Expanding the Role of Long-Acting Reversible Contraception in India

Background brief, Sep 2021

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Background

Despite reduction of total fertility rate over the last two decades in India, high levels of unmet need for contraception persist, especially in high focus states. More than half of all women of reproductive age, especially those of lower socio-economic status, are not using any contraceptive despite their desire to postpone or limit child birth, thereby facing risk of unintended pregnancy, unsafe abortion and a higher maternal and neonatal mortality.

After the launch of FP 2020[1] in 2014, Government of India introduced injectable DMPA, centchroman and progestin only pills. However, most women living in under-served areas of the country, especially in northern states, either do not use reversible methods or use them only when they have achieved desired family size. This stems from lack of awareness, access, and fear of side-effects. As a consequence, female sterilization continues to remain the key method for reducing fertility. However, with changing demographic, economic and social conditions, with increasing urbanization, migration and nuclearization of families in India, people's preferences and needs for contraception have evolved significantly. Couples now seek more flexibility and reversibility rather than permanence in their contraceptive practice. Moreover, the COVID-19 pandemic and lock down significantly affected fertility preferences as well as contraceptive access.

This background brief explores the current evidence on long-acting reversible contraceptives (LARCs) as applied to India and similar regions, highlights experiences from a few pilot studies in terms of acceptability and feasibility of use and discusses the scope for expansion of these methods within the country's family planning services.

What are long-acting reversible contraceptives (LARCs)?

LARCs are a group of contraceptives that act for 3 to 12 years without needing repeated user or provider intervention. They include the Copper-T as well as newer, hormonal preparations – Levonorgestrel Intrauterine System (licensed in India in 2000) and the Etonorgestrel subdermal implant (licensed in India in 2018). The Copper T 200B was used in the government FP programme till 2002, when it was replaced by Copper T 380A. The Multiload-375 has been popular in the private sector. It's advantage over Cu-T 380 A is that it comes pre-loaded on its inserter, allowing for no-touch insertion. Pilots conducted in the government sector using Multiload showed promising results, following which the device was introduced in public sector in 2011.

Newer hormonal LARCs such as LNG-IUS and sub-dermal implants have emerged globally as the choice of women across age groups. They have been widely popular in developed countries such as USA and Europe. However, despite proven benefits, their use in low resource settings including India has remained limited. Reasons cited for low uptake include limited provider and client awareness, high cost and insufficient state support.

Potential for expanding the role of LARCs in India

Long-term contraceptive options currently available within the national programme are not only limited in number (sterilization and Copper-T) but also witness challenges in terms of service quality and user

1 https://advancefamilyplanning.org/sites/default/files/resources/FP2020-Vision-Document%20India.pdf

acceptability, which limits uptake. Multi-level analysis of DLHS (2012-13) and NFHS (2015-16) around quality of care in female sterilization services at public health facilities revealed low facility readiness and non-uniform quality of care delivered across geographies which was associated with socio-economic characteristics of clients. A study conducted of public and private health facilities across UP and Bihar demonstrated lack of sterilized surgical equipment and sub-optimal provider adherence to infection prevention practices. On the demand side, the evidence suggests that a significant proportion of women who wish to limit, are not willing to undergo sterilization because of fear of surgery, side-effects and debility after the procedure. Pooled analysis of NFHS data showed an increase in post sterilization regret from 5% (NFHS-1) to 7% (NFHS-4), especially among younger women (< 30 years) which could likely be due to loss of an existing child or remarriage followed by desire for bearing another child.

Copper IUDs have had lower than expected popularity over the years, having been adopted by 1.9, 1.6, 1.7 and 1.5% married couples (NFHS 1 to 4, 1992 to 2016) at the country level. Apprehensions regarding side effects (heavy menstrual bleeding and abdominal pain), fear of complications such as uterine perforation and a range of misconceptions have contributed to reduced user acceptability. Some countries have achieved high levels of contraceptive uptake with LARCs – use of IUDs is high in China (33%), Scandinavia (18%), few Asian countries (13%) and North Africa (12%). The increase in LARC use in USA was accompanied by a 29% decrease in birth rates and a 34% decrease in abortion rates among young women. Newer LARCs such as LNG have recently been introduced in low-income countries including Kenya, Madagascar, Zambia, Zimbabwe and early evidence from these countries has demonstrated high acceptability by both clients and providers.

What do LARCs offer to the method mix?

LARCs offer various benefits to the contraceptive method mix. (see table 1 for details)

1. **Safety and efficacy**

LARCs are safe and 20 times more effective in preventing pregnancies than short acting reversible contraceptives including the DMPA and oral pills. They have a very low failure rate - unintended pregnancy rate with typical use within the 1st year is 0.8% (Copper T), 0.2% (LNG-IUS) and 0.05% (implant). What makes them widely acceptable is that they have limited contraindications and can safely be used by different groups, including younger (<20 years) and older (>40 years) women, those who are nulliparous or nulligravid, lactating and even women with HIV, at any stage of their reproductive life.

In addition to interval use, LARCs can safely be used in post-partum and post-abortion phases. A systematic review by Kapp et al comparing post-partum with interval insertion found no increase in risk of infections from postpartum IUD insertion. However, there was an increase in expulsion rates after delayed postpartum insertion when compared to immediate insertion, and after immediate insertion as compared to interval insertion. Expulsion rates vary by time of placement, type, and mode of delivery. Some commonly encountered side-effects with LARCs include heavy menstrual bleeding and dysmenorrhea with Copper-T and hormone-related effects, such as headaches, nausea, breast tenderness, mood changes and weight gain with LNG-IUS and implants. Changes in menstrual bleeding (especially during the 1st year) are common with LARCs. Uterine perforation and pelvic inflammatory disease, occur in less than 1% of women regardless of age or IUD type. Expulsion occurs in 2–10% of users and varies by IUD type. Complications with implants also include infection or hematoma at insertion site in a few cases, expulsion and difficult removal may rarely occur, most often due to incorrect insertion by the provider.[2] Women in US have also reported headache (15.3%) as a common complaint with implant but it led to discontinuation in only 1.6% of cases.

2. **High user acceptability**

LARCs have been widely accepted by users in high and low-income settings. A systematic review by Coombe et al, 2015 revealed that 'fit and forget', high efficacy and long-term protection were the most commonly liked attributes of LARCs. A user survey conducted in 18 countries from Europe and

2 http://pdf.usaid.gov/pdf_docs/PA00W86F.pdf

near east demonstrates that 95% of users were satisfied with LNG, this increased to 99% for second time users. High user satisfaction has also been reported from Africa for reasons including effectiveness, long action, reversibility, potential to reduce menstrual bleeding and relief from side effects. On the flip side, irregular bleeding, painful insertion-removal procedures and weight gain were reported to be reasons for disliking LARCs. Pilot studies from Africa have shown that while most women liked menstrual changes caused by hormonal LARCs especially LNG, some of them disliked changes in bleeding patterns and this led to early discontinuation. The need for counselling and follow up support to women before insertion as well as during the first few months after insertion has been shown to play an important role in improving user acceptability.

3. **Independent of user adherence and repeated provider action**

Since LARCs are not dependent on user adherence and frequency of problems after adoption are considerably low, they face comparatively lower discontinuation rates. (see table 1) They are also more likely to elicit better adherence since they work long term and do not need repeated interaction with the health provider. On average, LARCs offer three times the length of contraceptive protection offered by other modern, reversible methods. An in-depth assessment of IUD use in 14 developing countries in 2011 demonstrated median length of uninterrupted use of IUDs to be 30 or more months. (25)

4. **Meet the needs of users with both spacing/limiting intentions**

Having LARCs in the method mix gives more choice not only to women who intend to space child birth, but also to those who have decided to limit but are reluctant at that point, to adopt a terminal method.

5. **Non-contraceptive benefits**

The LNG-IUS offers additional non-contraceptive therapeutic benefits including reduction in menstrual bleeding (reduces 90% by the end of a year), reduced cramping as well as treatment of idiopathic menorrhagia, symptomatic uterine fibroids and endometriosis. A systematic review has shown that women with uterine fibroids have lesser menstrual blood loss and higher serum levels of hemoglobin, hematocrit and ferritin after insertion of LNG. These findings are substantiated by evidence from developing countries wherein users appreciated the freedom from heavy bleeding and improved quality of life, after adoption. Similar results have emerged from a few hospital-based Indian pilots from Karnataka, Mumbai and Delhi. The ability of LNG to reduce menstrual bleeding can serve as a boon for rural women from marginalized communities, that shoulder a heavy burden of nutritional anemia. Additionally, they offer a cost-effective alternative to hysterectomy for women with abnormal uterine bleeding.

6. **Promote agency and autonomy of women**

A mixed methods study of clients and providers in Nigeria reported that 41.7% women chose LNG-IUS because of its discreetness, stating that "*nobody would know about my contraceptive*". By maintaining women's privacy and confidentiality, LARCs can improve women's agency and autonomy, and protect their reproductive rights. However, dependence on providers can be a potential barrier. Hence, women need to have the autonomy to get the device inserted and removed at a time and facility of their choice.

Table 1 - Clinical features of LARCs – A ready reckoner[3]

	Copper-T	LNG-IUS	Sub-dermal Implant
			
Licensed in India	Cu-T 200B introduced in govt programme in 1975, Cu-T 380 A – in 2002	2000	2018-19
Availability and cost	Free of cost in public sector as part of National FP program Price = Rs 300 – 500 in private sector	Limited to private sector Price range – Rs 1000 – 4000 Pregna Eloira – Rs 3125[4]	Limited to private sector Etonorgestrel implant – Rs 3366
Brands	Pregna, Silverline	Mirena, Eloira	Implanon, Nexplanon, Jadelle, Sino-implant
Formulation	380 mm^2 of exposed copper surface area (continuous release of copper ions)	52 mg of Levonorgestrel (20 µg released/24 h in first 5 years then 14 µg)	Two types available: 1. Single rod with 68 mg of Etonorgestrel – released 60-70 µg/day declines to 25-30 µg/day by 3 years 2. 75 mg of Levonorgestrel with 2 rods, releases 40-50 µg/day at 1 year, declines to 25-30 µg/day in 5th year
Mode of action	Spermicidal, reduces sperm motility, inhibits migration of ovum	Cervical mucus thickening, impairs ability of sperms to fertilize ovum,	Cervical mucus thickening, prevents ovulation by diminishing LH surge
Insertion	Intrauterine Pelvic examination required before insertion to determine the position of the uterus and assess eligibility.	Intrauterine Pelvic examination required before insertion to determine the position of the uterus and assess eligibility.	Eligibility assessment required. Inserted under the skin in the medial aspect of the upper part of arm using an applicator under local anesthesia, insertion site closed with surgical tape and adhesive bandage
Removal	Using narrow forceps, the provider pulls the strings slowly until the device comes completely out of the cervix. Missing strings may suggest possible pregnancy, uterine perforation or expulsion. Retained/embedded devices may be easily removed in clinic based setting under USG guidance in a much less invasive and cost-effective way compared to hysteroscopic removal in OR.		Requires minor surgical procedure – incision near the site of insertion followed by pushing of the implant through the insertion and pull out by forceps. Infection/hematoma may occur at the site of removal in rare cases.
Duration	Copper T 380A - upto 12 years Copper T 200B - upto 3 years	5 – 7 years	3 to 4 years
Pregnancies within 1st year of typical use	0.8%	0.2%	0.05%
Non-contraceptive benefits	Can be used in treatment of endometrial cancer.	Reduces menstrual bleeding and pain, therapeutic effect in idiopathic menorrhagia (amenorrhea in 20-50% users at 1 year post insertion) Endometrial protection in women requiring hormonal replacement therapy	Reduction of Endometriosis associated pain, dysmenorrhea and adenomyosis.
Side effects	Increased menstrual bleeding, inter-menstrual spotting and/	Reduced menstrual bleeding, amenorrhea, inter-menstrual	Irregular menstrual bleeding, inter-menstrual spotting

3 https://www.who.int/reproductivehealth/publications/fp-global-handbook/en/

4 https://www.smartmedicalbuyer.com/collections/pregna-international-ltd

	Copper-T	LNG-IUS	Sub-dermal Implant
	or pelvic pain during first few months of usage	spotting, headache, acne, mood swings and weight gain	common during the first 3 months to one year, decreases with time, amenorrhea in 30-40% users, headache, acne and weight gain.
Advantages	Can be used as emergency contraceptive if taken within 5 days after unprotected intercourse. No interference with breastfeeding and safe for women with hormonal contraindication (eg breast cancer, DVT)	Reduce menstrual bleeding and anemia induced by heavy menses, also used as a treatment for menorrhagia, fibroids and endometriosis.	Safe for women with contraindication to estrogen Helps protect against symptomatic PID.
Contraindications to use (WHO)	Reproductive tract infection during the first 6 weeks after childbirth (puerperal sepsis) or septic abortion, unusual vaginal bleeding, genital cancer or pelvic tuberculosis, HIV infection with severe or advanced clinical disease SLE with severe thrombocytopenia	Hormonal IUDs - severe cirrhosis or severe liver tumor, deep vein thrombosis, breast cancer, unexplained vaginal bleeding and SLE with positive (or unknown) antiphospholipid antibodies, and not on immunosuppressive therapy. LNG-IUS: Reproductive tract infection during the first 6 weeks after childbirth (puerperal sepsis) or septic abortion, unusual vaginal bleeding, genital cancer or pelvic tuberculosis, HIV infection with severe or advanced clinical disease.	
Suitability for Post-partum and post-abortion users	Safe	Safe	Safe
Service delivery requirements (facility, equipment and training for insertion, removal and monitoring)	Insertion and removal can be done by trained health providers at a primary care level.	Insertion and removal can be done by trained health providers at a primary care level. Medical doctor may be required to screen for eligibility when used in women with heavy menstrual bleeding of unknown etiology.	Trained health providers required for insertion and removal (surgical). Medical doctor may be required to screen for eligibility when used in women with heavy menstrual bleeding of unknown etiology.
Continuation rate (CHOICE project, USA, 2015) One year % (95% CI) Two year % Three year %	 84.3 (80.7-87.3) 76.2 (72.1-79.9) 69.7 (65.1-73.7)	 87.3 (85.8-88.6) 76.7 (74.8-78.5) 69.8 (67.6-71.8)	 81.7 (78.3-84.7) 68.7 (64.7-72.3) 56.2 (51.8-60.3)
Common reasons for discontinuation	Increased bleeding, cramping during menses	Irregular menstrual bleeding	Irregular menstrual bleeding

Pilot studies on introduction of LARCs in India

Overall, there is a dearth of evidence on LARC usage and user acceptability in India. However, a few pilots and clinical trials so far, have shown promising results. (presented in Table 2)

Table 2: Pilot studies on LARCs from India

LARC method	Title and study setting	Key findings
Copper T	Improving service delivery for PPIUCD – Experiences from Gujarat and Rajasthan (2014-2020)	As part of the Expanding Access to IUD Services in India (EAISI) project, 359 health facilities were provided technical support by Engender health to increase the availability and quality of IUD services through provider training, monitoring quality of services, improving infection control and contraceptive commodity planning. By completion, 2793 providers were trained to deliver IUD, % of women adopting a PPIUCD increased from 17.5% to 23.9% and follow up was increased from 2.4% to 22.4%. A cross-sectional study conducted as part of the same project revealed that IUD continuation rates decreased from 85.6% to 78.3% and PPIUD rates decreased from 78.5% to 70.7% between month 3 and month 12. Clients who received IUD counselling prior to insertion were more likely to continue than those who did not and IUD continuation increased significantly in cases where both partners jointly selected the method compared to situations where women decided alone.
	Women's experience with PPIUCD use in 8 states of India (2014)	99.6% women reported that they were satisfied with IUCD at the time of insertion and 92% reported satisfaction at the six-week follow-up visit. The rate of expulsion of IUCD was 3.6% by six weeks of follow-up. There were large variations in rates of problems and complications, largely attributable to the individual hospitals implementing the study.
LNG-IUS	Introduction of LNG-IUS in a primary care setting in Rajasthan (2015-19)	LNG-IUS was offered by rural health clinics at a primary care level to women living in a low-income, rural-tribal community of southern Rajasthan, high user satisfaction at 91·6% was reported, with 92% women rating their experience as equaling or exceeding expectations. Twelve-month continuation rates were 87·3%. Moderate and severe anemia reduced, and mean hemoglobin levels increased by 0·7 g/dl ($p < 0·01$). LNG was well accepted by women who wished to limit childbearing because of long duration of action without need for repeated user action, relief from stress of unwanted pregnancies/abortions and freedom from side effects of short acting contraceptives. Furthermore, women appreciated LNG as compared to sterilization because of quick recovery post procedure without disruption of routine chores, its reversible action which allowed them the room to conceive in future and tendency to reduce menstrual bleeding. (ARTH, under publication)
Sub-dermal Implant	Clinical trials on user acceptability and effectiveness of implants by ICMR task force[5]	Phase III multi-center clinical trial with Norplant II (two covered rods) by ICMR Task Force on Hormonal Contraception, 1993 revealed that they retain their contraceptive efficacy for 5 years with a very low net cumulative pregnancy rate (0.8 /100 users). Overall continuation rates were 61, 49 and 42 per 100 users at 3, 4 and 5 years of use respectively. Commonest reason for discontinuation was prolonged and excessive bleeding. Side effects included increased body weight - about 43% women had gained more than 5 kg body weight over 5 years of Norplant use. Interim results of another Phase III multicenter Clinical Trial with Subdermal Single-Rod Contraceptive Implant conducted from 2004-2012 reported 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 was menstrual disruptions (19.6 per 100 users) and planning pregnancy (7.0 per 100 users).

5 http://pdf.usaid.gov/pdf_docs/PA00W86F.pdf

	Implant – User experiences from tertiary hospitals in UP and Delhi	Hospital based studies from UP and Delhi reveal a high acceptance of Implanon, sub dermal implant as a safe and effective contraceptive. Out of all the women receiving FP services at a tertiary hospital in Allahabad (UP), 3.4% accepted an implant (mean age = 26 years, para 2). The study showed an efficacy of 100% even after 36 months of use and continuation rate of 55% at the end of 3 years. Commonest cause of discontinuation was prolonged and irregular bleeding.[6] In another hospital-based study in Delhi, 1.5% women accepted implant from the method mix, showed high acceptance. 16.5% women discontinued for polymenorrhea, irregular bleeding or amenorrhea. 40% had return of ovulation within one month, 95.8% conceived within 12 months.

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