaphragms successfully even when they do not have access to private bathrooms or running water in the house.[7] Other studies in Zimbabwe, Kenya, and Madagascar[8], as well as Thailand, South Africa, Dominican Republic, and the United States have found

that diaphragms are well accepted even among women who have no previous experience.[9,10,11]

A June 2008 online discussion about diaphragm programmes worldwide can be accessed by joining the "Cervical Barrier Methods" community at the Knowledge Gateway for Reproductive Health at http://my.ibpinitiative.org/. The Cervical Barrier Advancement Society (CBAS) serves as a portal for diaphragm research and information (www.cbas.org).

Manufacturers/suppliers

ORTHO ALL-FLEX® Diaphragm

The ALL-FLEX® is a diaphragm with a shallow dome and a flexible rim with an arcing spring. The ALL-FLEX® diaphragm is now made from silicone and is available in four sizes (65 mm to 80 mm).[12] The ALL-FLEX® diaphragm is manufactured by Ortho-McNeil-Janssen Pharmaceuticals, Inc., the world market leader in diaphragm sales and distribution. ALL-FLEX® is available globally, though as of 2008 it has been discontinued in Canada.

Milex Wide-Seal® Diaphragm

Milex Wide-Seal® Arcing and Omniflex diaphragms are manufactured by Cooper Surgical and distributed in the United States, Canada, Europe, Asia, and the Middle East. Both styles are available in eight sizes (60 mm to 95 mm) and are made of silicone.[13]

Semina Diaphragm

The Semina Diaphragm is a clear, silicone diaphragm with a visible coil spring. It is available in six sizes (60 mm to 85 mm) and is manufactured by Semina Industries and Commerce Ltd. The product is marketed in Brazil.

Reflexions Flat Spring® Diaphragm

The Reflexions Flat Spring® is a rubber diaphragm with a rim that is similar to the coil spring but thinner and more delicate. It is available in nine sizes (from 55 mm to 95 mm). Reflexions is manufactured and marketed in Britain.[14]

Public-sector price agreements

None.

References

1 Behets F, Turner A, Van Damme K, et al. Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. *Sexually Transmitted Infections*. 2005;81:472–476.

2 Penman-Aguilar A, Swezey T, Turner AN, et al. Promoting continuous use as a strategy for achieving adherence in a trial of the diaphragm with candidate microbicide. *AIDS Education and Prevention*. 2009;21(6):512–525.

3 Female Barrier Methods page. Reproductive Health Outlook website. Available at: www.rho.org/html/cont-female_barriers.htm. Accessed August 1, 2008.

4 Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition*. New York, NY: Ardent Media, 2007. See www.contraceptivetechnology.com/table.html.

5 World Health Organization. *WHO/CONRAD Technical Consultation on Nonoxynol-9: Summary Report*. Geneva: World Health Organization; 2003. Available at: http://whqlibdoc.who.int/hq/2003/WHO_RHR_03.08.pdf.

6 Mauck C, Lai JJ, Schwartz J, Weiner DH. Diaphragms in clinical trials: Is clinician fitting necessary? *Contraception*. 2004;24(4):263–266. Available at: www.rho.org/html/cont-b-03.html#mauck04.

7 PATH. Re-examining the Role of Cervical Barrier Devices. *Outlook*. 2003;20(2). Available at: www.path.org/files/eol20_2.pdf.

8 Cervical Barrier Advancement Society website. Available at: www.cervicalbarriers.org/information/recentResearch.cfm. Accessed January 6, 2011.

9 Coffey PS, Kilbourne-Brook M, Brache V, Cochón L. Comparative acceptability of the SILCS and Ortho ALL-FLEX diaphragms among couples in the Dominican Republic. *Contraception*. 2008;78(5):418–423.

10 Coffey PS, Kilbourne-Brook M, Beksinska M, Thongkrajai E. Short-term acceptability of a single-size diaphragm among couples in South Africa and Thailand. *Journal of Family Planning and Reproductive Health Care*. 2008;34(4):233–236.

11 Schwartz et al. SILCS diaphragm: postcoital testing of a new single-size contraceptive device. *Contraception*. 2008;78(3):237–244.

12 Cervical Barriers Advancement Society website. Available at: http://www.cervicalbarriers.org/information/diaphragms.cfm. Accessed January 6, 2011.

13 Cooper Surgical. Milex™ Wide-Seal Diaphragms factsheet. Available at: http://www.coopersurgical.com/Documents/Milex%20Wide%20Seal%20Diaphragms%20Literature.pdf. Accessed January 6, 2011.

14 Williams Medical. Reflexions Flat Spring Diaphragm web page. Available at: http://www.wms.co.uk/Family_Planning/Contraceptive_Diaphragms/Reflexions_Flat_Spring_Diaphragm. Accessed January 6, 2011.

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Emergency contraceptive pills

Description

Emergency oral contraceptive pills are currently the most accessible, effective, post-coital contraceptive option. Low contraceptive-prevalence rates along with high levels of unmet need for family planning in many developing countries indicate a very high frequency of unprotected sexual relationships. As a result, many couples are at risk for an unplanned and/or unwanted pregnancy.

The most commonly available regimen involves a single dose, 1.5 mg levonorgestrel pill, which is taken up to 120 hours after unprotected sexual intercourse to prevent pregnancy, but is more effective the sooner it is taken. Also available is a two-pill regimen (0.75 mg each); both pills should be taken together, although some regimens include instructions to take one pill up to 72 hours after unprotected intercourse and the second one 12 hours later.[1] More recently, a regimen containing 30 mg of the compound ulipristal acetate has been made available and can also be taken up to 120 hours after unprotected intercourse.[2]

Emergency contraceptive (EC) pills work mainly by either preventing or delaying ovulation; this is likely the only mechanism of action, although there is some evidence showing that they may prevent the sperm and egg from meeting by altering the cervical mucus. EC pills are more effective the sooner they are taken. Regular oral contraceptives taken in specific doses also can serve as EC. For general information on EC, visit: www.plannedparenthood.org/ec/. For a list of regular oral contraceptives that can be used for EC purposes, visit: http://ec.princeton.edu/worldwide/default.asp#country.

Efficacy

Depending on the formulation used and timing of use, EC can reduce a woman's risk of becoming pregnant from a single act of intercourse between 75 and 89 percent.

Current program/sector use

EC is registered and available commercially in a number of countries. It is regulated as an over-the-counter or non-prescription product in many developed and developing countries. Still, many women are not aware of EC pills, and the pills often are not included in public-sector programs. For more information, visit: http://ec.princeton.edu/

Manufacturers/suppliers

There are many manufacturers of EC pills. Please see the following for a list of manufacturers:

http://ec.princeton.edu/questions/dedicated.html

www.cecinfo.org/database/index.htm

Registration status

Dedicated EC pill formulations are registered in more than 140 countries. For a list of country registration, please go to the International Consortium for Emergency Contraception site at www.cecinfo.org/database/index.htm.

Public-sector price agreements

Gedeon Richter, the manufacturer of Postinor-2, makes the product available to the public sector (government agencies) at a preferential price. Other manufacturers and distributors have demonstrated a willingness to provide a discounted price to public-sector agencies wishing to purchase their products.

References

1 The International Consortium for Emergency Contraception (ICEC). *Policy Statement: Regimen Update*. Washington, DC: ICEC; 2003. Available at: http://www.cecinfo.org/publications/PDFs/policy/Dosage_Timing_English.pdf.

2 European Medicines Agency (EMEA)/Committee for Medicinal Products for Human Use (CHMP). *CHMP Assessment Report for EllaOne*. Doc.Ref.: EMEA/261787/2009. London: EMEA; 2009.

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Female condom

Description

The female condom is a condom made of a soft, thin material that fits inside a woman's vagina. Like the male condom, the female condom is a barrier method, keeping the penis and sperm from contact with the cervix and vagina. But unlike the male condom, it also covers parts of the external female genitalia. The female condom offers protection against both unintended pregnancy and sexually transmitted infections (STIs), including HIV.

Current models on the market have a flexible ring, sponge, or capsule at the closed end of the condom, enabling insertion of the device and helping to keep the condom in place during sex. A ring or frame at the open end of the condom stays outside the vagina, lying flat across the genital area and ensuring that the condom stays in place, as well as protecting from external STIs. The female condom can be inserted into the vagina prior to sexual intercourse, is not dependent on a male erection, and can remain in place after ejaculation. It has no known side effects or risks and can be used by women of all ages.*

The first-generation female condom (FC1®), manufactured by the Female Health Company (FHC), was made from polyurethane—a thin, odorless material that is hypoallergenic, stronger than natural rubber latex, and conducts heat. The FC1® was launched on the market in 1992 but is no longer manufactured and has been replaced by a second-generation product, the FC2®.† The FC2® is made of nitrile rubber—a synthetic type of latex—and can be used with any type of lubricant, including oil-, silicone-, or water-based products.

In addition to the FC2® female condom, there are other female condoms made of natural rubber latex. Currently, there are two models of natural rubber latex female condoms on the market: the "VA w.o.w.®" or "Reddy" female condom and the Cupid™ female condom. Both come lubricated with silicone, but can also be used with water-based lubricants. Oil-based lubricants cannot be used with natural rubber latex condoms.

Three other female condom models are currently under development; this document will be amended and updated as needed once the condoms are available for purchase.

Efficacy

Data from the 2007 World Health Organization family planning handbook indicates that about 21 pregnancies occur per 100 women using female condoms over the first year. When female condoms are used correctly with every act of sex, about five pregnancies occur per 100 women over the first year.[1]

The most rigorous effectiveness studies were undertaken with the FC1® female condom (no longer on the market), and while one cannot extrapolate this data to all female condoms, they do provide basis for discussion. The World Health Organization and the US Food and Drug Administration have indicated that the FC2® is deemed equivalent to the FC1® and it is thus safe to assume that the studies conducted on the FC1® would produce similar results for the FC2®. Estimates on the contraceptive efficacy of the FC1® are within the range of other barrier protective methods (e.g., male condoms); over the course of one year, the accidental pregnancy rate ranges from 15 to 25 percent for actual use to as low as 5 percent for correct use with every act of intercourse.[2] FC1® maintains lower failure rates than either the cervical cap or diaphragm.

In vitro studies of the FC1® confirm that the product provides an effective barrier against many common STIs, including HIV. Calculations based on correct and consistent use estimate a 97.1 percent reduction in the risk of HIV infection for each act of intercourse.[2]

Research conducted on the FC1® in Brazil, India, Thailand, the United States, and Zambia indicates an increase of protected sexual acts and decrease in STI prevalence when FC1® is available alongside male condoms.[3,4,5,6,7] In a pilot study from Thailand, protected sexual acts increased from 57 to 88 percent, and STI prevalence decreased from 52 to 40 percent when both male and female condoms were available.[8]

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* Women who are allergic to latex are recommended to not use latex female condoms.

† See table below for additional information on currently available brands of female condoms.

Product	Regulatory status/ availability	General price estimates[a]	Distribution
FC2® female condom Nitrile (synthetic latex), pre-lubricated Manufactured by the Female Health Company	CE marking WHO approved, 2007 USFDA approved, 2009	US$0.57/unit Volume discounts may apply Retail: approximately US$1.96–2.80	Registered or distributed in 114 countries
VA w.o.w.® female condom (also known as: Reddy/V'Amour/L'amour) Polyurethane sponge and natural rubber latex, prelubricated Manufactured by Medtech Products Ltd.	CE marking India Drug Control Authority approval Brazil MOH approval USFDA Phase 1 clinical trials completed Under WHO review	US$0.23 at 35 million units Retail: US$1.00	Argentina, Brazil, Germany, India, Indonesia, Portugal, South Africa, Swaziland, and the United Kingdom
Cupid™ Condom Natural rubber latex prelubricated Manufactured by Cupid Ltd.	CE marking Under WHO review	US$0.40 approximately	India plus small scale distribution in Brazil and Indonesia. Limited private market sales in Europe

[a] Pricing information in this table is based on the most accurate information and/or estimates available. Prices may fluctuate depending on various procurement conditions, including volume and contractual stipulations.

Female condoms are the only female-initiated methods of HIV prevention that are safe and effective. Studies from 40 countries show acceptability rates ranging from 37 to 93 percent.[9]

Current program/sector use

Since 1993, approximately 260 million female condoms have been distributed in 114 countries, and public-sector programs are underway in over 90 countries. Availability of female condoms, particularly in developing countries, has increased from 14 million units in 2005 to 50 million in 2010.[10] However, based on data in the Reproductive Health Interchange, female condoms only account for approximately 0.19 percent of global condom procurement.[11]

The FC2® is purchased for public-sector programs by organizations such as the US Agency for International Development, the United Nations Population Fund, and governmental health ministries. The Female Health Company funds a global public-sector team consisting of professional program advisors that work with stakeholders on a pro-bono basis to build strong, comprehensive reproductive health, family planning, and HIV prevention programs. In addition, approximately five million VA w.o.w.® female condoms were sold commercially between 2003 and 2007.[12] The Cupid condom has limited distribution in India, Brazil, Indonesia, and some European countries.

Manufacturer

The Female Health Company manufactures, markets, and sells the FC2®. Medtech Products Ltd. of India manufactures, markets, and sells the VA w.o.w.® female condom, and Cupid Ltd. also of India manufacturers, markets and sells the Cupid™ condom.

Registration status

The FC2® has completed the evaluation process of the World Health Organization's (WHO) Technical Review Committee on female condoms, making it eligible for procurement by United Nations agencies. FC2® also received approval by the US Food and Drug Administration (USFDA) in March 2009.[13] In addition, the FC2® female condom has CE marking, which certifies that a product has met European Union consumer safety, health, and environmental requirements.‡

As of January 2010, the VA w.o.w.® female condom has not yet completed the WHO process, but carries the CE mark. The VA w.o.w.® female condom has received approval from the India Drug Control Authority and the Ministry of Health in Brazil.

‡ The manufacturer of a product affixes the CE marking to it, assuring the product meets European Economic Area regulations. However, the manufacturers does have to take certain obligatory steps before the product can bear CE marking: they must complete a conformity assessment, set up a technical file, and sign an European Community declaration of conformity. The documentation has to be made available to authorities on request.

The Cupid™ condom has received the CE mark and approval from the India Drug Control Authority, but has also not yet completed the WHO process.

Public-sector price agreements

FC2® is designed to replace the FC1® female condom and lowers the cost of female condoms for UN agencies, bilateral donors, governments, and nongovernmental organizations. Economies of scale allow for the cost of FC2® to drop as global distribution increases.

Public-sector pricing information on the VA w.o.w.® female condom is not currently available, although it has been supplied in small quantities to public-sector programs in Brazil, Finland, Portugal, Swaziland, South Africa, and Indonesia.

References

1 World Health Organization Department of Reproductive Health and Research and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), INFO Project. Family Planning: A Global Handbook for Providers. Baltimore and Geneva: CCP and WHO; 2007.

2 Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. *Family Planning Perspectives*. 1994;26:66–72.

3 Barbose RM, Berqu E, Kalckmann S. *Acceptability of the female condom in different social contexts: Final research report*. Brazil: Ministry of Health, National STD/AIDS Coordinating Office; 2007.

4 Hindustan Latex Family Planning Promotion Trust/The Female Health Company. *Female Condom: The Indian Experience: Final Research Report*. The Female Health Company; 2004.

5 Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS*. 1998;12(14):1851–1859.

6 Latka M, Gollub E, French P, et al. Male-condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. *Sexually Transmitted Diseases*. 2000;27(8):431–437.

7 Musaba E, Morrison CS, Sunkutu MR, et al. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sexually Transmitted Diseases*. 1998;25(5):260–264.

8 Hoke TH, Feldblum PJ, Van Damme K, et al. Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female sex workers. *International Journal of STD & AIDS*. 2007;18:461–466.

9 Female condom acceptability page. Family Health International website. Available at: www.fhi.org/en/RH/Pubs/Briefs/FemCondom/acceptability.htm. Accessed March 1, 2011.

10 Presentation of the WHO at the WHO/UNFPA workshop on the prequalification of female condoms. Bangkok, Thailand; December 2010.

11 Reproductive Health Supplies Coalition. Reproductive Health Interchange web page. Available at: www.rhi.rhsupplies.org. Access January 6, 2011.

12 Personal communications. Rino Meyers, IDA Solutions. July 3, 2008.

13 Reuters. USFDA approves new, cheaper female condom. March 11, 2009. Available online at: http://www.reuters.com/article/latestCrisis/idUSN10547381.

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HPV Vaccines

Two vaccines against human papillomavirus (HPV), a sexually transmitted virus that causes cervical cancer, were approved in 2006 and 2007 after more than ten years of intensive commercial research and development. More than half of sexually active people will contract an HPV infection at some point in their lives, although only a relatively small percentage of women will develop cervical cancer.[1,2] However, this translates to an estimated 530,000 women worldwide developing cervical cancer every year and 275,000 dying from the disease.[3] The vast majority of these women—around 85 percent—live in developing countries, where life-saving services to screen for and treat precancerous lesions are unavailable (e.g., using Pap smears or other screening technologies, followed by treatment).

Both vaccines—Gardasil®, the quadrivalent vaccine, and Cervarix®, the bivalent vaccine—prevent infection and precancerous lesions caused by HPV types 16 and 18. Gardasil® also prevents infection with types 6 and 11, which cause genital warts and respiratory papillomatosis. HPV types 16 and 18 account for approximately 70 percent of cervical cancer cases worldwide. Recently, some regulatory agencies approved language stating that both vaccines also offer some degree of cross-protection against a few non-vaccine cancer-causing types. Both vaccines are given in a series of three 0.5 mL intramuscular injections over six months—Gardasil® is administered on a 0-, 2-, and 6-month schedule, and Cervarix® on a 0-, 1-, and 6-month schedule.

Efficacy, target groups for vaccination, and duration of protection

In large, international clinical trials in young adult females, both vaccines were shown to be at least 92 percent efficacious in preventing HPV infections and precancerous lesions caused by vaccine types, when administered prior to HPV infection.[4,5,6] Young adolescent girls aged 10 to 14 years are the primary target group for HPV vaccination. While efficacy against infection and lesions was not demonstrated in young adolescents (because most were not yet exposed to infection), bridging studies have shown that antibody levels after vaccination are as high or higher in the young adolescent group as in young adult females.[7,8] Some countries are also targeting a secondary group for "catch-up," often women aged 14 to 18 years. There is evidence that duration of protection is at least seven years (the length of follow-up studies published to date), and longer-term efficacy is still being evaluated.[9] The potential benefit of vaccinating boys is still under investigation, but studies to date suggest that it is not currently cost effective. For more information, see the World Health Organization (WHO) position paper on HPV vaccines, available at: www.who.int/wer/2009/wer8415.pdf.

Global use

HPV vaccines are available through the private sector in more than 100 countries, and the vaccines have been introduced into routine immunization programs in approximately 30 countries. While they are not yet widely available in the developing world, a handful of low- and middle-income countries have introduced HPV vaccines into their immunization programs, at least in limited areas, and sometimes with the help of vaccine donations.[10] Research is underway to assess the feasibility, acceptability, and cost of HPV vaccination programs in low-resource settings. For more information, visit www.path.org/projects/cervical_cancer_vaccine.php.

Manufacturers

Gardasil® is manufactured by Merck & Co., Inc. (www.merck.com). Cervarix® is manufactured by GlaxoSmithKline (www.gsk.com).

Registration status

As of January 2011, Gardasil® was licensed in 121 countries and Cervarix® in 118. However, licensed vaccines may not yet be marketed in a given country.

WHO prequalification

In 2009, WHO regulatory authorities prequalified both HPV vaccines for procurement by United Nations agencies such as the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement.

Public-sector price agreements

The Global Alliance for Vaccines and Immunization (GAVI)—an immunization coalition of the world's top global health agencies, governments, and private partners—offers subsidized vaccines to more than 70 countries in the developing world. In late 2008, GAVI prioritized support for HPV vaccines as part of its new vaccine investment strategy, which identified the vaccines that would have the biggest impact on the disease burden in developing countries. WHO prequalification clears the way for GAVI to purchase the HPV vaccine in the future, and many low-income countries await GAVI subsidization, but this depends on GAVI raising additional donor funding.

References

1 Spitzer M. Human Papillomavirus: Epidemiology, natural history, and clinical sequelae. *OBG Management.* 2006;(Suppl 18):S5–S10.

2 Baseman JG and Koutsky LA. The epidemiology of human papillomavirus infections. *Journal of Clinical Virology* 2005;32S(2005) S16–S24.

3 Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM. GLOBOCAN 2008, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr Accessed January 6, 2011.

4 Paavonen J, Naud P, Salmeron J, et al. Efficacy of human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types (PATRICIA): Final analysis of a double-blind, randomised study in young women. *The Lancet.* 2009;374(9686):301–314.

5 Schiller JT, Castellsague X, Villa LL, Hildesheim A. An update of prophylactic human papillomavirus L1 virus-like particle vaccine clinical trial results. *Vaccine.* 2008;26:K53–K61.

6 Ault KA, FUTURE II Study Group. Effect of prophylactic human papillomavirus L1 virus-like particle vaccine on risk of cervical intraepithelial neoplasia grade 2, grade 3, and adenocarcinoma in situ: A combined analysis of four randomised clinical trials. *The Lancet.* 2007;369 (9576):1861–1868.

7 Reisinger K, Block S, Lazcano-Ponce E et al. Safety and Persistent Immunogenicity of a Quadrivalent Human Papillomavirus Types 6, 11, 16, 18 L1 Virus-Like Particle Vaccine in Preadolescents and Adolescents- A Randomized Controlled Trial. Pediatr Infect Dis J 2007;26:201–209.

8 Pedersen C, Petaja T, Strauss G et al. Immunization of Early Adolescent Females with Human Papillomavirus Type 16 and 18 L1 Virus-Like Particle Vaccine Containing AS04 Adjuvant. Journal of Adolescent Health; 2007;40;564–571 Block S, Nolan T, Sattler C et al. Comparison of the Immunogenicity and Reactogenicity of a Prophylactic Quadrivalent Human Papillomavirus (Types 6, 11, 16, and 18) L1 Virus-Like Particle Vaccine in Male and Female Adolescents and Young Adult Women. Pediatrics 2006;118:2135–2145.

9 De Carvalho N, Teixeir J, Roteli-Martins CM. Sustained efficacy and immunogenicity of the HPV-16/18 AS04-adjuvanted vaccine up to 7.3 years in young adult women. *Vaccine* 2010;28: 6247–6255.

10 Wang S. Update on HPV vaccines and WHO vaccine donations policy. Presented at: Global Meeting on Implementing New and Under-utilized Vaccines. 23 June 2010; Montreux, Switzerland.

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Levonorgestrel intrauterine system

Description

The levonorgestrel intrauterine system (LNG IUS) is a T-shaped, plastic, contraceptive intrauterine system (IUS) that releases the progestin hormone levonorgestrel into the uterus at a dose of 20 µg per day for up to five years. LNG IUS prevents pregnancy by thickening cervical mucus, inhibiting sperm motility, and suppressing the growth of the uterine wall.[1,2,3]

The LNG IUS must be inserted and removed by a qualified medical or health care practitioner using aseptic techniques. A gynaecological examination is advised before device insertion (to screen for infections and exclude pregnancy) and again four to twelve weeks after insertion. Thereafter, annual check-ups are recommended to ensure that the device remains in place and is functioning properly. There are no age or parity restrictions on its use, and women can use an LNG IUS throughout their reproductive life if it is replaced at the recommended intervals. Removal of an LNG IUS can be done at any time by a qualified medical or health care practitioner. Upon removal, fertility will return rapidly. LNG IUS is best suited for women who desire a long-term, reliable contraceptive method for birth spacing and limiting; and, women who have access to a qualified medical or health care practitioner for counselling, examination, insertion, and check-ups. The LNG IUS does not provide protection from sexually transmitted infections (STIs).

Efficacy, safety, and benefits

The LNG IUS is one of the most effective and long-lasting contraceptive methods available. Over the first year of use, the pregnancy rate is 2 per 1,000 women using an LNG IUS—in other words, 0.2 percent. After the first year, there is a lower risk of pregnancy—cumulatively only 5 to 8 pregnancies per 1,000 women over five years of use.[4,5]

Complications from LNG IUS use are rare, but may include uterine perforations at the time of insertion, expulsion due to inappropriate device location, and pelvic inflammatory disease.[6] Side effects associated with use of the LNG IUS include possible change in bleeding patterns (in frequency, duration, and amount), absence of bleeding, and benign ovarian cysts. In addition to the protection against pregnancy associated with use of LNG IUS, there are a number of significant health benefits related to the product's additional indication for the treatment of heavy menstrual bleeding.[7] These include the reduction of iron-deficiency anaemia, reduced volume of menstrual bleeding, and the lessening of menstrual cramps.[8] For more information on LNG IUS, its health benefits, and contraceptive dynamics, see the Special Issue on IUS/intrauterine devices of *Contraception*.[9]

Current programme/sector use

IUSs are now being introduced in both developed and developing countries and are gaining popularity in a number of countries in South Asia, Africa, and Latin America.[10] Mirena®, an IUS produced by Bayer Schering Pharma, is provided commercially through gynaecologists in the countries where it is registered. During 2009, approximately 3.03 million units were sold globally, with the largest sales reported in the United States and Europe. Since its introduction into the market, more than 18 million women have selected Mirena® as their method of choice.[11] The International Contraceptive Access (ICA) Foundation, founded by the Population Council and Bayer Schering Pharma, provides a bioequivalent LNG IUS that is now available in 13 countries through the public and non-profit sector via donations. Specifically, the ICA Foundation is currently providing one form of LNG IUS for projects in Brazil, Curacao, Dominican Republic, Ecuador, El Salvador, Ethiopia, Ghana, Indonesia, Kenya, Nigeria, Paraguay, Saint Lucia, and South Africa.

Despite the increasing popularity of the LNG IUS, there are several obstacles to its expanded use, including the upfront cost of the product in the private sector. In terms of costs over time, the LNG IUS is among the least expensive contraceptive method because of its long-term effectiveness, yet the initial cost of the product in the private sector is high.[12] Availability of the product is also a current constraint. The LNG IUS is generally not available in developing countries except through the ICA Foundation. The prevailing policies in many countries are also challenging access, as only certified nurses and medical practitioners are permitted to insert

IUSs. Authorizing trained allied health workers to carry out this procedure has been shown to be effective and cost-saving in a number of settings. Eliminating unnecessary follow-up visits may be another way to reduce costs and increase patient acceptability of the IUS. Requiring a clinic follow-up soon after insertion to ensure proper placement and absence of infection is important; thereafter, clinic visits only in response to negative signs and symptoms, or a woman's desire for removal, have been shown to be sufficient in treating complications and meeting patients' needs.[13]

Manufacturer

LNG IUS are manufactured in Turku, Finland by Bayer Schering Pharma Oy. The LNG IUS available in the private market as Mirena® is marketed internationally by Bayer Schering Pharma, and by Bayer Healthcare Pharmaceuticals in the United States.

Registration status/suppliers

The Mirena® IUS is registered in more than 120 countries worldwide, distributed commercially by Bayer Schering Pharma, and donated to public-sector organizations in the United States by the Arch Foundation. The LNG IUS provided by the ICA Foundation is registered in three countries (Ghana, Kenya, and Nigeria). This LNG IUS uses a different inserter than is used for Mirena® and often requires a different registration.

Public-sector price agreements

The ICA Foundation donates LNG IUSs to international development agencies and public-health organizations (both governmental and nongovernmental affiliates) who then offer the LNG IUS at reduced- or no-cost to poor women and families.[14] As of October 2010, more than 35,000 LNG IUS units have been donated by the ICA Foundation. The Arch Foundation provides donations to individuals meeting poverty criteria through qualified public-sector organizations in the United States.[15]

References

1 World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). *Family Planning: A Global Handbook for Providers*. Baltimore and Geneva: CCP and WHO, 2007.

2 Association of Reproductive Health Professionals (ARHP) website. Available at www.arhp.org. Accessed January 6, 2011.

3 International Contraceptive Access (ICA) Foundation website. Available at www.ica-foundation.org. Accessed October 28, 2010.

4 WHO/JHU/CCP, 2007.

5 Salem, R. New Attention to the IUD: Expanding women's contraceptive options to meet their needs. *Population Reports*. 2006; B(7). Available at: www.populationreports.org/b7/. Accessed January 6, 2011.

6 WHO, 2007.

7 Mirena® Significantly Reduced Heavy Menstrual Bleeding website. Available at http://www.mirena-us.com/hmb/mirena-reduces-heavy-menstrual-bleeding.jsp. Accessed October 28, 2010.

8 Fraser, IA. 2010. Non-contraceptive health benefits to intrauterine hormonal systems. *Contraception* 82: 396–403.

9 Special Issue on IUD/IUS of *Contraception*. 2007; 75(6S). Available at: www.contraceptionjournal.org.

10 Salem, 2006

11 Bayer AG 2009 annual report. Available at: http://www.annualreport2009.bayer.com/en/Bayer-Annual-Report-2009.pdfx. Accessed January 6, 2011.

12 Salem, 2006.

13 *Ibid*.

14 ICA Foundation, 2010

15 The Arch Foundation website. Available at: www.archfoundation.com. Accessed January 6, 2011.

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Manual vacuum aspiration

Description

Manual vacuum aspiration (MVA) can be used to manage a number of maternal health conditions—such as incomplete and spontaneous abortion or unsuccessful medical abortion—and can be used to perform first-trimester induced abortions and endometrial biopsies. MVA allows for evacuation of the uterus using a hand-held plastic aspirator attached to a cannula (a thin tube). Unlike electric suction, the suction used for uterine evacuation is created manually by extending the plunger of the syringe-like aspirator. MVA is similar to electric vacuum aspiration (EVA). The two methods share a mechanism of action—using suction as the force to remove uterine contents via the cannula. However, for EVA, a large electric machine generates the suction, and the aspiration is performed using a long tube connected to the EVA machine. The need for electricity, the larger size, and the greater cost of the machine precludes the use of EVA in many parts of the world, whereas MVA can be used in any location where basic medical care is provided.

MVA is safe, effective, easy to use, portable, and reusable. It is appropriate for use in many different clinical settings (including developing-country outpatient centres), does not require lengthy training for proper operation, and has yielded both high patient and provider satisfaction.[1, 2] Additionally, there is substantial evidence that mid-level providers—for example, midwives, clinical officers, nurse practitioners, physician assistants—can perform MVA procedures safely and effectively in a range of health care settings.[3,4]

Efficacy

MVA has been demonstrated to be effective and very safe through clinical studies over the last 30 years. The World Health Organization (WHO) recommends MVA as a preferred method of uterine evacuation.[2] When compared to sharp curettage (also known as dilation and curettage or D&C), MVA is a safer, more readily accessible, and potentially less expensive way to offer high-quality services to women.[5]

Studies demonstrate that the efficacy of MVA is comparable to EVA and is successful in approximately 99 percent of cases for early-elective abortion and management of early pregnancy loss. Studies show that 98 percent of vacuum aspiration procedures occur without complications, much higher than the alternative D&C method, which may induce incidences of excessive blood loss, pelvic infection, cervical injury, and uterine perforation.[6]

Current programme/sector use

Vacuum aspiration, both electric and manual, is used for about 97 percent of first trimester surgical-induced abortions in the United States. The United Kingdom, Canada, China, New Zealand, Singapore, and other countries use vacuum aspiration for most of their first trimester surgical-induced abortions.[7] In many developing countries, such as Bangladesh and Vietnam, MVA has been used for several decades to provide early-induced abortion, including procedures referred to as "menstrual regulation." MVA is well-suited for use in conjunction with medical abortion if there is a concern that the uterus has not been completely evacuated.

Manufacturer/supplier

MVA is available in many countries. Many governments have identified MVA in clinical guidelines as the preferred method for uterine evacuation, as well as in order to ensure adequate and reliable supplies of MVA instruments in their public health systems.

The original MVA device was developed by Ipas—an international organization that works to increase women's ability to exercise their sexual and reproductive rights, and to reduce abortion-related deaths and injuries. Ipas can be reached via the following contact information: PO Box 5027, Chapel Hill, NC 27514 USA. Telephones: (919) 967-7052, and (800) 334-8446 (toll-free in the United States). WomanCare Global LLC is the exclusive distributor of Ipas instruments. For information regarding availability, contact WomanCare Global at: customerservice@womancareglobal.com, or 1-919-442-2600, or visit www.WomanCareGlobal.com. Currently, there are a number of other MVA products available from other manufacturers, but quality is variable. Some efforts have been made to assess and document their relative quality.[8]

Registration status

Ipas MVA products are registered in a variety of countries throughout the world as accepted clinical procedures and approved medical devices. Each country defines the nature and limits of this registration.

Public-sector price agreements

None.

References

1 Manual vacuum aspiration—frequently asked questions page. Ipas website. Available at: www.ipas.org/Library/FAQs/Manual_Vacuum_Aspiration_-_Frequently_Asked_Questions.aspx?ht. Accessed January 6, 2011.

2 World Health Organization (WHO). 2003. *Safe abortion: Technical and policy guidance for health systems*. Geneva: WHO.

3 Goldman MB, Occhiuto JS, Peterson LE, Zapka JG, Palmer RH. Physician assistants as providers of surgically induced abortion services. *American Journal of Public Health,* 2004; 94(8).

4 Warriner IK, Meirik O, Hoffman M, et al. Rates of complications in first-trimester manual vacuum aspiration abortion done by doctors and mid-level providers in South Africa and Vietnam: a randomized controlled equivalence trial. *Lancet. 2006;* 368:1965–72.

5 Grimes DA, Benson J, Singh S, Romero M, Ganatra B, Okonofua FE, and Shah IH. Unsafe abortion: The preventable pandemic. *Lancet*, 368(9550):1908-1919.

6 Cates WJ, Grimes DA. Morbidity and mortality of abortion in the United States. In: Hodgeson, JE ed. *Abortion and sterilization: Medical and social aspects.* London: Academic Press; 1981.

7 Baird TL, Flinn SK. *Manual Vacuum Aspiration: Expanding Women's Access to Safe Abortion Services*. Chapel Hill, N.C.: Ipas; 2001.

8 Girvin S, Ruminjo J. An evaluation of manual vacuum aspiration instruments. *International Journal of Gynecology & Obstetrics*. 2003;83(2):219–232.

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Medical Abortion

Description

Medical abortion is a nonsurgical procedure in which drugs are used to induce abortion. The most effective and safest medical abortion regimen requires the use of two medications, mifepristone and misoprostol. The recommended regimen is 200 mg of mifepristone given orally, followed 24 to 48 hours later by 800 µg of misoprostol—given vaginally, sublingually, or buccally—up to 63 days since the last menstrual period.[1] Misoprostol can be given orally at a dose of 400 µg, but due to the higher failure rate, it is recommended that oral misoprostol use at this dosage be limited to pregnancy under 50 days, and even then other routes of administration are preferred.[2, 3, 4]

Mifepristone blocks the action of progesterone to enhance the contractility of the uterus and prompt the detachment of the implanted embryo. It also acts to soften and dilate the cervix. Misoprostol stimulates strong contractions of the uterus, expelling the products of conception. This process is very similar to that of a spontaneous abortion or miscarriage.[5] Repeated administration of misoprostol alone may lead to an abortion, but results in lower effectiveness rates and higher rates of side effects. However, misoprostol-only abortions may be an appropriate option in settings where mifepristone is not available.[6]

Quality abortion care should include counselling; confirmation of pregnancy; estimation of length of gestation; and screening for ectopic pregnancy by the patient's history, bimanual exam, or with ultrasound—although the latter is not required. Some settings offer a second visit to confirm the pregnancy is terminated. Contraceptive-options counselling should be provided at the time of the abortion or afterwards. The provision of safe abortion is an important component of reproductive health services. Medical abortion options have made abortion more available to women in a variety of health care settings.

Efficacy

Based on extensive research, mifepristone and misoprostol as a combined regimen have a success rate of complete abortion at 96 percent or higher and a rate of continued pregnancies at less than 1 percent.[1] Cramping and vaginal bleeding are associated and expected effects of medical abortions. Under medical supervision, the use of mifepristone and misoprostol is very safe. Medical abortion has not been associated with long-term health impacts and is statistically less risky than continuation of pregnancy.[7] Medical abortion may be preferable to surgical abortion for some women, and some providers, largely due to the avoidance of risks associated with such procedures (e.g., complications of anaesthesia), and also the fact that medical abortion is a less invasive and more private procedure.

Current programme/sector use

There are a number of political, logistical, cultural, religious, financial, and other barriers that limit universal access to medical abortion. Abortion is legally restricted in many countries. Where abortion is legal, challenges may arise in terms of health-system restrictions on where the services can be provided, procurement of the drugs (mifepristone products can be expensive, but lower cost products are becoming available), and provider training in order to properly inform and counsel patients about their options, the procedure, risks, and benefits. However, mifepristone and misoprostol are currently registered and being made available to women in numerous countries. The level of use in countries such as the United States and those in Europe suggests that women appreciate having an alternative to surgical abortion. Women in Europe have been using mifepristone and misoprostol for more than 20 years. In the United States, more than 1.4 million women have used Mifeprex since it was registered in 2000.[8]

Manufacturer/supplier

Mifepristone is branded as Mifegyne® by Exelgyn Laboratories and as Mifeprex® by Danco Laboratories. Misoprostol is most widely available as Cytotec®, which is manufactured and distributed by Pfizer; it is only registered by Pfizer for one indication—prevention and treatment of gastric ulcers secondary to chronic use of NSAIDs. Misoprostol products are registered for gynaecological indications in countries such as

Brazil, France, Russia, and Egypt, and registered specifically for use with mifepristone for pregnancy termination in France (registered by HRA Pharma as Gymiso®) and Russia (registered by Pentcroft Pharma as Misoprostol).The Concept Foundation has developed a combination-pack mifepristone-misoprostol product (Medabon®) to be marketed in developing countries for medical abortion; it is currently registered for this indication in Cambodia, Ghana, India, Nepal, and Zambia. For more information, visit www.medabon.info. Other manufacturers are also marketing combi-packs of mifepristone and misoprostol in the developing world. These manufacturers include, but are not limited to, MTP, Cipla, Sun, Discovery Mankind, and INTAS. In addition, generic and nongeneric misoprostol products are available through additional suppliers (other than Pfizer) in India, China, Egypt, Vietnam, Taiwan, Korea, Colombia, Brazil, and the United Kingdom.[9]

Registration status

Mifepristone has been approved for use in 48 countries worldwide.[10] Misoprostol has been approved for use in 85 countries for treatment and prevention of gastric ulcers and less frequently for treatment of gynaecologic conditions.[11] Mifepristone and misoprostol are listed on the WHO essential medicines list for use as abortifacients where legal and acceptable.[12]

Public-sector price agreements

The Concept Foundation has negotiated a preferential price for the public-sector in developing countries for Medabon®. Other suppliers are also offering their product (including combi-packs) at preferential pricing to the developing world. The number of suppliers is large and continuing to evolve. Pricing varies by manufacturer, is country-specific and is often dependent upon product demand.

References

1 World Health Organization (WHO). *Frequently Asked Clinical Questions About Medical Abortion: Conclusions of an International Consensus Conference on Medical Abortion in Early First Trimester, Bellagio, Italy*. Geneva: WHO; 2006.

2 Winikoff B, Dzuba IG, Creinin MD, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. *Obstetrics and Gynecology*. 2008;112(6):1303–1310.

3 Tang OS, Chan C, Ng E, Lee S, Ho P. A prospective, randomized, placebo-controlled trial on the use of mifepristone with sublingual or vaginal misoprostol for medical abortions of less than 9 weeks gestation. *Human Reproduction*. 2003;18(11):2315–2318.

4 von Hertzen H, Huong NTM, Piaggio G, et al., for the WHO Research Group on Postovulatory Methods of Fertility Regulation. Misoprostol dose and route after mifepristone for early medical abortion: a randomized controlled noninferiority trial. BJOG 2010; 117(10): 1186-96.

5 International Consortium for Medical Abortions (ICMA). *The ICMA Information Package on Medical Abortion: Information for Health Care Providers*. London: ICMA; 2008.

6 Misoprostol Alone page. Medical Abortion website. Available at: www.medicationabortion.com/misoprostol/index.html. Accessed February 7, 2011.

7 Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991 to 1999. *American Journal of Obstetrics and Gynecology*. 2006;194(1):92–94.

8 Mifeprex in the United States page. Mifeprex website. Available at: http://www.earlyoptionpill.com/section/health_professionals. Accessed February 7, 2011.

9 Fernandez MM, et al. Assessing the Global Availability of Misoprostol. *International Journal of Gynecology and Obstetrics*. 2009;105,180-186.

10 List of Mifepristone approval page. Gynuity website. Last updated June 2010. Available at: http://gynuity.org/resources/info/list-of-mifepristone-approval/ Accessed February 7, 2011.

11 Map of Misoprostol Approval page. Gynuity website. Last updated March 2009. Available at: http://gynuity.org/resources/info/map-of-misoprostol-approval/ Accessed February 7, 2011.

12 Mifepristone-Misoprostol page. WHO Essential Medicines Library website. Available at: http://apps.who.int/emlib/MedicineDisplay.aspx?Language=EN&MedIDName=443%40mifepristone%20+%20misoprostol. Accessed February 7, 2011.

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Progesterone-only vaginal ring

Description

The progesterone-only vaginal ring Progering® is used to extend the contraceptive effectiveness of lactation among breastfeeding women. Progesterone-only vaginal rings are inserted in the vagina for continuous use up to three months and replaced with a new ring if breastfeeding is continued and extended contraception is desired. Women can use these rings continuously for up to one year. Although not recommended, the ring may be removed for comfort during sexual intercourse for a period up to two hours. If the ring is removed for a longer period of time, an additional contraceptive method should be used for the following seven days. Upon weaning of the breastfeeding infant, progesterone rings should be replaced with a method that contains both a progestin and an estrogen if continued contraception is desired.[1]

The progesterone ring functions by diffusing a continuous flow of progesterone through the vaginal walls—approximately 10 mg per day—which then enters the blood stream and regulates the woman's fertility. Progesterone thickens the cervical mucus, inhibiting sperm penetration into the uterus, and prevents ovulation and building up of the endometrium.

Progesterone-only vaginal rings have a noteworthy presence in today's contraceptive method mix, especially as a contraceptive choice for breastfeeding women. Acceptability studies conducted with other contraceptive rings in Australia, Canada, Chile, the Dominican Republic, the United States, and 12 European countries have demonstrated that women generally like the vaginal ring for many reasons, including its effectiveness; its ease of use, including insertion and removal; the user control of these actions; and the lack of need to check it regularly.[2]

Efficacy

Clinical trials have shown a high contraceptive efficacy (over 98.5 percent) and a good safety profile. There have been some side effect reports of vaginal discharge, urinary discomfort, bleeding disturbances, and rare reproductive tract infections. Yet in a Chilean study, less than 5 percent of users experienced any one of these side effects.[3]

The effectiveness of the progesterone ring during the recommended three months of use has been shown to be comparable to that of the intrauterine device. While progesterone-only rings are less effective overall than rings containing both a progestin and an estrogen, they are highly effective among breastfeeding women because breastfeeding itself provides some protection from pregnancy. Also, they may be more appropriate for breastfeeding women because they do not contain estrogen, which can reduce milk production. The most common reason for discontinuation of progesterone-only rings is weaning, as mothers choose more effective contraception after they stop breastfeeding. Bleeding disturbances, a common side effect of all progesterone-only methods, is another frequent reason for discontinuation.[3]

Current programme/sector use

The product Progering® is sold commercially in Peru and Chile through gynaecologists. There is limited data on commercial sales in these two countries, but it does not currently have a great deal of market penetration. The product will also be tested in clinical trials in India during 2011, in anticipation of its registration and commercialization in Asia once approved by the Drug Controller of India.

Manufacturer/supplier

Progering® is the brand name of one progesterone-only vaginal ring currently available in Latin America, manufactured by Laboratorios Andromaco SA in Chile. The product is supplied by Laboratorios Andromaco.

Registration status

Progering® was registered in Chile and Peru in 1998 for use by breastfeeding women. It has also been approved and launched recently in 2010 in other countries in Latin America including Bolivia, Ecuador, Guatemala, and the Dominican Republic. The Population Council, CONRAD, the private companies Silesia SA and Andromaco SA funded its development.

Public-sector price agreements

None.

References

1 Nath A, Sitruk-Ware R. Progesterone vaginal ring for contraceptive use during lactation. *Contraception* 2010; 82: 428–434.

2 Upadhyay UD. New contraceptive choices. *Population Reports*, Series M, No. 19. Baltimore: The Johns Hopkins Bloomberg School of Public Health, INFO Project; April 2005. Available at: www.infoforhealth.org/pr/m19/

3 Massai R, Miranda P, Valdes P, et al. Preregistration study on the safety and contraceptive efficacy of a progesterone-releasing vaginal ring in Chilean nursing women. *Contraception*. 1999;60(1):9–14.

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