
Key Data and Findings

# *Contraceptive Commodities for Women's Health*

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Life-Saving Commodities for
Women and Children
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# A. BACKGROUND & RATIONALE

Under the auspices of the United Nations Secretary-General's Every Woman Every Child initiative, the Commission on Life-Saving Commodities for Women and Children will advocate at the highest levels for the increased availability, affordability and accessibility of essential but underutilized commodities for maternal and child health. When the creation of such a Commission was first proposed in 2011, the argument was made that positive health outcomes in reproductive, maternal, newborn and child health were being undermined by poor access to a limited set of life-saving commodities for which there were no global champions or institutionalized sources of financial and technical support. This emphasis on "neglected commodities", while widely applauded, did cause some to question whether contraceptive commodities, which have in the past benefitted from initiatives such as the Reproductive Health Supplies Coalition, could be considered neglected in the same way as other curative drugs and medicines.

The prospect that contraceptive commodities might be excluded from review by the Commission alarmed the broader reproductive health community. Their response was to re-affirm the critical role of family planning in averting maternal and newborn deaths and, perhaps even more importantly, to point out that among the array of family planning methods, certain methods were indeed neglected, underutilized and orphaned.

In October, representatives of the Commission called upon the Reproductive Health Supplies Coalition to identify one contraceptive commodity that most closely fit the criteria of "orphaned" and that held out the greatest promise for improving reproductive health outcomes. The Coalition's Executive Committee responded by identifying three: contraceptive implants, emergency contraception and the female condom.

The Commission's subsequent decision to include family planning in its mandate is an important testament to the need to build on the progress made in meeting the need and desire for contraception over the last four decades. In selecting these three overlooked contraceptive methods—contraceptive implants, emergency contraception and the female condom—the Commission has appropriately focused on ensuring access to methods that are in demand, show promise for increasing public health benefits (including beyond pregnancy prevention), and have received inadequate attention from the public and private sector. Yet, to realize the full public health benefits of increased availability of overlooked contraceptive methods, it is also essential to ensure access for all to a full range of methods and the ability of women to choose a method that fits within their own fertility goals and life circumstances.

Sexually-active women of reproductive age in developing countries experience high rates of unintended pregnancy. Nearly 90 percent of the estimated 208 million pregnancies in 2008 occurred in the developing world, according to the Guttmacher Institute. Globally, 86 million

pregnancies were unintended; of these, 41 million ended in abortions 33 million in unplanned birth and 11 million in miscarriage. Roughly as many women with unintended pregnancies obtain induced abortions as give birth to a child they had not planned for. The majority of these induced abortions take place in non-medical settings under unsafe conditions.

When women and couples can access a wide range of contraceptive methods, they are more likely to find a method they like and can use over a period of time, to switch methods when life circumstances change, and to meet their contraceptive intentions. Even among those who currently use contraception, many who would like to have no more children have no access to long-acting and permanent methods. Similarly those who are at risk of HIV/AIDS or other sexually transmitted infections (STIs) too often do not have access to the means for prevention of both infection and pregnancy. Youth, in particular, must overcome significant barriers to access contraception that meets their needs and vulnerability to unprotected sex.

Among investments in public health, those made to ensure access to contraceptive supplies and services are proven to result in significant improvements in the health of women and children.[1] The 603 million women who currently use modern contraception in developing countries, combined with the 215 million women with an unmet need for modern contraception, attest to the need and desire for contraceptive services and related commodities overall.

The choice of these three specific contraceptive commodities reflected two principal considerations. The first was that all three had long been classified by the Coalition's Caucus on New and Underutilized Methods as being "underutilized". The selected three were among 10 technologies that, to use the caucus' definition, were "not routinely available in the public, private, or social marketing sectors, ... [nor] routinely procured by the major procurers". They also reflected the criteria set forth in the Commission's original concept paper. All three were inadequately funded by existing mechanisms. In the case of implants and the female condom, both of which are currently witnessing price declines, there was evidence of the prospects for "… innovation and rapid scale up in product development and market shaping" (including potential for price reduction and improved stability of supply).

The second reason for their selection was that, as a group, the three serve as a bellwether for identifying opportunities for improving access, use and effectiveness of family planning and

[1] Each year, the current level of modern contraceptive use averts 188 million unintended pregnancies, which in turn results in 112 million fewer abortions, 1.1 million few newborn deaths and 150,000 fewer maternal deaths. If unmet need for modern methods were fully satisfied, an additional 53 million unintended pregnancies would be averted each year, resulting in 22 million fewer unplanned births, 25 million fewer induced abortions and seven million fewer miscarriages. The immediate health benefits of averting these unintended pregnancies would be substantial. Each year, an additional 90,000 women's lives would be saved and 590,000 newborn deaths would be averted. Guttmacher Institute, International Planned Parenthood Federation, *Facts on Satisfying the Need for Contraception in Developing Countries,* November 2010

for meeting Millennium Development Goal 5b—universal access to reproductive health. Many of the access issues that clients and health systems face when seeking to provide safe protection from unwanted pregnancy or infection (e.g. high unit cost, political opposition, poor supply chains, need for ancillary equipment, poor training of providers) are indicative of barriers faced by health systems in providing all contraceptive methods, and particularly those that exist outside mainstream donor and corporate priorities.

In considering improved access to these three and all contraceptive commodities, the Commission is urged to prioritize the following recommendations or interventions:

- Provision of the full range of contraceptive methods needed to meet women's and couples need for short-term, long-term and permanent methods of contraception and, where relevant, for prevention of STIs, including HIV;
- Ensuring equitable access to contraceptive commodities for all who are at risk of unwanted pregnancy;
- Streamlined regulatory processes and national-level responses to increase opportunities for the introduction and use of all services and commodities to improve maternal and child health.

# B. DATA SYNTHESIS

## 1. Contraceptive implants

**Overview**

Hormonal implants consist of small, thin, flexible plastic rods, each about the size of a matchstick, that release a progestin hormone into the body. They are safe, highly effective, and quickly reversible long-acting progestin-only contraceptives that require little attention after insertion. Clients are satisfied with them because they are convenient to use, long-lasting, and highly effective. Implants, which are inserted under the skin of a woman's upper arm, prevent pregnancy for an extended period after a single administration. No regular action by the user and no routine clinical follow-up are required.

Implants are available from three main manufacturers, Bayer Pharma AG (Germany), Merck/MSD Inc (USA), and Shanghai Dahua Pharmaceuticals Co., Ltd (China) with a cost ranging from $8 to $18.00 per unit.[2] The most common types include Jadelle (two rods each containing 75 mg of levonorgestrel, effective for five years); Sino-implant (II), which is currently marketed under various trade names including Zarin, Femplant and Trust (two rods each containing 75 mg of levonorgestrel, effective for at least four years); Implanon and Nexplanon (both with one rod containing 68 mg of etonogestrel, effective for three years). Nexplanon is radio-opaque, allowing x-ray detection if the rod is difficult to locate due to deep insertion, and also has an improved trocar. Norplant (six rods each containing 36 mg of levonorgestrel, effective for five to seven years) was discontinued in 2008.

**Policy – Guidelines, protocols, technical**

Implants are included in the WHO Essential Medicines list (2011) and specified as the two-rod levonorgestrel-releasing implant, each rod containing 75 mg of levonorgestrel (150 mg total). One rod implants are still not included in the WHO list. In addition, service delivery policies and protocols, are in place in many countries which support implant provision, including both two-rod and one-rod presentations. Given the different implant products that are available in diverse markets, technical requirements for competent training in counseling, insertion and removal of each product as well as related procurement processes is required to ensure that these commodities are provided appropriately. In some settings, policies allow task-shifting which permit lower cadres of health care providers (i.e. providers other than doctors such as nurses or midwives) to insert and/or remove implants. In Ethiopia since 2009, Health Extension Workers (HEWs) have offered Implanon at the community level through the Health Extension Program with nurses or midwives trained for removal.[3]

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[2] All amounts are in US dollars (US$)

[3] Under this scheme, female high school graduates are recruited and trained for one year (candidates must have completed grade 10 in school, need to be from the local community, and speak the local language).

### Regulatory: Registration and distribution

Jadelle is prequalified by the World Health Organization. It has been registered in more than 47 counties worldwide with review underway in an additional 10 countries. It is distributed commercially by Bayer Pharma. Sino-implant (II) is registered in 19 countries worldwide and is under active regulatory review in 10 additional countries. In addition to the manufacturer's name for the product (Sino-implant (II)) the product is marketed under a variety of names by different distributors: as Zarin by Pharm Access Africa, Ltd., as TRUST by DKT Ethiopia, and as Femplant by Marie Stopes International. Implanon is prequalified by the World Health Organization and registered in approximately 80 countries. It is distributed commercially by Merck/MSD.

### Financing and commodity costs

High commodity costs and a lack of supplies at the country level, due to lack of procurement or distribution networks within the country, contribute to unsatisfied demand for implants. Donors and governments may be more likely to purchase large quantities of short-acting, less expensive hormonal methods such as oral contraceptives (OCs) instead of more expensive, longer-acting methods such as implants. However, implants are more cost-effective in the long term than repeated use of short-acting methods.

Significant increases in procurement of contraceptive implants have been reported worldwide over the last several years. Data gathered by the RH Interchange show that in 2005 approximately 132,000 implants were donated in sub-Saharan Africa. By 2011, donations rose to more than 2.5 million. In 2011, Merck/MSD lowered the price of Implanon to $18/unit in developing countries. If sales volumes of 4.5 million units or more are reached by December 2012, the price will be reduced to $16.50, including retroactive price reductions. In addition, in March 2012, Bayer Pharma lowered the price of Jadelle to $18.00/unit in developing countries. Sino-implant (II) costs agencies seeking procurement approximately $8/unit.

For Jadelle**,** public-sector price agreements with organizations such as the U.S. Agency for International Development (USAID), the United Nations Population Fund (UNFPA), PSI and others have been established. For Sino-implant (II), public-sector price agreements are established with distribution partners. For Implanon, public-sector price agreements have been made through contracts with individual ministries of health, UNFPA, USAID and non-governmental organizations (NGOs) engaged in family planning.

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They are trained as HEWs to deliver a package of 16 preventive and basic curative services that fall under four main components: hygiene and environmental sanitation; family health services; disease prevention and control; and health education and communication.

Given the up-front cost of implants, their high level of effectiveness and their longer duration of use, both public and private sector financing strategies are used. In the public sector, subsidies are provided to clients who are unable to pay, either through lower prices to users or through alternative financing arrangements such as vouchers. In the private sector, users in the higher wealth segments usually pay full price for this product, or modest subsidies are provided through public-private partnerships such as franchises or social marketing schemes.

### Manufacturing and labeling

Currently there are three main manufacturers of implants, with both Bayer Pharma and Merck products being pre-qualified by WHO; pre-qualification has been applied for by Shanghai Dahua Pharmaceuticals Co., Ltd., the manufacturer of Sino-implant (II). (See the overview for formulations of each product). Each manufacturer has the capacity to significantly expand production, if sufficient demand was reflected in orders and financing was available in national markets or through donors. Quality assurance efforts are integrated within each manufacturer's production plans and marketing strategy. All products are shipped pre-packaged with appropriate labels, inserters, and instructions for providers and clients. Given the size of the global market for implants, the know-how required for manufacturing quality implant products and the pricing context. There are two smaller manufacturers who are working in some of these same markets. A second Chinese manufacturer (Ludan) is already making a two rod implant using the same "Sino-implant" technology and there is another manufacturer in Indonesia which is making Indoplant using a similar technology. Ludan is selling implants in China, while Indoplant has been registered in a few countries outside Indonesia as well.

### Effectiveness

Implants are one of the most effective contraceptive methods. In three years of Implanon use, less than one pregnancy per 100 users can be expected. For Jadelle, the cumulative pregnancy rate at the end of five years is 1.1 per 100 users. For Sino-implant (II), the cumulative pregnancy rate at the end of four years is 0.9-1.06 percent. These efficacy rates are comparable to those of other long-acting and permanent methods, including the IUD and female and male sterilization. The contraceptive effect of implants ends immediately after removal and fertility returns rapidly. In general, long-acting methods, including implants, are more effective in practice than shorter acting methods, including oral contraceptives and injectables, because compliance and continuation rates are higher with methods that do not require regular action by the user.

### Safety

Implants are safe for use by most women, including lactating mothers, women living with HIV, women who smoke cigarettes, women over the age of 35, women who have just had an abortion, women with diabetes, women at risk for cardiovascular disease (including those with high blood pressure), and adolescents. Women on antiretroviral therapy should discuss the use of implants with their doctor as the possibility of an interaction exists which might lead to somewhat reduced implant effectiveness. Implants can be initiated immediately after

childbirth if a woman is not breastfeeding, and six weeks postpartum if a woman is partially or fully breastfeeding. Studies have shown that use of implants has no impact on breastfeeding or the healthy development of breastfed babies. Compared to nonusers, users of implants could have reduced risk of ectopic pregnancies and pelvic inflammatory disease (PID). In some women, implants might help alleviate iron-deficiency anemia through reduced menstrual bleeding. Implanon might also help with dysmenorrhea and can help treat symptomatic endometriosis.

### Insertion and removal

Complications during insertion and removal of implants are rare. Implants can be inserted at any time during the menstrual cycle if the provider can be reasonably certain that the woman is not pregnant. Implants are effective immediately if inserted within the first seven days after monthly bleeding begins (five days for Implanon and Nexplanon). If a woman has implants inserted after the seventh day (fifth day for Implanon and Nexplanon), she must use a backup contraceptive method for the next seven days after insertion. In studies of experienced providers, insertion required an average of one to five minutes, and removal took three minutes to fifteen minutes, with faster times associated with implants with fewer rods.

Traditionally, reusable stainless steel trocars have been used to insert implants. However, these require sterilization between uses, and sterilization equipment is not always available in low-resource settings. Both Sino-implant (II) and Jadelle are now available with a disposable trocar (the one-rod Implanon has always been provided in a pre-loaded disposable trocar). Disposable trocars may make implant insertion more feasible in developing countries, enable a more decentralized provision of the method, and reduce the risk that improperly cleaned equipment could lead to transmission.

It is crucial that policymakers, donors and service delivery groups work together to guarantee that women have access to reliable, affordable implant removal services. This includes providing information about removal services at the time of insertion; ensuring adequate training of providers and sufficient commodities to support same-day removals when requested; and establishing adequate referral systems especially for women who receive implants through mobile services or community-based programmes.

### Side effects

The majority of implant users experience menstrual disturbances, although the menstrual changes are typically not as severe as those experienced by DMPA users. Disturbances can include heavy and prolonged menses, light intermenstrual bleeding, oligomenorrhea and amenorrhea. Such disturbances are the overwhelming reason that women stop using implants, followed by minor medical side effects and the desire to have children. Tolerance is lowest for prolonged bleeding (more than seven days), an excessive amount of blood, and frequent and irregular episodes of bleeding. Older women and more educated women tend to have lower rates of removal due to side effects. In addition to menstrual disturbances, side effects that can be attributed to implant use include weight gain, vaginitis, acne, breast pain,

headache, abdominal pain, ovarian cysts and mood changes. In contrast to injectable contraceptives, the hormone does not remain in the body after discontinuation, so side effects should resolve quickly after removal.

### Supply chain management

Stock-outs of contraceptive commodities and other needed equipment, instruments, and supplies for family planning provision are commonly reported in service programmes. The unavailability of either the method or other needed instruments and supplies means that implants services are also unavailable. Thus, attention to logistics is critical, and must include instruments, expendable medical supplies as well as the contraceptive implant itself. A table indicating which instruments and supplies are needed for both insertion and removal of the hormonal implants currently available can be found at http://www.k4health.org/toolkits/implants/logistics/instruments. One challenge for supply-chain management is that implants are often combined in information systems and on procurement lists leading to challenges in supply management.

### Demand for prescription and availability of services/products

Because of implants' effectiveness and ease of use, they are popular and in demand when available in family planning programmes. However, the upfront commodity cost can be a barrier to both procurement and client access especially in resource-constrained settings. Still, because they are long acting (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.

Although use of implants, as a percent of the method mix, remains low worldwide, demand often exceeds supply. In many settings where there are not enough supplies to meet demand, potential implant users go on waiting lists or choose another method. While total demand therefore is unknown, significant increases in procurement of contraceptive implants have been reported worldwide over the last four years.

### Demand by consumers and accessibility

Despite a high incidence of adverse menstrual events, overall levels of user satisfaction are high. Furthermore, implants have higher continuation rates than most other reversible methods. According to a recent Cochrane review, implants have continuation rates as high as 82 percent after two years. Users' attitudes about side effects are strongly influenced by the quality of information and counseling provided. Evidence indicates that thorough pre-insertion counseling can help women accept side effects and, as a result, can reduce their early discontinuation of the method. Providers should address not only menstrual disturbances but also the possibility of infection at the insertion site, the fact that implants do not protect against HIV or other STIs, the availability of removal services, and other contraceptive options.

Although increased use of implants could substantially reduce the numbers of unintended pregnancies, abortions, and maternal deaths, worldwide use of implants is low. Among married women between the ages of 15 and 49 around the globe, 53 percent use a modern method of contraception but less than one percent use implants. A study of HIV-positive pregnant women in Rwanda found that when access to long-acting reversible contraceptive methods was provided, a substantial number of women chose to initiate use of hormonal implants, but not IUDs. This suggests a need for improved access to implants for postpartum family planning and for HIV-positive women. Several studies have investigated the effectiveness and acceptability of the implant as a method of contraception for adolescent mothers after pregnancy.

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.

## 2. Emergency contraception

**Overview**

This description refers to the main method of emergency contraception (EC) currently available around the world, the levonorgestrel-alone dedicated product. While several other compounds – as well as IUDs – can be used as emergency contraception, the LNG product is the only one that is widely available in developing countries. The levonorgestrel-alone emergency contraceptive pill (ECP) is optimally taken in one dose of 1.5 mg, as soon as possible after sexual activity. A product containing two tablets of 0.75 mgs each, labeled to be taken 12 hours apart, is widely available.

A survey of 40 developing countries conducted by JSI/DELIVER found that ECP was most often offered in the commercial sector (81 percent of countries) followed by NGOs at 58 percent and the public sector at 54 percent. Thus, EC occupies a somewhat different market position than many other contraceptive methods that require the involvement of a clinician; there are benefits and disadvantages to EC's strength in the private sector.

A major restriction on women's use of EC is their very low rates of awareness of EC in most developing countries as captured in DHS surveys. Because EC is generally accessed at the pharmacy level women must know about it in order to seek it out. In this regard, EC differs significantly in the commodity and supply chain issues from the other two methods described here. It offers important lessons for other more user-initiated reproductive health technologies, such as misoprostol at the community level to prevent post-partum hemorrhage. This method is of particular importance for all those who have a limited access to contraceptives, adolescents in particular.

### Policy issues related to emergency contraception

Emergency contraception is well-supported by policies at the global level. It is included as part of the World Health Organization's Model List of Essential Medicines and is included in norms, protocols and guidelines issued by global organizations such as the International Federation of Gynecology and Obstetrics (FIGO). An EC product is registered in most developing and developed countries; where a product is not registered it is generally because of conservative policies and a conflating of EC with abortion (this is the case in Costa Rica, Honduras and the Philippines).

EC is safe and appropriate for dispensing without a prescription by a pharmacist or drug seller. Currently, it is registered as a non-prescription product in over 50 countries, including many lower income countries. Additionally, it is available directly from pharmacists informally even in many developing countries where it is registered as a prescription product.

In some countries, EC faces opposition due to confusion with abortion, and general opposition to family planning methods. Legal restrictions on sale or use are rare but do exist in a few countries. More commonly, restrictions on access are due to unnecessary prescription requirements or lack of provision in the public sector.

### Regulation

There are currently over 60 manufacturers of EC. Of these only two have received stringent regulatory approval from the U.S. Food and Drug Administration (USFDA) or the European Medicines Agency (EMA); they are products manufactured by Gedeon Richter and HRA Pharma. One product has received WHO Prequalification (Gedeon Richter's). The optimum formulation of the drug (the one-pill product) is patented and the two-pill non-patented product is more widely available to women in developing countries. Because EC is widely used in the developed world (Europe and USA) it is subject to extensive post-marketing surveillance and has been found to be safe.

### Financing

EC has found its niche in the commercial sector. Globally, the majority of EC that is used is purchased by women for their own use in the commercial sector; this is true in the developed and developing countries alike. Donor support is required for this method specifically to promote equitable access for poor women who seek services from the public sector, for post-rape care (usually provided in public hospitals) and for crisis and post-conflict settings. Donor support is needed for programming, including training providers and making women more aware of EC. Because women generally pay for EC out of pocket, attention should be paid to affordability and comparative cost of EC compared to other family planning methods.

### Monitoring and evaluation

Increasingly EC is being tracked in DHS surveys and country-level monitoring systems. This should be encouraged and strengthened.

### Manufacturing: Package, dose, formulation, instructions

Currently the package, dose and instructions are adequate but not optimum due to patent issues. The ideal EC package is a single pill formation which is currently under patent in both developed countries and member states of the African Regional Intellectual Property Organization. There are instances of developing countries selling a generic version of the single-pill formulation, but the majority of the product sold outside of Europe and the US is a two-pill formulation. The benefits of the single pill formulation are ease-of-use; there are no safety or effectiveness issues associated with the two-pill formulation.

### Supply chain management

EC, like other new and underutilized commodities, can prove challenging for supply chain management. Forecasting in particular is difficult with little historical data. Since EC is still little known by health care providers, there have been examples of countries (such as Kenya and Uganda) that have purchased EC for their public sector services only to see it underutilized as providers did not order it for their clinics. Programming must always accompany supply.

### Demand by consumers and accessibility

Because many consumers prefer to access EC from the commercial and social marketing sectors, they need to learn about it outside of clinic services. Media, social marketing and other demand generating strategies are all very important.

## 3. The female condom

### Overview

While a range of contraceptives protect against unintended pregnancies, only condoms—male and female—provide dual protection by stopping HIV transmission and preventing unintended pregnancies. Male and female condoms, when used consistently and correctly, are highly effective at preventing sexually transmitted infections (STIs), including HIV. Indeed, male and female condoms are central to efforts to halt the spread of HIV as recognized at the International Conference on Population and Development in 1994 as well as by the UNGASS Political Declaration on HIV/AIDS, adopted unanimously by United Nations Member States on 2 June 2006 and 10 June 2011 respectively. In particular, the female condom is currently the only technology that gives women and adolescent girls greater control over protecting themselves from HIV, other STIs and unintended pregnancy. The product, however, has not yet achieved its full potential due to inadequate promotional activities, insufficient supply and comparatively higher cost than male condoms (there is no fixed price, but the average price is about $0.57 for a female condom versus $0.03 for a male latex condom).

The total need for family planning condoms in low- and middle-income countries in 2015 is estimated at almost 5 billion pieces, according to a report by the Reproductive Health

Supplies Coalition report that estimates condom requirements separately (those used primarily for family planning and those used primarily for prevention of HIV and other sexually transmitted infections). The total for both purposes would be nearly 18 billion pieces in 2015. Large countries such as Brazil, China, India and South Africa, however, do not depend on donors for their condom supply, For this reason, the requirement for donor support is much less: approximately 4.4 billion pieces in 2015 of which 2.4 billion are for STI/HIV prevention and 2 billion are for family planning. (Reproductive Health Supplies Coalition, 2009)

**Policy – Guidelines, protocols, technical**

Condoms, both male and female, are currently the only available and most effective technology to prevent HIV and other sexually transmitted infections, as well as unintended pregnancies, among sexually active people. They are inexpensive, cost-effective, do not need a prescription, have no side effects[4], and can be used by every sexually active person in need of a barrier method.

An estimated 10 billion condoms are needed every year to cover all risky sex acts. In 2010, 2.8 billion male condoms and 18 million female condoms were provided by the donor community, mostly to sub-Saharan Africa. Though the number of condoms distributed by the private sector is not known, this market is almost nonexistent in sub-Saharan Africa, where commodity support, including male and female condoms, is heavily dependent on donation from development partners.

One female condom was distributed for every 13 women of reproductive age in sub-Saharan Africa in 2010. Nine male condoms were available for every adult male of reproductive age in sub-Saharan Africa. These results were confirmed by a USAID review of 16 sub-Saharan countries in 2010, which noted large variations the availability of male and female condoms:[5]

> The review identified large variations in condom availability—ranging from nearly 30 male condoms per man per year in Zimbabwe to only 1.1 male condoms per man per year in Côte d'Ivoire—among the 14 countries for which data were available. The median average availability of male condoms was 9.65 condoms per man per year. While no standard guidance exists on the appropriate number of condoms needed per man per year to protect against HIV infection, less than 10 condoms per man per year appears at face value to be insufficient given the number of sex acts that are likely to take place in one year. Female condom availability was significantly lower than male condom availability in all countries. With the exception of Zimbabwe, less than one

[4] People with an allergy or intolerance for latex should refrain from using latex male or female condoms.

[5] The review focused on 16 countries in sub-Saharan Africa: Botswana, Côte d'Ivoire, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

female condom per woman per year was available. With the exception of Zimbabwe, less than one female condom was available per woman aged 15-64 in all 14 countries and the average availability of female condoms was 148 times lower than that of male condoms.

Despite years of advocacy with parliamentarians and other stakeholders, the vast majority of low- and middle-income countries do not have a budget line for male and female condom acquisition. If condoms are mentioned in policies, female condoms are rarely included, or only for high risk groups and not as a family planning commodity.

Though new HIV prevention strategies and policies at the global level have integrated female condoms as a vital commodity for protection[6], this is still not the case in many countries. The female condom is not included in the 2010 WHO Model List of Essential Medicines, making it difficult for countries to enter it in their national essential list of commodities.

A number of new female condom (FC) products are available in limited distribution in some countries or are in the development process. The Cupid FC, made in India has a limited global distribution. The Phoenurse FC is available in China, with approval from the Chinese State Food and Drug Administration (SFDA) and European CE marking (Conformité Européene). The Innova Quality S.A.S "Condon Femenino" FCS Panty Condom is available in Colombia, with European CE marking. The Woman's Condom is available in limited distribution channels in China, including online, and has Chinese SFDA approval and European CE marking. All of these female condoms are currently under review by the WHO/RHR Female Condom Technical Review Committee to determine their suitability for public-sector purchase. The Origami FC made of silicone is still being developed and plans to test the device for its reusability potential will be a part of future testing.

**Regulation**

The most widely distributed female condoms are FC2, produced by the Female Health Company. Today, FC2 is the only female condom to have completed the technical review process by the WHO, which found it acceptable for bulk procurement by all United Nations agencies in 2007, followed by USFDA approval in 2009.

As noted above, other female condoms (e.g. Cupid FC in India, the Natural Sensations Panty Condom in Colombia, and Women's Condom in China) have received the CE marking for sale in Europe and are in limited global distribution. The Phoenurse FC is available in China. These new condoms are currently under review by the WHO/UNFPA Technical Committee to determine their suitability for public-sector purchase.

[6] Among others UNFPA, UNAIDS, PEPFAR, USAID, DFID

### Financing – Traditional, innovative

The vast majority of female condoms are procured and donated by the international community to low and middle income countries. In 2010, more than 90 percent of supplies went to sub-Saharan Africa, and most of the remaining went to Asia.

In terms of trends in donor expenditures for female condoms, there was an increase from 2007 to 2008 of about $2 million and then a sharp rise in 2009, doubling support by all donors for the procurement of female condoms from $14 million to $29 million. In 2010, donors' support for the procurement of female condoms significantly decreased to about $12 million. A relatively small number of countries use domestic funds to buy female condoms, including Botswana, Brazil, India and South Africa.

Female condoms remain very expensive to procure. It was expected that the new material used to produce FC2 would result in a significant reduction of the price. Though the price did drop by 25 percent, the average FC2 unit cost is still $0.57 which is almost 20 times more costly than male condoms ($0.03). Given the fact the female condom is more complex to produce than the male equivalent and that more materials are used, the cost will never be as low as the male condom. However, female condom experts expect a drop in the procurement price to at least $0.35 per unit. A combination of increased demand, increased competition (because of more WHO prequalified female condom models from different manufacturers) and pooled procurement could result in even lower prices.

Female condom programming requires at least four to five times the product cost to ensure that service providers are adequately trained and that educational materials including demonstration models are made available to women and couples. This is particularly true when first introducing the female condom in an area. As the results of the female condom programme in Zimbabwe show, female condom programme costs do decrease over the years as more people acquire knowledge on the female condom and its use.

Unlike male condom distribution, there is currently no private sector involvement in the sale of female condoms at the country level, with the exception of small enterprises distributing condoms through social marketing.

### Monitoring and evaluation, and information systems

The female condom is not integrated into any monitoring and evaluation system at the global nor, for most countries, at the national level. This makes it difficult to measure its added value as an HIV prevention option or an effective contraceptive. Special studies to assess the impact of the female condom on STI/HIV prevention, cost-effectiveness studies or efficacy/effectiveness studies, have received limited funding in the past decades. The only research data that exists on female condoms are related to the original or first generation female condom (FC1). The PATH Woman's Condom is currently being assessed as a contraceptive method.

### Manufacturing: Package, dose, formulation, instructions

The first female condom (FC1) was introduced on the market by the Female Health Company in 1992. This female condom, made of polyurethane, has been replaced by a new version, the FC2. This condom is nearly identical to its predecessor but is made of synthetic nitrile and considerably less expensive to manufacture. After technical consultation with WHO in January 2006 to review the new female condoms dossier, experts concluded that FC2 was compatible with FC1 and recommended it for UNFPA procurement for public sector programmes. Production of the FC1 has since ceased.

More manufacturers are currently in the process of either developing a female condom or are having their model assessed by WHO for prequalification. A thorough but quick prequalification procedure would mean a big step towards more choice and variety and more competition and therefore lower prices on the international female condom market. This will facilitate more and better access for men and women who want to use them and who would highly benefit from the female condom.

An important aspect of programming is the marketing of the condom, as was the case for the male condom when it was introduced to new markets. To make it an attractive and appealing product, presentation and marketing needs to be taken into account.

### Acceptability of the female condom

Women may be able to negotiate use of the female condom more easily than the male condom, giving them potentially more power to protect themselves in a sexual relationship. But the female condom must be acceptable to both men and women in order to be used consistently and correctly, thus providing effective protection against sexually transmitted infections and pregnancy.

Studies conducted in more than 40 countries in Africa, Asia, Europe, Latin America and North America have found good initial acceptability of the device by people with varying sexual histories, ages, social situations and economic status. Acceptance rates in these studies varied widely, from 37 percent to 96 percent of study participants.[1] More research is needed to confirm whether initial acceptors continue female condom use over time. Research and programme experience suggest several conclusions:

- Counseling helps overcome women's initial difficulties in using the device;
- Directing promotion campaigns to men and providing women with negotiation skills are important to overcome men's resistance to use; and
- Over time, use tends to become concentrated among a subset of women or couples with high motivation to use it.

### Supply chain management

Poor distribution systems significantly restrict male and female condom accessibility. When donors ship large numbers of condoms to a country, they are not always distributed in an effective and efficient manner, contributing to their decreased accessibility for end-users.

Problems with distribution systems may be due to a lack of transport capacity (particularly availability of vehicles) and poor infrastructure such as roads and bridges, which can make distribution to rural and remote areas difficult. UNFPA estimates that in Mozambique only 25 percent of condoms provided by USAID and UNFPA reached end-users in 2008, and that 85 percent of the available 50 million public sector condoms sat in central warehouses in June 2009. This was largely a result of limitations in space available in vehicles due to increased distribution of HIV essential drugs and treatment commodities.

### Demand for prescription and availability of services/products

The female condom does not require a prescription but is based on user-awareness of the method and its benefits. It is often distributed free of charge or at a very subsidized price by NGOs, community-based organization or public sector organizations. It is a coital dependent method, which necessitates some training for proper insertion. The female condom is a visible internal device, effective and recommended for penile-vaginal intercourse. The female condom also has been reported for use for penile-anal intercourse but research on this topic is very limited. In either case, it involves the two partners' collaboration for use.

### Demand by consumers and accessibility

The female condom is a powerful dual protection tool that has been much neglected. The female condom is barely available to women and couples to protect themselves when needed. As discussed above, acceptability of the female condom, once consumers are educated about the product and its usage, is not the issue. It is the accessibility, availability and affordability of the female condom that hampers the demand and uptake. When governments do not include female condom in their prevention programmes, when there is little variety of choice like with the male condom, the female condom remains an unknown answer to the often posed question of family planning. Men and women need to be able to make the choice whether they want to use a male or female condom when they are looking for a dual protection method. Currently that choice is rarely an option.

Barriers to the accessibility and availability of female condoms limit demand and uptake:

- There is no budget line in most national programmes for FC procurement;
- Limited funds are allocated to programming including human resources for education and promotion, job aids, demonstration models, raising awareness campaigns and more. Without proper and adequate training and demonstration, men and women who want to use the female condom for the first time can experience difficulties inserting the tool correctly and may feel intimidated or discouraged. With practice, insertion becomes easy;
- Global public sector distribution of female condoms was about 35 million in 2010 (50 million in 2009) for all sexually active women at risk of HIV and unintended pregnancy and whose partner is reluctant to use a male condom. That translates to 1 female condom available for 13 women in sub-Saharan Africa, most hit by the HIV epidemic; and

- The female condom is absent from the contraceptive mix of family planning products.

**Areas of need and potential impact, with country examples**

Effective female condom interventions can increase the proportion of protected sex acts and decrease STI prevalence. The contribution of the female condom to overall increased protection and decreased prevalence of STIs depends on who uses it, how correctly and consistently it is used, and whether it is a substitute for the male condom. The female condom is also likely to reach women in relationships in which other barrier methods have not been used, and to help empower women in negotiating safe sex.

Several studies show that providing the female condom as part of a comprehensive prevention strategy results in increased levels of protection.[7] Protected sex among women in the United States and Brazil doubled after they received female condoms and counseling on their correct use. In Madagascar, protected sex increased by 10 percent among sex workers due to their use of the female condom. Studies in other countries, including Kenya, Nigeria, South Africa, the United States, Zambia and Zimbabwe found that encouraging use of either male or female condoms contributed to increases in the proportion of protected sex acts. When both types of condoms are available, consistent condom users often alternate use of female and male condoms. These studies provide important evidence that the female condom is not just a substitute for the male condom, but is complementary and contributes to increased use of both types of condoms.

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# C. RECOMMENDATIONS FOR FOCUS BY UN COMMISSION

**Contraceptive implants**

Contraceptive implants offer a safe and effective means of contraception to those women who seek a long-acting contraceptive product that is private in use and can be used for both spacing and limiting births for women of reproductive age.

We therefore call on the United Nations Commission on Life-Saving Commodities for Women and Children to advocate to governments and the donor community to expand their support to:

- Further expand innovative financing strategies for subsidizing the cost of procurement and provision of implant services as well as the cost to users. (Market Shaping)
- Support efforts by health systems to adopt policies and guidelines for the provision of implant services, both insertion and removal, by a range of qualified providers, which may include physicians, nurses and other paramedical personnel where competency is assured. (Regulatory Environment)
- Ensure access to safe removal of implants for all women either at the time the product loses efficacy according to the label or whenever the women would like to have it removed for any reason. (Regulatory Environment)
- Improve record keeping on both users and supplies of implants to ensure timely access to removal, as well as reporting on the specific product used for better forecasting of the need for implants and related supplies. (Regulatory Environment)
- Review medical eligibility criteria for women to use implants, eliminating medical barriers to their use due to age, parity or exposure to the risk of HIV acquisition or transmission. (Regulatory Environment)

**Emergency contraception**

Emergency contraception is a unique family planning method that is woman-controlled and can be used as needed to substantially lower the risk of pregnancy from an individual act of coitus. It can safely be provided in pharmacy settings without clinical supervision, so it is a good fit for the commercial and social marketing sectors.

We therefore call on the UN Commission to advocate to governments and the donor community to expand their support to:

- Support and strengthen quality assurance mechanisms at the country, regional and global levels, including WHO's Prequalification work. (Regulatory Environment)

- Support the capacity of the pharmacy and drug-selling sectors to provide high quality family planning products and advice. (Regulatory Environment)
- Ensure that supplies are coupled with programmatic support (e.g. training of providers, strengthening of clinic systems in all cases to ensure that commodities that are purchased are pulled through the system and delivered at service delivery points. (Market Shaping)
- Support evidence-based advocacy to increase women's awareness of a full range of contraceptive options and reduce provider and systemic barriers to access to all contraceptive methods. (Best Practices, Innovation)

**Female condom**

The male and female condoms are the only technology currently available that enables women to protect themselves against unintended pregnancies and sexual transmitted diseases. When men are reluctant to use a male condom, women and girls are left with only female condom as a choice. Access to the female condom will empower them by giving them more control over their own bodies and reproductive health. It offers a life-saving alternative when male condoms are not used and helps reduce unprotected sexual activity.

We therefore call on the UN Commission to advocate to governments and the donor community to expand their support to:

- Create an enabling environment among policy makers and providers so that users will be made aware of their risk, feel free to demand and access male and female condoms and have the knowledge to use them correctly and consistently. (Demand Generation)
- Augment their funding for essential commodities, including male and female condoms for HIV prevention and as a dual protection method. (Market Shaping or Innovation Strategies for Demand Generation)
- Allocate funds for integrated programming, including capacity-strengthening for service provision, global awareness campaigns on the role of condoms, demand-creation to stimulate and sustain their use, and monitoring and evaluation systems to improve programme delivery and measure the effectiveness and impact of condom use. (Strategies to Increase Demand, Innovation for Scaling Up)
- Allocate financial resources to female condom research and development. Having only one female condom manufacturer whose product is approved by WHO and FDA is too risky. In case that company ceases production, women and couples will be left with no alternative to female condoms in the fight of sexually transmission of HIV and dual protection. (Regulation)

# D. CITED WORKS & SUPPLEMENTARY MATERIAL

## Contraceptive implants

A peer-reviewed synthesis of existing information on contraceptive implants can be found here: http://www.path.org/publications/files/RHSC_implants_br.pdf


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