

Recommendations

- **Addition of Nexplanon to current Family planning scenario in the public health sector of India is found to be cost-effective. It could be considered for program introduction to improve the contraceptive basket of choice in a phased manner. The model shows that larger the proportion of method users, the higher is the cost-effectiveness.**
- **The pre-requisites recommended for Nexplanon introduction into the public health sector of India are recommended to be:**
 - **Conducting feasibility and acceptability studies before introducing Nexplanon with due consideration to ethical issues of autonomy and coercion.**
 - **Creating awareness regarding Nexplanon among all stakeholders and eligible couples.**
 - **Program introduction could be phased top-down from Medical Colleges to 24X7 PHC level manned by Medical Officers (MBBS), as Nexplanon requires surgical removal.**
 - **Effective pre-insertion counselling and preparedness for management of side-effects by trained health personnel.**
 - **Efficient follow-up and tracking mechanism for users of Nexplanon**

Summary

Currently, India's National family planning program has two Long Acting Reversible Contraceptive (LARC) methods: Copper-Intra Uterine Device-380-A and Depot Medroxy Progesterone Acetate (DMPA) three-monthly injections. The policy question of whether another LARC (Nexplanon, a sub-dermal contraceptive implant) should be added to this basket is addressed in this brief. Health Technology Assessment (HTA) has been the chosen approach to explore this question. Literature review, primary data collection for costing and economic evaluation via decision analytic modelling was done as a part of HTA. The decision analytical model, which is a mathematical model, that simulates reality, showed that an additional cost of 17,716 INR will be incurred by the Indian government to gain one Quality adjusted life year (QALY) if Nexplanon is added to the current basket of contraceptive choices in the public health system. This shows that the intervention is very cost-effective, using the comparator as the threshold of GDP per capita.

Context and Gap Analysis

India's journey of providing family planning services to her people has seen multiple shifts in focus and strategy. The current approach tries to balance the demographic (population stabilization) and the health (improving, maternal, adolescent and child health) and economic benefits of family planning. The unmet need of spacing methods of contraception has increased over the past few decades(1). To counter this, one of the strategies has been to roll-out new contraceptives. The launch of two new contraceptives into the public health system of India in recent years: the injectable contraceptive Medroxyprogesterone acetate (MPA) named as 'Antara' and the contraceptive pill, named 'Chhaya'; reiterates this strategy of the National family planning program (2). Including these, we currently have seven modern contraceptive methods in our program.

Indian Council of Medical Research (ICMR) has conducted a phase-3 clinical trial on Implanon during 2004-2008 enrolling 3119 women across India. Implanon was offered along with other existing contraceptive methods available in the National family welfare program. The relative acceptability of Implanon was observed to be 2.1 % among all contraceptive methods and 3.4% among spacing methods.

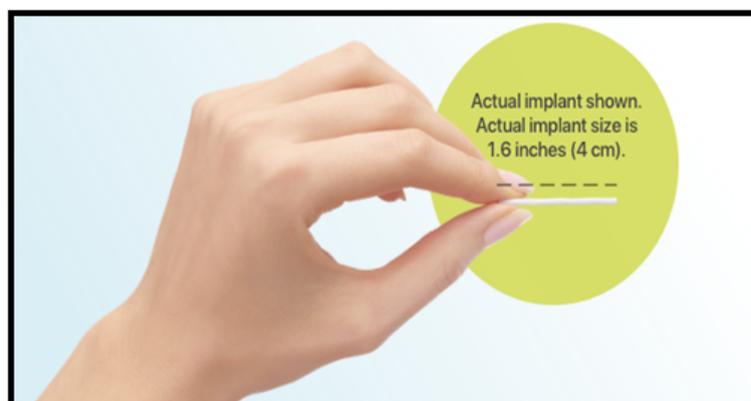


Figure 1: Shows the implant, Nexplanon

Aims and Objective

This policy brief addresses the policy question of whether adding a new contraceptive, Nexplanon into the National Family Planning program in India would be cost-effective. It summarizes the results of a Health Technology Assessment study on Nexplanon, conducted by the HTA Resource Hub, ICMR-National Institute for Research in Reproductive Health, Mumbai.

Methods and Approach

To answer the policy question, a 'Health Technology Assessment' (HTA) approach was adopted. It is a systematic evaluation of properties, effects, and/or impacts of health technology. HTA is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues

of a health intervention or health technology(5). As per the HTA India reference case, QALY is used as a measure of outcome (6). It is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health (7)The following steps were followed for the HTA:

- 1) A systematic review (A systematic review is an appraisal and synthesis of primary research papers using a rigorous and clearly documented methodology in both the search strategy and the selection of studies (8). for clinical effectiveness of Nexplanon
- 2) Extensive literature review for other contraceptive methods, costing, cost-effectiveness, quality of life during contraceptive use and related states and HTA on Nexplanon
- 3) Primary data collection for collecting cost data from four levels of public health system in Maharashtra
- 4) Estimation of age specific transition probabilities from Calendar data of National Family Health Survey-4
- 5) Review of literature on social and ethical issues
- 6) An economic evaluation to assess whether adding Nexplanon to the current system would be cost-effective. This involved conceptualization and running a decision analytic model, in our case a Markov model (shown in Figure 2).

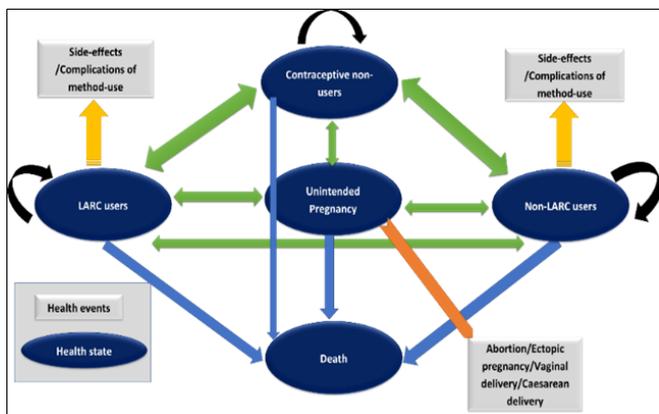


Figure 2: A Decision Analytic Model: Markov Model

- 1) When a simulated cohort of 15-year olds (from census 2011) went through the markov model, experiencing the mentioned health states, about 10.48 lakh pregnancies 1.17 lakh maternal deaths and 10.22 lakh child births could be averted by adding Nexplanon to the public health system.
- 2) Increase in contraceptive users will improve cost-effectiveness (shown by sensitivity analysis)

About Nexplanon

- **What is it?** A subdermal contraceptive implant, the size of a match stick, inserted beneath the skin in the upper arm of the woman. Contains 68 mg of Etonorgestrel (Progestin-only-contraceptive).
- **How is it different from Implanon?** Nexplanon is bio-equivalent to Implanon but has an addition of barium sulphate that makes it radio-opaque.
- **Period of use:** Approved for a period of three years
- **Clinical effectiveness:** Highly effective. Best among long acting reversible contraceptives. 0.05% of Nexplanon users would have an unintended pregnancy during the first year of use(3)
- **Safety:** Commonest side effect is Menstrual irregularities; with Amenorrhea being highest (30%) and Menorrhagia being at 10%. Headache, acne and weight gain are other reported side-effects(4).
- **Return to fertility:** Within one month of removal(4)
- **Insertion and Removal:** Requires doctors who are trained in the procedure of insertion and removal. Removal involves a small incision in the upper arm

Results

The economic evaluation using age specific data on contraceptive use demonstrates that an additional cost of INR 17,716 would have to be incurred by the government to gain one additional Quality adjusted life year (QALY). This is well within the threshold of GDP per capita (about 137945 INR). Represented in Figure 3.

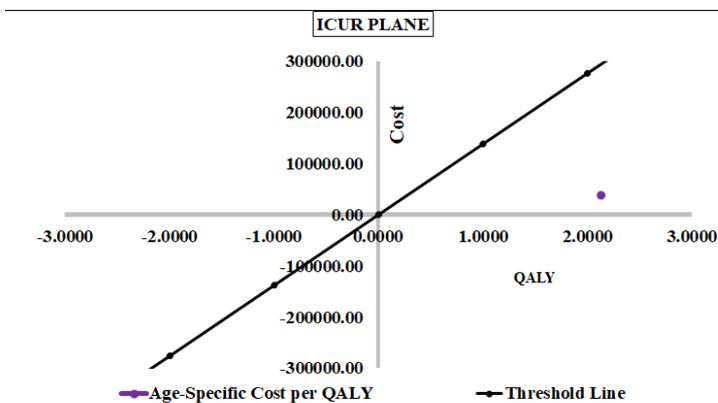


Figure 3. Incremental Cost-Utility Ratio. (Additional cost incurred by government to gain one QALY)

Budget Impact Analysis

A Budget Impact Analysis (BIA) was done to assess how introduction of Nexplanon into the Public health system of India would impact the budget of India. We considered the additional expenditure for Nexplanon over a period of three years at different levels of public health care facilities. This was expressed as a percentage of family planning budget and as a percentage of health budget. This is depicted in figure number 4.

Figure 4 shows that expenditure towards Nexplanon will amount to less than 0.5% of the health budget of the country. The expenditure for Nexplanon (A) included product of price of Nexplanon device and estimated number of acceptors, information education and communication activities, training of health personnel, incentives on acceptance of Nexplanon

and management of side-effects. The savings (B) due to unintended pregnancies that were prevented due to Nexplanon introduction were calculated. To calculate net savings over a period of three years, A was subtracted from B. Net savings were estimated to be at ₹ 76,04,85,91,940.

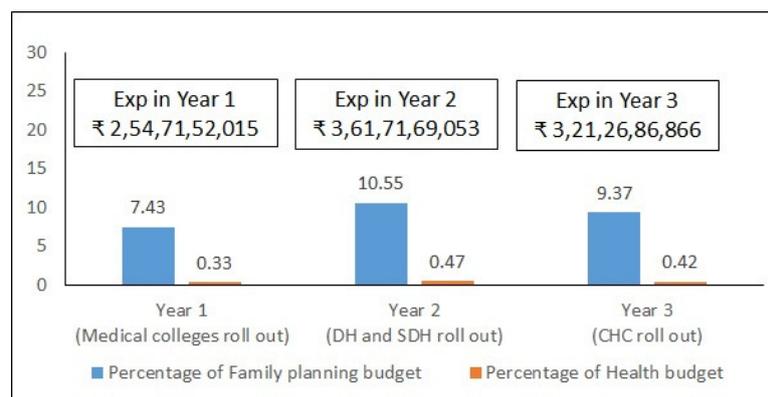


Figure 4. Expenditure for Nexplanon as a percentage of Family planning Budget and Total health budget

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