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Injectable Contraceptives in India: Past, Present and Future

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The authors' views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.



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FOREWORD

There has been a significant increase in the use of modern contraceptive methods in India, from forty-three percent in 1998-99 to forty-nine percent in 2005-06. The Government of India's family planning program largely promotes and provides services for limiting methods, particularly female sterilization. As a result, over 75 percent of modern methods users rely on female sterilization. Expanding the basket of contraceptives and providing method choice, particularly for modern spacing methods, helps to increase use of modern methods. Evidence also indicates that use of modern spacing methods increases intervals between births, which in turn helps to reduce infant and maternal morbidity and mortality.

The contraceptive Depot Medroxyprogesterone Acetate (DMPA) was introduced in India in 1994 by the Drug Controller General of India for provision through the private sector as a prescription drug that could be provided by qualified allopathic health practitioners. Injectables as a contraceptive method were not introduced into the government-funded family planning program, due to objections raised by select representatives of civil society, who erroneously considered that the method would be harmful to women. The main health concerns raised by these groups were related to menstrual irregularity, amenorrhea, screening and follow up of clients on the method, overall safety of the drug, and potential problems associated with its long-term use. It should be noted that the evidence does not bear out these concerns. Currently, an estimated 16 million women worldwide are using injectable contraceptives. As in other countries, this method could be an excellent contraceptive option in India.

USAID commissioned this study through the Innovations in Family Planning Services Technical Assistance Project (ITAP) to understand the historical and legal legacy that restricts access to injectables; document information on manufacturers and suppliers of injectables in India; document the experience of distribution, provision, and use of injectables in India; summarize relevant country experiences from the region; and prepare recommendations for introduction of injectables in the public sector and expansion of their use in the private sector.

The ITAP team has reviewed various materials available on injectables in India, discussed the issues with several stakeholders, and recorded experiences of projects that piloted injectables in different parts of the country. This report is an outcome of that effort. I would like to take this opportunity to thank all those who have contributed to the preparation of this document, which provides invaluable information on policy issues that have important implications for programs on reproductive health and family planning, as well as for women's health and population growth in India.

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ABBREVIATIONS

AIDWA	All India Democratic Women's Association
ARC	Advocating Reproductive Choices
ASHA	Accredited Social Health Activist
BCC	Behavior Change Communication
CBD	Community-Based Distribution
CPR	Contraceptive Prevalence Rate
CSMP	Contraceptive Social Marketing Program
DFID	Department for International Development
DMPA	Depot Medroxyprogesterone Acetate
DOFW	Department of Family Welfare
DOHFW	Department of Health & Family Welfare
DTAB	Drug Technical Advisory Board
EAG	Empowered Action Group (of states)
EC	Emergency Contraception
ECP	Emergency Contraceptive Pills
FOGSI	Federation of Obstetrics and Gynecological Societies of India
FP	Family Planning
FPA	Family Planning Association
FPAI	Family Planning Association of India
FW	Family Welfare
GMP	Good Manufacturing Practice
GOI	Government of India
HLL	Hindustan Latex Ltd.
IC	Injectable Contraceptive
ICMR	Indian Council of Medical Research
ICPD	International Conference on Population and Development
IEC	Information Education Communication

IPPF	International Planned Parenthood Federation
IUCD	Intrauterine Contraceptive Device
IUD	Intrauterine Device
KfW	Kreditanstalt für Wiederaufbau (German government-owned development bank)
MFC	Medico Friend Circle
MNC	Multinational Corporation
MOHFW	Ministry of Health & Family Welfare
MRP	Maximum Retail Price
MSI	Marie Stopes International
NET-EN	Norethisterone Enanthate
NFHS	National Family Health Survey
NFWP	National Family Welfare Program
NGO	Non Governmental Organization
OCP	Oral Contraceptive Pill
PATH	Program in Appropriate Technologies in Health
PHSI	Population Health Services (India)
PMS	Post-Marketing Surveillance
POI	Progestin only Injectable (contraceptive)
PSI	Population Services International
PSP-One	Private Sector Partnerships-One (project)
PSS	Parivar Seva Sanstha
R&D	Research and Development
RSS	Research Studies & Standards (Division of MOHFW/GOI)
SMO	Social Marketing Organization
UNFPA	United Nations Population Fund
USA	United States of America
US FDA	United States Food and Drug Administration
USAID	United States Agency for International Development
WHO	World Health Organization

INTRODUCTION

In 2001, India's population surpassed one billion people. Demographic experts predict that India will overtake China as the world's most populous nation by 2030.¹ These milestones have led politicians and community leaders to once again examine the impact of population growth on the health and economic stability of the nation, and reinstate family planning as an essential component of the national development plan. As part of this agenda, the Government of India and United States Agency for International Development (USAID) seek to expand access to safe, effective, and culturally appropriate contraception.

Much of India's population growth is the result of failed or inadequate prevention of unintended pregnancy. According to the National Family Health Survey (NFHS) - 3 (2006), one in five births is 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.²

As in most countries, India's contraceptive method mix is highly skewed toward single method use. Over 75 percent of modern method users rely on female sterilization. Condom (10 percent), pill (6 percent), and intrauterine device (IUD) (4 percent) use account for relatively smaller segments of modern contraceptive use.² India's current method mix 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.

Currently, 35 million women worldwide use injectable contraception to prevent pregnancy, twice as many as a decade ago.³ In sub-Saharan Africa, one in three users of modern contraceptives relies on injectables, more than any other modern contraceptive method. Contraceptive use is much higher in Asia compared to sub-Saharan Africa and injectables account for only 5 percent of modern method use in the Asian region.⁴ Progestin-only injectable are highly effective and are generally considered safe for use by most women.⁵

SCOPE OF ASSESSMENT AND METHODS

USAID seeks to support the Government of India (GOI) in its efforts to improve the quality and coverage of family planning services in India. At the request of USAID, Futures Group India conducted an assessment with the following scope:

- Review the historical and legal legacy that restricts access to injectables
- Document information on

manufacturers and suppliers of injectables in India

- Document the experience of distribution, provision, and use of injectables in India
- Summarize relevant country experiences from the region, and
- Prepare recommendations for introduction of injectables in the public sector and expansion of their use in the private sector.

The assessment will be used to assist the GOI/Ministry of Health & Family Welfare (MOHFW) in its efforts to expand access to injectable contraception and to inform future USAID investments. In order to fulfill the scope of work, the assessment team gathered information through document review, informant interviews (see Appendix I for list of informants), and site visits.

HISTORY OF INJECTABLES 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. Today, several leading non governmental organizations (NGOs), professional bodies and private medical practitioners are providing injectable contraceptives – mostly DMPA, along with other available contraceptives.

The subject of injectable contraceptives has been controversial in India from the time these were introduced and continues to be so. 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. Though injectables have been extensively studied, both in India and other parts of the world, many health activist and women's groups in India have opposed their introduction since the 1980s and have even filed court cases in this connection. Even now, a few civil society groups continue to harbour concerns about them. As a result, the Government of India has not yet included injectable contraceptives

in the basket of contraceptive choices available under the cafeteria approach in National Family Welfare Program (NFWP).

3.1 THE FIRST COURT CASE

The Indian Council of Medical Research (ICMR) has been conducting clinical trials on various injectables since the 1970s. The trials in the 1970s included small exploratory studies with DMPA and NET-EN alone and in combination with estrogens in varying dosing schedules. These were followed by Phase II trials using monthly injections according to various regimens. (See *Appendix II* for information on ICMR-led trials on injectables from the seventies till date). In 1974, United States Food and Drug Administration (US FDA) withheld approval for Depo-Provera following which, in 1975, ICMR discontinued the Depo-Provera trials.

At that time there was no licensing policy and hence Depo-Provera could not be imported. In the early 80s, a renowned gynecologist and former Chairperson of Indian Association of Fertility and Sterility, Dr. C. L. Jhaveri, having been refused a license to import Depo-Provera, filed a case against the Drug Controller of India and the Government of India.

Following this, in 1985 a women's organization (Women's Center, Mumbai) and a health network (Medico Friend Circle) joined the government as respondents in the case. These NGOs and government together argued that the use of the drug in India's Family Planning Program could be harmful to women's health. As a result, the court prohibited Dr. Jhaveri from importing the drug.^{6,7}

It is most ironic that soon after the above court case and through till the present, government and certain women's activist groups have taken diametrically opposite positions, both in court and outside. 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.

3.2 HISTORY OF NET-EN AND CYCLOFEM

The Indian Council of Medical Research (ICMR) generated considerable data on one monthly and two monthly injectable contraceptives in the 1970s and 1980s. A multi-centric Phase III study involving NET-EN was carried out in the early 1980s. During 1983-84, in order to assess

the acceptability of NET-EN with a view to introducing injectable contraceptives in the National Family Welfare Program, ICMR initiated Phase IV (pre program introduction) trials in both urban and rural centers (see *Appendix II*).

Since NET-EN had already been approved in its country of origin, Germany, in April 1986, the Drug Controller General of India gave approval for the import and marketing of NET-EN in India for use by private practitioners.⁸

In 1986 women's groups petitioned the Supreme Court to stay NET-EN trials citing safety issues, violation of ethics in conduct of trials, and inadequate health delivery systems. The case ended in 2000 – the Supreme Court did not grant stay on trials (see *Box I*).

Thereafter, the Government set up a sub-committee to organize operations research on NET-EN in 12 medical colleges. Women's groups protested that such research would be technically inadequate. The Government then decided to conduct a feasibility study of NET-EN in Indian women.⁸ During 2002-2008, ICMR conducted a feasibility study of NET-EN and Phase-III trial of Cyclofem (one monthly injectable). Based on positive results of that study, the government has now initiated pre-program introduction of NET-EN and Cyclofem through 31 district hospitals and 9 NGO clinics.⁹

3.3 HISTORY OF DMPA

In 1992, DMPA was approved by the US FDA. Subsequently, the Depo Provera supplier Upjohn approached

TABLE I: HISTORY OF NET-EN-TWO MONTHLY INJECTABLE AND CYCLOFEM-ONE MONTHLY INJECTABLE

1983-84	ICMR initiates Phase IV (pre program introduction) trials of NET-EN
1986	NET-EN approved for marketing in India
1986	Women's groups petition Supreme Court seeking stay on trials of NET-EN and on its entry into government program, citing issues relating to safety, ethics and inadequate health systems
2000	Supreme Court case ends – stay not granted
2002-2008	ICMR conducts feasibility study of NET-EN and Phase-III trial of Cyclofem
2009	Based on positive results, government initiates pre-program introduction of NET-EN and Cyclofem at 40 centers

the Indian drug regulatory authority and in June 1993, approval was given for marketing of DMPA in India

for use by private practitioners.⁸ In 1994, DMPA was also approved for social marketing in India. Women's

BOX I: SUPREME COURT CASE PERTAINING TO NET-EN

The NET-EN case (case 680 of 1986)⁸ was filed in the Supreme Court of India in 1986 by Stree Shakti Sanghatana, Saheli, Chingari and others against the Union of India through the Secretary, Union Ministry of Health and Family Welfare (MOHFW), Indian Council of Medical Research (ICMR), State of Andhra Pradesh and the Drugs Controller of India (DCI). The writ petition pleaded for a stay on Phase-IV clinical trials of the injectable contraceptive NET-EN and on its entry into the National Family Welfare Program. The grounds on which a stay was sought included: the hazards of NET-EN both short term and long term, violation of requirements of informed consent and the unsuitability of this, hormonal long acting contraceptive for the ill equipped health delivery system.¹⁰

An interim order passed by Supreme Court in February 2000 indicated that the Court was confusing NET-EN with DMPA, apparently because the common term injectables was being used by the petitioners. The Deputy Commissioner (RSS), MOHFW/GOI then filed an affidavit on 21 August 2000 clarifying the difference between NET-EN and DMPA, and stating the government's position regarding both. Concerning NET-EN, the affidavit stated that it "was under examination for clinical trials with ICMR and a Technical report had already been filed before the court after finalizing their trials. Thereafter, the Department of Family Welfare has also filed an affidavit indicating that Ministry of Health and Family Welfare is proposing to introduce NET-EN injectable as a new contraceptive in National Family Welfare Program in such places only where adequate facilities for follow up and counseling are available".¹¹

Soon thereafter, on 24 August 2000, the Supreme Court disposed of the writ petition pertaining to NET-EN, recording in its order that the petitioners (Stree Shakti Sanghatana and others) had stated that, in view of the government affidavit, petitioners were now satisfied and had no remaining grievance.¹² The Court did not grant stay on trials nor bar introduction of the drug in the National FW Program.

groups responded with strong protests saying that the case against NET-EN was still pending in court, and that the issues concerning injectables raised in that petition had not been satisfactorily answered by the government.

Following the approval of DMPA by the Drug Controller of India, ICMR initiated work on a preparatory study on DMPA for its introduction in the public sector. Women's groups, however, objected and said that the drug had been approved based on data from other countries, and that the necessary clinical trials had not been conducted on Indian women. ICMR confirmed that in view of the US FDA approval of DMPA and studies by World Health Organization (WHO) and various other agencies on its safety and efficacy, no further clinical trials

were required. Instead, ICMR recommended that post-marketing surveillance (PMS) be conducted to address specific concerns regarding safety and effectiveness in the Indian population.

PMS on DMPA was carried out on 1079 Indian women during the period 1994-97 at 10 independent private centers across the country. The study indicated that Depo Provera 150 mg is a safe and effective contraceptive, and that adequate counseling on its expected hormonal effects would greatly increase the acceptability of this method of contraception.⁸ The PMS also indicated a very high continuation rate.¹³ These findings were in conformity with what had been observed in other countries. Women's groups, however, alleged that the study was biased since it

was conducted by Upjohn, which stood to profit from the results of the research, and that the study did not address certain serious safety concerns.

During 1993-1994, cases were filed in Supreme Court asking for a ban, among others, on DMPA. In 1995, the Drug Technical Advisory Board (DTAB),ⁱ on the direction of the Supreme Court, made an interim recommendation that DMPA should not be allowed for mass use in the National Family Planning Program and its use should be restricted to women who are aware of the implications of its use (see Box 2).

The litigation was concluded in February 2001. While a number of drugs were banned, DMPA was not. The court stipulated that Drugs Technical Advisory Board (DTAB) and its Expert Committee continue to meet at the specified regular intervals, as committed by government, to review any drug concerning which there were questions of safety. There is no indication that DMPA has been reviewed by DTAB thereafter. However, there are indications that MOHFW and ICMR are in the process of preparing documentation on DMPA for review by DTAB.

3.4 ACTIVISTS' REASONS FOR OPPOSING INJECTABLES

Many women's groups, health groups and human rights groups have opposed the introduction of injectables alleging serious safety

TABLE 2: HISTORY OF DMPA-THREE MONTHLY INJECTABLE

1992	DMPA approved by the US FDA
1993	DMPA approved for marketing in India. ICMR confirms that in view of the US FDA approval and studies by WHO and others, no further clinical trials required. Instead, ICMR recommends post-marketing surveillance (PMS)
1993-1994	Cases filed in Supreme Court asking for a ban, among others, on DMPA
1994-1997	PMS on 1079 Indian women finds DMPA safe and effective
1995	Drug Technical Advisory Board (DTAB) interim recommendation filed in court, advising: no DMPA in Family Planning Program; restrict DMPA use to women aware of all the implications
2001	Court case ends – DMPA is not banned, although other drugs are. Court directs that DTAB continue its regular meetings to review drugs with safety issues
2001-2009	No indication that DTAB has reviewed DMPA after court verdict, but it is understood that government is now taking steps to facilitate such review
1994-2009	Significant growth in DMPA provision via NGOs

ⁱ The Drug Technical Advisory Board (DTAB) is the highest technical body constituted under the Drugs and Cosmetics Act. It is assisted by various technical committees and expert committees as required.

BOX 2: SUPREME COURT CASES PERTAINING TO DMPA

In November 1993, a public interest litigation case (Case 698 of 1993) was filed in the Supreme Court by the Drug Action Forum (DAF) along with the All India Drug Action Network (AIDAN).⁸ This case sought a ban on several drugs stated to be hazardous – the list included Depo-Provera (DMPA). Another case seeking a ban on Depo-Provera was filed in the Supreme Court in 1994 by Jagori, AIDS Awareness Group and other individuals along with some women's groups.⁶ Subsequently, Jagori and others became co-petitioners in the former case, apparently since DMPA was common to both cases.¹⁴

The Court directed that DTAB and its expert committee should examine the matter and make recommendations to the Court. As a result of lobbying by the activist groups, three external medical experts who were sensitive to the activists' concerns were, on the direction of the Court, co-opted into the Drug Technical Advisory Board to assist in the deliberations about banning of drugs stated to be irrational or hazardous.¹⁵

Concerning DMPA, the Expert Committee opined that it could be used in the private sector and by NGOs, but should not be used in the National FW Program till such time the side effects of the drug had been adequately assessed. In 1995, after much lobbying and pressure from Sama, Saheli, All India Democratic Women's Association (AIDWA), Jagori, Medico Friend Circle and many other women's and health groups, the Drug Technical Advisory Board (DTAB) made an interim recommendation with regard to DMPA.⁶ The recommendation was: "DMPA should not be allowed to [sic] mass use in the National Family Planning Program and its use should be restricted to women who would be aware of all the implications of use". This interim recommendation of DTAB was cited by MOHFW in an affidavit dated August 2000 filed in Supreme Court; although this affidavit pertained to the NET-EN case it clarified the government's position on both DMPA and NET-EN (see Box 1).¹¹

During the course of this case, a number of drugs were banned at various junctures – these did not include DMPA. The Court disposed of the case (Case 698 of 1993) on 23 February 2001 with the stipulation that Drugs Technical Advisory Board (DTAB) and Expert Committee continue to meet at the specified regular intervals, as committed by government. The Expert Committee appointed by DTAB would examine whether drugs concerning which there were doubts should be permitted to be manufactured and marketed. Petitioners (Drug Action Forum and others) or any other body could send suggestions/representations concerning any drug to DTAB for consideration.¹⁶ There is no indication that DMPA has been reviewed by DTAB thereafter, however, it is understood that the government is now taking steps to facilitate such review.

concerns, potential for their abuse, waiver of mandatory trials and the lack of accountability of drug companies. These groups also oppose injectables because these are "provider-controlled" – medical professionals must give the injection and the contraceptive

effects are irreversible for the period of efficacy. Hormonal oral contraceptives, on the other hand, are acceptable to these groups because these are "user-controlled". In the opinion of these groups there should be a complete ban on injectable contraceptives, at a

minimum injectables should not be introduced in the public sector. The major issues and concerns raised by activists are discussed below. (A list of prominent groups and individuals involved in the campaign against injectables is given as *Appendix III*).

3.4.1 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.

In 2004, the United States Food and Drug Administration (FDA) and the Depo-Provera manufacturer Pfizer agreed to put a black-box warning on Depo-Provera's label in view of recent findings that the osteoporotic effects of the injection grow worse the longer Depo Provera is administered and they may last long after the injections are stopped. The black-box warning is cited by activists as a vindication of their concerns.

3.4.2 Inadequate Infrastructure and Accountability

Women's groups emphasize that administration of injectables requires ruling out contra-indications 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 Program. 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.

3.4.3 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, amenorrhea, and the concern that breastfeeding is a contra-indication for DMPA.

3.4.4 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. Further, activists argue that Depo Provera was approved for marketing in India in 1993 without the mandatory Phase III clinical trials,ⁱⁱ and a post-marketing surveillance was conducted instead.¹⁷

3.5 DEVELOPMENTS FOLLOWING THE COURT CASES

There have been several developments following the disposal, during 2000-2001, of the court cases pertaining to NET-EN and DMPA. Some developments have been led by government, others by the activists opposing injectables, and yet others by NGOs and other organizations that support injectables use.

As mentioned earlier, during 2002-2008, ICMR conducted a feasibility study of NET-EN and Phase-III trial of Cyclofem (one monthly injectable). Based on positive results of that study and trial, government has now initiated pre-program introduction for the government program of NET-EN and Cyclofem through 31 district hospitals and 9 NGO clinics.

In 2004, a national workshop (27-29 Oct 04) was organized and co-ordinated at Manesar in Haryana by Parivar Seva Sanstha (a national-level NGO), in collaboration with Government of India, United Nations Population Fund (UNFPA) and Packard Foundation through Population Foundation of India. The

workshop theme was "expanding choices of contraception" through the introduction of injectables. To enable a free sharing of views and evidence, representatives of women's groups and activist organizations were also invited. The latter, including members from Sama, AIDWA, Saheli and Delhi Science Forum agreed to participate but backed out at the last minute.⁸ In fact, soon after the workshop these organizations mobilized many health and women's groups across the country and submitted a memorandum to the Union Health Minister spelling out the reasons for their strong opposition to use of injectables. This memorandum was endorsed by 62 health and women's groups across the country. (See *Appendix III* for list of groups and individuals involved).

In response, MOHFW replied to the NGO Saheli in April 2005 stating that GOI was not contemplating introduction of injectables in the National Family Welfare Program (NFWP) till ongoing studies being conducted by ICMR were completed and their findings were favorable. A decision will be taken only after the findings are at hand.⁶

The year 2005 also saw the formation of an influential coalition called Advocating Reproductive Choices (ARC). ARC is a coalition of leading national and international organizations whose aim is to expand contraceptive choices for the Indian population by widely promoting and making available safe, effective and quality contraceptives in the public and private health service delivery

ⁱⁱ Subsequent to the approval for marketing of DMPA in India, no clinical trials on this drug have been conducted in India.

system at affordable cost. ARC's initial emphasis is on emergency contraception, injectables and non-scalpel vasectomy. Currently, 32 organizations are members and supporters of this coalition. Members include, among others, social marketing agencies, Abt Associates, Packard Foundation, USAID, PATH, the Indian Medical Association, and FOGSI. Technical support is provided by various organizations including WHO, ICMR, and UNFPA. ARC's thrust areas include increasing awareness among various sections of society, evidence-based public education, increasing provider and consumer knowledge. One of ARC's major aims is promotion of injectables.¹⁸ At present, ARC's Secretariat is located at FPA India. ARC's sub-group on injectables is led by Abt Associates.

Meanwhile, the campaign of the women's and activist groups to resist the introduction of injectable contraceptives in the Family

Welfare Program continues. When MOHFW announced in April 2008 that it proposed to initiate pre-program introduction of NET-EN and Cyclofem in the public sector, health and women's groups were mobilized around the issue, and submitted a memorandum to the Union Minister for Health. The memorandum was endorsed by over 50 groups, organizations and individuals; it opposed the introduction of the injectables in the public health system and challenged the basis of the conduct of trials.

Interestingly and significantly, the memorandum highlighted the fact that the Technical Committee of Drugs Technical Advisory Board had opined (in 1995) that DMPA, the key constituent of Cyclofem, should not be allowed for mass use in family planning program and demanded to know on what scientific basis this recommendation was being overridden.

Subsequently, a meeting was held between MOHFW officials and representatives of women's groups, following which MOHFW uploaded summary reports of the feasibility study of NET-EN and Phase-III trial of Cyclofem on the Ministry's website for feedback from the public.

Following this, a few letters were exchanged between the activist groups and MOHFW/ICMR. In its letters, the MOHFW responded to some of the technical queries and concerns raised by the activists and assured them that the proposed pre-program introduction of NET-EN and Cyclofem would not be launched without taking these concerns into consideration. A recent issue of a health activist publication indicates that the campaign is being sustained through disseminating information and raising awareness on the issue.¹⁹

INJECTABLES: LEGAL STATUS AND STAKEHOLDERS' POSITIONS

4.1 CURRENT LEGAL STATUS AND GOVERNMENT'S POSITION

The Government wishes to introduce injectables in the FW Program 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, but this is likely in the near term.

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 Program unless this was endorsed by 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. For this MOHFW needs to build a case in favour of DMPA and ask for DTAB to review the product. According to informants the case should be based on developments since 2001, including improvements in government health infrastructure,

safety evidence, and positive experience with service delivery in India. There are indications that such exercise is underway.

Both NET-EN and DMPA are approved for social marketing in India.

4.2 FEDERATION OF OBSTETRICS AND GYNECOLOGICAL SOCIETIES OF INDIA (FOGSI)

Based on the approvals from WHO, FDAs of the USA and the UK, Drug Controller of India as well as its own multicentric trials, the managing committee of the Federation of Obstetrics and Gynecological Societies of India (FOGSI) issued a consensus statement, in September 2003, on injectable hormonal contraceptives to its 18,000 members. FOGSI confirmed WHO guidelines on injectables and stated that injectable contraceptives are safe, effective and convenient form of contraception particularly for lactating and estrogen sensitive women. It further confirmed that extensive trials had proved that the method is reversible with additional health benefits. The statement also stressed the importance of proper counseling regarding menstrual irregularity to improve compliance. FOGSI advised its members to use

injectable contraceptives within the WHO guidelines. FOGSI also wrote to GOI recommending inclusion of injectables in the National Family Welfare Program.⁸

4.3 ADVOCATING REPRODUCTIVE CHOICES (ARC)

One of ARC's major aims is promotion of injectables. Some of the strategies and issues that have been considered by ARC in this connection are:

- There should be efforts to continue strengthening presence of injectables in the private sector
- The key to making injectables part of an expanded basket of choice is to create more demand for the product. Hence there is need for demand generation to achieve critical mass
- Social marketing organizations (SMOs)/NGOs are barely able to meet their distribution and marketing costs, hence they cannot undertake demand generation by themselves
- There should be sustained advocacy among providers, civil society and government to challenge current paradigms. Moderate NGOs and groups should be contacted and a

- dialogue started with them.
- Experiences and evidence should be documented to support advocacy. There should be emphasis on documenting the voices of users rather than gathering medical/technical evidence. Another forum for sharing experiences could be an advocacy newsletter.²⁰

4.4 ACTIVIST AND WOMEN'S GROUPS

Women's and health activist groups cannot be viewed as a homogenous entity. Over the years there has been, by their own admission, a divergence of opinion among the groups involved in the movement against injectable contraceptives. One of the dilemmas they grappled with was whether to advocate a

blanket rejection of all hormonal contraceptives or only those – such as injectables – which do not grant user control to women (according to many women's groups, oral contraceptive pills are “user controlled” and are therefore acceptable whereas injectables are “provider controlled”). Many individuals and groups within the movement defend the use of injectables. They believe that using contraceptives such as injectables and implants is the only way poor and powerless women can gain control over their lives (since these methods can be used without husbands and in-laws getting to know).⁶

According to informants many of the activist groups have moderated

their stand over the years and are receptive to new evidence on injectables; some even have a favorable attitude. However, the die-hard groups and individuals are still trying to rally fellow NGOs and oppose injectables in the public sector. Among the latter, some still believe that the widespread availability of injectables can dilute efforts to challenge the basic social and economic conditions that produce women's powerlessness.

Some ARC members – notably Packard Foundation – are aware of and in touch with women's groups and individuals who have a favorable attitude towards injectables, as also those with moderate views who are willing to review evidence.

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. Further, the Schering subsidiary German Remedies had been supplying Noristerat, a brand of NET-EN, in India till a few years ago. However, according to DKT India, supplies of Noristerat have more or less stopped in recent years.

During the last six years, certain Indian companies have initiated supply of injectable contraceptives,

and some others propose to start their manufacture in the near future. At present the primary incentive for the new entrants is the international market, since the Indian market for injectables is small. 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.

An important concern is the need to assess the quality of injectables produced, especially by companies

that are recent entrants in the area of injectables. Useful information on this topic may be found in the report of a consultancy study commissioned in 2005 by Partners in Population and Development (an inter-governmental alliance of 19 developing countries including India).²¹ Another useful study, done in 2005, is an assessment of Indian contraceptive manufacturers, though the information therein about individual companies is now rather dated.²²

This section briefly discusses the India-based companies that currently supply injectables, or propose

TABLE 3: 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 ⁱⁱⁱ	Rs.60-100
HLL Lifecare	DMPA	-Import 2006-07 -Manufacture 2010-11	Obs/Gynecs	Rs 175 retail (imported)
Famy Care	DMPA initially	To launch end-2009	NGOs (proposed)	To decide
Sun Pharma	Cyclofem	Licensed to manufacture. Preparation for manufacture underway	To decide	To decide

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

to do so. Summary information on injectables supply by these companies is given in the table below, followed by a more detailed discussion on each company.

5.1 PFIZER LIMITED

Depo-Provera was originally introduced in India by Upjohn, but following a series of mergers, Pfizer took it over in 2003. Pfizer, which is based in Mumbai, currently markets Depo-Provera in India. The product is manufactured at Pfizer's overseas plants and is packaged in two dosage forms – vials and pre-filled syringes.

In addition to marketing Depo-Provera commercially, Pfizer also supplies it to DKT India at a discounted price. Both vials and pre-filled syringes are sold commercially; the former is retailed at Rs 162 per dose and the latter at Rs 232 per dose. Pfizer supplies Depo-Provera vials to DKT at Rs 70 per vial; DKT provides the product to its clients at Rs 100 per vial.

As part of its commercial marketing strategy Pfizer sales representatives promote Depo-Provera to obstetricians/gynecologists and female general practitioners. Pfizer does not sell the product directly to doctors. The clients purchase the product from chemist shops and get the injection from their doctors. The value of the annual sales of Depo Provera in India (including sales to DKT) is in the region of Rs 30 to 40 million.²³

5.2 STAR DRUGS AND RESEARCH LABORATORIES LTD.

Star Drugs and Research Laboratories Ltd, which is based

in Bangalore, was established in 1995. Star Drugs offers branded and generic pharmaceutical formulations in collaboration with overseas associates.

The company obtained approval from the Drug Controller of India in 2002 for manufacture and export of DMPA and initiated exports in the same year. The company later obtained approval for marketing DMPA in India. The company's motivation for producing DMPA was mainly to cater to the international market, especially in neighboring countries. The company has succeeded in tenders for DMPA in Sri Lanka (Ministry of Health) and Nepal (World Bank). Each of these tenders was for a procurement of at least one million doses. Star Drugs has also supplied DMPA to Marie Stopes International (MSI) in Afghanistan.

Domestic sales were launched in 2006, starting with supplies to PHSI. In India, Star Drugs' main customers for DMPA are social marketing agencies, namely PHSI, PSI and Janani. In 2008 the company sold 150,000 doses to PHSI and 15,000 doses to PSI. In the current year Star Drugs has sold 100,000 doses to Janani. The company does not itself promote the product, but leaves it to the social marketing agencies to do so.

Star Drugs has this year obtained a license from Drug Controller to manufacture and export a once monthly combined injectable product, namely, medroxyprogesterone (MPA) plus estradiol cypionate (E2C).²⁴

5.3 HLL LIFECARE LTD.

The Indian manufacturer HLL Lifecare Ltd, which is based in Thiruvananthapuram, is the biggest supplier of condoms and OCPs to public sector and social marketing programs in India. HLL also has a presence in the commercial market with progestin-only pills, non-steroidal pills, ECPs, and other medical products, such as blood collection bags and auto-destructive needles. The company markets these products through sub-distributors and maintains its own sales force and detailing team. The company has three main divisions: a manufacturing unit, an SMO, and a commercial operation.

HLL entered the injectables market two years ago after signing an agreement with Helms Manufacturers of Germany to distribute Petogen, a DMPA product manufactured in South Africa. In line with HLL's standard strategy, HLL plans to market Petogen in India for at least two or three years to gain experience with the product, before venturing into manufacture of DMPA. HLL is currently looking for a technology partner with which it could tie up to launch DMPA manufacturing operations. HLL plans to market its proposed DMPA product internationally and in India. According to HLL's assessment, government is planning to introduce DMPA in the national program.

HLL's pharmaceutical division has a field force of about 150 staff deployed across India who are responsible for distribution of Petogen in addition to other products. At present HLL distributes Petogen to Obstetricians/

Gynecologists only. Total sales so far are 40,000 doses; the company has recently ordered another 20,000 doses. HLL sells Petogen at Rs 129 per vial and the MRP is Rs 175; the company offers a scheme of four vials free along with every purchase of 10 vials.²⁵

5.4 FAMY CARE LTD.

The Mumbai-based company Famy Care is a leading manufacturer and exporter of contraceptives. Famy Care supplies Oral Contraceptive Pills (OCPs) and IUDs to more than 50 countries across Asia, Africa and Latin America. Famy care is a pre-qualified supplier to UNFPA for both these products and also to leading NGOs like PSI, DKT, Marie Stopes and IPPF, besides local NGOs in Asia and Africa.

Famy Care recently added injectable contraceptives to its portfolio. Over the last year, the company has been involved in registering the product in about 15 countries and has already started supplies to some of these countries.

Famy Care has also established a state-of-art plant for injectables and

OCPs at Ahmedabad on the lines of a USFDA approved plant. The plant is likely to be commissioned within a few months and the company plans to offer one, two and three monthly injectable contraceptives from that plant. Famy Care will initially produce DMPA, and later, based on demand assessment, will consider producing one and two monthly injectables. The company would soon be applying for the WHO Geneva pre-qualification for the DMPA; this is expected to be in place by end of 2010. The company intends registering its injectables products in all the countries where it is already present besides many newer countries like the Commonwealth of Independent States (CIS) region, Central America etc.

The capacity of the plant is close to 60 million vials and ampoules per annum; Famy Care believes this capacity should be sufficient to take care of most of the emerging markets as well as regulated markets. Famy Care is yet to decide the price at which it would offer DMPA – this would be determined by prices prevailing globally and demand volumes.²⁶

5.5 SUN PHARMACEUTICAL INDUSTRIES LTD.

Concept Foundation recently licensed the Mumbai-based company Sun Pharmaceutical Industries Ltd to manufacture Cyclofem. The preparatory processes for manufacture are underway.²⁷

BOX 3: CONCEPT FOUNDATION

Concept Foundation was established in 1989 in Bangkok, Thailand, through an initiative funded by WHO's Special Program of Research, Development and Research Training in Human Reproduction (WHO/HRP), UNFPA and World Bank, with organizational support from PATH. Concept Foundation, a globally operating not-for-profit organization, was initially established as a mechanism through which WHO's rights associated with an injectable contraceptive, Cyclofem, could be licensed to potential producers in developing countries. Over the years the Foundation has added additional projects and products to its portfolio, and more manufacturing licensees to the list of established public-private partnerships.²⁸

CURRENT USE OF AND ACCESS TO INJECTABLES IN INDIA

6.1 WOMEN'S PERSPECTIVE

Evidence indicates that most women have very limited or no knowledge of injectable contraception in India. Data from NFHS-3 show that less than half (49 percent) of all women have heard of injectable contraception.² Informants believe this figure to be an overestimate of actual knowledge. Informants suggest that women often confuse injectable contraceptives with other medical injections and the IUD which is sometimes referred to as an “injection from below”. This belief is supported by evidence from the endline survey of the Dimpa project which found that even after behavior change communication (BCC) activities only 37 percent^{iv} of women in the intervention communities were aware of injectable contraception.²⁹

Data from the NFHS-3 (2006) show that use of injectables remains low; injectables are used by 0.1 percent of married women of reproductive age. Examination of differentials in injectable use indicates that this method is used by women from a wide range of economic and social backgrounds. Use is slightly higher than average among unmarried

adolescent girls, Muslims, and in some States.² Caution should be used when interpreting disaggregation of injectable use as the total number of injectable users in this sample was small. Current sales figures suggest that injectable use has steadily increased over the last several years with marked increase since 2006 (see below *Private sector and NGOs*).

More than half (53 percent) of all injectable users in India will discontinue in the first year of use.² 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).³⁰ 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 rises.³¹

6.2 PUBLIC SECTOR

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 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. One provider reported that between 20 to 30 percent of her family planning clients request injectable contraception. The physicians interviewed believe that their clients would benefit from including DMPA in the National Program and expressed the desire to be able to provide this method within their facility.

6.3 PRIVATE SECTOR AND NGOs

Over the last several years, many organizations – mainly social marketing agencies – and private providers have introduced injectables through clinic-based services. (See case studies in *Appendix IV* for program details) The method is currently distributed via social marketing channels and clinic/

^{iv} The figure for “real awareness” was reported as 28 percent in PSP-One. *Delivering injectable contraceptives at scale through the private sector*. Presentation. 12 May 2009. New Delhi.

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) (See Table 4).^v In addition to directly supported clinics, many agencies/ NGOs also distribute to private providers either individually or as part of a network, such as the *Dimpa Network*. The organizations listed in Table 4 represent an extensive network of providers which reaches most states in India.

Generally, the distribution points shown in the table refer to those that stock injectables. 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.

The majority of NGO programs offering injectables have been operating without donor support.

According to NGO informants, although NGOs sell DMPA at a markup over cost, this is barely adequate to meet their distribution and selling costs, leave alone undertake promotion and demand generation. The lack of promotion has significantly hampered expansion of the market for injectables.

With the exception of Abt Associates' DiMPA project (funded through a USAID unilateral funding modality), donor support for projects of other organizations has been made available on a limited scale and generally for short periods of time. Two of the injectables projects implemented by Parivar Seva Sanstha were supported under bilateral aid frameworks – one by Department for International Development (DFID) (as part of Orissa Urban Reproductive Health Project) and another by the German development bank KfW (as part of Social Marketing Project). Parivar Seva Sanstha was also funded by a United States-based foundation for a reproductive health project in Rajasthan which included provision of injectables. A few years ago Population Services International implemented a Hewlett Foundation supported project to promote various contraceptive methods including injectables.

Organizations interviewed for this assessment document maintained or increased sales of DMPA, particularly since 2006 (Figure 1). Sales data from DKT also show a steady increase in sales of DMPA over time (Figure 2). During 2008,

TABLE 4: DMPA DISTRIBUTION NETWORKS IN INDIA

Organization	Service Provision	# of Distributors	DMPA Doses Sold in 2008	Price to Client
Abt Associates	Private doctor network (Dimpa)	1,150 doctors	57 400	Rs 65-200 + consult fee
DKT ^{vi}	Social marketing (SM)	4,000 doctors	159 300	Rs 60/Rs 100 + consult fee
Family Planning Association of India	Clinic network	37 RH centers 23 urban FW centers	3128	NA
Janani	Clinic network (Surya) and SM	30 clinics, 750 doctors, 30,000 retailers	28 800	Rs 50 + Rs 5 consult fee (at clinics)
Parivar Seva Sanstha	Clinic network	36 clinics	10 000	Rs 85 + consult fee
Population Health Services India	Clinic network (Jyoti) and SM	14 clinics + private doctors	80 000	Rs 60 + consult fee
Population Services International	Network doctors (Saadhan) + other doctors	300 network doctors + 200 other doctors	28 400	Rs 100 + consult fee

^v There are some organizations not listed in Table 4 (e.g., ARTH) which also provide DMPA within their private sector clinics. These organizations generally have smaller annual sales compared to those listed in Table 4.

^{vi} DKT supplies injectables to private doctors. DKT also supplies to NGOs if and when they need the product (a recent instance is PSS).

about 80 percent of DKT's supplies was accessed by its own provider network, and the balance (20 percent) was distributed to other NGOs.

The potential demand for injectable contraception in India is demonstrated by the results of a project implemented by Parivar Seva. (Figure 3). In this study, DMPA was provided in two districts, Bhubaneswar and

Balasore, using two different service delivery strategies – clinic-based and Community-Based Distribution (CBD). In both districts injectables were made available at clinic facilities at a subsidized rate of Rs 50 plus a consultation fee. Clinics in both districts recorded a steady increase in sales over time (dotted lines).

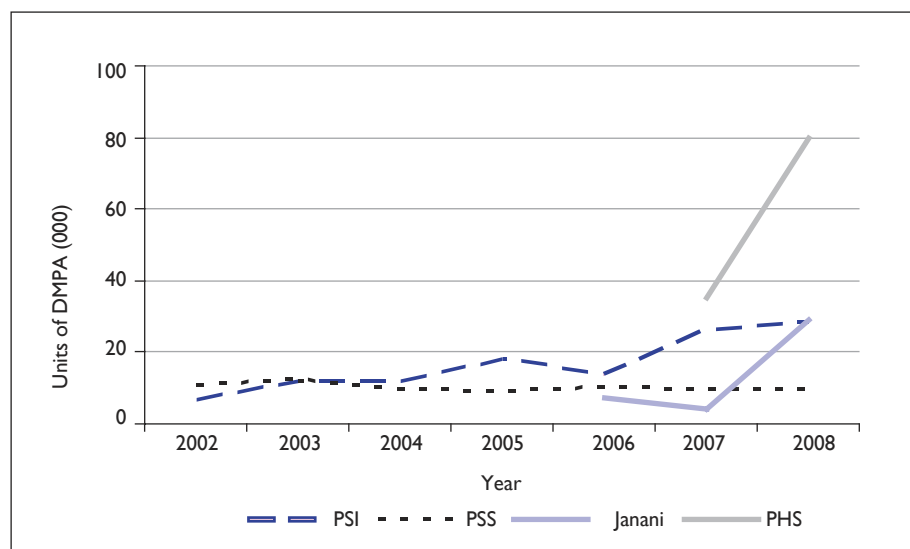
The most dramatic results were documented in the CBD sites. CBD provided doorstep delivery of

injectables in slum areas and rural communities – underserved by clinic-based services. CBD clients were screened, counseled, and provided the first injection by physicians at a cost to the client of Rs 20 with no consultation fee. Follow-up and re-injections were provided by nurses under the supervision of doctors. Uptake of community-based DMPA services was substantially higher compared to clinic-based services. In addition, clients of CBD recorded a higher rate of method continuation at 12-months compared to clinic clients (80 percent versus 60 percent, respectively).³² Results of this study demonstrate significant demand for high quality injectable services which are easily accessible and affordable.

Providers in both the public and private sector report the current cost of DMPA is a significant barrier for some women, even at subsidized rates. The price sensitivity of DMPA is documented by the experience of NGOs. Figure 4 shows the effect of a price increase on sales of DMPA in the Janani network. In 2003, the price of DMPA was increased from Rs 39 to Rs 79. Sales fell by 30 percent in the same year as the price increase came into effect.⁸ Likewise, evidence from an operations research project funded by USAID and conducted by PSS with support from the Population Council demonstrated that uptake of DMPA increased when the cost to clients was reduced and promotional activities were undertaken. The most significant increase in sales of DMPA was documented in Varanasi where the price of DMPA was reduced from Rs 150 per vial to free (Figure 5).³²

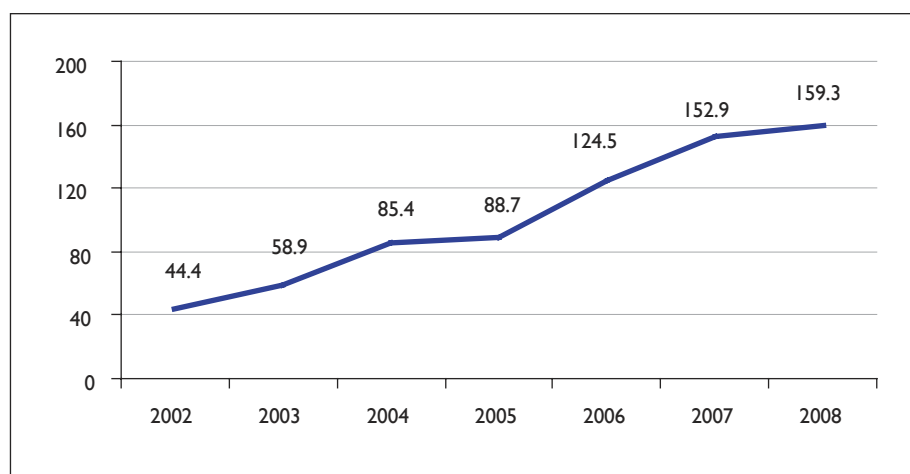
Two studies have demonstrated the feasibility and acceptability of

FIGURE 1: ANNUAL SALES OF DMPA IN INDIA BY FOUR NGOs



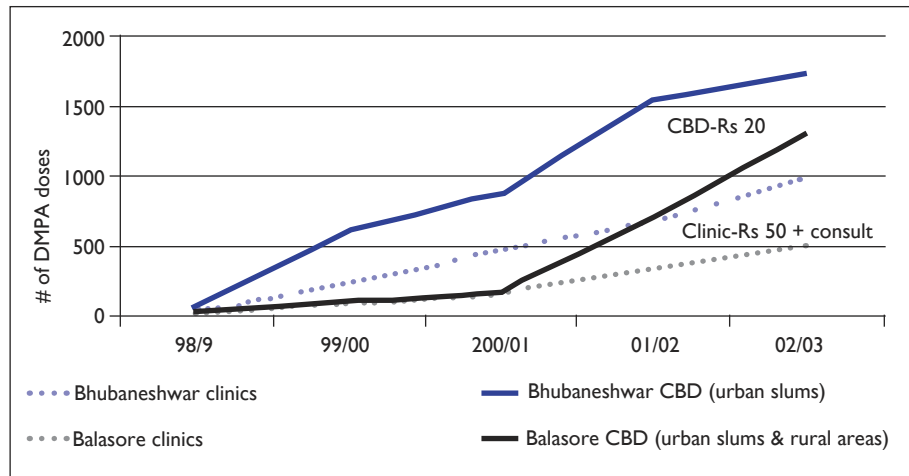
Source: Personal communication, 2009.

FIGURE 2: ANNUAL SALES OF DMPA IN INDIA BY DKT



Source: Personal communication, 2009.

FIGURE 3: RESULTS OF PARIVAR SEVA ORISSA URBAN REPRODUCTIVE HEALTH PROJECT



Source: Parivar Seva, 2002.

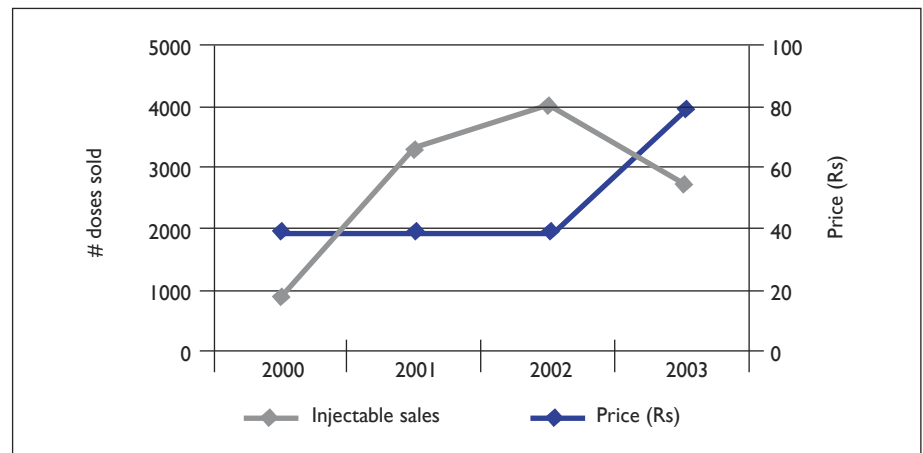
- With counseling and support, menstrual irregularities are acceptable to many women.
- Demand for injectables is price sensitive. When the price of injectables increases demand shrinks. Even with highly subsidized products, middle income clients make up the major proportion of program beneficiaries.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

providing DMPA through private sector physicians. An operations research study conducted by Population Council in collaboration with DKT India, EngenderHealth, and CORT in three urban centers in Gujarat was unfortunately disrupted by the earthquake in 2001. However, despite several limitations of the study, the results showed that private practitioners are interested in providing DMPA to their clients, in-service training can be adapted to accommodate the demand schedule of these providers, and these services are acceptable to clients.³³ More recently, and evaluation of the Dimpa Project also provided evidence of feasibility and acceptability of DMPA provision through the private sector.³⁴

The various projects discussed in this section also serve to demonstrate the acceptability of injectables in the Indian context. Evidence from these projects suggests:

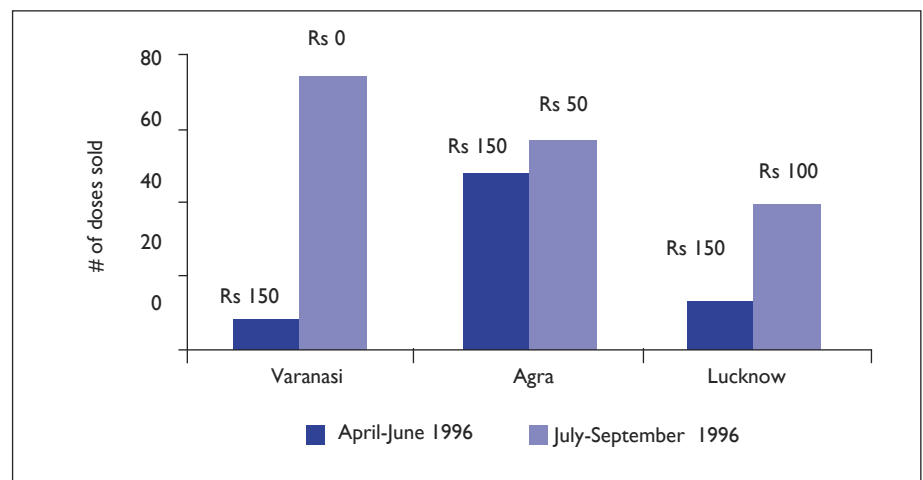
- When provided the choice, many women will choose injectables over other methods.

FIGURE 4: PRICE SENSITIVITY – JANANI’S EXPERIENCE



Source: Parivar Seva Sanstha (2004)⁸

FIGURE 5: PRICE SENSITIVITY – PSS OPERATIONS RESEARCH



Source: Parivar Seva, 2002

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 (Figure 6). Injectables are becoming increasingly popular in other regions as well. In sub-Saharan Africa, injectables account for one-third of all modern method use in the region.⁴

Asia served as the launching point for injectable contraception. Researchers conducted numerous clinical trials on

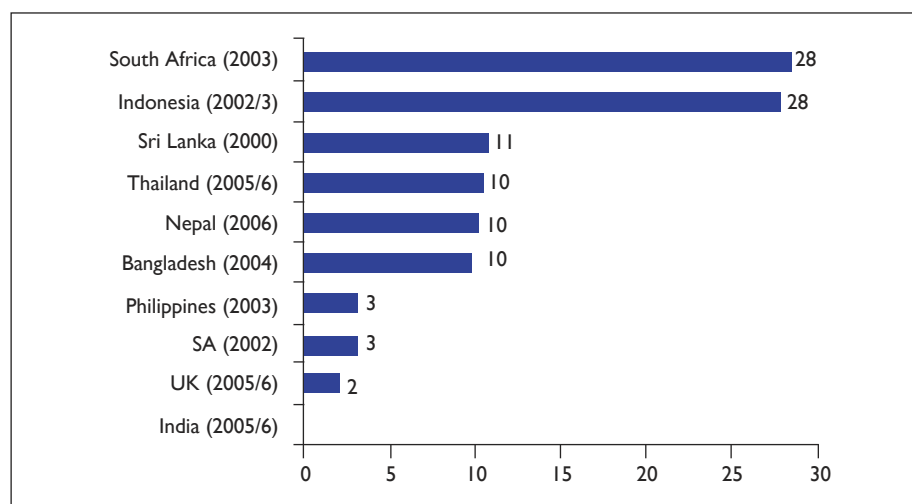
the safety and efficacy of the method, and later tested innovative service delivery approaches in the region. The experiences of Bangladesh and Nepal, in particular, provide a rich body of evidence on the benefits and challenges of expanding access to injectables.

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 (Figure 7). In contrast, private sector providers supply the vast majority of injectable users in India and Indonesia (83 percent and 80 percent, respectively). In Indonesia, this pattern is reflective of the national trend toward greater reliance on the private sector as the major source of supply for family planning provision.³⁵

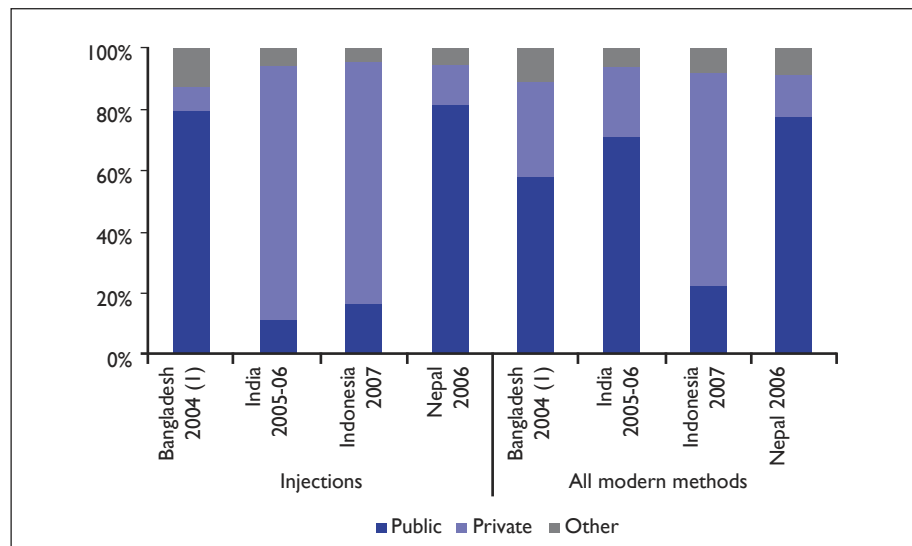
Introduction of injectables as a clinic-based service is an essential first step in making injectables available to the population. Evidence from Bangladesh, Indonesia, Nepal and Thailand demonstrates that limiting provision of the method to clinic-based physicians severely restricted access. In these countries, utilization of a broader base of providers including nurses, paramedics, community health workers, and pharmacists allowed for increased uptake of injectables over time. Evidence from these countries was used in a technical consultation organized by the World Health Organization, USAID, and Family Health International. Based on this and other country

FIGURE 6: PREVALENCE OF INJECTABLE USE AMONG MARRIED WOMEN OF REPRODUCTIVE AGE IN SELECT COUNTRIES



Source: United Nations, 2007

FIGURE 7. SOURCE OF SUPPLY FOR INJECTABLES AND ALL MODERN METHODS FOR SELECT COUNTRIES



Source: Macro International, Inc, 2009.

experiences, the consultation concluded that provision of progestin-only injectables by appropriately trained community health workers is safe and effective and that

...there is sufficient evidence to support expansion of community-based health workers providing progestin-only injectable contraceptives, especially DMPA.²

Injectable contraception has the highest rate of 12-month

discontinuation of any modern method (49 percent).³⁰ On average, this rate is similar to discontinuation among pill users (48 percent). Method specific discontinuation at the country level varies substantially and is inversely correlated with prevalence of use.³⁰ Table 5 shows 12-month discontinuation rates for pills and injectables. As seen in this table, 12-month discontinuation for injectables varies from a high of 53 percent in India to a low of 18 percent in

Indonesia. Discontinuation among injectable users is only slightly higher compared to pill users in Bangladesh and India. In Indonesia and Nepal, discontinuation among injectable users is substantially lower compared to pill users.³⁵ Continuation rates for temporary methods are generally lower than continuation rates among long-term, permanent methods. This is a factor of both the type of method used and the intention of the user. For injectables, method continuation is positively associated with the level of injectable use. In other words, as the percentage of women using injectables increases the more women are likely to use injectables for 12 months. Ensuring easy access and high quality service delivery are keys to maximizing method continuation.

TABLE 5: 12-MONTH DISCONTINUATION FOR INJECTABLES AND PILLS IN SELECT COUNTRIES

	Injectables	Pills
Bangladesh 2004	49	46
Indonesia 2002/3	18	32
India 2006	53	49
Nepal 2006	42	64

CONCLUSIONS

Based on the information collected as part of this activity, the assessment team was able to draw a number of conclusions pertinent to current and future provision of injectable contraception.

- Provision of DMPA in the public sector is at present legally restricted awaiting endorsement by DTAB, as implied by the Supreme Court's directions in the relevant case that ended in 2001.
- Providers within the public and private sectors are aware of injectable contraception and are most familiar with DMPA. Those with experience providing the method believe the method is safe, effective and acceptable to Indian women. Providers note

that menstrual irregularity is challenging for some clients and emphasize the need for high quality counseling and follow-up. None of the providers interviewed mentioned clinical concerns or serious complications with the method.

- Providers in the public and private sector report significant client demand for the method. Program reporting and sales data document sustained or increased sales of DMPA over time. Overall, sales of DMPA appear to have significantly increased over time.
- Cyclofem and NET En are in the process of pre-program introduction trials for the government program; these trials will be completed in 2011.

Currently, DMPA is legally available as a Schedule H drug (available by prescription only) through providers in the private sector and in clinics supported by non governmental organizations (NGOs) only. DMPA is also marketed to pharmacies and drug shops. The current organization of services severely restricts availability of DMPA, mainly targeting urban clients with the financial resources to purchase contraception at market or subsidized prices.

- 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.

RECOMMENDATIONS

9.1 OVERALL STRATEGY RECOMMENDATION

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. As a result, many are unwilling to enter into a national level dialogue on the need and feasibility of including DMPA and other injectables into the national FW program. What remains is a one-sided diatribe unimpeded by current realities and unanswered by medical professionals. The result is an uninformed population and marginally trained medical professionals. Therefore, any effective strategy to expand access to injectable contraceptives should include the following:

- Provide support to the Government of India to take the necessary steps to provide DMPA under the national Family Welfare Program
- Develop a more equitable service delivery strategy which provides high quality services to women living below the poverty line and those in rural areas.
- Increase awareness and accurate knowledge of injectables among every section of society – clients, providers, civil society,

and policy-makers, and

- Continue efforts to improve and ensure high quality family planning services.

9.2 STRATEGY RECOMMENDED FOR THE SHORT TERM

In the short term, USAID and its partners can:

- *Organize requisite support to Central MOHFW*
 - ◆ Support the Central MOHFW to build a case for introducing DMPA in the public sector. For this effort the MOHFW requires data on current service delivery experience in India, specifically user profile information, uptake of services, prevalence of side effects and management, and continuation rates. The MOHFW requires evidence which is irrefutable. Preferably the information would be collected and analyzed by a well-respected Indian organization such as FOGSI supported by an organization considered unbiased by critics, for example, WHO.
 - ◆ Organize a donor forum to build consensus to support MOHFW in expanding

access to injectable contraceptives. The forum could include, e.g., WHO, UNFPA, DFID, Packard Foundation and Bill and Melinda Gates Foundation (BMGF). USAID should share findings of this report and any other relevant information at the forum.

- *Support awareness raising and advocacy efforts*
 - ◆ Support FOGSI, ARC, and other relevant social and political organizations to launch a national campaign to raise awareness among all sections of society – clients, providers, the press, and policy makers. A large-scale communication campaign would support current marketing and provision of DMPA through NGO and private sector providers who often lack the resources for such investments.
 - ◆ Support FOGSI to involve the Indian Medical Association (IMA) which could then help to raise awareness about injectables among a wider base of doctors
 - ◆ Support the coalition

Advocating Reproductive Choices (ARC) and FOGSI in advocacy efforts to raise awareness among key stakeholders including clients, providers, the media, and policy makers.

- *Support service delivery*
 - ◆ Support NGOs/SMOs currently marketing or providing injectables to strengthen and expand injectables provision. Additional funding is needed to support training, communication and promotion, logistics strengthening, improve counseling skills, and record keeping and monitoring.
 - ◆ Support expanded use of public-private partnerships, e.g. inclusion of DMPA in ongoing voucher schemes. Program monitoring of such efforts will also provide state and national policy
- ◆ makers with essential information regarding the uptake and use of injectable services.
- ◆ Prioritize inclusion of DMPA in alternative service delivery models such as mobile clinics, to increase the number and distribution of service delivery points, particularly in underserved areas.
- ◆ Support current provision of injectables through continuous quality improvement, specifically,
 - Refresher training for physicians, paramedics, nurses, and Accredited Social Health Activists (ASHAs)^{vii}
 - Development or adaptation of Information Education Communication (IEC) material specific to DMPA provision
 - Develop mechanisms to strengthen follow-up and counseling for injectable users

9.3 RECOMMENDED MID AND LONG TERM STRATEGY

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
- Support small scale operations research to identify program inputs which lead to improved contraceptive continuation (all methods), ensure informed choice, and provide appropriate counseling.

^{vii} 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.

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APPENDIX

Appendix

I. PERSONS CONTACTED

Name	Position	Organization	Location
MOHFW/GOI			
Dr. Kiran Ambwani	Deputy Commissioner FP Division	MOHFW/Government of India	New Delhi
Dr. Amrita Kansal	Consultant, FP	MOHFW/Government of India	New Delhi
Dr. Malabika Roy	Scientist-F	Indian Council of Medical Research (ICMR)	New Delhi
Mr. A B Ramteke	Joint Drugs Controller, Central Drugs Standard Control Organization	Directorate General of Health Services, MOHFW/GOI	New Delhi
Dr. Deoki Nandan	Director	National Institute of Family and Health Welfare (NIHFW)	New Delhi
Dr. Kalaivani		NIHFW	New Delhi
Donor/International agencies			
Dr. Dinesh Agarwal	Technical Advisor (RH)	UNFPA India	New Delhi
Mr. Lester Coutinho	Country Program Advisor	Packard Foundation	New Delhi
Mr. Peter Hall	CEO	Concept Foundation	Thailand
Manufacturers			
Mr. Venkatesh Iyer	Vice President International Marketing	Famy Care Ltd	Mumbai
Mr. Suresh Kumar	Director- Marketing	HLL Lifecare Ltd	Thiruvananthapuram
Mr. Sreeraj Roy	Director- Speciality Business I	Schering Plough	Mumbai
Anjan Sen	Marketing Director	Pfizer Ltd	Mumbai
Ms. Priya Manjrekar		Pfizer Ltd	Mumbai
Mr. Harpreet Singh Walia	Marketing Advisor	Star Drugs and Research Laboratories Ltd	Bangalore

Name	Position	Organization	Location
NGOs/SMOs			
Ms. Sudha Tewari	President	Parivar Seva Sanstha (PSS)	New Delhi
Dr. Alok Banerjee	Technical Advisor	PSS	New Delhi
Mr. Ajay Singh	Legal Officer	PSS	New Delhi
Mr. Shejo Bose	Program Director	Janani	Patna
Ms. Rajula Ekka		Janani	Patna
Mr. Ranjan		Janani	Patna
Mr. Sanjeev Dham	Country Program Director	Population Services International (PSI)	Gurgaon
Mr. Chhatrapal		PSI	Gurgaon
Dr. Manisha Bhise	Medical Officer, HQs	Family Planning Association of India (FPA India)	Mumbai
Mr. Vivek Malhotra	Managing Director	Population Health Services (India) (PHSI)	Hyderabad
Dr. Sandeep Ghiya	General Manager - Clinical Initiatives	DKT India	Mumbai
Mr. Anand Sinha	Country Director	PSP-One/Abt Associates	New Delhi
Mr. Debu Satpathy	Program Director	Abt Associates	New Delhi
Others			
Dr. M S Jayalakshmi	Former Deputy Commissioner [RSS], MOHFW		New Delhi
Dr. V K Behal	Former Deputy Director General, MOHFW, GOI		New Delhi
Ms. Sashwati Banerjee	Former Marketing & Communication Adviser, Abt Associates		New Delhi
Futures Group			
Dr. Gadde Narayana	Director	Futures Group International	Gurgaon
Dr. Nidhi Chaudhary	Senior Program Specialist	Futures Group International	Gurgaon
Ms. Shuvi Sharma		Futures Group International	Gurgaon
Field visit: Uttarakhand			
Dr. Ganga Mahesh	Acting Chief Medical Officer	DOHFW Uttarakhand	Haridwar
Dr. Aggarwal	Deputy Chief Medical Officer, Haridwar	DOHFW Uttarakhand	Haridwar
Dr. Sushma	Deputy Chief Medical Officer, Luxor	DOHFW Uttarakhand	Haridwar
Dr. Arjun Singh Sangor	Anesthetist	Mela Hospital	Haridwar
Dr. Lata Bist	Lady Medical Officer	Doon Female Hospital	Haridwar
Mr. Surendra Thakur	District Program Manager	DOHFW Uttarakhand	Haridwar

Name	Position	Organization	Location
Dr. Deepa Sharma	Female Hospital Haridwar	DOHFW Uttarakhand	Haridwar
Dr. Renu Jain	Vardhaman Nursing Home	DiMPA Clinic	Haridwar
Dr. Sangeeta	Sanjeevan Hospital	DiMPA Clinic	Haridwar
Anita Chauhan	IFPS Program Support Officer	UKHFWS Uttarakhand	Dehradun
Ms. Parul Singh	Manager – Capacity Building	ITAP Uttarakhand	Dehradun
Field visit: Uttar Pradesh			
Dr. C B Prasad	Director	DOHFW Uttar Pradesh	Lucknow
Dr. Manju Mehrotra	General Manager FP/MCH	State Project Management Unit, NRHM (Uttar Pradesh)	Lucknow
Dr. Meenu Sagar	Superintendent	Dufferin Maternity Hospital	Lucknow
Dr. Vinita Das	H.O.D	King George Medical College	Lucknow
Dr. Sulbha Swaroop	Consultant	Futures Group	Lucknow

II. ICMR-LED STUDIES AND TRIALS ON INJECTABLES SINCE THE SEVENTIES

Starting in the 1970s, ICMR and institutes affiliated to it have conducted several clinical trials and research studies on injectable contraceptives in India. Most of the clinical trials even when exploratory were carried out in a multi-centric mode such that the results/outcomes could be applicable to the entire country.

During the 1970s and 1980s there was particular focus on one-month and two-month injectables in the trials and studies conducted. During the 1970s, ICMR carried out many small exploratory studies with DMPA and NET-EN alone and in combination with estrogens in varying dosing schedules. These were followed by Phase II trials using monthly injections in which four different regimens (including progestins alone and in combination) were studied. In this study trials using Medroxy Progesterone Acetate (MPA) were discontinued in view of a policy recommendation to evaluate only those products that were marketed in the country of origin.

Further clinical trials were carried out in the early 1980s on preparations containing the

progesterone NET-EN but not containing DMPA since the US FDA had still not approved DMPA.

Based on the results of these trials, a multi-centric Phase III comparative study of NET-EN 50 mg + estradiol valerate 5 mg (marketed as Mesigyna) injected monthly and NET-EN 200 mg injected every two months was conducted to observe the menstrual pattern and acceptability.

In the mid 1980s a pre-program introductory study involving NET-EN 200 mg was initiated through 42 postpartum centers and 33 PHCs across several states; the purpose was to assess the logistical requirements for providing injectables under the existing program conditions.¹

In 1993, following the approval of DMPA by the US FDA, approval was given for marketing of DMPA in India. ICMR gave its opinion that in view of the accumulated evidence on DMPA, no clinical trials were required in India. Instead, it recommended that MOHFW/Drug Controller arrange for post-marketing surveillance (PMS). PMS on DMPA was carried out during the period 1994-97 at ten independent private centers across the country, on 1079 Indian women.

During 2002-2008, ICMR carried out a NET-EN 200 mg feasibility study in eight Human Reproduction Research Centers (HRRCs) of ICMR and National Institute for Research in Reproductive Health (NIRRH), Mumbai. The objectives were: to assess user acceptability/continuation rates; to assess users' perceptions; and, to study return to fertility. Of the 2,352 eligible women, 51.4 percent accepted injectable contraceptives.²

Also during 2002-2008, ICMR conducted Phase III clinical trials of one monthly injectable contraceptive Lunelle/Cyclofem (MPA 25 mg and oestradiol cypionate 5 mg) at 16 HRRCs, through a cafeteria approach. The purpose was to study the efficacy, side effects and acceptability of the injectable in the Indian population. A total of 1,275 women were enrolled and observed for a total of 109,344 woman months of use. The continuation rate at one year was 63.2 percent. Further, 59 percent of women had acceptable bleeding patterns at 12 months of use.³

Based on positive results of the NET-EN feasibility study and Cyclofem trial, government has now initiated pre-program introduction of NET-EN and Cyclofem through 31 district hospitals and nine NGO clinics.

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III. ACTIVIST AND WOMEN'S GROUPS WHO ENDORSED MEMORANDUM OF 2005 AGAINST INJECTABLES

List of health and women's groups who endorsed the memorandum submitted to the Union Health Minister in 2005 spelling out the reasons for activists' opposition to use of injectables.⁴

1. Aalochana Documentation and Research Center, Pune: Simrita Gopal Singh
2. AIDS Awareness Group, Delhi: Elizabeth Vatsayan
3. Akshara, Mumbai: Nandita Gandhi
4. All India Democratic Women's Association (AIDWA): Brinda Karat
5. All India Progressive Women's Association (AIPWA): Srilata Swaminathan
6. Anandi, Gujarat: Neeta Hardikar
7. Catholic Medical Association of India: Joe
8. CEHAT, Pune: Sunita Bandewar
9. Center for Social Medicine and Community Health, JNU: Dr. Mohan Rao
10. Center for Social Medicine and Community Health, JNU: Dr. Imrana Quadeer
11. Chetna, Ahmedabad:
12. Community Health Cell, Bangalore: Thelma Narayan
13. Delhi Science Forum: Dr. Amit Sengupta
14. Dynamic Action Group, Lucknow: Ram Kumar
15. Dr. Amar Jesani, Mumbai
16. Dr. Anant Phadke, Pune
17. Dr. Dhruv Mankad, Nasik
18. Dr. Mira Sadgopal, Pune
19. Dr. Navsharan Singh, Independent Researcher
20. Dr. Vandana Prasad, Delhi
21. Dr. Veena Shatrughna, Hyderabad
22. Eklavya, Dewas: Anu Gupta
23. Ekta, Madurai: Bimla
24. Explorations, Mumbai: Jaya Velankar
25. Forum Against Oppression of Women, Mumbai: Sandhya Gokhale
26. Forum for Women's Health, Mumbai: Meena Gopal
27. Gramya Resource Center for Women: Ashima Roy Choudhury
28. Dr. Hanif Lakdawala, Gujarat
29. Health Watch U.P., Bihar: Dr. Abhijit Das
30. Jagori, Delhi: Abha Bhaiya
31. Jashodhara Bagchi, Chairperson West Bengal State Women's Commission
32. Jan Swasthya Abhiyan, Madhya Pradesh: Dr. Ajay Khare
33. Jan Swasthya Abhiyan
34. LABIA, Shalini
35. Maati, Munsiri, Uttaranchal: Malika Viridi
36. Madhya Pradesh Mahila Manch: Lorry Benjamin
37. Magic Lantern Foundation, Delhi: Gargi Sen
38. Majlis, Mumbai: Flavia Agnes
39. Medico Friend Circle
40. Masum, Pune
41. MPVS: Dr. Ajay Kumar Khare, Bhopal
42. National Federation of Indian Women: Sehba Farooqi
43. Nirantar, Delhi: Jaya Sharma
44. OLAVA and Muslim Women's Rights Network: Sabah Khan
45. People's Health Movement (India): Dr. B. Ekbal
46. Prabir, Godda, Jharkhand
47. Prayas, Rajasthan: Dr. Narendra Gupta
48. Rahi, New Delhi: Anuja Gupta
49. Ravi Duggal, CEHAT, Mumbai
50. Sanchetana, Kolkata: Rajashri Dasgupta
51. Saheli, Delhi: Laxmi Murthy
52. Sahiyar, Baroda: Trupti Shah
53. Sama, Delhi: Sarojini N.B
54. Sangram, Sangli: Meena Seshu
55. Stree Adhikar Sanghatan, Delhi: Anjali Sinha
56. Dr. Sunil Kaul, The Ant, Assam
57. Dr. Shashikant Ahankari, Halo Medical Foundation, Anandur, Maharashtra
58. Tamil Nadu Women's Collective: Sheelu
59. Tathapi Trust, Pune
60. Vacha, Mumbai: Sonal Shukla
61. Vimochana, Bangalore: Donna Fernandes
62. Women's Center, Mumbai: Ammu Abraham

IV. CASE STUDIES: DISTRIBUTORS AND PROVIDERS OF DMPA IN INDIA

ABT ASSOCIATES

Injectables: when introduced, products provided and geographical coverage

The *DiMPA* program and network for promoting use of injectable contraceptives through private healthcare providers was launched under the USAID funded Commercial Market Strategies project in 2002. The goals of the program are: to create awareness about DMPA as a safe and effective method of contraception; to increase access to and use of DMPA through the private health sector by establishing a network of clinics; and promote correct use and compliance through sustained high quality of service. The network consists of Obstetricians/Gynecologists and general practitioners trained to provide quality family planning services with a focus on the depot-medroxyprogesterone acetate (DMPA) three-month injectable. The project has followed a fractional franchising approach wherein injectables are added to methods already available to qualified private providers. The project is intended to demonstrate the feasibility of providing DMPA through the private sector with high quality of care.

The pilot program was initiated in three cities in Uttar Pradesh, the program has since expanded to an additional 45 cities in Uttar Pradesh, Jharkhand and Uttarakhand.

How injectables are provided: service delivery/marketing

'Network of clinics' model. Given the prevailing operating environment, where DMPA faced considerable opposition by women's groups who were not convinced about the safety of the product and concerned about ensuring high quality standards required for providing the method – the project adopted a 'network of clinics' model as its entry strategy. This strategy allowed for collective ownership of the project by providers, training of doctors in the network, monitoring the quality of service provision, ensuring product access and largely focused on supply side issues with low-key consumer directed communications. Organizing providers into the network provided this base and enabled the program to obtain the support of the Federation of Obstetric and Gynecological Society of India (FOGSI), which issued a consensus statement approving DMPA as a safe and effective method and encouraged its 18,000 members to promote the product within the WHO guidelines.

When the pilot began the network consisted of only 105 providers in three towns and today it covers 45 towns with 1,150 providers. The scale-up has taken place over four phases, throughout which PSP-One has developed partnerships with the private, commercial sector and has implemented low-cost and scalable interventions to increase network members' knowledge and skills related to family planning.

Implementation strategy. The program screens, identifies and trains leading Obstetricians/Gynecologists and General Practitioners in the provision of DMPA, patient counseling, and management of adverse effects, to ensure high quality provision of a basket of contraceptive methods that includes DMPA. The program also employs Field Representatives to detail to *DiMPA* providers with technical updates, job aids, and clients materials (Field Representatives also conduct interpersonal communication with potential family planning users, informing them of the different options available and encouraging them to discuss family planning with their provider).

The program components include:

- 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 program for increased use and knowledge and sustained quality of care

Donors, other partners and their roles

Various partners are involved to help the program to accomplish its goals. USAID provides funding and technical assistance through PSP-One, the Family Welfare Committee of FOGSI provides a platform to build consensus

and support among Obstetrician/ Gynecologist providers for DMPA. Other partner include Family Planning Association of India (which conducted the Training of Trainers till 2005, subsequently PSP-one using its in-house capacity has been conducting provider training and updating training modules), Pfizer (was the sole manufacturers and marketer of DMPA in India and as a partner they reduced the price of the product and ensured supplies to all network clinics), DKT (responsible for product distribution), IPAN (managed public relations and advocacy), and Ogilvy and Mather (managed communications and field operations till end of 2005). In the 4th scale-up phase in 2007 Lowe advertising agency has been retained to manage and support mass media activities for the promotion of DMPA in the project towns.

The program works closely with the leading manufacturers and marketers of injectable contraceptives, to reduce product costs and ensure supply to all DiMPA network clinics.

Procurement and distribution system, field force

Procurement and distribution system for DMPA

DiMPA program does not do any direct procurement/selling of DMPA in project towns.

DiMPA program only facilitates the supply linkages between DMPA marketers and trained providers in project towns. Each marketer uses its own field force for supply of DMPA to the provider clinics.

Injectable brands being provided

Number of DMPA marketers has increased since 2003. Four marketers making available DMPA in Urban and rural parts of three states - Pfizer, HLL, DKT and PHS

- DKT procures Depo-Provera from Pfizer and sells across India, DKT also imports Depo-Progestin from Indonesia and sells across India.
- Pfizer sells Depo-Provera across India
- PHS sells “Khushi” brand of DMPA injectable in India. This DMPA is manufactured in India by Star Drugs Labs, Chennai
- HLL imports “Petogen” from Germany and sells in India.

Primarily DKT, PHS and Pfizer DMPA brands are available in most of the DiMPA project towns. There is keen interest among current DMPA marketers to continue product distribution in project areas.

Stocking of DMPA by providers and retailing chemists

As per the end line survey of April 2009, 70 percent of DiMPA providers stock DMPA; 53 percent of providers stock DMPA in their clinic and 17 percent stock DMPA with a chemist attached to their clinic. Only 25 percent of chemists are currently stocking DMPA at their outlets.

It has been observed that while quite a few providers prefer the Pfizer product, many choose DMPA brands based on the client’s paying capacity. Many low income clients are being prescribed *Khushi* which is distributed by PHSI.

Prices and subsidies

With multiple marketers operating in the DiMPA areas, there is a wide range of DMPA price options for consumers. The prices charged for DMPA by different marketers are as follows:

DKT: Rs 100/-
HLL: Rs 175/-
PHS (Khushi): Rs 65/-
Pfizer: Rs 200/-

Providers charge consultation fees to clients in addition to the product price.

Promotion, communication and advocacy

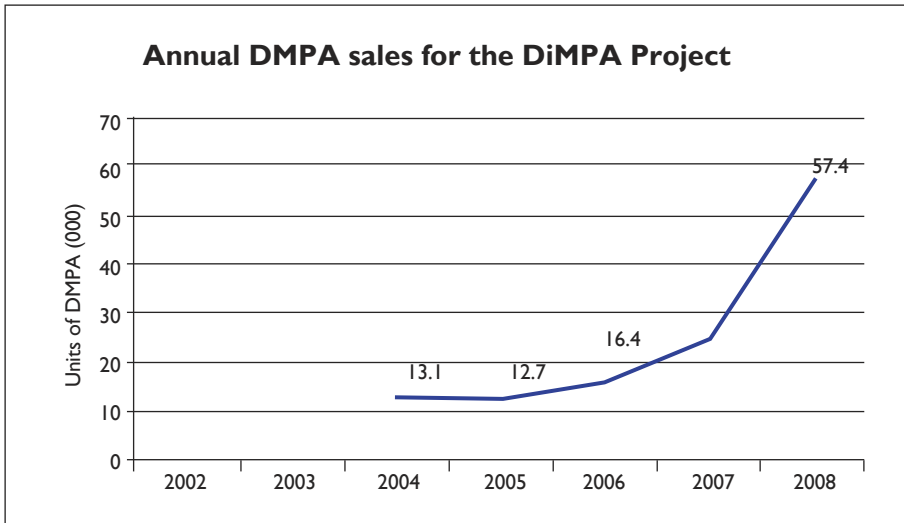
The program has developed a DMPA communication campaign for increasing correct knowledge on DMPA, including point of sale and educational material at clinics, interpersonal communication tools for doctors and outdoor advertising materials like cable, cinema and press advertisements promoting DMPA and DiMPA clinics in each town.

In addition to launching the network, the project also implemented an advocacy campaign to increase correct knowledge about injectables and neutralize negative media reporting about the product.

The program was able to create an advocacy board that includes medical experts, UNFPA and WHO. A consensus statement supporting DMPA was released by FOGSI.

Sales figures and coverage

The following graph depicts DMPA annual secondary sales in DiMPA project towns:



Ensuring service quality

The program conducts regular technical detailing and updating for providers and paramedics to enhance their performance and quality of services. This includes issues such as safe injection and needle disposal practices, improved client counseling, handling client concerns about menstrual changes from DMPA use, record keeping for better management of clients and return visits.

The program conducts regular mystery client surveys to monitor and track quality of care parameters. It is also developing and piloting self-assessment quality improvement tools for the providers.

Experiences and lessons learnt

Since the inception of the network, use of injectables has increased from 0.004 to 0.7 per cent in Uttar Pradesh just as sales have steadily increased with DKT reporting 91 per cent annual growth.

The following observations are based on the experience of implementing the program:

- Network providers have better performance in Mystery client studies compared to those who are just trained
- There is need to segment the providers so that inputs can be properly targeted. The two key variables for segmentation are provider confidence levels in prescribing and supporting DMPA users, and levels of DMPA users/prescriptions.
- One of the key reasons that providers join the network is for the promotional and advertising support their clinic receives as part of the network
- Developing and delivering simple overarching communication objectives through sustained media briefings with regional press has yielded strong support and positive or neutral reporting for the method
- Conversion rate from training to enrolment into network was initially very low while the program used external trainers, but with a dedicated in-house program management team consisting of Obstetricians/ Gynecologists who train, and

support the DiMPA network this has increased significantly.

- Commercial manufacturers and marketers will respond quickly to increased support and provision for a new contraceptive method by introducing new brands and reducing prices.
- Record keeping and proper counseling by providers continues to be a challenge and is one of the areas that requires strong support from the program and field teams

DKT INDIA

Injectables: when introduced, products provided and geographical coverage

DKT India has been marketing injectable contraceptives in India since 1996 as part of its contraceptive social marketing program. Sales of injectables have been rising steadily over the years.

1996: Noristerat launched

1999: Depo Provera launched

2005: Noristerat discontinued

2006: Depo Progestin launched

Noristerat, which was being source from German Remedies, had to be discontinued because of supply problems. The injectable contraceptives currently being provided include:

- Depo Provera: 150 mg depot medroxyprogesterone acetate/ml, aqueous solution; sourced from Pfizer, made available through a network of doctors with a price of Rs. 100 for the client.
- Depo Progestin: 150 mg depot medroxyprogesterone acetate/ 3 ml, aqueous solution; sourced

from Harsen, Indonesia, made available through a network of doctors with a price of Rs. 60 for the client.

DKT markets injectable contraceptives across all its areas of operations, namely, Maharashtra, Goa, Gujarat, Rajasthan, Madhya Pradesh, Chhattisgarh, Andhra Pradesh, Uttar Pradesh, Uttaranchal, the North East (all seven states), Sikkim, West Bengal, Delhi, Punjab, Haryana and Chandigarh.

How injectables are provided: service delivery/marketing

DKT promotes injectable contraceptives to approximately 10,000 service providers, of whom an estimated 4,000 stock and dispense the product. DKT does not have any franchise networks for providing injectable contraceptives.

Procurement and distribution system, field force

DKT procures product from Pfizer and Harsen. The product is then supplied to stockists against a primary order procured from the stockist by DKT India field personnel. The product is then supplied by stockists to doctors against one of the following:

1. A secondary order procured from doctors by DKT field personnel (this forms the bulk of the secondary sales)
2. Orders procured from doctors by stockist personnel
3. Orders placed directly by doctors.

The doctor maintains stocks of the injectables and then dispenses them to clients who wish to use

injectables as their contraceptive method. In the case of Depo Progestin, some doctors prefer to prescribe the product and in such cases, the product is made available at retail outlets, where it is sold to clients against the doctor's prescription.

DKT promotes injectables through a field force comprising over 130 sales representatives and 25 business development executives in the frontline, supervised by a structure of product executives, area sales managers, regional managers and zonal managers in the field and supported by Head Office staff.

DKT does not promote Depo Provera to those retailers who are supplied by the Pfizer distribution system – this is to avoid being in a competitive situation vis-à-vis Pfizer.

* C&FA: carrying and forwarding agent

Prices and subsidies

The price structure for Depo Provera is as follows:

- Price to stockist: Rs. 76.50 per vial
- Price to doctor: Rs. 85.00 per vial
- Price to client: Rs. 100.00 per vial

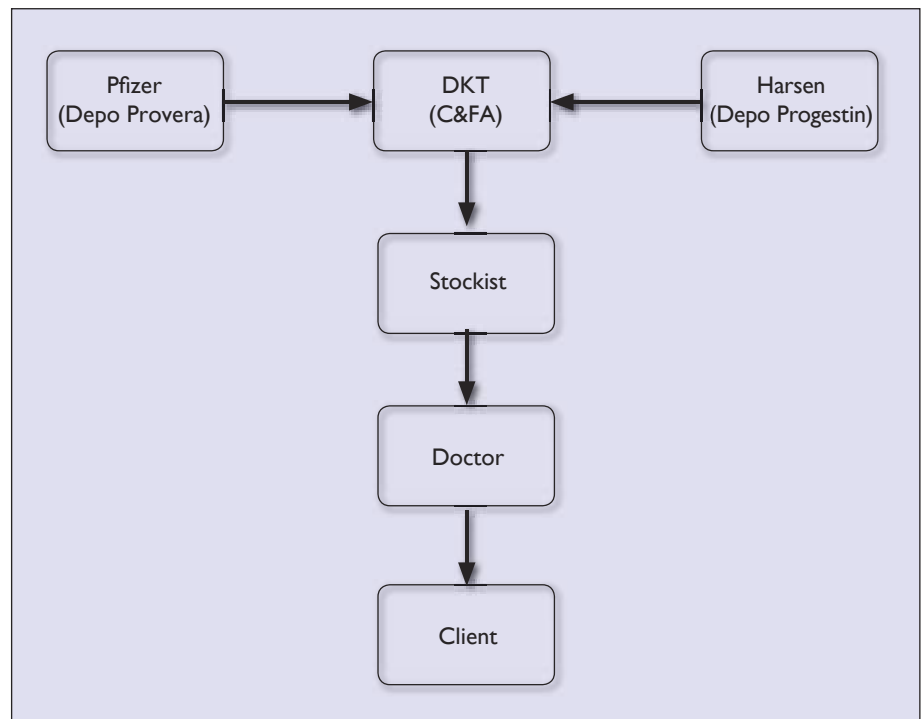
The price structure for Depo Progestin is as follows:

- Price to stockist: Rs. 45.00 per vial
- Price to doctor/retailer: Rs. 50.00 per vial
- Price to client: Rs. 60.00 per vial

Providers charge consultation fee in addition to price of product.

Promotion, communication and advocacy

Injectables are a provider-controlled method, especially since the injectables are dispensed by the doctors in most cases. Hence the bulk of DKT's promotional effort is directed at doctors. DKT works through a field force of



sales representatives and business development executives (in selected states) to promote injectables to doctors by means of regular detailing calls. Doctors who are interested in providing injectables to their clients as part of their contraceptive basket are provided the product through a network of stockists. Depo Progestin is also made available through retailers in selected cases.

Promotional materials used include:
For doctors:

- Detailing visual aid
- Service provider manuals
- Screening guidelines
- (occasional) Clinical studies and third party articles

For clients:

- Client education leaflets
- Posters
- Community meetings

DKT has no experience with advocacy for injectables in India. However, DKT remains open to supporting such efforts.

Sales figures and coverage

The tables below give the DKT sales figures for injectables starting from 1996. Figures in brackets indicate returned vials. Injectables distributed by DKT reach not only DKT's own provider network, but are also accessed by provider networks established by other agencies such as Abt Associates. DKT has also been supplying injectables directly to other NGOs. During 2008 about 80 percent of DKT's supplies were accessed by its own provider network, and the balance 20 percent were distributed to other NGOs.

During 2007 – 2008, DKT ran three primary schemes for injectable sales, wherein the stockists were provided one free unit for every nine units that they purchased. These free units are typically passed on to doctors, so that the doctor receives a free unit for every nine purchased.

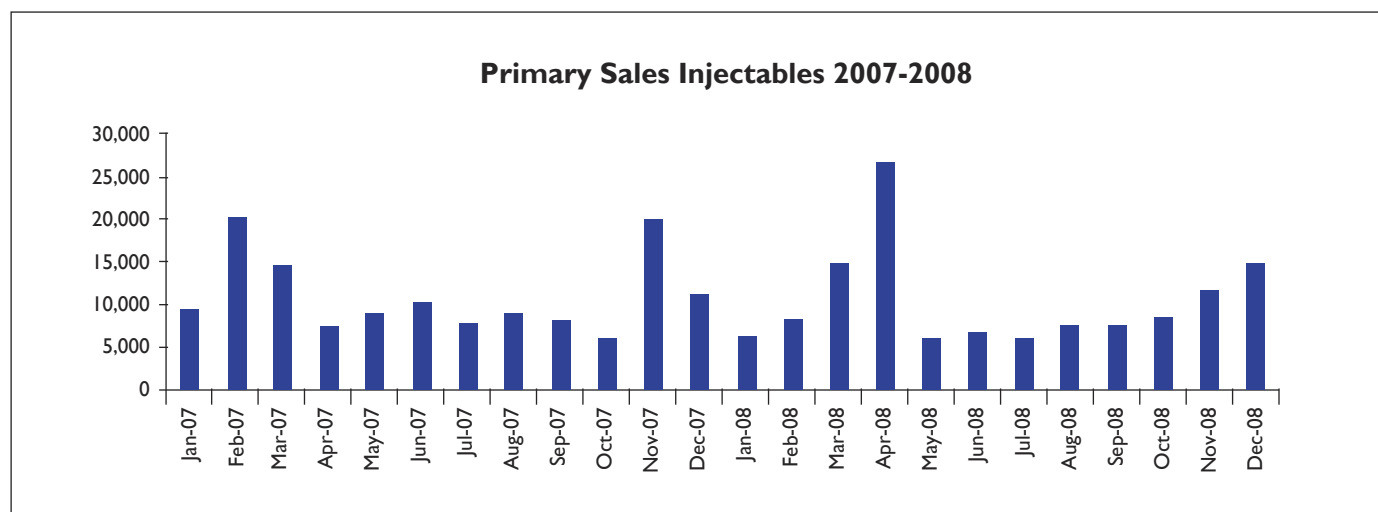
These schemes were run between February 16, 2007 – March 15, 2007; November 16, 2007 – December 15, 2007 and March 16, 2008 – April 15, 2008. During the scheme period, sales are much higher than usual, but are followed by a dip for the next few months. Generally, what DKT

Regional sales for 2008

Year	All-India Primary Sales Figures			Total
	Noristerat	Depo Provera	Depo Progestin	
1996	732			732
1997	5,300			5,300
1998	9,132			9,132
1999	20,635	7,903		28,538
2000	33,901	35,592		69,493
2001	15,747	25,017		40,764
2002	13,589	44,433		58,022
2003	18,370	58,927		77,297
2004	7,429	85,372		92,801
2005	1,969	88,742		90,711
2006	(561)	89,778	34,612	123,929
2007		112,737	40,190	152,927
2008		110,385	48,870	159,255
2009 (till June)		59,278	22,639	81,917

Sales over the years

	Depo Provera	Depo Progestin	Total
Maharashtra, Goa and (parts of) Karnataka	31,501	1,063	32,564
Madhya Pradesh, Chhattisgarh	8,536	2,891	11,427
Gujarat	12,133	1,126	13,259
Rajasthan	253	2,468	2,721
Uttar Pradesh	17,042	8,481	25,523
North East (seven states)	18,040	1,217	19,257
Wes Bengal, Sikkim	5,865	5,945	11,810
Andhra Pradesh	6,239	310	6,549
Punjab, Haryana, Delhi, Chandigarh	5,726	369	6,095
Others (Direct supplies to NGOs)	5,050	25,000	30,050
Total	110,385	48,870	159,255



has observed is that the sales settle at a level higher than that seen prior to the scheme, thereby suggesting that the scheme helps draw in providers and encourages them to increase their stocking and usage of injectables.

Ensuring service quality

DKT is working with independent private practitioners for distributing injectables. As such they are not in a position to monitor the quality of service provision. However, they do provide information to the doctors regarding safe injection techniques including disposal of the syringe/needle. They also distribute client education leaflets to clients which list out the frequently asked questions regarding injectables and the expected sequelae.

Experiences and lessons learnt

The acceptance of injectables is rising throughout the country. However, the main concerns remain the bleeding seen with the product (especially the spotting in the initial phases) and the delay in return to

fertility. Based on informal feedback from doctors relayed by the field force, amenorrhoea seems to be better accepted when the client has been counseled about the same in the start. This reinforces the need for correct selection of clients for DMPA.

During the period it was on offer, there was reasonably good demand for Noristerat – in fact some providers favoured it because they felt there were fewer problems of bleeding associated with it.

Over the years, there have been situations where doctors have stopped providing injectables as part of their basket of contraceptive options. This has been either in response to adverse media reports regarding injectables or in quite a few cases, when the proportion of clients returning with side effects has been higher. What DKT has also found is that in most such cases, the very same doctors start providing injectables again after sustained follow-up visits.

POPULATION HEALTH SERVICES INDIA

Injectables: when introduced, products provided and geographical coverage

Population Health Services India (PHSI) is a not for profit organization, affiliated to Marie Stopes International, U.K. (MSI, UK). PHSI is one of the larger social marketing organizations in the country. The organization is involved in promoting the usage of various types of contraceptive products and other related products at retail outlets throughout India. PHSI also promotes reproductive health care through its specialized clinics operating on International Standards & Scrutiny under the brand name of Jyothi Clinic. These clinics are operated according to standards established by Marie Stopes International, UK (MSI,UK). PHSI’s operations cover all states in India.

Injectables were introduced by PHSI in 2007 and their distribution was expanded to cover 12 states in the country within three months

of introduction. The product being provided is Khushi Depo Injectable 1 ml Medroxy Progesterone Acetate 150 mg for three months contraception sourced from Star Drugs and Research Laboratories Ltd.

How injectables are provided: service delivery/marketing

Injectables are provided through PHSI's 14 clinics – each clinic is staff with a doctor and appropriate paramedical staff. Also, PHSI's sales staff are attached to the clinics for promotion of clinic services.

PHSI also promotes injectables to independent private practitioners – these doctors avail of the product supplied via PHSI's social marketing setup. For this purpose each Sales Officer meets about 100 doctors (gynaecs, general physicians and rural medical practitioners) every month.

Procurement and distribution system, field force

Distribution system

- Manufacturer to central warehouse
- Stock transfer to C & A/C & F
- Stock transfer to distributors/stockists based on primary order booking by field staff in all principal towns
- Secondary booking from retailers by sales executives.

Among the Rural Medical Practitioners (RMP) who prescribe DMPA, the percentage that stocks it varies from state to state; it ranges between 50 percent and 75 percent. Most RMPs stock small quantities (about 5 vials).

Field organization

- Director of Sales - 1
- Zonal Managers -2
- Regional Managers - 5
- State Managers – 18
- Territory Sales Managers – 70
- Sales Officers – 250

Prices and subsidies

The procurement price is Rs.26, price to distributor Rs. 33 and MRP Rs. 60. Procurement price includes manufacturer's conversion cost, margins etc. Private practitioners charge consultation fee from the client in addition to price of product.

Promotion, communication and advocacy

Promotion strategy is finalized in strategy meetings at head office with top management. It is then communicated to Zonal Managers for endorsement and implemented by State Managers.

Sales figures and coverage

Primary sales in 2007 were 35,000 vials and in 2008 were about 80,000 vials. Significant growth has been recorded in the last six months, during which, on an average, each state has sold over 1000 vials per month. Substantial increase in sales is envisaged in all the 12 states in which PHSI operates.

It has been observed that schemes have a very significant impact on sales – they help to improve product availability and increase usage.

Service quality monitoring

Service quality is monitored through various checks, controls and documentation with periodic on-site visit by each level of manager.

Experiences and lessons learnt

- There is significant scope for expansion of injectables use, especially through doctors, nursing homes, private and corporate hospitals.
- Consistent quality with price advantage over promoted brands helps grow sales
- Cash recovery from doctors for supplies made to them can be a slow process, sometimes requiring repeat visits spread over a few months.

JANANI

Injectables: when introduced, products provided and geographical coverage

Janani began operations in Bihar (subsequently bifurcated into Bihar and Jharkhand) in 1995. Janani's activities started as a vertical family planning program using social marketing as the strategy for distribution; today its program has expanded to deliver the entire range of contraceptives and also comprehensive abortion care. Janani's delivery systems now include:

- Own clinics
- Franchise clinics
- Outreach services at government facilities
- Social marketing of contraceptives and medical abortion kits

Injectables as a method of contraception were added to the basket of services from 2000. Currently DMPA is being provided.

How injectables are provided: service delivery/marketing

Janani delivers family planning services/products through a network of its own *Surya* clinics as also through a large state-wide network of pharmaceutical shops. Injectables too are made available through both routes.

- Janani operates a total of 30 *Surya* Clinics across Bihar and Jharkhand. Injectables are provided at all *Surya* Clinics.
- There are approximately 750 doctors listed with Janani in Bihar and Jharkhand who deliver family planning services through their own set-up. These doctors are visited on a periodic basis by Janani's Project Coordinators who procure orders for various products and facilitate their fulfilment. Among them those doctors who prescribe injectables obtain the product directly from Janani's redistribution stockist. Some doctors prescribe but do not stock the injectables; in such cases the client gets the injection from the retailer.

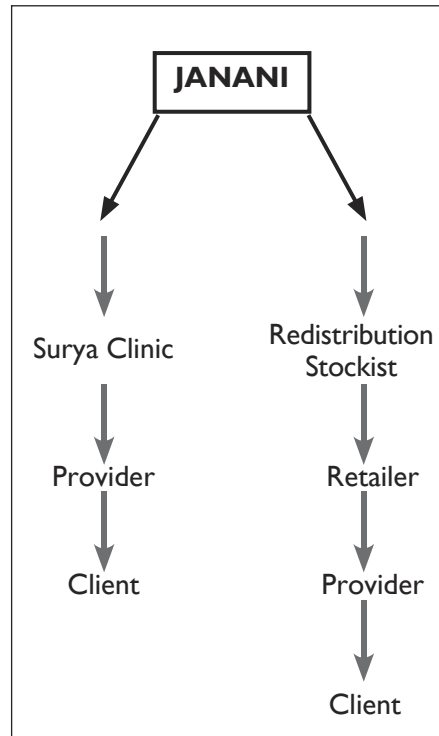
Previously, Janani used to franchise the *Surya* brand to the private practitioners – this practice was put on hold some time back but is now proposed to be revived. The franchisees too would provide the entire range of family planning services.

Procurement and distribution system, field organization

DMPA is sourced from Star Drugs and Research Laboratories Ltd, Bangalore. Janani arranges for supply of the product to the *Surya* Clinics and also to the distribution system of the sales network. The

sales network includes about 100 redistribution stockists and over 30,000 retailers spread across Bihar and Jharkhand.

The distribution system is shown below:



Field organization and its size

All operations are headed by the state head with state office in each state with a managerial support staff of line manager at its three field offices with 144 frontline project coordinators.

Prices and subsidies

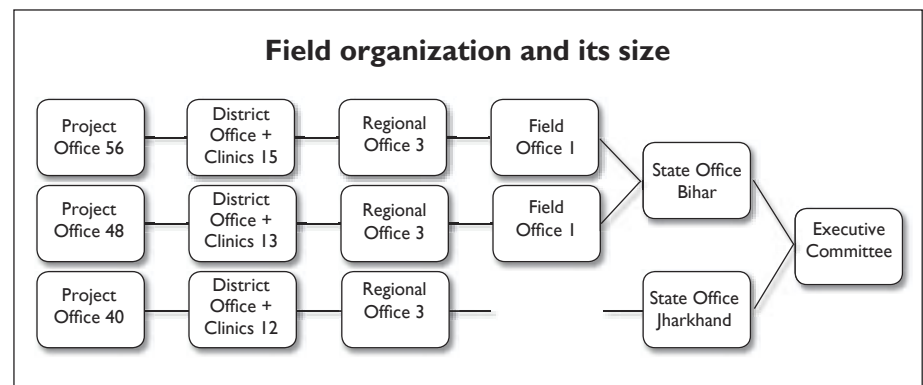
DMPA is purchased at about Rs 30 per dose (inclusive of syringe and needle) from Star Drugs. Clients at *Surya* clinics are charged Rs 50 per dose, and registration and consultation charges of Rs 5. For supplies received via the sales network, the retailer pays Rs 40 per dose. Janani does not dictate the price (and related consultation fee) at which private practitioners provide the product.

Promotion, communication and advocacy

Janani does not have a communication and promotion strategy specific to injectables. Rather, Janani promotes the entire range of family planning services/products that it offers, by way of counseling by the providers in the *Surya* Clinics, implementation of promotional activities during various events like world population day, organizing panel discussions and advocacy seminars on family planning as a whole, among others.

Sales figures and coverage

The following table shows the year-wise primary sales of DMPA in Bihar and Jharkhand during the period 2006 to 2009.



Primary Sales – DMPA			
Year	Bihar	Jharkhand	Total
2006	7,149	200	7,349
2007	3,375	817	4,192
2008	25,927	2,850	28,777
2009 (till July)	4,808	1,617	6,425
Total	41,259	5,484	46,743

operation from the much cheaper smuggled DMPA products from Nepal. These products are available in the retail market at Rs 15-20 per dose. The good news for Janani is that as of last year there has been some abatement in the quantities smuggled in.

PARIVAR SEVA SANSTHA ***Injectables: when introduced, products provided and geographical coverage***

The national NGO Parivar Seva Sanstha (PSS) has been in existence for the last 30 years. The organization provides a range of reproductive health services and products in 21 states of India. Though a variety of RH projects have been taken up by the Sanstha, socially marketed RH clinics/franchised centers, social marketing of RH products, and education and training projects on sexual and reproductive health are its three main thrust areas.

PSS introduced DMPA on a pilot basis in August 1994, following approval by Drug Controller General of India for its use by PSS. PSS also participated in the post-marketing surveillance (PMS) program for DMPA in India (in Mewat, Haryana state) during the period November 1994 to April 1997. Of the 10 sites where the PMS was carried out, Parivar Seva's was the only rural site. In January 1996, DMPA was introduced as an additional contraceptive method in all PSS clinics in the country. In April 1996, PSS carried out an operations research project at three sites in Uttar Pradesh in collaboration with Population Council (analysis of price change on the perceptions and use of DMPA among clients using reproductive health services in Uttar Pradesh).

The following table shows the month-wise primary sales of DMPA in Bihar and Jharkhand for the calendar year 2008

Year 2008			
Period	Bihar	Jharkhand	Total
Jan-08	953	300	1,253
Feb-08	178	70	248
Mar-08	130	20	150
Apr-08	310	110	420
May-08	395	165	560
Jun-08	1,195	80	1,275
Jul-08	-	-	-
Aug-08	6	-	6
Sep-08	3,800	-	3,800
Oct-08	950	700	1,650
Nov-08	13,530	-	13,530
Dec-08	4,480	1,405	5,885
Total	25,927	2,850	28,777

Ensuring service quality

Janani has established service quality standards for all services provided at its Surya clinics, including for injectables provision. Since the Surya clinics are Janani's own, Janani uses its internal mechanisms to ensure quality.

At present Janani does not have a system to monitor the quality of services provided by the independent private practitioners who access the injectable from Janani's sales network.

Experiences and lessons learnt

Clients' profile

Most of the women opting for this method have a parity of two children (53 percent) and fall within the age

group of 21 to 25 years (45 percent) or 26 to 30 years (37 percent). The women opting for this method are mainly from urban areas.

Reasons for low sales

One of the reasons for the relatively low sales is that so far hardly any promotional activity has been directed at the independent private practitioners serviced by Janani's sales network. However, Janani now plans to promote the DMPA product under a brand name; this would be initiated later this year.

However, the biggest challenge by far to sales growth has been the stiff competition in Janani's area of

In November 1998, Parivar Seva introduced DMPA as an additional contraceptive option under a DFID supported project in Orissa. DMPA was also introduced under a project in Rajasthan supported by a United States based foundation; the project period was 2000-2007. During the period January 2006 to March 2008, under a KfW funded project, a pilot project with focus on injectables was implemented in West Bengal. Currently Depo Progestin is being provided through PSS's own network of 36 clinics spread over 12 states; these clinics are located in both urban and rural areas and are staffed with multi-skilled teams of doctors, counselors and nurses.

How injectables are provided: service delivery

As mentioned earlier, injectables are currently being provided through PSS's own network of 36 clinics spread over 12 states.

Donors, other partners and their roles

DFID support – Orissa Urban Reproductive Health Project

During the period April 1997-March 2003 PSS implemented the comprehensive state wide Orissa Urban Reproductive Health Project, with support from the Government of Orissa and DFID under the bilateral agreement between Government of India and Government of UK. In order to have smooth funds flow project funds were routed through Marie Stopes International. The project included several components such as RH clinics for women, contraceptive social marketing, Community-Based Distribution (CBD), RH education and training, state wide multi

media promotional campaign and innovative “Purush” clinics for men.

In November 1998, Parivar Seva introduced DMPA as an additional contraceptive option in this project, mainly through CBD and clinics. The CBD project covered a slum and rural population of 200,000 in Bhubhaneswar and Balasore districts of Orissa state. DFID funded a multi-media campaign around the injectable. In 1998-99, when intervention was initiated, DMPA contributed only 1.8 percent to the contraceptive acceptance mix, which increased to 31 percent in 2002-03.

Support from Private US foundation – Project to improve Reproductive Health in all 32 Districts of Rajasthan

During the period November 2000-April 2007 Parivar Seva was funded by a United States based foundation to substantially expand its presence in Rajasthan. This project had several components. Under the project seven additional hub clinics, supported by 20 spoke centers were set up to serve the rural areas to cover all the districts in the state with clinical services. In addition, the contraceptive social marketing program of PSS was strengthened in the entire state along with setting up of innovative information, education, communication and training programs. Injectables were included in all project components. A statewide promotional campaign on family planning was taken up – this included a campaign on injectables. Special commercials were produced to promote injectables on TV. Parivar Seva continues to operate most components, though at reduced scale.

KfW support – social marketing project

A Financing and Project Agreement was entered on 8 April 2004 amongst MOHFW/Government of India, Population Services International, Parivar Seva Sanstha and KfW for a social marketing project in selected states of India. This was part of the bilateral support framework between Governments of India and Germany. Details of the project were provided in two separate agreements concluded by KfW with PSS and PSI; these agreements were known to the MOHFW and mentioned in the Financing and Project Agreement.

Oral contraceptive pills and condoms were the two main products to be marketed by both Parivar Seva Sanstha and Population Services International. In addition, Parivar Seva Sanstha was to initiate a pilot project on injectables, using a franchise approach in selected districts of West Bengal. KfW specified the procurement procedure for injectables in its agreement with Parivar Seva Sanstha.

During the period January 2006 to March 2008, PSS franchised with private doctors in Burdwan and Hooghly districts of West Bengal to establish “Blue Star” centers to promote family planning methods. PSS franchised 49 doctors, 30 in Burdwan and 19 in Hooghly. The doctors/clinics were branded as Blue Star Center/Blue Star Doctor. During the induction phase training on technical aspects and in counseling skills was given to all involved. The Blue Star clinics were established in a space of a few months; the pilot project ran for about one-and-

half years. The branded centers and injectables were aggressively promoted. Besides outdoor promotion, cable TV was extensively used for which special commercials were developed. The main product was injectables though OCPs and condoms were also supplied as a part of CSMP to the franchised doctors.

Doctors franchised under the project were provided with the following: Depo Provera with syringe and needle; technical guidelines and product information; client record format; and, leaflets on DMPA and other FP methods. Periodic supervision visits to the clinics were utilized to provide technical support, to supply DMPA and IEC materials, and to collect data.

Procurement and distribution system, field force

Till 2002, PSS was importing DMPA from Indonesia – subsequently DMPA was sourced from Pfizer Ltd India and later on from DKT India. DKT India supplies Depo Progestin, which is a product of Harsen, Indonesia. PSS collects Depo Progestin from stockists in Kolkata – who are part of

DKT’s distribution system. According to PSS it is cheaper to procure Depo Progestin from Kolkata than from Delhi. On an average, PSS procures about 10,000 vials per year.

Prices and subsidies

Under the KfW funded project the procurement costs of all contraceptive products – including injectables – were met out of project grants. Under the project, PSS gave a subsidy on the price that it charged to private practitioners for injectables. DMPA prices at different levels of the distribution system were as follows:

- Procurement price from Pfizer was Rs. 75
- Price to the franchised private practitioners Rs. 25
- Price charged to clients by the franchised doctors Rs. 85

Currently, PSS procures Depo Progestin at Rs. 45 and provides it to clients at Rs. 85. Consultation fee is charged in addition.

Promotion, communication and advocacy

Under the project supported by it,

DFID funded a multi-media campaign around the injectable. Under the KfW funded project wherein Blue Star Centers were established in West Bengal, the following media were used in a campaign to promote DMPA use: hoardings, wall paintings, bus/auto-rickshaw panels, taxi boards, video film in local cable network, mobile vans, and inter-personal communication through community meetings.

At present, since there is no project funding for injectables, promotion and communication mostly takes place through inter-personal communication and word of mouth communication from satisfied clients.

A total of 100,908 doses have been provided to clients from the time PSS introduced DMPA in 1994 till March 2009.

Ensuring service quality

PSS has developed its own quality protocols based on direct experience with clients – this has considerably strengthened service delivery. PSS uses the following approach to ensure service quality:

- Correct selection of clients – by following the medical criteria as well as understanding personal and family priorities
- Proper counseling with assured confidentiality
- Correct drug delivery system and post injection instruction to clients
- Strong follow-up services with reassurance and re-counseling concerning the effects of the injectable

Experiences and lessons learnt

PSS has collected considerable

Sales figures and coverage

Year	No. of doses provided		
	At Own Clinic	Under Project	Total No.
1999-00	3542	1067	4609
2000-01	5186	554	5740
2001-02	6095	289	6384
2002-03	7585	3503	11088
2003-04	10740	1553	12293
2004-05	9625	27	9652
2005-06	8065	1000	9065
2006-07	8543	1650	10193
2007-08	8779	1400	10179
2008-09	8958	930	9888

data from DMPA acceptors over the years but has not been able to analyze it because of inadequate resources and manpower. Data collected includes, among others: source of information on DMPA; socio-demographic profile of acceptor (including age, education, religion, parity, earlier contraceptive usage); side effects experienced; menstrual changes details.

Findings

Analysis of data obtained in respect of approximately 6000 acceptors of DMPA during the period April 1997 to December 2007 showed that after using DMPA for at least 1 year, 34 percent clients were highly satisfied, 55 percent were satisfied and 11 percent were not satisfied.

The usage of DMPA in PSS clinics has steadily increased over the years both in regard to new recruits and continued clients. There appear to be state-wise cultural differences in acceptance of the method in the country; for example, in Orissa the acceptance is very good. Latterly, other states such as West Bengal and Rajasthan are also improving. This may partly be attributed to the program inputs being given to this new method.

The continuation rate of PSS clients for this method ranges between 55 percent and 86 percent. This wide variation is due to regional differences, varied preferences amongst different communities, degree of counseling/follow-up support etc. The maximum number of drop-outs is around the time of the 2nd and 3rd doses, mainly due to sudden alteration in menstrual cycle pattern which are not acceptable to

many clients, despite the counseling given. Clients who pass the 4th dose mostly continue till their desired spacing or sometimes till they reach menopausal age. Some clients have been using this method for over four or five years.

The ratio of DMPA users amongst all contraceptive methods users is 30 percent, and ratio of DMPA users amongst spacing methods users is 48 percent. Sales of OCPs and condoms via social marketing have not been included for these calculations.

Success factors

Success factors include:

- Affordable pricing as current commercial prices are too high for lower income groups
- Strong follow-up services with reassurance and re-counseling concerning the effects of the injectable
- Empathetic approach of the team of service providers
- Periodic follow-up through field visits

Suggestions

Based on its experience with injectables PSS has made the following observations: it is crucial to provide affordable products, availability of good follow-up services improves continuation, investment in promotional activities would greatly help to increase acceptance.

Suggestions for increasing usage of injectables:

- Work towards rapidly creating a 'critical mass' of injectables users
- Work with government to introduce injectables in the public sector

- Promote increased usage of injectables in the private sector by supporting programs such as:
 - ◆ The DiMPA initiative
 - ◆ Current PSS clinics (with promotion and product support)
 - ◆ New franchise operations by PSS in the states of West Bengal, Orissa, Himachal Pradesh and Uttarakhand (on the lines of the Blue Star clinics brand established by PSS with KfW support)

Other observations

Parivar Seva is keen to participate in any further studies/pilots on this contraceptive. PSS is also keen to carry out advocacy efforts to include this additional contraceptive in the contraceptive basket of choices in the National Family Welfare Program. Parivar Seva can take up projects to enhance knowledge, attitude and adoption of this method by the women in different parts of the country.

POPULATION SERVICES INTERNATIONAL

Injectables: when introduced, products provided and geographical coverage

Population Services International (PSI) India promotes birth spacing by creating informed demand and providing a reliable supply of quality, affordable contraceptive products like condoms, oral contraceptive pills, intra-uterine devices, emergency contraceptives and injectable contraceptives in several states. PSI introduced injectable contraceptives in 2002 as one more option among the basket of contraceptive options.

Injectables are being provided since 2002, mainly in Rajasthan. Last year, injectables were also introduced in Uttar Pradesh and Madhya Pradesh on a small scale; their provision is proposed to be expanded.

PSI currently provides DMPA from Star Drugs and Research Laboratories Ltd.

How injectables are provided: service delivery/marketing

DMPA was introduced in Rajasthan through the Saadhan franchisee network of 136 private sector doctors. The Saadhan network was initiated in 2001. At present the network includes about 300 doctors who are providing injectables; in addition approximately 200 doctors not belonging to the network are also buying injectables from PSI. Thus in all, about 500 qualified doctors are now providing injectables. Since 2004, PSI has restricted its injectable contraceptives provision to urban areas. All the doctors in the PSI network stock injectables

The project started with recruitment and training of qualified doctors. This was followed by demand creation for a basket of birth spacing methods including injectable contraceptives. The strategy followed was to restrict supply of injectable contraceptives to those doctors capable of counseling and managing side effects appropriately.

Donors, other partners and their roles

Various contraceptive methods were promoted by PSI under a Hewlett Foundation supported

project during the period 2001-2004; among these were injectables. Hewlett Foundation provided support for various project components including communication, training, research and project staff. During the project the cost of procuring injectables was subsidized by Hewlett Foundation; there have been no subsidies after that project.

Procurement and distribution system, field force

During the Hewlett Foundation project, PSI was sourcing DMPA from Pfizer. Thereafter PSI was supplied by UNFPA till 2007; UNFPA procured the product from Pfizer, Belgium. Since last year, PSI has been sourcing DMPA from the Indian company Star Drugs and Research Laboratories Ltd; the product is given the brand name Procosteron 150.

Distribution Network

- Mfg Unit
- PSI/Warehouse
- Super Stockist
- Stockist
- Health Care Provider/Retailer
- Consumer

Approximately 80 percent of the sales are to doctors and the rest to chemists. The product is placed with chemists to cater to the situation where certain doctors prescribe but do not stock the injectable.

Field organization

The field organization team consists of an Area Network Manager who supervises a team of four or five Network Coordinators. Each Network Coordinator covers three or four districts and details to the doctors in his/her area on the

product and places injectables with them.

Prices and subsidies

Price and subsidy during the Hewlett Foundation supported project

In 2004, when the Hewlett Foundation supported project was ongoing, the product was being purchased from Pfizer at a cost per vial of Rs. 70, and the cost of accessories and packaging was about Rs. 13.60 per unit, hence the total cost was Rs. 83.60. However PSI was providing the product package to Saadhan providers at Rs. 21.97 per unit i.e. at a huge subsidy. A survey at that time showed that 66 percent of clients were being charged in the range of Rs. 32-100 for consultation, vial and injection.

Current prices

Currently, PSI is selling DMPA on cost recovery basis. PSI procures DMPA at Rs 32-35 per unit [inclusive of vial, syringe and needle].

Price to Super Stockist	Rs 50.12
Price to Stockist	Rs 53.88
Price to Retailer	Rs 59.27
MRP	Rs 100.00
Retailer's Percent Profit	69 percent

PSI runs periodic promotion schemes wherein the offer is: buy two units and get one free. Most doctors charge their regular consultation fees over and above the price of the injectable.

Promotion, communication and advocacy

Detailers regularly visit doctors to promote contraceptive use including injectables and EC. Display boards

are placed inside the provider clinics to ensure visibility of method among clients. Interpersonal communication is directed at the community, with the main focus on communities in slum areas.

Providers are required to record the client's consent to being administered the injectable by obtaining her signature or thumb impression. Providers are given small gifts for making the extra effort for this purpose.

“Gatekeeper strategy”. One of the key strategies employed is to promote injectables among clients visiting private doctors for ANC and PNC. PSI sees such clients as an accessible and important group especially since they would be receptive to communication on contraception. This approach is still being followed.

Sales figures and coverage

Injectables Primary Sales 2002-08

2002	2003	2004	2005	2006	2007	2008
6,525	12,160	11,927	18,253	13,850	26,400	28,425

Injectables Secondary Sales 2002-08

Year	Total
2002	3451
2003	4225
2004	455
2005	277
2006	5157
2007	20356
2008	23190

Ensuring service quality

PSI is ensuring compliance of WHO recommended guidelines on screening and counseling by the network doctors before they

dispense the product to the client. For this purpose, Client Record Logs were designed and made available to the providers through a team of detailers. Detailers have been trained on the method and they make periodic visits to the providers to sell the products and provide information using specially designed kits. Regular orientations of these providers on injectables are conducted through reputed subject matter specialists. The Client Record Logs contain information on the woman's medical history and the information that needs to be communicated to her during counseling.

Experiences and lessons learnt

Observations

- Providers are not as diligent about counseling as they should be. There is a need to invest in training for counseling.
- PSI does not have the resources for the requisite promotion activities. Unless project funding is available, PSI cannot invest in promotion.
- A survey conducted during 2003-04 showed that providers felt that even at the relatively low prices at which injectables were offered under the Hewlett Foundation supported project, injectables was considered an expensive method beyond the reach of many.

Suggestions

- Each contraceptive method has its own 'threshold levels'. Hence injectables should be promoted if CPR is to be increased. Promotional efforts should especially focus on the EAG states.

- The “Gatekeeper strategy” should be used to expand coverage; hence special efforts should be made to promote injectables among ANC, delivery and PNC cases.
- There is need to incentivize providers to promote injectables. This is because providers have to make extra efforts to increase the current low awareness levels among clients. Also, providers have to give extra time for proper screening and counseling of clients.
- Efforts should be made to track doctors' prescriptions and to analyze why some prescribe injectables and others do not. Promotion and communication efforts should then be designed and directed at those doctors who do not prescribe injectables.
- There is need to design and invest in appropriate strategies to ensure continuation of use of injectables. It is crucial to provide support and counseling during the early stages of use by a new client. Efforts should be made to prevent dropouts that occur for want of counseling. An unsatisfied user could become a source of negative publicity. A customer care approach should be developed. In addition to personal counseling, establishing a telephone helpline could be useful for providing counseling once a client has started using the injectable.

FPA INDIA

Established in 1949, Family Planning Association of India (now renamed as FPA India), is amongst India's

leading reproductive and sexual health organizations. It provides information on sexuality education and family life and a wide range of services in sexual and reproductive health including family planning. FPA India works closely with NGOs and the Government. FPA India is a member association of IPPF, London. FPA India works through 38 branches covering 18 States and one Union Territory and special projects spread across the country which are assisted by national/international funding.

The Branches manage:

- 37 Reproductive Health and Family Planning Centers (RHFPs)
- 23 Urban Family Welfare Centers (UFWCs)
- 38 Outreach Service Units
- 31 Sexuality Education, Counseling, Research, Training/Therapy Centers

The above centers are supported by:

- 5,448 Community-Based Distributors
- 2,671 Local Voluntary Groups
- 3,483 Peer educators
- 46,934 Grass-root level volunteers

FPA India works with diverse cultures and communities such as tribals in Jharkhand and migrants in Mumbai. FPAI's sexual and reproductive health care services include contraceptives – male and female sterilizations, IUD insertions, oral pills, condoms and injectables; abortion services (incl. medical abortion); gynaecological

problems, male reproductive health problems, infertility, RTI/STI/HIV/AIDS, and other such services. Special emphasis is laid on young people who have been recognized as vulnerable to reproductive morbidity and mortality.

The secretariat of ARC, which till two years ago was hosted by PSS, is currently located at FPAI office.

Injectables provision

- FPA India introduced injectable contraceptive through its network of clinics in 1994.
- FPA India conducted the Training of Trainers for training of doctors on DMPA under the DiMIPA project from 2002 till 2005.
- Currently, FPA India is providing DMPA through all its service delivery outlets and is promoting DMPA use through its network of Mumbai-based private doctors established under the FPA India – NIMA (National Integrated Medical Association) project. The NIMA network comprises of family physicians working on voluntary basis.
- Procurement of DMPA has been decentralized to the FPA India branches/clinics, however the head office provides support to them whenever needed to negotiate lower prices.

Injectables service provision during 2008

As per the year 2008 service statistics of FPA India the injectable DMPA was provided through RHFPs, UFWCs and Outreach

Service Units/Special Projects located in 18 cities (Agra, Bangalore, Belgaum, Bhopal, Bidar, Gomia, Gwalior, Indore, Lucknow, Mumbai, Mysore, New Delhi, North Kanara, Pune, Nagaland and Jaipur) spread across eight States of India

The doctors who are members of the FPAI-NIMA project network are provided injectable DMPA at wholesale rates by FPA India and they, in turn, are free to charge additional consultation fees to their clients while providing injectable DMPA.

During 2008, injectable DMPA was provided to 1082 users who were registered as 'new' users through FPA India clinics. This means that these users have accepted injectable DMPA for the first time through an FPA India service delivery unit, irrespective of whether they were taking DMPA earlier from elsewhere. Seventy four clients who were using other methods of contraception switched over to injectable DMPA during the same year. In the same year 1728 renewal injections were provided.

In addition to above, injectable DMPA was also provided to 94 women as extra protection (for example, female partner of vasectomy acceptor). Outside agencies (such as the FPAI-NIMA project) were provided with 222 vials of injectable DMPA.

A total of 3128 vials of injectable DMPA were sold as 'retail sales' to new and continuing users.

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