

Introducing Injectable Contraceptives in National Family Planning Program of India: A Policy Perspective

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INTRODUCTION AND CONTEXT

Much of India's population growth is the result of failed or inadequate prevention of unintended pregnancy. National Family Health Survey-III (2005-06)ⁱ reveals that one in five births are either mistimed or unwanted resulting from inadequate or incorrect contraceptive use. Nearly 20 percent of married women of reproductive age are either not using any form of contraception despite an expressed desire to limit or space their next birth; or are currently using less effective traditional methods to prevent pregnancy. As in most countries, India's contraceptive method mix is highly skewed toward single method use i.e. female sterilization and includes few options for women seeking to space births or whose cultural beliefs preclude them from using permanent methods or inserting foreign objects into the body. Increasing access to injectable contraception will expand method choice – providing a new option for women unsatisfied or not served by the current method mix. On this backdrop, Futures Group International has carried out the present study to: (a) review the historical and legal legacy that restricts access to injectables in India; (b) document the experience of distribution, provision, and use of injectables; (c) summarize relevant country experiences from the region; and (d) prepare recommendations for introduction of injectables in the public sector and expansion of their use in the private sector.

DATA AND METHODS

In-depth information was collected from policy makers, researchers, donor agencies, manufacturers, NGOs and practitioners in the year 2010 (N=50). Respondents from Ministry of Health and Family Welfare, Indian Council of Medical Research, Director General of Health Services, National Institute of Health and Family Welfare were interviewed to understand the scope for injectable contraceptives in India along with exploring the barriers (legal, clinical and infrastructural) to their introduction in the public sector. Donor agency representatives were interviewed to know their current and future approach towards injectable contraceptives as a viable option in the basket of contraceptives provided by the Government. Manufactures provided valuable information about demand for and distribution system of contraceptives in the country, while NGO representatives acquainted the study team about the attitude and concerns of civil society towards injectable contraceptives and its side effects. Information about the client's awareness and demand for injectable contraceptives was gathered from practitioners. It is worth mentioning that a team of public

health experts with thorough knowledge about government functioning and policy issues gathered the necessary data from the stakeholders associated with injectable contraceptives.

FINDINGS

History of injectable contraceptives in India

Injectable contraceptives have been in use by registered medical practitioners in India for decades – norethisterone enanthate (NET-EN) since 1986 and depot medroxyprogesterone acetate (DMPA) since 1993. Attempts to introduce injectables (initially NET-EN and later DMPA) in the government program began in the 1980s and have been dogged by controversies throughout. Broadly, the controversy relates to the way these contraceptives were introduced in India, concerns about their health impact, and concerns about inadequate infrastructure for follow-up and care.

i. Adverse health consequences

According to women's groups injectables can cause menstrual irregularities, general weakness, migraine headaches, and severe abdominal cramps. The groups also refer to studies that show that DMPA causes bone demineralization, and claim that DMPA has been indicted for climacteric-like syndrome; irreversible atrophy of the ovaries and endometrium; deaths due to thrombo-embolism; increased risk of HIV infection from an infected partner; increased risk of Downs Syndrome in babies born to women users; increased chances of still births; increase in the risk of breast cancer, cervical cancer including carcinoma in situ. The groups also argue that there are doubts regarding the return of fertility after discontinuation of the drug.

ii. Inadequate infrastructure and accountability

Women's groups emphasize that administration of injectables requires ruling out contraindications and close monitoring over long periods and claim that such monitoring is totally absent in India. The groups point out that it was for this reason that in 1995 the Drugs Technical Advisory Board advised against inclusion of Depo Provera in the Family Welfare Programme. Activists also argue against the policy of allowing injectables provision in the NGO sector, since according to them government has not evolved definitive standards for NGOs in terms of care, follow-up or accountability.

iii. Lack of credibility of post-marketing surveillance of Depo Provera

Women's groups question the credibility of post-marketing surveillance (PMS) study that was conducted on Depo Provera, alleging that the study was biased since it was conducted by Upjohn, which stood to profit from the results of the research. The groups claim that the PMS did not address certain serious concerns, including the potential side-effects of bone density loss, cancer risk, amenorrhoea, and the concern that breast feeding is a contra-indication for DMPA.

iv. Waiver of trials, lack of informed consent in conduct of trials

Women's groups claim that ethical norms relating to requirements of informed consent were violated in the conduct of NET-EN trials in 1985, and that this has happened on many occasions thereafter with injectables and other hormonal contraceptives.

Injectables: Legal status and stakeholders' positions

Government wishes to introduce injectables in the FW Programme and has recently initiated pre-program introduction of NET-EN and Cyclofem in the public sector. NET-EN is licensed for marketing in India; Cyclofem is not yet licensed for marketing. DMPA was approved for marketing in 1993 and there is no judicial ban on its use in India. The Supreme Court's directions in the case, disposed of in 2001, involving allegedly hazardous drugs (including DMPA) imply that DMPA should not be introduced in the FW Programme unless this was endorsed by Drug Technical Advisory Board (DTAB). From all indications DTAB has not reviewed DMPA after its interim recommendation of 1995 advising against its mass use in the government program. Informants are of the opinion that DMPA could be introduced in the public sector once DTAB endorses it. Nevertheless, both NET-EN and DMPA are approved for social marketing in India.

Manufacturers and suppliers of injectables in India

Till recently, Depo-Provera was the only injectable contraceptive marketed in India (by Pfizer, which imported it from its plants overseas). Also, social marketing NGOs such as DKT India and Janani were importing injectables from Indonesia for their programs. During the last six years, certain Indian/ India-based companies (Pfizer limited, Star Drugs and Research Laboratories Ltd, HLL Lifecare Ltd, Famy Care Ltd, and Sun Pharmaceutical Industries Ltd) have initiated supply of injectable contraceptives. While figures for domestic commercial sales of injectables were not available, on the basis of data provided by the

various NGO projects and the Dimpa project, it is estimated that during 2008 the total secondary sales of DMPA through the social marketing agencies were about 367,000 doses.

The following table briefly discusses the India-based companies that currently supply injectables, or propose to do so.

Table 1: India-based suppliers of injectables

Supplier	Product	When started	Customers distribution channels	Retail price
Pfizer (earlier Upjohn)	DMPA	1993-94	- Commercial retail - DKT India	Rs 162 (commercial) Rs 100 (DKT)
Star Drugs and Research Labs	DMPA	2002 (exports) 2006 (in India)	PHSI, PSI and Janani ¹	Rs.60-100
HLL Lifecare	DMPA	-Import 2006-07 -Manufacture 2010-11	Obs / Gynecs	Rs 175 retail (imported)
Famycare	DMPA initially	To launch end-2009	NGOs (proposed)	To decide
Sun Pharma	Cyclofem	Licensed to manufacture. Preparation for manufacture underway	To decide	To decide

Current use of and access to injectables in India

NFHS-3 (2005-06) shows that less than half (49 percent) of all women have heard of injectable contraception, which is being debated as a figure over estimated. The same data reveals that use of injectables remains low; injectables are used by 0.1 percent of married women of reproductive age. More than half (53 percent) of all injectable users in India will discontinue in the first year of use. This rate is only slightly higher compared to the 12-month discontinuation rate for pill use in this population (49 percent) and to the global average for injectable use (49 percent)ⁱⁱ. Discontinuation is inversely correlated to the prevalence of injectable use; therefore it is likely that the discontinuation rate will fall as the level of injectable use risesⁱⁱⁱ.

Injectables are not currently available in the public sector for contraceptive use. Interviews with physicians in the public sector reveal that providers at all levels are trained on provision

¹ PHSI (Population Health Services (India)) and PSI (Population Services International) and Janani are social marketing NGOs.

of injectables and generally have knowledge of this method including benefits and side effects of use. Of those interviewed, none expressed clinical concerns related to provision of this method. Informants emphasized the importance of good counseling and believe that irregular bleeding would be a problem for some women in India. All those interviewed reported that women visiting their facilities request this method, despite the fact that it is not yet available in the public sector. The physicians interviewed believe that their clients would benefit from including DMPA in the National Programme and expressed the desire to be able to provide this method within their facility.

Over the last several years, many organizations – mainly social marketing agencies – and private providers have introduced injectables through clinic-based services. The method is currently distributed via social marketing channels and clinic / provider networks. The largest injectable distribution projects are supported by DKT India, Parivar Seva Sanstha (PSS), Family Planning Association of India (FPA India), Population Services International (PSI), Janani, Abt Associates and Population Health Services (India) (PHSI). However, the large retail network shown for Janani indicates the potential reach of this system; currently only a fraction of those retailers stock DMPA. A significant limitation of the current distribution is that most providers and distributors included in these networks are located in urban or peri-urban areas with limited access to rural areas. Small scale operations research finds the potential demand for injectable contraceptives in the country and private practitioners are interested in providing DMPA to their clients.

Evidence from many small scale injectable projects undergoing in different parts of the country suggests:

- When provided the choice, many women will choose injectables over other methods.
- With counseling and support, menstrual irregularities are acceptable to many women.
- Demand for injectables is price sensitive. When the price of injectables increases demand shrinks. Even with highly subsidized products, middle income clients make up the major proportion of program beneficiaries.
- Sales figures from DMPA distributors and service delivery organizations show an increase in demand for the product.

Other country experiences

DMPA was first made available to women in Asia in the 1970s and injectable contraception remains one of the most popular methods in the region. More than one in 10 married women of reproductive age uses injectables in Bangladesh, Indonesia, Nepal, Sri Lanka, and Thailand^{iv}. Injectable users in the region rely on a wide range of providers from both the public and the private sectors to supply this method. While in many countries the private sector and NGOs have become an increasingly important source of supply, in Bangladesh and Nepal these providers account for a small percentage of injectable use. In these countries, the public sector continues to supply the majority of users, accounting for 79 percent of injectable users in Bangladesh and 81 percent of users in Nepal^v. In contrast, private sector providers supply the vast majority of injectable users in India and Indonesia (83 percent and 80 percent, respectively). Evidence from Bangladesh, Indonesia, Nepal and Thailand demonstrates that limiting provision of the method to clinic-based physicians severely restricted access.

CONCLUSIONS AND RECOMMENDATIONS

The study finds that Provision of DMPA in the public sector is at present legally restricted awaiting endorsement by DTAB while Cyclofem and NET En are in the process of pre-program introduction trials for the government program. Providers in the public and private sector are most familiar with DMPA and report significant client demand for the method. Moreover, program reporting and sales data document sustained or increased sales of DMPA over time. Menstrual irregularity is challenging for some clients and providers emphasize the need for high quality counseling and follow up. Additionally, evidence and experience from other countries in Asia (Bangladesh and Nepal) shows that provision of injectables within a public health system similar to India is feasible and acceptable to women.

The long and complex history of injectables in India has resulted in a chilling effect among medical professionals, development organizations, and civil society sympathetic to the need for expanded contraception choice. An uninformed population and marginally trained medical professionals further worsen the situation. Therefore, any effective strategy to expand access to injectable contraceptives should include: support to the Government of India to take the necessary steps to provide DMPA under the national Family Welfare Programme; develop a more equitable service delivery strategy which provides high quality

services to women living below the poverty line and those in rural areas; and increase awareness and accurate knowledge of injectables among every section of society – clients, providers, civil society, and policy-makers.

The study recommends that in the short term, USAID and its partners can: Organize requisite support to Central MoHFW; Support awareness raising and advocacy efforts; Support service delivery; Refresher training for physicians, paramedics, nurses, and Accredited Social Health Activists (ASHAs)^{vi}; Development or adaptation of Information Education Communication (IEC) material specific to DMPA provision; and Develop mechanisms to strengthen follow-up and counseling for injectable users. Moreover, as mid and long term strategies, MoHFW and its partners should: Seek ways to expand provision of DMPA by using frontline providers to support method initiation, continued use, efficient method switching and repeat injections; Examine the benefits and challenges of incorporating multiple injectables (NET-EN and Cyclofem) into the national program; Establish systems to assess quality of injectables produced, especially those supplied by companies that are recent entrants in injectables manufacture; and Support small scale operations research to identify program inputs which lead to improved contraceptive continuation (all methods), ensure informed choice, and provide appropriate counseling.

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- ^{iv} Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2007). *World Population Prospects: The 2007 Revision. Highlights*. New York: United Nations.
- ^v Macro International Inc, (2009). MEASURE DHS STATcompiler. Accessed at: <http://www.measuredhs.com>.
- ^{vi} The topic of injectables is already part of ASHAs' current training. It would be useful to include a refresher as part of other training that they receive so that ASHAs can support women in using the method although they cannot provide it