about PFI

Population Foundation of India (PFI) is a national NGO which promotes and advocates for the effective formulation and implementation of gender-sensitive population and development strategies and policies. PFI was founded in 1970 by a group of socially committed industrialists under the leadership of the late JRD Tata and Dr Bharat-Ram.

PFI addresses population issues within the larger discourse of empowering women and men, so that they are able to take decisions related to their lives, health and well-being. The organisation works with the government and like-minded NGOs to give men and women the knowledge and means to plan and raise healthy families. PFI is guided by an eminent governing board and advisory council comprising renowned personalities from the civil society, the government and the private sector.
Evidence and Experience in India

Developed by the Central Drug Research Institute of India in the late Nineties, Centchroman (or Ormeloxifene), a non-steroidal weekly oral contraceptive pill, has undergone extensive clinical trials. Centchroman is a selective Estrogen Receptor Modulator. It acts on the estrogen receptor in the body to either stimulate or suppress it.

While it acts as a birth control pill by suppressing the receptor organs like the ovaries, the uterus, and the breasts, it helps in the formation of new bones by stimulating estrogen receptors in the bones. The role of centchroman in prevention of breast and uterine cancers is significant. Since December 1995, Centchroman (popularly known as Saheli and Novex), used to prevent pregnancy, is being subsidised by the Government of India.

Centchroman acts at three points in the reproductive cycle:

1. It increases the movement of the fertilised ovum through the fallopian tubes so that it reaches the uterus 'too early' when the endometrium is not ready for implantation at the time.

2. It increases the rate of maturation of the ovum, so that it is hypermature when it reaches the endometrium and fails to implant in it.

3. It slows down the growth and development of the endometrium so that it is not adequately prepared to receive the fertilised ovum when it reaches the uterus.
About the method

- Centchroman (or Ormeloxifene) is a Selective Estrogen Receptor Modulator (SERM), a potent non-steroidal, non-hormonal birth control method. It acts on estrogen receptors in the body by either stimulating or suppressing them, possessing potent estrogen antagonistic and weak estrogen agonistic activities.
- Centchroman is available as 30mg tablets. A single tablet should be taken twice a week (For example on a Sunday and a Wednesday) for the first three months, and then weekly (every Sunday) thereafter. The first pill is taken on the first day of the period. Additional contraceptives like condoms should be used for the first month.

Effectiveness

- It has a failure rate of less than 2%.

Advantages

- It is highly effective.
- It is safe to use, but a thorough pelvic examination is necessary as ovarian cyst formation may occur, and it is important to exclude pre-existing cysts.
- Being non-hormonal, it does not cause nausea, dizziness, weight gain and other side effects associated with birth control pills.
- It has no adverse effect on blood coagulation, liver function and lipid profile. So there are no chances of blood clots or increase in the cholesterol level due to centchroman.
- It is not toxic. In women, who became pregnant while on centchroman, no congenital anomalies were noted in the babies.
- Since it does not stop ovulation, return to fertility is faster once the pills are stopped and the risk of infertility is minimal.

Possible side effects

- Centchroman causes delayed periods in some women. But this occurs in less than 10% of users and usually in the first three months. The periods tend to settle down to a rhythm once the body gets used to the drug.
- There may be heavier periods in the first three months with tender breasts, water retention, and some amount of acne.
- Periods can get scanty over time in some women.

Sources
Global Evidence and Programme Experiences

The diaphragm has been in use as a contraceptive method for a long time. Women in developed countries find these devices acceptable. The SILCS diaphragm – a new, single-size device – is part of an effort to develop new cervical barrier devices for prevention of STI/HIV and pregnancy. The design has had high acceptability, efficacy and is easy to administer and use.

In a 2008 study conducted among couples in South Africa and Thailand, women reported that the SILCS diaphragm was easy to use and provided good comfort in over 80% of all product uses. Men also reported good comfort in over 60% of all product uses.

In a comparative crossover study of the SILCS diaphragm with a traditional diaphragm in the Dominican Republic, 19 of 20 women preferred the SILCS diaphragm after short-term use. Data from clinical studies confirm the single-size device fits most women.

In INDIA

In the 1960s and 1970s, diaphragms were a part of the National Family Planning Programme. However, the introduction of Intrauterine Devices (IUDs) led to the decline in their use. Studies on the SILCS product are being conducted in Rajasthan and Karnataka by PATH.

About the method

- A diaphragm is a soft latex, plastic or silicone cup (comes in different sizes) with a flexible rim to keep it in place. It is placed deep in the vagina before sex and covers the cervix.

- The first time use of diaphragm must be prescribed by a health care provider or clinician who will make sure that you get the right size, and teach how to insert and remove the device. Pelvic examination is needed before it is inserted.

Effectiveness

- 84 of every 100 women using the diaphragm in the first year will not become pregnant.

- The use of diaphragms with spermicide during every intercourse reports 6 pregnancies per 100 women.

- Fertility returns immediately after stopping the use of diaphragms.

- Requires correct use during every intercourse for greater effectiveness.

Advantages

- No hormonal side effects.

- May help protect against certain STIs (chlamydia, gonorrhea, pelvic inflammatory disease, and trichomoniasis), cervical pre cancer and cancer.

- Can be inserted ahead of time, so does not interfere with sexual activity.

Possible side effects

- Irritation in or around the vagina or penis.

- Vaginal lesions.

- Health risks:
  - Common to uncommon: Urinary tract infection.
  - Uncommon: Bacterial vaginosis, Candidiasis.
  - Rare: Frequent use of nonoxynol-9, a spermicide may increase risk of HIV infection.
  - Extremely rare: Toxic shock syndrome.
  - Diaphragms should not be used when the user has any history of vaginoplasty, rigid vaginal walls, vaginal malformations, strictures, recurrent cystitis (urinary tract infection), or toxic shock syndrome.

FEMALE CONDOMS

Global Evidence and Programme Experiences

The female condom is a contraceptive for use by women. It also protects from HIV.

Studies from 40 countries show acceptability rates ranging from 37% to 93%1. In a pilot study from Thailand, protected sexual acts increased from 57% to 88%, and STI prevalence decreased from 52% to 40% when both male and female condoms were available.

A study on male acceptance of female condoms in Zimbabwe, Cameroon and Nigeria in 2011 revealed that nearly all participants believed in the superior effectiveness of the female condom for prevention of pregnancy and protection against HIV/STIs, in comparison to other contraceptive methods and male condoms2.

Research conducted on the first generation of female condoms (FC1®) in Brazil, India, Thailand, the United States and Zambia indicated an increase of protected sexual acts and a decrease in STI prevalence when FC1® is available alongside male condoms.

In INDIA

Female condoms are available only in the private sector. The female condoms programme of National AIDS Control Organization (NACO) in India empowers female sex workers (FSWs) to protect themselves from HIV infection in low-negotiable environments. NACO’s female condom programme implemented through NGOs in six high prevalence states indicated high levels of acceptance among FSWs and close to 5% reduction in unprotected sex. NACO is currently funding the female condom scale-up programme in four states - Tamil Nadu, Andhra Pradesh, West Bengal and Maharashtra. NACO also plans to scale up the programme in two to three districts each in nine more states. Another female condom scale-up programme funded by UNFPA is being implemented in four states - Bihar, Jharkhand, Orissa and Rajasthan. NACO provides female condoms at a highly subsidized rate3.
About the method

Female condoms are sheaths, or linings, made of thin, transparent, soft plastic film that fits loosely inside a woman’s vagina. They have flexible rings at both ends.

Effectiveness

- As commonly used, there would be about 21 pregnancies per 100 women using female condoms over the first year, i.e. 79 of every 100 women using female condoms will not become pregnant.
- When used correctly with every sexual activity, the effectiveness increases to about 5 pregnancies per 100 women over the first year.
- Female condoms reduce the risk of STIs and HIV when used correctly with every act of sex.

Advantages

- Female condoms help protect against both pregnancy and STIs, including HIV.
- They have a soft, moist texture that feels more natural than male latex condoms during intercourse.
- No known health risk.

Possible side effects

Mild irritation in or around the vagina or penis (itching, redness or rash).

Implants

Implant as a Contraceptive Choice

Contraceptive use has recently increased substantially in a number of Eastern and Southern African countries. While this has been mainly due to increased use of injectables, the use of implants has also risen notably over a short time span in countries such as Ethiopia, Malawi, Rwanda, and Tanzania. For example, one in every seven women using modern contraception in Rwanda currently relies on an implant, compared with less than one in 25 in 2005. These trends suggest that wider availability of implants could lead to much greater use in countries where they are currently available easily. High rates of user satisfaction (79%) and continuation (around 84% at one year of use) further support this likelihood.

Between 2008 and 2012, Marie Stopes International (MSI) provided 1.7 million contraceptive implants in Sub-Saharan Africa as part of a comprehensive method mix. High levels of client satisfaction were attained, service quality maintained, and access increased for underserved clients through mobile outreach, social franchising and clinics.

Key Characteristics of the 3 Available Contraceptive Implants

<table>
<thead>
<tr>
<th></th>
<th>IMPLANON*</th>
<th>JADELLE*</th>
<th>SINO-IMPLANT II*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Merck</td>
<td>Bayer HealthCare</td>
<td>Shanghai Dahua</td>
</tr>
<tr>
<td>Active ingredient and amount</td>
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<td>150 mg levonorgestrel</td>
<td>150 mg levonorgestrel</td>
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<tr>
<td>Labeled duration of effective use</td>
<td>3 years</td>
<td>5 years</td>
<td>4 years</td>
</tr>
<tr>
<td>Number of rods</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Approximate insertion and removal time</td>
<td>Insertion: 1 min</td>
<td>Insertion: 2 min</td>
<td>Insertion: 2 min</td>
</tr>
<tr>
<td>Cost of implant (US$)</td>
<td>$16.50*</td>
<td>$8.50</td>
<td>$8.00</td>
</tr>
</tbody>
</table>

*The cost of Implanon may be lowered in the future to be comparable with that of Jadelle.
Source: Modified from a table prepared by FHI 360, the RESPOND Project and USAID.

In INDIA

In an Indian Council of Medical Research (ICMR) study conducted in 1993, a total of 8,077 women were given a balanced presentation of all available contraceptive methods and Norplant® (one of the brands of implant) was the first choice for 35% of women (Baveja et al 2000).

About the method

- Implants are small plastic rods or capsules, each about the size of a matchstick, that release progestin, like the natural hormone, progesterone.
- A trained provider performs a minor surgical procedure to place the implant under the skin of a woman’s upper arm.
- These can be used by women who cannot use methods containing estrogen and can be used throughout breastfeeding.

Effectiveness

- Less than 1 pregnancy per 100 women using implants over the first year (5 per 10,000 women).
- Fertility returns immediately after implants are removed.

Advantages

- Helps to prevent unwanted pregnancy, symptomatic pelvic inflammatory disease and iron-deficiency anemia.
- Does not require the user to do anything once it is inserted.

Possible side effects

Some Implant users report the following changes in bleeding patterns:

- First several months: Lighter bleeding and fewer days of bleeding; irregular bleeding; no monthly bleeding.
- After about one year: Lighter bleeding and fewer days of bleeding; irregular bleeding.

Global Evidence and Programme Experiences

LEVONORGESTREL INTRAUTERINE SYSTEM

A Levonorgestrel Intrauterine System (LNG-IUS) mobile outreach in Kenya showed that even a limited introduction of the LNG-IUS, without any special promotion, resulted in good uptake. Providers viewed it positively, particularly because of its non-contraceptive benefits.

The Mirena™ LNG-IUS and the Paragard™ T380A are effective and safe contraceptive devices even for women who have not given birth to a child (nulliparous). When compared to other methods of contraception, LNG-IUSs have comparable or higher continuation rates of use in nulliparous women. LNG-IUSs do not increase the risk of pelvic infection or infertility.

In INDIA

LNG-IUS is sold under the brand name of Mirena in India. It is available only in the private sector. A study conducted during 2008-11 concluded that LNG-IUS can be a good alternative to the medical and surgical treatment for menorrhagia (excessive menstrual bleeding) with high acceptability rate and good efficacy. It dramatically reduces the amount of bleeding within a few months. LNG-IUS has minimal side effects leading to a good continuation rate.

1 ‘Introduction of the levonorgestrel intrauterine system in Kenya through mobile outreach: Review of service statistics and provider perspectives’, David Hubacher,a Vitalis Akora,b Rose Masaba,a Mario Chen,a Valentine Veenaa. Global Health: Science and Practice 2014 | Volume 2 | Number 1
About the method

- The LNG-IUS is a T-shaped plastic device that steadily releases small amounts of levonorgestrel each day.
- It is inserted into the uterus by a trained provider.

Effectiveness

- The method is highly effective with less than 1 pregnancy per 100 women using an LNG-IUS over the first year, i.e. 998 of every 1000 women using LNG-IUSs in the first year will not become pregnant.
- Fertility returns immediately after its removal.

Advantages

- LNG-IUS helps to protect risks of pregnancy, iron-deficiency anemia and pelvic inflammatory disease. It reduces menstrual cramps and symptoms of endometriosis (pelvic pain, irregular bleeding).
- No known health risks.

Possible side effects

- Changes in bleeding patterns, including lighter bleeding and fewer days of bleeding, irregular bleeding, no monthly bleeding and prolonged bleeding.
- Other side-effects could be: Acne, headaches, breast tenderness or pain, nausea, weight gain, dizziness.
- Mood changes.

**INJECTABLE CONTRACEPTIVES**

**Global Evidence and Program Experiences**

*Depot-medroxyprogesterone acetate (DMPA) and Norethisterone Enanthate (NET-EN) have been available in many countries since 1983. The United States approved DMPA in 1992, which greatly increased access to the method in the country. Across continents, the percentage of users is highest in Africa.*

*Recent studies in Madagascar, Malawi and Uganda have demonstrated that community health workers who receive proper training in screening, injection technique and counselling can administer DMPA injections to women in rural areas just as safely as clinic-based providers and with comparable rates of acceptability and continuation.*

*Injectable contraception was first made available to women in Asia in 1970s, and remains one of the most popular methods in the region. The proportion of injectable use to total use of modern methods (mCPR) is 42% in Bhutan, 22% in Bangladesh, 21% in Nepal and 55% in Indonesia.*

**In INDIA**

DMPA is available in India only through commercial and social marketing channels. About 0.2% women in India (both urban and rural) are using the three-monthly progestin-only injectable contraceptive. About 0.4% women have reported an earlier use of injectables and 0.3% used them before adopting sterilisation (NFHS 3, 2005-06). The cost of injectable contraceptives ranges from Rs 25 through social marketing agencies to Rs 250 for commercial products.

Recent initiatives to make DMPA available through the public sector include: In Rajsamand district of Rajasthan where DMPA has been introduced in Community Health Centres, Primary Health Centres and some sub-centres, and the Urban Health Initiative project implemented by FHI 360 in public facilities of 11 towns of Uttar Pradesh (UP).

A recent study in Rajsamand and UP revealed that young married women (mean age of 27) were using DMPA for spacing births, about 21% women had adopted DMPA after first child. The study revealed that among the current users of DMPA, 41% had taken four or more doses. Eighty per cent women believed that DMPA is a good long acting contraceptive method for spacing births.

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About the method

- Progestin-only injectable contraceptives include Depot-medroxyprogesterone acetate (DMPA) and Norethisterone Enanthate (NET-EN). Combined injectable contraceptives (with progestin and estrogen), also called monthly injectables, include Cyclofem.
- DMPA is given every three months in the arm, hip or buttock.

Effectiveness

- 99.7\(^2\) of every 100 women using progestin only injectables regularly over the first year will not become pregnant.
- The return of fertility is on average about 4 months for DMPA and 1 month for NET-EN.

Advantages

- DMPA helps protect against:
- Risk of pregnancy.
- Cancer of the lining of the uterus.
- Uterine fibroids
- Symptomatic pelvic inflammatory disease.
- Iron-deficiency anemia.
- DMPA can reduce:
  - Sickle cell crises among women with sickle cell anemia.
  - Symptoms of endometriosis (pelvic pain, irregular bleeding).

Possible side effects

Some users report the following:

- Weight gain, headaches, dizziness, abdominal bloating and discomfort, mood changes, decreased sex drive, and loss of bone density.
- Changes in bleeding patterns in DMPA:
  - First three months: Irregular to prolonged bleeding.
  - At one year: No monthly bleeding to infrequent bleeding or irregular bleeding.
- NET-EN users have fewer days of bleeding in the first six months and are less likely to have no monthly bleeding after one year than DMPA users.


PROGESTIN-ONLY PILLS

Global Evidence and Programme Experiences

The current desogestrel Progestin-Only Pill (PoP) combines safety with high levels of effectiveness and was first approved in 2003. A World Health Organization case-control study found no significant increase in the risk of stroke, myocardial infarction, and venous thromboembolism among users of PoPs compared with non-users (WHO 1998). Although there are some concerns regarding the impact of combined oral contraceptives on lactation, there are no such concerns for PoPs (Moggia 1991; Dunson 1993; McCann 1994; Bjarnadóttir 2001; FFPRHC 2004).

In INDIA

The first desogestrel PoP was launched in 2005. Currently five brands of desogestrel PoPs are available in the Indian commercial market. The total market is estimated at around 180,000 cycles per year. Cerazette is the market leader with annual sales of approximately 145,000 cycles, growing at a compounded annual growth rate of over 15% over the last three years.

**About the method**

PoPs contain very low doses of progestin, like the natural hormone, progesterone, in a woman’s body.

**Effectiveness**

- PoPs prevent unwanted pregnancies:
  - 99 of every 100 breastfeeding women using PoPs in the first year will not become pregnant.
  - 90-97 of every 100 women (not breastfeeding) using PoPs in the first year will not become pregnant.
- Fertility returns immediately after PoPs are discontinued.

**Advantages**

- PoPs can be used while breastfeeding. They add to the contraceptive effect of breastfeeding.
- They can be discontinued at any time without a provider’s help.
- PoPs can be used by women who cannot use methods that contain estrogen.
- There is no known health risk.

**Possible side effects**

- PoPs affect bleeding patterns:
  - Longer delay in the return of monthly bleeding after childbirth for breastfeeding women.
  - Frequent, irregular, prolonged or no monthly bleeding.
- Headaches, dizziness, mood changes, breast tenderness, abdominal pain and nausea.
- Enlarged ovarian follicles for women who are not breastfeeding.

Realising Commitments to Family Planning

The programme aims to provide information to key influencers and decision makers (Members of Parliament, officials of the Ministry of Health and Family Welfare and related departments, the media and civil society organisations) on family planning. It works at increasing availability and access to quality family planning services with an expanded basket of contraceptive choice. It advocates for improved policies using a human rights and women’s empowerment framework.