# Table of Contents

**EXECUTIVE SUMMARY**                                                                                      3

**INTRODUCTION**                                                                                             4

**HISTORY AND DEVELOPMENT**                                                                                  5
  - The Milestones                                                                                           6
  - Current Status of Products                                                                              7

**THE PROMISE OF CONTRACEPTIVE IMPLANTS**                                                                    8
  - Contraceptive Implants: Definition and Key Facts                                                      8
  - Insertion and Removal of Implants                                                                      9
  - Other Key Product Information                                                                          9
  - Wide Acceptance by Women                                                                               10
  - Unmatched Effectiveness                                                                                10
  - Suitable for Nearly All Women and All Reproductive Intentions                                         10
  - Increasing Use in Developing Countries                                                               11
  - Increasingly Affordable and Available                                                                 12

**THE EVIDENCE**                                                                                            12
  - Global Evidence                                                                                        12
  - Evidence from India                                                                                    18

**MARKET DYNAMICS**                                                                                        20
  - The Barriers                                                                                           20
  - The Implants Access Program (IAP)                                                                      20
  - The Impact                                                                                            21
  - Limitations and Lessons Learned                                                                         23
  - The Future                                                                                            23

**OPPORTUNITIES AND CHALLENGES**                                                                            23
  - Policy Environment and India’s Commitments                                                           23
  - The Evidence Base                                                                                      24
  - The Economics                                                                                        24
  - Potential for Partnerships                                                                             24
  - Pending Technical Issues                                                                               24
  - Program Challenges                                                                                    24
  - Reproductive Rights of Women and Equity                                                               24

**NEXT STEPS**                                                                                               25
**List of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMGF</td>
<td>Bill and Melinda Gates Foundation</td>
</tr>
<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiatives</td>
</tr>
<tr>
<td>DCGI</td>
<td>Drugs Controller General of India</td>
</tr>
<tr>
<td>DGHS</td>
<td>Director General of Health Services</td>
</tr>
<tr>
<td>DLHS</td>
<td>District Level Household Survey</td>
</tr>
<tr>
<td>DMPA</td>
<td>Depot Medroxy Progesterone Acetate</td>
</tr>
<tr>
<td>DTAB</td>
<td>Drugs Technical Advisory Board</td>
</tr>
<tr>
<td>ENG</td>
<td>Etonogestrel</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FOGSI</td>
<td>Federation of Obstetric and Gynaecological Societies of India</td>
</tr>
<tr>
<td>FP</td>
<td>Family Planning</td>
</tr>
<tr>
<td>HERC</td>
<td>Highly Effective Reversible Contraception</td>
</tr>
<tr>
<td>ICMR</td>
<td>Indian Council of Medical Research</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>mCPR</td>
<td>Contraceptive Prevalence Rate, Modern Methods of Contraception</td>
</tr>
<tr>
<td>MEC</td>
<td>Medical Eligibility Criteria</td>
</tr>
<tr>
<td>PPIUCD</td>
<td>Post Partum Intra Uterine Contraceptive Device</td>
</tr>
<tr>
<td>NFHS</td>
<td>National Family Health Survey</td>
</tr>
<tr>
<td>NHM</td>
<td>National Health Mission</td>
</tr>
<tr>
<td>NGO</td>
<td>Non Governmental Organisation</td>
</tr>
<tr>
<td>POP</td>
<td>Progestin Only Pills</td>
</tr>
<tr>
<td>RMNCH+A</td>
<td>Reproductive Maternal Newborn Child and Adolescent Health</td>
</tr>
<tr>
<td>SAE</td>
<td>Serious Adverse Events</td>
</tr>
<tr>
<td>SIDA</td>
<td>Swedish International Development Cooperation Agency</td>
</tr>
<tr>
<td>TFR</td>
<td>Total Fertility Rate</td>
</tr>
</tbody>
</table>
EXECUTIVE SUMMARY

In spite of significant progress in fertility regulation, India has missed the National Population Policy Goal of a TFR of 2.1 by 2010, and in the year 2013, the national TFR stood at 2.3. Although some states have reached replacement level or low fertility, the others have a long way to go. Recent results from the National Family Health Survey 4 (NFHS 4) indicate that married women are less likely to be using modern family planning methods in about half of the States/Union Territories covered in the first phase.

At the London Summit on Family Planning India unveiled its commitments to FP2020 in the document: India’s Vision FP2020. The country has, inter alia, committed to providing access to family planning services to an additional 48 million women by 2020; expanding the basket of choices and ensuring availability of free commodities and services to all clients.

Introduced over three decades ago, contraceptive implants are one of the most effective long acting reversible methods of contraception. Much progress has been made in the technology since the introduction of the first generation Norplant in 1983. Some of the latest versions offer contraception for as long as five years after insertion.

Global experience over the years indicates that contraceptive implants are readily accepted by women in places where these are made available. This is not surprising since they offer many advantages. Implant insertion procedures are short and uncomplicated; fertility is restored soon after removal of the implant since the continuous-release hormones in implants have a short half-life, this is particularly helpful for women who have yet to complete their family. As implants do not contain estrogen, they do not affect production of breast milk and are thus suitable for breast feeding women in the immediate postpartum period. They are also a good choice for women who do not want more children but are not willing to adopt a permanent method. Implants can be used by almost all women; a new implant can be inserted at the same time as the previous one is removed and are a user-independent contraceptive method.

The only major side-effect, as with other hormone-based contraceptives, is a change in the frequency, amount and duration of menstrual bleeding which may lead to discontinuation of the method, especially if not accompanied by good quality counselling of the client. However, any associated side effects resolve soon after removal due to the short half-life of the hormone.

Since they are effective for a long duration (3-5 years), are independent of user compliance and do not require frequent re-supply, implants are more cost-effective than shorter-acting contraceptive methods.

Subdermal contraceptive implants are now used by 11 million women around the world. Implants are registered and approved for use in more than 100 countries, including the United States, Western European countries, as well as many middle- and low-income nations.

In India, contraceptive implants have not yet been registered for manufacture and marketing by the Drugs Controller General of India (DCGI). The issue of introduction of implants into the basket of choice of contraceptives is under the active consideration of the Government of India. The recommendations of the DCGI will be factored in before the final policy decision is taken.

This paper examines the milestones in the evolution of contraceptive implants at a global level. It also documents some key scientific evidence on their safety, efficacy and acceptability from global and Indian studies, the market dynamics over the years; and data on cost effectiveness. All these are an affirmation of the promise of this method as a contraceptive choice in the national family planning program.
INTRODUCTION:

While much progress has been made in reducing the Total Fertility Rate (TFR) in India, there is still more that needs to be done. The country has missed the National Population Policy Goal of a TFR of 2.1 by 2010 and in the year 2013, the national TFR stood at 2.3. Although many states have reached replacement level or low fertility, the others have a long way to go. Recent results from the National Family Health Survey 4 (NFHS 4) indicate that married women are less likely to be using modern family planning methods in eight of the States/Union Territories covered in the first phase. The NFHS 4 has reported some increase in the use of modern family planning methods only in Meghalaya, Haryana, and West Bengal. The decline in use of these methods is highest in Goa followed by Karnataka and Tamil Nadu. However, despite this decline, about half or more married women are using modern family planning in eight of the 15 States/Union Territories.

At the London Summit on Family Planning, the global goals articulated under FP2020 included ensuring the use of modern methods of contraception by an additional 120 million women in the 69 poorest countries, and accelerated universal access to these methods, information and services. India unveiled its commitments to FP2020 in the document: India’s Vision FP2020. The country has, inter alia, committed to providing access to family planning services to an additional 48 million women by 2020; expanding the basket of choices and ensuring availability of free commodities and services to all clients.

Introduced over three decades ago, contraceptive implants are one of the most effective long acting reversible methods of contraception. However, globally, while 6% of women using modern contraception use injectable contraceptives, only 1% use implants. Much progress has been made in the technology since the introduction of the first generation Norplant in 1983. Some of the latest versions offer contraception for as long as five years after insertion. Global experience over the years indicates that contraceptive implants are readily accepted by women in places where these are made available. This is not surprising since implant insertion procedures are short and uncomplicated when conducted by well-trained health care providers; fertility is restored soon after removal of the implant since the continuous-release hormones in implants have a short half-life, and this is particularly helpful for women who have yet to complete their family. As implants do not contain estrogen, they do not affect production of breast milk and are thus suitable for breast feeding women in the immediate postpartum period. They are also a good choice for women who do not want more children but are not willing to adopt a permanent method. Implants can be used by almost all women; a new implant can be inserted at the same time as the previous one is removed and are a user-independent contraceptive method.

The only major side-effect, as with other hormone-based contraceptives, is a change in the frequency, amount and duration of menstrual bleeding which may lead to discontinuation of the method especially if not accompanied by good quality counselling of the client. However, any associated side effects get resolved soon after removal, due to the short half-life of the hormone.

Prima facie, the upfront commodity cost of contraceptive implants may potentially pose a barrier to their widespread use in resource-constrained programs. However, since they are effective for a long duration (3-5 years); are independent of user compliance; and do not require frequent re-supply, implants turn out more cost-effective than shorter-acting contraceptive methods. Further, with the recent initiatives taken through donor partnerships in giving volume guarantees to manufacturers in return for price reductions in the 69 FP2020 priority countries, access and availability of implants is expected to improve in the future.
Subdermal contraceptive implants are now used by more than 11 million women around the world. Implants are registered and approved for use in more than 100 countries, including the United States, Western European countries, as well as many middle- and low-income nations. In 2012, the United Nations Commission on Life-Saving Commodities for Women and Children endorsed contraceptive implants as one of its 13 Life Saving Commodities.34

In the current context, markedly reduced prices and innovative service delivery models using dedicated non-physician service providers offer a historic opportunity to help satisfy women’s growing need for family planning.

In India, contraceptive implants have not yet been approved by the Drugs Controller General of India (DCGI) for manufacture and marketing. Based on the available global evidence and that from recent clinical trials conducted by the Indian Council of Medical Research (ICMR) on Implanon, the one-rod Implant, it is understood that introduction of contraceptive implants into the basket of choice of contraceptives is under active consideration at national policy level. The recommendations of the DCGI will be factored in before a final policy decision is taken. This has the potential to open a window of opportunity for the manufacture and introduction of contraceptive implants in the country, both in the public and private health sector.

**HISTORY AND DEVELOPMENT**

Long-acting, reversible hormonal contraceptive methods have been available for decades. Indeed, a three-monthly injection of medroxyprogesterone acetate in a depot formulation has been marketed since 1960. Recently, a new category of contraceptive modalities has been identified, grouping together methods of family planning affording effective protection for an extended period of time: Long-Acting, Reversible Contraception (LARC). In principle, only subdermal implants and intrauterine devices are comprised in this category although, recently Halpern et al have included injectable contraceptives also in the definition and coined the acronym LAI (Longer Acting Injectables).15

Introduced almost 30 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 from three to five years.

The development of contraceptive implants was made possible by the discovery of silicone and its bio-compatibility in the human body. Silastic tubes with sealed ends, and filled with steroids, provided a sustained release of the steroids in vitro over months; these models were the precursors of many of today’s contraceptive implants. This technology resulted in the development and patenting of Norplant and Norplant-II /Jadelle by the Population Council. The latter consist of two small silicone rods, each containing 75 mg Levonorgestrel (LNG) in a polymer matrix. On the other hand, the Etonogestrel implant, under the brand names Nexplanon and Implanon, is a single rod made of the plastic ethylene vinyl acetate (EVA) co-polymer covered by a thin EVA membrane and with a core of 68 mg of Etonogestrel. Addition of Barium Sulphate to the core in Nexplanon makes it detectable on X-Ray.
<table>
<thead>
<tr>
<th>Years</th>
<th>Milestone</th>
<th>Country</th>
<th>Associated Scientists /Experts/Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1966-69</td>
<td>1st Contraceptive Implant - Norplant (1st generation, Levonorgestrel, 6 rods) developed and initial clinical experience was reported</td>
<td>Population Council’s Centre for Bio-medical research: by scientists Sheldon J. Segal and Horatio B. Croxatto</td>
<td></td>
</tr>
<tr>
<td>1974-76</td>
<td>Clinical Trials on the 6 - Levonorgestrel containing capsules were underway</td>
<td>6 countries including US</td>
<td>First American investigation of Implant contraception by Daniel Mishell Jr.</td>
</tr>
<tr>
<td></td>
<td>2-rod levonorgestrel releasing implants were studied since early 1980s by Population Council, Indian Council of Medical Research and Chinese State Family Planning Commission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1980s</td>
<td>Norplant (6- rod) first approved for production and marketing</td>
<td>Finland- 1st country to give regulatory approval</td>
<td>Leiras company of Turku, Finland was first manufacturer</td>
</tr>
<tr>
<td>1984-85</td>
<td>Norplant introduced in other countries</td>
<td>23 countries including US and UK</td>
<td></td>
</tr>
<tr>
<td>1992-93</td>
<td>Jadelle (2nd generation 2-rod levonorgestrel(LNG) implant) approved by USFDA for use upto 3 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sino-Implant II (same ingredient as Jadelle) introduced</td>
<td>China</td>
<td></td>
</tr>
<tr>
<td>1996</td>
<td>Implanon (One-rod Etonogestrel (ENG) implant) first introduced</td>
<td>First launched in Indonesia and then in International market</td>
<td>Developed by Organon International (Netherlands)</td>
</tr>
<tr>
<td>2002</td>
<td>Jadelle re-approved by USFDA for use upto 5 years.</td>
<td>US</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Production of Jadelle discontinued in US due to earlier adverse publicity associated with removal problems with the 6-rod Norplant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Current Status of Products

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Presentation</th>
<th>Registration</th>
<th>WHO Prequalification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jadelle</td>
<td>Bayer HealthCare</td>
<td>Disposable, sterile trocar</td>
<td>Registered in more than 50 countries. Review underway in additional countries.</td>
<td>Yes</td>
</tr>
<tr>
<td>Sino-implant (II)*</td>
<td>Shanghai Dahua Pharmaceuticals Co., Ltd.</td>
<td>Disposable, sterile trocar</td>
<td>**Registered in more than 20 countries. Review underway in additional countries</td>
<td>No</td>
</tr>
<tr>
<td>Implanon</td>
<td>Merck/MSD</td>
<td>Preloaded, disposable, sterile insertion device</td>
<td>Registered in 73 countries.</td>
<td>Yes</td>
</tr>
<tr>
<td>Nexplanon/ Implanon NXT</td>
<td>Merck/MSD</td>
<td>Preloaded, disposable, sterile insertion device</td>
<td>Registered in 55 countries. Nexplanon/Implanon NXT will progressively replace Implanon in all countries in the next few years.</td>
<td>No</td>
</tr>
</tbody>
</table>

*Currently undergoing the WHO Prequalification process  
** Also marketed under a variety of other trade names by different distributors: Zarin, TRUST, Femplant and Simplant  

---

2006  Implanon (One-rod Etonogestrel) approved by USFDA

2012  Nexplanon /Implanon NXT 4 (bioequivalent to Implanon) made available  
Progressively replacing Implanon in all countries where registered

2016- current  **Uniplant, Capronor and Nesterone (new products) under development

*Merged with Bayer Healthcare in 2011

** Consist of different Progestins: in form of biodegradable rods, pellets and microcapsules

---

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Presentation</th>
<th>Registration</th>
<th>WHO Prequalification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jadelle</td>
<td>Bayer HealthCare</td>
<td>Disposable, sterile trocar</td>
<td>Registered in more than 50 countries. Review underway in additional countries.</td>
<td>Yes</td>
</tr>
<tr>
<td>Sino-implant (II)*</td>
<td>Shanghai Dahua Pharmaceuticals Co., Ltd.</td>
<td>Disposable, sterile trocar</td>
<td>**Registered in more than 20 countries. Review underway in additional countries</td>
<td>No</td>
</tr>
<tr>
<td>Implanon</td>
<td>Merck/MSD</td>
<td>Preloaded, disposable, sterile insertion device</td>
<td>Registered in 73 countries.</td>
<td>Yes</td>
</tr>
<tr>
<td>Nexplanon/ Implanon NXT</td>
<td>Merck/MSD</td>
<td>Preloaded, disposable, sterile insertion device</td>
<td>Registered in 55 countries. Nexplanon/Implanon NXT will progressively replace Implanon in all countries in the next few years.</td>
<td>No</td>
</tr>
</tbody>
</table>
THE PROMISE OF CONTRACEPTIVE IMPLANTS

Contraceptive implants offer immense potential to meet the need for family planning. More than 220 million women in developing countries are currently estimated to have an unmet need for modern contraception, mainly in South Asia and sub-Saharan Africa. Many other women are using less effective “resupply” methods, short-acting methods, that require users to continually replenish their supplies of the contraceptive, because highly effective, more convenient methods such as implants are not easily accessible. In all countries, access is lower among poorer, less educated, rural, and younger women.20

<table>
<thead>
<tr>
<th>Contraceptive Implants: Definition and Key Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition:</strong> The contraceptive implant is a form of Long-Acting Reversible Contraception (LARC, also sometimes referred to as Highly Effective Reversible Contraception, HERC).4</td>
</tr>
<tr>
<td><strong>Key Facts</strong> 29, 31, 33, 36</td>
</tr>
<tr>
<td>• LARC, including intrauterine devices and implants are the most effective methods of reversible contraception.</td>
</tr>
<tr>
<td>• Implants consist of Progestogen-only hormone-filled capsules or rods that are inserted under the skin of a woman’s upper arm.</td>
</tr>
<tr>
<td>• The advantage of this form of contraception is that it provides effective long-term contraception (3-5 years) that does not depend on the recipient’s daily compliance.</td>
</tr>
<tr>
<td>• The most recent generation of implantable devices is the most effective form of birth control available and can usually be inserted by specifically trained providers in less than one minute.</td>
</tr>
<tr>
<td>• The pregnancy rate with the implant is 0.05%, which is slightly lower than the levonorgestrel intrauterine device (0.2%) and the copper intrauterine device (0.6%).</td>
</tr>
<tr>
<td>• The major side effects are changes in menstrual bleeding patterns causing most of the discontinuations. These are not harmful and resolve almost immediately after removal.</td>
</tr>
<tr>
<td>• Minor side effects include headaches, acne, weight gain, breast tenderness and others.</td>
</tr>
<tr>
<td>• Complications are uncommon – infection at insertion site (within first 2 months), difficult removal which is rare and usually due to incorrect insertion and expulsion (within 4 months) which is also rare and due to infection or incorrect insertion.</td>
</tr>
<tr>
<td>• There is rapid return of fertility after removal.</td>
</tr>
</tbody>
</table>
**Inserting Implants**

- Usually takes a few minutes, may take longer depending on the skills of the provider.
- Implant is inserted just under the skin through a small incision on the inside of the upper arm or a specially made applicator similar to a syringe.
- Procedure is performed under local anaesthesia and all infection prevention protocols are followed.
- Suturing is not required and the area is covered with an adhesive bandage.

**Removing Implants**

- Removal is done using a forceps to pull out the rods through a small incision in the skin near the site of insertion, using local anaesthesia and following infection prevention protocols.
- Incision is covered with an adhesive bandage.

### Key Product Information

<table>
<thead>
<tr>
<th></th>
<th>Implanon</th>
<th>Jadelle</th>
<th>Sino-implant II</th>
<th>Nexplanon/Implanon XT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Merck</td>
<td>Bayer HealthCare</td>
<td>Shanghai Dahua</td>
<td>Merck</td>
</tr>
<tr>
<td>Active ingredient and amount</td>
<td>68 mg etonogestrel</td>
<td>150 mg levonorgestrel</td>
<td>150 mg levonorgestrel</td>
<td>68 mg etonogestrel</td>
</tr>
<tr>
<td>Labelled duration of effective use</td>
<td>3 years</td>
<td>5 years</td>
<td>4 years</td>
<td>3 years</td>
</tr>
<tr>
<td>No. of rods</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Approx. insertion and removal times</td>
<td>1 – 1 min. R -2-3 min.</td>
<td>1 – 2 min. R – 5 min.</td>
<td>1 – 2 min. R – 5 min.</td>
<td>1 – 1 min. R -2-3 min.</td>
</tr>
<tr>
<td>Cost of Implant (US $)</td>
<td>8.50 (2013)</td>
<td>8.50 (2012)</td>
<td>8.00</td>
<td>8.50</td>
</tr>
</tbody>
</table>

Sources:
## Wide Acceptance by Women

Women who use implants find them to be very convenient—they are effective immediately (within 24 hours) and offer up to 3 to 5 years of extremely reliable contraceptive protection upon one client action. Only a brief, very minor surgical procedure under local anesthesia is needed to place 1 or 2 matchstick-sized plastic rods beneath the skin of the inner upper arm. Some women also like that pelvic exams and laboratory tests are not required and that implants can be used discreetly. Furthermore, implants do not interfere with sexual intercourse, and return to fertility upon removal is not delayed or negatively affected.20

## Unmatched Effectiveness

Effectiveness is a key feature for women and couples using contraception to avoid unwanted pregnancy, although even family planning professionals do not always fully realize just how effective implants are: Only 1 unintended pregnancy occurs among every 2,000 implant users in the first year of use. In contrast, failure rates in the first year of typical use of the commonly used resupply methods are considerably higher: 150 unintended pregnancies per 1,000 users of male condoms, 80 unintended pregnancies per 1,000 users of pills, and 30 unintended pregnancies per 1,000 users of the progestin-only injectable Depo-Provera. Thus, implants are 60 times more effective than the injectable, 160 times more effective than the pill, and 300 times more effective than the condom.20 36

## Suitable for Nearly All Women and All Reproductive Intentions

Implants are an excellent choice to achieve any reproductive intention—to delay a first pregnancy, space a subsequent birth, or end childbearing. According to the World Health Organization’s (WHO’s) Medical Eligibility Criteria for Contraceptive Use (2015) and Family Planning: A Global Handbook for Providers, implants are safe and suitable for nearly all women, including women who are of any age (including adolescents); have never been pregnant or have never had children; are living with HIV, have AIDS on ARV; have just had an abortion; or are breastfeeding. The only absolute contraindication to their use is current breast cancer.

Recommendations among normative bodies differ about the suitability of implants use by breastfeeding women during the first 6 weeks after childbirth, however. WHO guidance states that the risks outweigh benefits during this period. The U.S. Centers for Disease Control and Prevention (CDC) advises that the benefits outweigh risks during the first 4 weeks and places no restrictions on use after 4 weeks. The U.K.’s Royal College of Obstetricians and Gynaecologists (RCOG) places no restrictions on use of implants by breastfeeding women at any time.

Immediate postpartum provision of implants (within 48 hours) offers expanded programmatic opportunity, as women are increasingly receiving safe delivery services and there is almost universal interest among postpartum women in avoiding a subsequent pregnancy for at least 2 years. Implants also offer great promise for helping to meet the needs of younger women, who often face many barriers in accessing effective modern contraception.20
Increasing Use in Developing Countries

Increased use of implants in Malawi, Tanzania, Ethiopia and Rwanda, 2004-2011


Although modern contraceptive use lags in sub-Saharan Africa, where only 1 in 6 married women uses it, 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 injectable contraceptives, implants’ use has also increased notably over a short time span in countries such as Ethiopia, Malawi, Rwanda, and Tanzania. For example, 1 in every 7 women using modern contraception in Rwanda currently relies on an implant, compared with less than 1 in 25 in 2005. These trends suggest that wider availability of implants could lead to much greater use in other African countries and elsewhere where implants currently cannot be accessed widely or easily. High rates of user satisfaction (79%) and continuation (around 84% at 1 year of use) further support this likelihood.20
Increasingly Affordable and Available

Prospects for increased availability and use were greatly enhanced due to some important initiatives taken by international donors/development partners to reduce the prices of contraceptive implants, through the Implants Access Partnership (IAP). As a result of volume guarantees from the donor partners, Bayer HealthCare (2012) and Merck, Sharpe and Dohme (2013) agreed to make their products available at markedly reduced prices, with a priority on the 69 FP2020 countries. This is likely to be a signal milestone on the long road towards wider use of implants. The commodity cost of implants, once as high as US$23.80 per set, has been a major impediment to their wider availability. Having more types of implants in the market appears to have helped induce these lower commodity prices, and hopefully prices will continue to fall.7,20

THE EVIDENCE

Global Evidence

Cochrane Review on Subdermal implantable contraceptives: Power et al (Cochrane Collaboration 2008) 31

Objective: Determine the effectiveness, acceptability and tolerability of subdermal implantable contraceptives

Summary of Review

- All studies included in the review were comparisons of different types of implants (6-rod Norplant, 2 -rod Jadelle and 1-rod Implanon), rather than studies comparing implants with other types of contraceptive methods
- Subdermal contraceptive implants were very effective methods, giving pregnancy rates of 0.05, 0.13 and 0 per 100 women years of use for Norplant, Jadelle and Implanon respectively
- No difference in continuation rates or rates of hormonal side effects for the 3 types; continuation however, was much higher in developing than developed countries, probably reflecting access to alternative methods as well as differences in culture and expectations.
- Menstrual disturbances were common with all types of Implants. Infrequent and prolonged bleeding was more likely among Implanon users compared to Norplant, however, there was no significant difference for amenorrhea.
- Cumulative discontinuation rates for medical or menstrual problems were similar for all the types
- Problems at insertion were rare, with the mean time for insertion being much less for Implanon (1.1 min) than for Norplant (4.3 min). However, Norplant users were significantly more likely to experience problems at removals than Implanon or Jadelle users, with mean time for removal for Norplant (10-11 min) being much more than for Implanon (2-3 min) or Jadelle (5 min)
- No information could be provided on the characteristics of women who withdrew or were lost to follow up and therefore no insight into the tolerability or acceptability of the method.

Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel: A multi-centric clinical trial: Funk et al. 200512
**Objective:** To investigate the safety and efficacy of a single-rod implantable contraceptive containing etonogestrel (Implanon)

**Summary of Review**

**Overall conclusions:** Compared to other contraceptive methods, the advantages of Implanon include excellent safety and efficacy, rapid onset and long duration of action and rapid return to fertility after removal.

- High efficacy rates, with no pregnancies reported in the 2-year period of use, confirming the rates reported in other studies
- Return to normal menstrual cycles (88% of subjects) and to fertility (as indicated by posttreatment pregnancies) was rapid following removal of the implant
- Insertion and removal of the ENG implant was usually fast and uncomplicated and on an average took less than 1 and 4 min, respectively
- Uterine bleeding pattern changes were common, as expected, the most common being infrequent bleeding and the least common frequent bleeding.
- Bleeding pattern changes led to premature discontinuation of treatment in 13% subjects, with the highest rate of withdrawal in the first 8 months
- 23% subjects discontinued as a result of other Adverse Effects (AEs), such as headache, vaginitis, acne, dysmenorrhea, emotional lability, weight increase, depression and urinary tract infection
- Use of the ENG Implant up to 2 years had no clinically meaningful effects on laboratory parameters, physical and pelvic examinations, vital signs or body mass index


**Objective:** A summary review of the available Implanon literature

**Summary of Review**

Implanon literature is complicated by the retraction of eight publications of the original clinical trials. These papers were withdrawn because of data collection errors in the Indonesian study centres, which were the source of more than 40% of all Implanon users during clinical trials.

**Overall Conclusions:** Implanon offers promise as a high-efficacy, long-term contraceptive and is both, safe and effective. Implanon has both advantages and disadvantages, and it is important to establish a good fit with the woman’s needs before insertion of the device. User satisfaction may also be improved with careful counseling about potential side effects and ongoing clinician support during use. When side effects arise, symptomatic treatment may help avoid early discontinuation in women wanting to continue the device.

**Excellent contraceptive efficacy:** Unintended pregnancy is anticipated in less than 1 in 100 users (0.05%) during the first year of use, which compares favourably to other high-efficacy contraceptives, such as the Mirena intrauterine device (0.2%), female sterilization (0.5%) and male sterilization (0.15%)

**Effects on carbohydrate and lipid metabolism:** These are insignificant in normal subjects. WHO Medical Eligibility Criteria (MEC) states that the benefits of Implanon outweigh the risks in diabetic
women and women with dyslipidemia.

**Effects on Bone Mineral Density (BMD):** WHO MEC Criteria does not place any restrictions on Implant on use with regard to BMD.

**Side-Effect Profile**

**Serious Adverse Events (SAEs)**

Investigators defined SAEs as those side effects that cause permanent disability, severe illness, require or extend hospitalization, and/or are fatal.

No Implanon deaths have been reported. In a small percentage of the users, potentially drug related SAEs were identified such as intra-ductal papilloma with fibrocystic mastopathy, ovarian cysts, uterine fibroid, headache with fever, gastrointestinal problems and others.

**Bleeding irregularities**

This is the leading side effect and reason for early discontinuation in Implanon users. Cumulative rates for discontinuation for bleeding disturbances range from 8% to 21%. Frequent and prolonged bleeding prompted most removals, while amenorrhoea and infrequent bleeding rarely lead to early discontinuation. These are greatest during the first 3 months of use and the pattern varies. Among women experiencing prolonged, heavy or frequent bleeding in the first 3 months, 50% reported an improvement in bleeding patterns with continued use. Amenorrhoea trends are relatively consistent across studies, with a peak incidence at the end of year one, ranging from roughly 7% to 23%. These rates decline to 11% to 14% at the end of year three.

**Other Side Effects**

Headache, acne, weight gain, mastalgia, mood disturbances and vaginitis appear to be the most common and their incidence appears to decrease over time. Overall rate of discontinuation related to non-bleeding side effects ranges from 6.9% to 23%.
### Safety and efficacy of a single-rod etonogestrel implant (Implanon): results from 11 international clinical trials: Darney et al (2009)\(^\text{10}\)

**Objective:** To present efficacy, safety, and bleeding profile results from the clinical trials that supported the U.S. Food and Drug Administration filing for the approval of a single-rod etonogestrel (ENG) contraceptive implant (Implanon)

<table>
<thead>
<tr>
<th>Summary of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Results demonstrate that the ENG implant is a highly effective contraceptive for up to 3 years after implantation</td>
</tr>
<tr>
<td>• Among women ≤ 35 years of age at entry, a cumulative Pearl Index of 0.38 pregnancies per 100 woman-years of use is reported (all the pregnancies happening in the 14 days after implant removal) which is similar to other long-acting contraceptive methods, including sterilization.</td>
</tr>
<tr>
<td>• The ENG Implant was generally well tolerated when administered as described in the product labelling.</td>
</tr>
<tr>
<td>• Acceptability of drug related AEs associated with the use of ENG implant such as headache, weight increase, acne, breast pain, emotional lability, and abdominal pain varies widely among women. Headache and breast pain appear to be common and more acceptable side effects, but weight increase and emotional lability are less acceptable, making them two of the more common reasons for discontinuation.</td>
</tr>
<tr>
<td>• The amount of vaginal bleeding associated with the use of the ENG implant was generally modest, but the pattern over the duration of treatment was unpredictable. Discontinuation rates owing to bleeding irregularities were approximately 14% in the U.S. and Europe, but only 4% in Southeast Asia, Chile, and Russia. These local differences in discontinuation may be explained by cultural and social factors.</td>
</tr>
<tr>
<td>• The need to counsel women on bleeding irregularities and other side effects associated with the ENG implant is underscored, so that women can make a decision on using this highly effective method.</td>
</tr>
</tbody>
</table>

### Tolerability and clinical safety of Implanon: Blumenthal et al (2008)\(^\text{5}\)

**Objective:** To evaluate the tolerability and clinical safety of the subdermal, long-acting hormonal contraceptive Implanon through an integrated safety analysis of 11 international studies

<table>
<thead>
<tr>
<th>Summary of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Implanon was safe and well tolerated. Two-thirds of users completed their respective trials.</td>
</tr>
<tr>
<td>• Most frequently cited reasons for Implanon discontinuation were AEs (13.9%), bleeding irregularities (10.4%), and the desire to become pregnant (4.1%).</td>
</tr>
<tr>
<td>• Discontinuation particularly occurred during the first 6 months of use and then leveled off, the first 6 months being associated with an increased incidence of bleeding irregularities and of some AEs which were considered drug related, like headache, acne and emotion lability. This points to a need for discussing such trends during pre-insertion client counselling. Similar reasons have been reported for both Norplant and Jadelle.</td>
</tr>
</tbody>
</table>
Lactogenesis After Early Postpartum Use of the Contraceptive Implant -A Randomized Controlled Trial: Gurtcheff SE et al (2011)\textsuperscript{14}

Objective: To evaluate lactogenesis after early postpartum insertion of the etonorgestrel contraceptive implant

Summary of Review

- Healthy peripartum women with healthy, term newborns who desired the etonogestrel implant were randomly assigned to early (1-3 days) or standard (4-8 weeks) postpartum insertion
- Breastfeeding outcomes, measured in terms of time to lactogenesis stage II and lactation failure, were similar in women who underwent early compared with standard postpartum insertion of the etonogestrel implant
- Other studies which have specifically studied the use of the ENG Implant initiated at 4-8 weeks postpartum have noted no change in the volume and composition of breast milk and there were no effects associated with the small amount of ENG ingested by the infant. Three year follow up of child growth and development in this population showed no difference between implant users and copper IUD users, suggesting no adverse effect of the hormone.
- One-third of women randomly assigned to standard insertion never received their implants compared with just 3% of those assigned to early insertion, highlighting the need for provision of contraception before hospital discharge, especially in women perceived to be at high risk for non-contraception and short inter birth intervals.

<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective:</strong> To evaluate Body Composition and Bone Mineral Density in ENG-releasing implant users as compared to copper intrauterine device (Cu-IUD) users</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Weight, fat mass and percentage of fat mass in ENG-releasing implant users increase at 12 months of use, although early discontinuations due to this reason is low</td>
</tr>
<tr>
<td>• Use of the implant for more than 12 months was not associated with clinically significant changes in BMD at the lumbar spine or the femoral neck in this and other similar studies, when compared to users of non-hormonal methods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The WHO Medical Eligibility Criteria (MEC) (2015)³⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective:</strong> This document is part of the process for improving the quality of care in family planning. MEC for contraceptive use, the first edition of which was published in 1996, presents current WHO guidance on the safety of various contraceptive methods for use in the context of specific health conditions and characteristics. These have been developed through an exhaustive, transparent and evidence-based process.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The document has clearly defined who can safely take implants-</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All women in the reproductive age group, right from menarche, irrespective of parity, can use the method in any circumstances if there is no other contraindication (MEC Category 1).</td>
</tr>
<tr>
<td>• Breastfeeding women who are ≥6 weeks to &lt;6 months postpartum can use implants, without restriction (MEC Category 1).</td>
</tr>
<tr>
<td>• Breastfeeding women who are &lt; 6 weeks postpartum can generally use the method, that is, the advantages outweigh the theoretical or proven risks (MEC Category 2).</td>
</tr>
</tbody>
</table>
Evidence from India


Objective: Study the safety, efficacy and acceptability of Norplant II contraceptive over a 5 year period of use

Summary of Review

Contraceptive Efficacy:
Norplant II implants retain contraceptive efficacy for 5 years. Net cumulative pregnancy rate at 5 years was very low at 0.8/100 users; similar findings reported from other countries such as Singapore and Indonesia.

Continuation Rates:
Overall continuation rates were 61, 49 and 42 per 100 users at 3, 4 and 5 years of use respectively which were somewhat lower than the rates reported in studies from other countries.

Discontinuation Rates:
Majority of the discontinuations from the study were due to menstrual irregularities, the net cumulative discontinuation rates being 22, 26 and 28 per 100 users at 3, 4 and 5 years of use respectively; the commonest reason being prolonged or excessive bleeding.

The next common reason for discontinuation was for planning a pregnancy. Other reasons included infection at site of implant, expulsion of the rod(s), and other medical and personal reasons, the rates for which were low.

Complications at site of Implant:
These were few and much less than those reported with Norplant I implants.

The implant was found displaced from its original site of insertion in 5.8% of cases, although this did not warrant removal of the device except in 2 subjects. Difficulty in removal was reported in 3.5% of subjects due to displacement/fibrous sheath/breakage of the device.

Changes in body weight:
Significant change in body weight at 5 years of use. 43% of women had gained more than 5 Kg. of weight during Norplant II use over 5 years.
Objective: To evaluate the subdermal single rod contraceptive implant, Implanon for efficacy, safety and acceptability in terms of continuation rates, return of fertility and women’s perceptions about the method

Summary of Review

Overall: Interim results indicate that the method is efficacious and acceptable with a cumulative continuation rate of 64.1 per 100 users at 3 years.

Main reason for discontinuation is menstrual disruptions (19.6 per 100 users) and planning pregnancy (7.0 per 100 users).

- The proportion of women (12%) with normal bleeding patterns in first 3 months of use increased to 24% at 3 years.
- Reduced/ infrequent bleeding was the dominant menstrual disturbance, which reduced marginally from 76.1% women at 3 months to 69.3% at 36 months.
- Return of fertility was estimated at about 70% at one year after discontinuation.
- About 60% women indicated after counselling that the main reasons for accepting Implanon was its long duration of effectiveness and convenient site of insertion in the arm.

Conclusions: The available evidence demonstrates that the contraceptive implant is an option that provides women with a highly effective method that is easy to use, generally well tolerated by users and has a favorable safety profile compared to other hormonal methods. Complications are few- infection at insertion site, expulsion and difficult removal may rarely occur and are most often due to incorrect insertion by the provider. The evidence also underscores the need for effective counselling of clients before and throughout the use of the method, to allay their fears and anxieties, help them to cope with the side effects and make decisions about their contraceptive choices for the future. As family planning programs seek to decrease barriers to LARC methods and the popularity of implants grows, it is important for providers to respect women’s decisions to use, not use, or discontinue the method.

Further, postpartum implants appear to have the same side effects as interval implants and no adverse impact on breast milk or infant growth has been demonstrated. Most international evidence based guidelines support the initiation of this method in the immediate postpartum period as they regard the advantages of provision at this opportune time to outweigh the potential risks. Implants can therefore be provided for immediate postpartum use to women after delivery in a hospital who can then leave the hospital secure in the knowledge that unintended pregnancy will be prevented.
MARKET DYNAMICS

Few developments have received as much attention or palpable enthusiasm in the reproductive field in recent decades as long-acting reversible contraception (LARC) including intrauterine contraception (IUC), implants and other in development methods that prevent pregnancy for extended time periods without user action. However, despite the efficacy, effectiveness and availability of quality assured implants at global level, evidence from national family planning programs indicates that a number of market barriers prevent easy access particularly in low and middle income countries. Some of these barriers are high pricing compared to other contraceptive methods (with limited donor purchasing), a lack of coordinated global supply planning or forecasting and lack of trained workers providing implants as a part of routine family planning services.

In India, contraceptive implants are as of now not approved by the national drug regulatory body for manufacture and marketing.

In the year 2012, the London Family Planning Summit and the FP2020 goals which emerged catalyzed development partners and other technical agencies to enter into discussions to determine the scope for reducing prices of and expanding uptake of contraceptive implants in low and middle income countries.

An initial analysis of the market by the Clinton Health Access Initiative (CHAI) at that time indicated that the cost of producing implants was less than US $ 5 per unit (far lower than the selling price of US $ 18 for Jadelle and US $ 16.50 for Implanon) and that purchases of implants by international donors had increased five-fold in the past few years with only limited reductions in price.

The Barriers

- High prices were due in part to lack of visibility into demand, and thus sub-optimal management of production costs and assets.
- Production costs were not optimized due to fragmented and uncertain ordering patterns, differing labelling and packaging configurations, and underutilization of available capacity.
- The contraceptive implant market was characterized by a ‘high price/low volume trap, in which suppliers are forced to keep implant unit pricing high due to unpredictable volumes while governments and partners are unable to purchase additional implants due to high prices.

The Implants Access Program (IAP)

Drawing on the successful experience of developing a mechanism of a guarantee fund to reduce the price of a critical vaccine by BMGF and CHAI in the same year, a similar approach was employed for implant price reductions through the following activities:

- Approach donors to participate in a volume guarantee partnership that could effectively operate in the implants market.
- Identified guarantors to provide financial backing to the volume guarantee via sharing of risk with BMGF.

* A volume guarantee is typically a contract between a guarantor and a supplier, which guarantees that procurement groups will buy specified order volumes over a period of time in exchange for a reduction in price.
• Negotiated a volume guarantee based price reduction agreement with suppliers by which both Bayer and Merck agreed to reduce prices of their products -Jadelle and Implanon- to US $ 8.50 per unit in return for purchase commitments over 6 years.

BMG, Norad, the Swedish International Development Cooperation Agency (SIDA), and the Children’s Investment Fund Foundation (CIFF) served as guarantors, while USAID, Norad and DFID agreed to support implementation. The Implants Access Partnership/ Program (IAP), a partnership between Bayer, Merck, and their respective guarantors, purchasers, donors and implementing partners is expected to ensure a consistent supply of implants to be made available to meet demand at the reduced price for all 69 priority countries of FP2020, over the 6 years covered by the guarantees and beyond.

The purpose of the IAP is not only to increase access to implants and support the volume guarantees, but to catalyze changes that create healthier market dynamics for all contraceptive commodities in support of global family planning efforts spearheaded by FP2020 and the UN Commission on Life-Saving Commodities.

The Impact
• An increase in demand, secured by donors through a volume guarantee, allows implant suppliers to achieve scale efficiencies and thus reduce prices. The price reduction resulted in an increased total implant distribution by 56 % from 2012 to 2013 and is expected to result in procurement savings of more than US $ 300 million over 6 years, making implants one of the most cost effective options available, and freeing up funding to increase service delivery capacity.

According to the Family Planning Market Report (CHAI, May 2015), short acting methods continue to dominate the FP2020 market despite a significant increase in Implant purchase volumes. Between 2011 and 2013, there was a shift in the method mix towards implants and injectable contraceptives. Although the implant market size in terms of monetary terms declined during this period, this being largely driven by the price reductions in 2013, the purchase volumes of implants have nearly doubled between 2011 and 2013.

Consistent with volume and spending trends, the number of women utilizing product based methods grew from 85 million to 101 million from 2011 to 2012, and declined to 90 million in 2013. However, the use of implants increased from 6 million to 10 million and then to 11 million in the same time periods.

The increase in access in low and middle income countries would be expected to reduce the numbers of unintended pregnancies, contributing to improved health outcomes, and averting thousands of maternal and child deaths.

**Limitations and Lessons Learned**

- To estimate demand forecast, it was recognized that publicly available sources of implant market data did not provide a reliable assessment of current demand. Steps were taken by the stakeholders doing assessments to visit Ministries and implementing partners to understand demand, product preferences, barriers to access and trajectory of implant use in order to understand market potential.

- Further, additional funding was mobilized by the partners for other groups like Jhpiego, John Snow International (JSI) to contribute to scale up efforts through improved forecasting and supply planning; gap analysis and coordination of resources; and targeted service delivery and supply chain interventions.

**The Future**

- Testing of lower cost service delivery interventions to rapidly increase coverage of family planning services.

- Key partners need to continue to work with new implant manufacturers, including Shanghai Dahua Pharmaceuticals to support market entry of additional LARC suppliers and thereby increase competition in the market. These efforts aim to ensure sufficient high quality, affordable supply of implants beyond the timeframe of the IAP volume guarantees.

**OPPORTUNITIES AND CHALLENGES**

**Policy Environment and India’s Commitments:**

- Recent policy pronouncements recognize that improving access to safe, effective and affordable contraception is an essential intervention for ensuring women’s development. The increased focus on this vital input is one of the priority areas of the national family planning program. It is unconscionable that the unmet need for family planning in India remains as high as 21.3%. This is also reflected in the TFR which at 2.3 in 2013 remains higher than the goal of 2.1 which is enunciated in the National Population Policy 2000.

- One of the interventions that the national program is committed to is expanding the contraceptive choices available to women, backed by a service delivery system that provides requisite information, service and follow-up. The National Health Mission, and within its framework the RMNCH + A strategic approach, is geared towards providing the necessary inputs in terms of skilled human resources, financial investments, mechanisms for enhancing geographic reach, improving quality of care, and strengthening procurement and supply chain mechanisms. Family Planning is being posited as a critical input for improving women’s health and for reducing maternal and child mortality.

- The success of postpartum family planning interventions such as Postpartum Intra Uterine Contraceptive Device (17 lakh insertions since inception of the scheme in 2009) and the recent introduction of newer contraceptives such as the injectable contraceptive DMPA, Progestin-Only Pills and Centchroman into the basket of choice in the public sector have the potential to pave the way for other long acting reversible methods such as implants.
The Evidence Base:

Contraceptive implants offer safe and effective long term contraception. The global evidence includes clinical trials, post marketing surveillance data, market survey data on trends in sales volumes and key economic indicators. In addition, evidence from clinical trials in India, including the recent multicentre clinical trials conducted by ICMR, provides ample proof of the safety, efficacy, acceptability and cost-effectiveness of implants.

The Economics:

- Market Survey reports for FP2020 countries where implants are in use show encouraging increase in users with the decline in prices in these countries, on account of volume guarantees provided to the manufacturing companies.
- The seemingly initial high costs in a country like India are likely to be offset by economies of scale once they are introduced into the private and public sectors and usage rates increase.

Potential for Partnerships:

The vibrant private and NGO sectors are avenues through which implants may be introduced along with select sites in the public health sector. The lessons learned may then be incorporated for wider usage in the national program. The capacity and commitment of donors, professional bodies such as FOGSI, technical agencies and NGOs, to public health programs can be leveraged for promoting their use in the public sector.

Pending Technical Issues:

- The inclusion of contraceptive implants in the basket of choice of contraceptives to be offered in the public health sector is under active consideration of the Government of India.
- Contraceptive implants are not yet registered for manufacture and marketing in India.
- The report from a recently completed Phase III Clinical Trial with the one-rod Etonogestrel implant (Implanon) done by ICMR (2004-2012) is awaiting examination and recommendations by the technical experts under the DCGI. The results of this study are a critical input to enable the product to be registered in India.

Program Challenges:

As contraceptive implants is a provider dependent method, building program capacities using a health systems approach is critical to the success of delivery of this intervention. Introduction of implants in the basket of contraceptive choices on offer in the national family planning program will have to factor-in a number of challenges such as improving consumer awareness through an effective communication plan, competency-based provider training including skills for counselling, logistics and supply management, monitoring and supportive supervision, data management and analysis, with use of Information and Communication Technology (ICT).

Reproductive Rights of Women and Equity:

- Notwithstanding the many benefits of long acting reversible methods such as implants, it is important for providers to keep in mind that these methods are not acceptable to all women. Socio-economic disparities cannot be resolved solely by increased access to these methods. Being provider-dependent methods, there may be attempts to undermine women’s reproductive autonomy and disproportionately target women of marginalised and vulnerable communities.
It would become important for providers to use a client-centred approach to counselling about all safe and effective contraceptive options and support women's reproductive autonomy, irrespective of their status. As the popularity of implants grows, while attempting to reduce barriers and increase access to this method, providers will have to respect women's decisions to use, not use, or discontinue the method.2

**NEXT STEPS**

- In the light of the existing global evidence and the latest evidence generated by the ICMR through a clinical trial on the single-rod implant- Implanon, the introduction of implants into the basket of contraceptive choices in the national program is under active consideration of the Government of India. This needs to be formalized as early as possible.

- The results of the clinical trial on Implanon are in the process of being placed before the DCGI. The technical experts under the DCGI may examine the results expeditiously and consider granting concurrence for registering the product for manufacture at an early date.

- Once approved for manufacture and marketing, price reductions may be effected through negotiations and agreements between donors, manufacturers, the national government and other partners. Lowering of prices would be critical to making the method available both through the private sector and the public health system, to the women most in need.

- Different service delivery models for both public sector, private/ NGO sector will have to be evolved to plan and implement the intervention, so as to achieve maximum impact on key family planning indicators such as Contraceptive Prevalence Rate, modern methods (mCPR) and unmet need.

- Once the commodity is available, operations research in the form of demonstration projects at identified service delivery sites may be conducted to provide evidence for implementation at scale.
REFERENCES


