Advancing Family Planning in India: Single-rod implants as a cost-effective long-acting reversible contraceptive (LARC) method

Introduction

Family planning is a key investment in the health and well-being of women and children. Evidence suggests that out of 1.1 billion women aged 15 to 49 worldwide in 2021, 874 million used modern contraceptives, while 164 million still lacked access to contraception [1]. In India, 9.4% of currently married women (15-49 years), which translates to 21 million currently married women, have an unmet need for family planning [2]. An Indian study noted that as of 2021, the estimated number of women with an unmet need for family planning was 24 million [3]. Policymakers and program managers can improve family planning by using data on unmet needs, understanding who has these needs, and removing barriers to using family planning methods.

An unmet need for contraceptives can lead to unintended pregnancies, which pose risks for women and their families. An increased use of modern contraceptive methods in the country averted more than 10 million unintended pregnancies, 1.9 million unsafe abortions, and 22,000 maternal deaths in 2020 alone [4]. Estimates by the Guttmacher Institute show that a significant saving of $1.40 or 40 per cent of the cost of maternal and new-born healthcare would be made for each dollar spent to move from the current levels of modern method use to a full-needs-met scenario [5].

Global evidence shows that every additional contraceptive method made available to the population leads to an overall increase in modern contraceptive use [6]. The availability of a basket of contraceptive choices, including both spacing and limiting methods, is crucial for meeting the changing needs and preferences of women and couples. A more comprehensive range of contraceptive choices is key to a successful family planning programme, allowing people to choose and switch methods as they wish. Contraceptive preferences change with different stages of life and depend on factors like age, pregnancy risk, number of children, work, and cultural norms.

Introduction of Implants in India

The Government of India has increasingly acknowledged the need for expanding the basket of contraceptive choices. As part of the "Mission Parivar Vikas" programme launched in 146 high fertility districts in seven states in 2017, two new contraceptive methods were added to the basket to meet the country's FP2020 commitment (now FP2030).[1] These included an

[1] Family Planning Division, Ministry of Health and Family Welfare, Government of India, INDIA'S VISION FP 2030, July 2022, https://nhm.gov.in/images/pdf/programmes/family-planing/guidelines/FP2030_Vision-Document.pdf

injectable contraceptive called Antara (Medroxy Progesterone Acetate) and a non-hormonal pill called Chhaya (Centchroman).

In 2023, the Government of India expanded the contraceptive basket further by adding the Subdermal Single-Rod Contraceptive Implant and subcutaneous Injectable MPA contraceptive (Antara-SC).

The introduction of implants in the country is based on strong research and global programmatic evidence. International and national experiences confirm that subdermal implants are safe and effective. When offered with quality services, including counselling and follow-up care, they are acceptable to women, and client satisfaction results in higher continuity of the process [7].

What are Implants?

- An implant is a long-acting reversible contraceptive in the form of a small flexible plastic rod placed under the skin in the medial aspect of the non-dominant upper arm, usually by a doctor or a qualified nurse. However, in India, only allopathic doctors are allowed to insert implants after proper training.
- Implants are mainly used as a contraceptive option, but they have also been used in cases of endometriosis and hormone replacement therapy (HRT).
- They release ultra-low doses of the hormone progestin into the bloodstream to prevent conception.
- They do not contain estrogen and can be used throughout breastfeeding and by women who cannot use methods containing estrogen.
- Implants are highly effective for three to even five years, depending on the type of implant, and their effect is reversed without much delay upon removal.
- They become cost-effective when women continue to use the contraceptive for the entire term of its efficacy (three, four or five years).

Types of Implants

Jadelle: Two rods containing levonorgestrel (LNG), highly effective for five years

Implanon NXT (also known as Nexplanon; replaces Implanon) is a one-rod containing etonogestrel (ETG) labelled for up to three years of use (a recent study shows it may be highly effective for five years). It can be seen on X-ray and has an improved insertion device.

Levoplant (Sino-Implant (II)): Two rods containing LNG, labeled for up to three years of use

Norplant: It consisted of six capsules and was effective for five to seven years. However, it was discontinued in 2008 and is no longer available for insertion. A small number of women, however, may still need Norplant capsules removed.

Health Benefits

Helps protect against:

- Pregnancy and associated risks

May help protect against:

- Iron-deficiency anemia
- Pelvic Inflammatory Diseases (PID)

Reduces:

- Risk of ectopic pregnancy

No known health risks

Side Effects of Implants

Clinical studies conducted in developed and developing countries found menstrual irregularities to be the most common side effects, along with others, such as mild pain and bruising at the insertion site, abdominal pain, mood changes, nausea, breast tenderness, acne, etc. These changes are temporary and not harmful, and the menstrual bleeding pattern returns to normal once the method is discontinued [8].

Users of Implanon and Implanon NXT are more likely to have infrequent bleeding, prolonged bleeding, or no monthly bleeding than irregular bleeding.

Limitation of Implants

- It requires a minor procedure for insertion & removal by a trained provider
- May be visible under the skin
- Does not protect from RTI/STI, including HIV infection

Who can use Implants

- Can be used by any woman, irrespective of age & parity, who needs contraception
- Safe to use in breastfeeding women even immediately after delivery, as it does not affect the initiation as well as quality & quantity of breast milk, and also does not harm the infant
- Safe for women who cannot use oestrogen-containing contraceptives, such as patients with high BP, diabetes, vascular diseases, smoking, etc.

Initiation of the Method

- In normal menstruating women – within the first seven days of her menstrual cycle
- Immediately after delivery and abortion/miscarriage as PP or PA method
- Concurrently with EC
- Switching from other hormonal methods such as Injectable (before the scheduled next dose) & COC (within 24 hours after stopping)
- Switching from non-hormonal methods such as Chhaya (before stopping the pill), IUCD both IUCD 308A, IUCD 375 & LNG-IUD (concurrently following removal)

Counselling (initial, pre-, and post-insertion) is the key to acceptance, continuation, acceptance of minor side effects, and overall satisfaction. Counselling also dispels misconceptions and myths associated with Implants.

ICMR Study on Implanon[R][2]

The Indian Council of Medical Research (ICMR) based in New Delhi conducted a multicentre, Phase III trial on Implanon[R] from 2004 to 2008 to assess its efficacy. Of the 3,161 women who enrolled for the study, the data from 3,119 women were considered for analysis. The relative acceptability of Implanon[R] was 2.1 per cent among all contraceptive methods and 3.4 per cent among spacing methods. Nearly 73 per cent of the women responded positively to the counselling and said they had understood the method, what it does and how it works. The overall continuation rate was 66.1 per 100 users at the end of three years, with 2,050 women completing three years of use.

The advantages of Implanon[R] insertion cited by most women (70.5 per cent) were the method's efficacy for three years, the ease of its insertion and its placement externally in the arm. A total of 1069 women discontinued Implanon[R] use before three years, mainly due to erratic menstrual bleeding. The return of fertility (ROF) was not delayed for those who continued to use Implanon[R] for the three years of the study, nor was it compromised for women who discontinued the method.

Global Evidence and Program Experiences on Implants

Historically, the first implant to reach the market was Norplant, licensed in 1983 in Finland, with a 5-year lifespan. Norplant's successor, Norplant-2 or Jadelle®, was approved in the United States in 1996 as a 3-year implant and in 2001 as a 5-year method [9]. Norplant production was discontinued globally in 2008. With a redesigned applicator, implants were relaunched as Implanon NXT® (Nexplanon®) in 2010 [9].

[2] It is important to note that Implanon Classic is no longer available and has been replaced by Implanon NXT (same drug but improved inserter device, and now radio-opaque rod for locating the implant in case of difficult removal)

According to the WHO's statement on contraceptive implants, implants are registered in more than 100 countries, including the United States and Western European countries, as well as many middle and low-income nations [7]. Subdermal implants are chosen by an estimated 25 million women worldwide as their preferred contraceptive method, accounting for 2.6% of the total usage of modern and traditional contraceptives, according to the 2022 UN database [10]. As per World Contraceptive Use, 2022[3], the Sub-Saharan African countries report the highest use of Implants, with Rwanda (27%), Kenya (22%) and Malawi (18%); its use in Burkina Faso, Uganda and Ethiopia ranges from 10 to 15%. A 2011 study reviewing FP programmes in Sub-Saharan Africa indicated that in barely five years, the use of implants doubled in Malawi, rose four times in Tanzania, etc [11]. It is not surprising that this rapid growth in implant usage in East Africa also corresponds with the most significant increase in mCPR among FP2020 regions, from 32.2% (2012) to 39.5% (2017), as reported in the Lancet [12].

In the government-run FP programs of many Asian countries, two-rod or single-rod subdermal implants are now provided, significantly contributing to the various methods employed. Among the South Asian and East Asian countries, substantial use of Implants is seen in Nepal (5%), Indonesia (4%), Bangladesh (2%), Thailand (2%) and Philippines (1%) [10]. In Indonesia, implant insertions reached half a million women between 1986 and 1995 after formally registering with the health ministry [13].

Proper counselling, client selection, skilled service providers for insertion, and follow-up care contribute to increased acceptability and continuation of subdermal implants, as demonstrated by experiences in various Asian, African, and South American countries.

According to a statement by the World Health Organization, Intrauterine devices (IUDs) and contraceptive implants, also called long-acting reversible contraceptives (LARC), have been globally recognized as the most effective methods of reversible contraception [10]. 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 [10].

Implants in India's Health Market

Public Health Sector	Private Health Sector
• According to the MoHFW, implants in the public health system in India have been initiated since July 2023. • This rollout is part of Phase 1 implementation, scheduled to span the next three years and encompass ten states. The initiative's geographical	• IMPLANON NXT was approved by the Drug Controller General of India (DCGI) [11] in 2017 and was launched for use in the private sector in 2018. • It has been made available in the private market by a pharma company, MSD (Merck Sharp & Dohme), which Organon

[3] World Contraceptive Use 2022, United Nations, https://www.un.org/development/desa/pd/data/world-contraceptive-use

scope extends to 22 districts across the country. • Subsequently, Phase 2[4] It is anticipated to witness a pan-India rollout.	now takes over under the brand name Etonogestrel. • MSD started to roll out in December 2018 with the training of Obstetricians and Gynecologists in large cities.

Factors to be considered during expansion/more comprehensive coverage of single rod Implants in the public health system in India

Recognizing the potential impact of subdermal single rod implants on reproductive choices for the women of India, the following measures are suggested to ensure the effective integration of single rod Implant into India's public health system:

1. **Systems preparedness assessments**: Conduct systems preparedness assessments in various states in their geographical contexts to identify the gaps and clients' needs regarding trained service providers, including health workers and ASHAs, available infrastructure, IEC materials, products, registers for record-keeping, client cards, etc.
2. **Community Engagement and Awareness**: Design and disseminate IEC (Information, Education, and Communication) & **SBCC (Social and Behavior Change Communication)** materials to foster community awareness and demand generation through multiple platforms.
3. **Capacity Building and Training**: Doctors, health personnel, and ASHAs should be trained to mobilise communities for implant provision and ensure competency among service providers. An additional pool of Master Trainers should be established to train and build the capacity of more service providers using a cascade training model.
4. Ensure **effective logistics and supply chain management** for the ready availability of implants at public health facilities, as well as the availability of printed registers for record keeping of clients who have availed themselves of implant insertion and client cards.
5. Ensure an effective mechanism for **regular monitoring and reporting of the use and availability of implants**, as well as the required IEC materials and trained manpower.
6. Conduct **periodic support supervision visits (SSV**) to ensure the quality provision of implant services, including client-centred counselling based on informed choice and seeking feedback for continuous service improvement. This should be done during the initial three-year pilot phase by the public and private/NGO sector organisations, which will help strategise the next phase of the pan-India introduction of single-rod contraceptive Implants.
7. **Engage and leverage the private sector's potential** in implant delivery with the support of both the central and state governments, thereby accelerating progress towards FP2030

4 The commencement of this initiative is marked by its presence in diverse districts, including Kampur Mero, Dibrugarh, and Dhubri in Assam; Patna and Bhagalpur in Bihar; South Delhi, New Delhi, and Shahdra in Delhi; Ahmedabad and Surat in Gujarat; Bangalore and Bidar in Karnataka ; Cuttack and Ganjam in Odisha ; Jaipur and Udaipur in Rajasthan; Chennai and Dharmapuri in Tamil Nadu; Lucknow and Aligarh in Uttar Pradesh; and finally, Kolkata and Malda in West Bengal.

objectives. Facilitate private and CSO partnerships and integrate SBCC into frontline worker training to equip them for effective community engagement.

8. **Conduct periodic operational research studies and clinical trials**, focusing on stakeholder collaboration and generating **user experience and community preparedness data**. More in-depth research studies will inform strategising the post-removal phase, including integrated approaches within FP programs and developing strategies for three years post-implant.
9. Focus on regular follow-ups similar to IUD methods and exploring **partnerships** to extend counselling services among implant users, especially during postpartum.
10. **Investment in Quality Services and Sustainability**: Allocate resources for further investment in quality services, encompassing insertion and removal procedures, ensuring they meet international standards. The government should allocate more resources as the implant programme is rolled out in additional districts nationwide. In addition, due compensation may be offered to ASHAs for promoting and creating demand for implants in their areas.

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