

Injectable Contraceptives to Expand the Basket of Choice under India's Family Planning Programme: An Update

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I. Purpose

India's contraceptive method mix is skewed towards female sterilisation, and the range of methods women can use to space their births is narrow. A skewed method mix in combination with the guidelines of the public sector programme suggests a significant lack of choice for clients. The Policy Unit¹ at the National Institute of Health and Family Welfare (NIHFW) aims to (1) provide updated information on effective policies and strategies; (2) identify barriers to policy implementation and the need for new or revised policies, as well as identify policy and programme trends; (3) study innovative approaches to document best practices; and (4) convene programme and policy experts for enriched policy dialogue. In reflection, the Policy Unit, with support from Health Policy Project (HPP), has placed a priority on policy analysis and advocacy for the expansion of contraceptive choices offered within the government programme.

The injectable contraceptive, while considered a highly effective method, has had an ambiguous status in India. Although the method is permitted through the private sector and other social marketing channels, it is not widely available and the National Family Welfare Programme (NFWP) does not offer it.

This brief, prepared by the Policy Unit, provides a status update on injectable contraceptives in India. It is based on both primary and secondary research analysis to understand the barriers to including injectable contraceptives as a method of choice in the basket of family planning (FP) services being offered by the NFWP.

HPP conducted a stakeholders' analysis to (1) understand key barriers preventing the inclusion of injectables in the basket of contraceptives under the government's FP programme, (2) determine the status in terms of the approval processes, and (3) identify the key influencers and advocates.

To Know

The injectable contraceptive is the fourth most popular family planning method worldwide, after female sterilisation, the intrauterine contraceptive device, and oral contraceptive.

The absence of bleeding (amenorrhoea) that can occur as a result of use of injectables is not harmful. Many women consider it to be convenient, and it might even be beneficial to women who are anemic.

Although India permits the provision of injectables, the method is not widely available and the National Family Welfare Programme does not offer it.

Incorporating women's perspectives into contraceptive introduction strategies can help local family planning programmes to increase user satisfaction, improve continuation rates, and expand method use.

¹ The Policy Unit was established at the NIHFW with initial support from the United States Agency for International Development through the Health Policy Project. The mission of the Policy Unit is to improve the quality of life of people through sustainable health, nutrition, and population development.

Those interviewed included key technical experts engaged in advocacy with India's Ministry of Health and Family Welfare (MoHFW), members of the expert committee on injectable contraceptives, and programme implementers and donor representatives. In addition to the key barriers, the analysis helped identify significant milestones of the latest advocacy efforts, as well as the potential solutions.

II. About Injectable Contraceptives

Injectable contraceptives have an effectiveness rate of more than 99 per cent when used correctly and consistently and 97 per cent when commonly used (WHO, 2012). They are available in two forms: progestin-only and combined (WHO and CCP, 2008). Combined injectable contraceptives, also called monthly injectables, contain two hormones—progestin and estrogen—that act like the natural hormones progesterone and estrogen found in a woman's body. Both progestin-only and combined injectable methods work primarily by preventing ovulation and thickening cervical mucus.

The contraceptive prevalence of injectable contraceptives is 3.5 per cent worldwide (Department of Economic and Social Affairs, 2011). Currently, an estimated 42 million women worldwide use injectables as a method of choice. This is a significant increase over the years from 12 million in 1995. Developed in the 1950s and made available in the 1960s, injectable contraceptives are the fourth most popular contraceptive method worldwide after female sterilisation, intrauterine devices, and oral contraceptive pills. DMPA and NET-EN have been available in many countries since 1983, and additionally, the approval of DMPA in the United States in 1992 greatly increased access to the method. Until 2006, DMPA was registered in 179 countries, NET-EN in 91 countries, and Cyclofem in 12 countries. Across continents the percentage of users is the highest in Africa.

Examining the proportion of modern method use represented in South Asia,

Types available

- *Depo-medroxyprogesterone acetate (DMPA), commonly known as Depo, Depo-Provera, Megestron, and Petogen*
- *Norethisterone enanthate (NET-EN) / norethindrone enanthate, commonly marketed as Noristerat and Syngestal*
- *Medroxyprogesterone acetate (MPA) / estradiol cypionate, commonly marketed as Cyclofem, Ciclofem, Ciclofemina, Cyclo-provera, Feminena, Lunella, Lunelle, and Novafem, among others (WHO and CCP, 2008)*

injectables account for about 15 per cent of users in Sri Lanka, 10 per cent in Nepal, seven per cent in Bangladesh, 5.9 per cent in Bhutan, 5.4 per cent in Afghanistan, and 2.7 per cent in Pakistan (Department of Economic and Social Affairs, 2011).

III. Injectables in India: Historical Perspective

Injectable contraceptives have been in use by registered medical practitioners in India for decades—NET-EN since 1986 and DMPA since 1993. However, importation and marketing of NET-EN for use by private practitioners was approved by the Drug Controller General of India in 1989.

Attempts to introduce injectables (initially NET-EN and later DMPA) in the government programme began in the 1980s (see Table 1 and Figure 1). The subject has been contentious from the time they were first introduced by a pharmaceutical company on a trial basis. Broadly, there were concerns about the health impact of injectables and whether there was adequate infrastructure for follow-up and care.

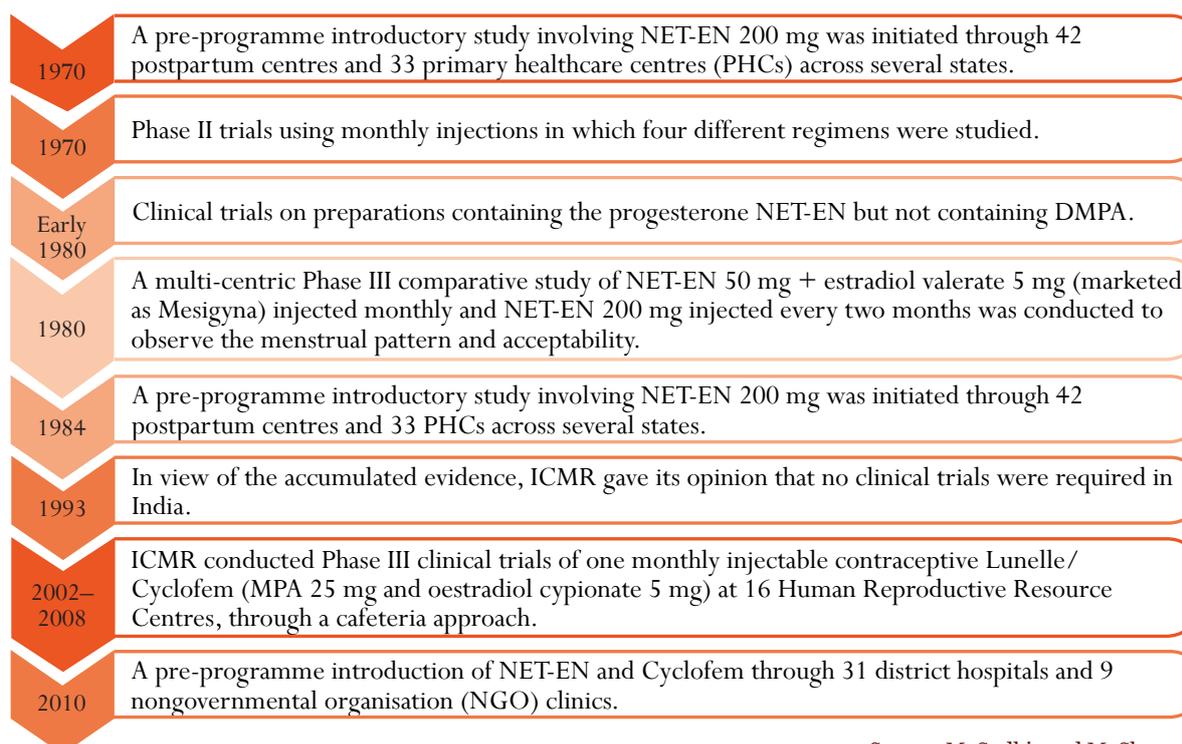
Though injectables have been extensively studied, both in India and other parts of the world, and endorsed as a safe and effective method of contraception, many health activists and women's groups in India have opposed their introduction.

Table 1. At a glance: Historical background by type

	NET-EN	CYCLOFEM	DMPA
1981–1985	<ul style="list-style-type: none"> Indian Council for Medical Research (ICMR) initiates Phase IV pre-programme introduction trials of NET-EN ('83–'84) 		
1986–1990	<ul style="list-style-type: none"> Approved for marketing in private sector ('86) Women's groups file petition in Supreme Court, seeking stay on trials and on its entry into government programme ('86) 		
1991–1995			<ul style="list-style-type: none"> Approved by United States Food and Drug Administration ('92) Approved for marketing in India. ICMR recommends post-marketing surveillance ('93) Case filed in Supreme Court, asking for a ban ('93–'94) Drug Technical Advisory Board—interim recommendation filed in court, advising no DMPA in government FP programme ('95)
1996–2000	<ul style="list-style-type: none"> Expert group meeting on injectable contraceptives in Mumbai ('98) Supreme Court case ends; stay not granted (2000) 		<ul style="list-style-type: none"> Post-marketing surveillance finds DMPA safe and effective ('94–'97)
2001–2005	<ul style="list-style-type: none"> ICMR conducts feasibility study (2002–08) 		<ul style="list-style-type: none"> Court case ends; DMPA not banned. Court directs DTAB to review drugs with safety issues regularly (2001) Expert group meeting on injectable contraceptives in Manesar (2004)
2006–to date	<ul style="list-style-type: none"> Based on the positive results from the feasibility study by ICMR, the government initiates pre-programme introduction at 40 centres (2009) 		<ul style="list-style-type: none"> Expert group meeting on injectable contraceptives—DMPA at MoHFW (2010)

Source: M. Sudhir and M. Shawn, 2010.

Figure 1. Clinical trials on injectable contraceptives in India



Source: M. Sudhir and M. Shawn, 2010.

Women's groups have been mostly concerned with:

- Adverse health consequences—including menstrual irregularities, headaches, severe abdominal cramps to bone demineralisation, increased risk of HIV infection, increased risk of Down's Syndrome, and breast and cervical cancer.
- Inadequate public health infrastructure and quality of service—counselling on contra-indications and close follow-up are essential for administration and continuation of injectables, which is severely absent in the public health system in India and also to a large extent in the private sector.
- Lack of credibility of post-marketing surveillance of Depo Provera—women's groups question the credibility of the Post-Marketing Surveillance (PMS) study conducted on Depo Provera, alleging that the study was biased since it was conducted by Upjohn (Depo Provera supplier), which stood to profit from the results of the research. The groups claim that the PMS study did not address certain serious concerns, including the potential side effects of bone density loss, cancer risk, amenorrhea, and the concern that breastfeeding is a contra-indication for DMPA.
- Waiver of trials and lack of informed consent in conducting the 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.

The NFWP does not offer injectable contraceptives as a method choice for family planning. For the government to introduce the method under the programme, the DTAB will have to endorse it. From all indications, the board has not reviewed DMPA after its interim recommendation of 1995, advising against its mass use in the government programme.

IV. Injectables See Steady Growth in the Private Sector

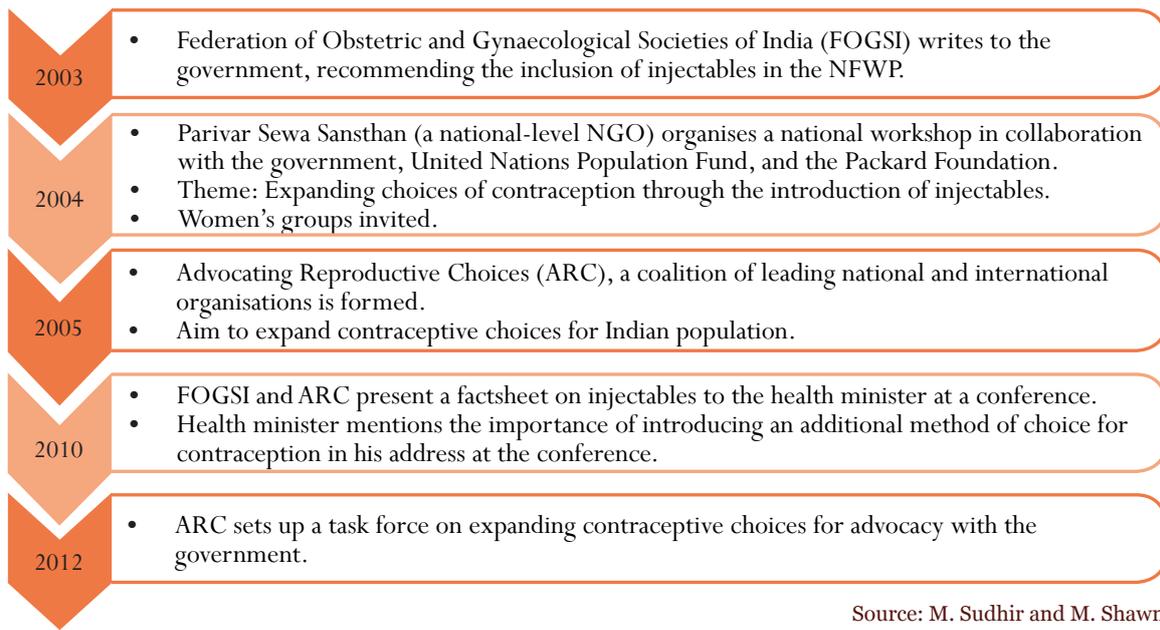
Injectable contraceptives have primarily been made available through the private sector in India. NGOs, such as Janani, DKT India, Family Planning Association of India (FPAI), Population Services International, Parivar Seva Sanstha and Population Health Services (India); some government and quasi-governmental institutions, such as the Employee State Insurance Corporation of the Ministry of Labour; and many private sector clinics provide injectables in India. These organisations make the product available through market channels, using the social marketing model, or through their clinic networks.

According to the third National Family Health Survey (NFHS), most users of injectables (69%) obtained their method from a private hospital, a private doctor or clinic, or a pharmacy or drugstore (NFHS-3 2005–06). Although some service outlets offer injectables, the method is not widely available and usage is low. Nationally, the current use of NET-EN and DMPA is 0.1 per cent (NFHS-3 2005–06).

There is a growing demand for injectables from women visiting public sector facilities. According to the NFHS-3, 53 per cent of married women in India have knowledge about injectable contraceptives. Apart from its lack of availability in the public health system, the method is available in urban and peri-urban areas through marketing channels but has limited access to women in rural areas. There are three main manufacturers of injectable contraceptives in India: Akum, Famy Care, and Accent.

The growing availability of injectables in other sectors, combined with the wealth of research on the safety of the method, is encouraging for the potential addition of injectables to the NFWP. The government has shown interest in introducing injectables and, in 2010, initiated pre-programme introduction of NET-EN and Cyclofem in the public sector. Moreover, the government is devoting additional resources

Figure 2. Advocacy efforts for injectables in India



Source: M. Sudhir and M. Shawn, 2010.

to improve reproductive and child health services through the National Rural Health Mission (NRHM), which will also help address issues related to quality of care.

A series of advocacy efforts for the introduction of injectables have been initiated in the last decade. Based on approvals from the World Health Organization (WHO), food and drug administrations of the United States and United Kingdom, and the Drug Controller of India and its own multi-centric trials, FOGSI issued a consensus statement on injectable contraceptives in 2000, stating and confirming that injectables are a safe, effective, and convenient form of contraception, particularly for lactating and estrogen-sensitive women and therefore advised its members to use injectable contraceptives within WHO guidelines. It further confirmed that extensive trials carried out by ICMR have proved that the method is reversible with additional health benefits. FOGSI had also written to the government recommending the inclusion of injectables in the NFWP, stressing the importance of proper counselling along with provision in order to improve compliance. In 2005, an influential coalition called

ARC was formed to expand contraceptive choices for the Indian population by widely promoting and making available safe, effective, and high-quality contraceptives in public and private health service delivery. Figure 2 highlights the key advocacy efforts around injectables in India.

V. Are Injectables a Worthwhile Choice for Inclusion in the Government's Family Planning Programme?

See figures 3a and 3b.

Figure 3a. An insight into evidence and user preference: examples from successful donor-driven projects

The DiMPA experience in Uttar Pradesh, Jharkhand, and Uttarakhand

As part of its Commercial Market Strategies project, in 2002, USAID launched the DiMPA programme and network for promoting the use of injectable contraceptives through private healthcare providers.

The objectives were to create awareness about DMPA through the private health sector by establishing a network of clinics and promoting correct use and compliance through sustained high-quality of service.

The project was designed with a fractional franchising approach, wherein injectables were added to methods already available to qualified private providers.

The pilot programme was initiated in three towns in Uttar Pradesh with a network of 105 providers and through the course of four phases of implementation was scaled up to 45 towns in Uttar Pradesh, Jharkhand, and Uttarakhand, with 1,150 providers.

A “network of clinics” model was adopted as an entry strategy, considering opposition from women’s groups. The programme screened, identified, and trained leading practitioners in the provision of DMPA, patient counselling, and management of adverse effects.

Key components of the programme included

- Training providers with an evidence-based approach
- Voluntary provider enrolment in the DiMPA network to increase access to DMPA at an affordable price point
- Employing accessible and multiple communication channels to create awareness about DMPA
- Monitoring and evaluating the programme for increased use, knowledge, and sustained quality of care

Collective efforts from various partners helped the programme accomplish its key objectives—funding and technical assistance was supported by USAID; the Family Welfare Committee of FOGSI was a platform to build consensus among obstetrician/gynaecologist providers for DMPA; and training of trainers was conducted by the Family Planning Association of India,

Pfizer (manufacturer and marketer of DMPA), DKT (product distribution), the International Policy Analysis Network (advocacy), and Ogilvy and Mather/Lowe (communications and field operations).

The programme was not involved in direct procurement and selling of DMPA but rather facilitated linkages between DMPA marketers and trained providers in project towns.

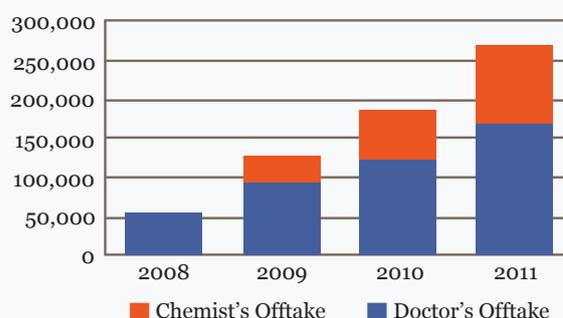
An advocacy and communication campaign was developed to increase correct knowledge on DMPA and neutralise negative media reporting about the product.

The programme conducted regular technical detailing and update meetings for providers and paramedics to enhance their performance and quality of services. Regular random client surveys were also conducted to monitor and track quality of care parameters.

Based on a baseline and endline analysis conducted in 2009 and 2011, respectively, the off-take of DMPA from network clinics and chemist shops grew at 70 per cent annually (see Figure 3a.1).

Figure 3a.1: Consolidated OB/ GYN/Chemist’s Sales Data

The off-take of DMPA from network clinics and chemist shops grew at 70 per cent annually during the last three years (2008–2011)*



* Off-take based on the internal project MIS of DMPA sales and off-take data collected by MBPH field representatives from network clinics and retail chemists trained by the programme in 45 towns in UP, UK, and JH.

**Figure 3b. An insight into evidence and user preference:
examples from successful donor driven projects**

Injectables: A preferred choice in Gumla, Jharkhand

A case study from the Sambhav Voucher Scheme

In the context of low FP uptake in Gumla District, Jharkhand, the Sambhav Voucher Scheme (a public-private partnership initiative) helped contribute to the government's goals for increasing FP service access in two pilot blocks of Sadar and Sisai.

The Sambhav Voucher Scheme was implemented in two phases from September 2009 to December 2011, with intervals in service delivery. The scheme revealed a strong interest in other modern FP methods, with injectables accounting for about 43 per cent of the FP methods availed through the vouchers from October 2010 to September 2011 (ITAP, 2012).

Between November 2010 and October 2011, out of the total number of married women between ages 15–49 years old in the Gumla Sadar and Sisai blocks (35,561), the number of first dose users for injectables was 1,023. The rate of discontinuation, though high, was similar to the discontinuation rate among users of oral contraceptive pills. Injectables provided women with the choice of another contraceptive method. This experience suggests that injectables could potentially contribute to significant increases in the couple protection rate (CPR). In the case of the Sadar and Sisai blocks, the CPR increased by 2.88 percentage points.

Usha Devi, a mother of three living in Bargain Village of the Gumla District, was married at a young age of 17 years. Even though she was aware of the benefits of adopting an FP method, family pressure and lack of access to health services around her village did not allow her to adopt a contraceptive method. Due to this lack of access, she delivered her three children at home with the help of traditional birth attendants and was unable to space her pregnancies, resulting in her three children being born before she turned 21. Her husband, a petty cash farmer, had a tough time managing a big family of five.

Indu Devi, a community health worker (Sahiyya) in the village, informed Usha Devi about the FP services being offered under the Sambhav Voucher Scheme. Usha and her husband collectively decided to opt for injectable contraceptives under the scheme. Indu Devi guided the couple to access services at a private hospital accredited under the scheme, informed them about the dosage intervals, and counselled them on the probable side effects.

Usha Devi has completed her third dosage of injectables. Gratiified with her choice, Usha Devi is able to take care of her children and family and has gone out to motivate her friends and relatives about the benefits of FP and the Sambhav Voucher Scheme.

**VI. Barriers to the
Inclusion of Injectable
Contraceptives as a
Method Choice in the
Government Programme:
Stakeholders' Analysis**

Increasing access to an additional method of contraception will affect the CPR and total fertility rate. The stakeholders' analysis

identified the following key pre-requisites for effectively introducing injectables in the government programme: strengthening the overall health system, with appropriate training for service providers, paramedics, and field staff; generating large-scale awareness and advocacy efforts; and addressing the regulation of demand and supply requirements.

The key barriers to the inclusion of injectable contraceptives occur at three levels: the policy level, the advocacy

level, and the demand and supply level. Prioritising injectable contraceptives on the government agenda is seen as a key emerging barrier by all stakeholders. The NFWP currently prioritises other methods of contraception. A review of DMPA for endorsement by the DTAB has been awaited for a while, based on which MoHFW will take further action. There has been a steady increase in sales of injectable contraceptives through the private sector in the last five years. Identifying actual bottlenecks at the policy level for introduction in the public sector remains a challenge.

Lack of systematic evidence to contest the arguments raised by women's groups is another key barrier. Current data available are mostly based on studies from other countries, and even within India, data have been collected from smaller sample sizes and not across different ethnicities and geographic locations. At this stage, the findings from the pre-programme trials being conducted by ICMR are eagerly awaited. The results will be important for providing clinical evidence and building a case for injectables within the government and women's groups. Advocacy with women's groups is also seen as a key barrier, with certain groups not open to discussion on injectables, not enough efforts being made by advocates to engage with these groups, and the lack of presentations with evidence to counter arguments of certain women's groups. Demand- and supply-side barriers include high costs, limited availability, limited awareness, lack of proper counselling, difficulty in ensuring high-quality service provision, and provider-bias related to counselling on injectables.

An organised effort is needed to approach the DTAB, ICMR, and other key stakeholders to revive the discussion on injectables. An effective strategy should be created to advocate with the government based on the changed scenario of better healthcare infrastructure under the NRHM. The requisite support is needed to help MoHFW build a case for injectables by presenting current data from successful implementation experiences—specifically related to user profile information, the uptake of services, the prevalence of side

effects, and management and continuation rates. Advocacy efforts need to be expanded and not limited to certain advocates and stakeholders. Establishing a collective campaign is recommended, building on prior awareness-raising and advocacy efforts and, in doing so, building relationships with FOGSI, ARC, and other relevant social and political organisations.

Incorporating women's perspectives into contraceptive introduction strategies can help local FP programmes increase user satisfaction, improve continuation rates, and expand method use. Client fears and myths are barriers to the provision of injectables, and the general lack of knowledge about injectables means that these fears persist even when many of them have been proven to be unfounded. Involving women's groups, who are open to discussions, will also be important.

Advocates and champions need to be built within the government and Parliament, especially women champions, as well as within women's groups. The stakeholders identified key advocates and champions to participate in advocacy efforts and play a significant role in influencing policy decisions on injectables. These advocates include representatives from the government (MoHFW), FOGSI, FPAI, ARC, All India Institute for Medical Sciences, cooperating agencies, and donor agencies (United Nations Population Fund, USAID, Packard Foundation).

Alongside these efforts, support for service delivery through alternate channels on a pilot implementation basis is recommended—for example, in the form of social marketing channels and public-private partnerships.

A professionally managed and consistent advocacy effort, based on evidence, is central to achieving a continuous growth in demand and user base for injectable contraceptives.

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