Unveiled Realities

A study on women's experiences with Depo-Provera, an injectable contraceptive

A study by Sama - Resource Group for Women and Health

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We dedicate this report to the women's movement, which has been tirelessly fighting for safe contraceptive methods for years, and has provided all of us a platform to come together and raise our voices against injustice to women.

Context of the study

Women's groups, health groups and human rights groups throughout the country have opposed the introduction of injectable contraceptives (Depo-Provera and Net En) given the inadequacy of trials and the lack of conclusive information about their efficacy and potential long-term risks.

The key reasons for opposing injectables are:

1. Severe side-effects;
2. Potential for abuse;
3. Inability of the present health care infrastructure to meet the basic requirements for proper screening, counselling, administration, follow-up and management of side-effects;
4. Comparative and consistent higher expenditure on family welfare, at the cost of larger primary health care issues;

However, in their bid to meet population targets under the World Bank tutelage, and as part of the 'liberalisation' policies, the Indian authorities have in the past few years relaxed Drug regulations, paving the way for the introduction of long acting, invasive and hazardous contraceptives into India. Unchecked over-the-counter sales, misinformed doctors and shallow Post Marketing Studies (PMS) are the harsh realities of this strategy, which is poised to subject millions of Indian women to contraceptives, such as hormonal injectables and subdermal implants, that can cause irreversible damage to theirs' and their progeny's health.

The injectable contraceptive Depo-Provera was approved for marketing in India in 1993 without the mandatory Phase III trials. Instead, the Drugs Controller of India (DCI) asked Upjohn, the manufacturing company, to conduct a PMS. Yet, at the same time as the DCI asked for a PMS, the drug was quietly introduced in the social market.

Women's groups launched an intensive campaign against the introduction of injectables and succeeded in filing a petition in the Supreme Court, seeking a ban on Net En and Depo-Provera. In 1995, the Drug Technical Advisory Board (DTAB), on the direction of the Supreme Court, passed a recommendation stating that Depo-Provera is not recommended for inclusion in the Family Planning programme.

After much lobbying and pressure from women's groups, in early January 2002, the Government finally dropped its plan to introduce injectables for women in the Family Welfare Programme (FWP).

"The Government will not have injectable contraceptives in its programme, though they might be available in the private sector to give women a wider choice." – Sources in MOHFW.

– The Hindu, 4 January 2002

Although injectables have been kept out of the FWP for now, the risk of their inclusion continues to exist. Of late, the upper segments of the society have been extremely vocal about their growing anxiety for population growth. Their anxiety goes to the extent of perceiving population as the reason behind every social evil, and hence the need to control it in a war footing. They are brought up with strong First World views and influences, blindly believing in and upholding their agenda. What is a matter for concern is that these are the sections from which scientists, researchers and doctors come from; these are the sections that control the media and public opinion; and these are the sections that make decisions and author the development pattern of the country. Interestingly, these are also the sections that are loyal guardians of patriarchy and sectarian outlook. So, there is little reason for us to believe that decisions could be taken in the country for greater good or in favour of women, especially the poor and underprivileged women, who are the prime targets for any measure to control population.

Injectables	Commonly known as	Dosage	Manufacturing Company
Depot Medroxyprogesterone Acetate (DMPA)	Depo Provera	150 mg every 3 months	Upjohn Co., USA
Norethisterone Enanthate	Net En	200 mg every 2 months	Schering AG, Germany

At another level, the pharmaceutical lobby, international funding agencies and development banks with their singular motivation for profit, have made population control a condition for loans and grants to Third World governments, and have come to play a significant role in the FWP of countries such as ours. In what can be seen as a response to both the above trends, several state governments, with direct and indirect patronage from the Centre, are already showing signs of aggression by introducing punitive measures against those unable to meet the two-child norm. It is therefore important to recognise the link between the issue of contraceptives, particularly injectables, and issues surrounding population in it's entirety, and to challenge the strident language of population control that is gaining ground in the country.

Need for the study

Women's groups in India have been aware of the controversy surrounding Net En and Depo-Provera in the United States and Britain, where women's organisations and health activists have been raising questions about the health risks associated with long acting hormonal contraceptives and the potential for abuse. However, in India, due to the extreme secrecy surrounding the clinical trials and the decision to introduce these methods, women's groups have always struggled to gather information and data.

Although injectables are not included in the Family Welfare Programme, doctors, whether private practitioners or even those in public hospitals, are prescribing them. Depo-Provera is easily available over the counter, even without a doctor's prescription. In such a situation, it exposes an immense number of women to the risks associated with these contraceptives. However, there is negligible data on the conditions under which these are prescribed, as also on the follow-up and counselling services they provide. Along with examining this, there is a need for a long-term interaction with women who have used Depo-Provera, to document and learn from their experiences with the injectable.

Both manufacturers and propagators of Depo Provera have been using concepts such as 'choice', 'convenience' and 'empowerment' to support the introduction of the injectable in the market and the Family Welfare Programme. On many occasions the government too announced that the central idea behind introducing Depo in the Family Welfare Programme – along with other injectables and implants – was what it called a 'cafeteria approach', in order to provide a 'wider choice' to women. From time to time, a number of pro-birth control institutions and NGOs have talked about a 'basket of choices'.

Women's groups involved in the campaign against new reproductive technologies have consistently been raising their voices against the sudden concern of the establishment – which is otherwise intensely anti-women – for 'women's choice'. Why a choice in contraception alone, they argue; why shouldn't women be given choices in employment, food, education, access to health care, civic amenities, or, at a more basic level, to have equal rights as men in the family and society or to not be killed in the womb?

For us, the study was also important because we wanted to give voice to women's own experiences, their perceptions about fertility control and place women's decisions within the context of their family dynamics and complex realities. While studies on the fertility of Third World women are numerous, very few have tried to understand what women themselves feel about fertility control. Most studies implicitly seem to hold women responsible for their lack of control over fertility without understanding the reality of women's lives and the compulsions they are subjected to. Of late, however, there have

been some initiatives to determine women's responses to fertility control and our study was conceived against this backdrop.

When we decided to undertake the study and began talking with women on the issue of injectables, we found to our utter dismay that in spite of the Supreme Court's recommendation and the Government's announcement against inclusion of injectables in the FWP or continuing trials, a public hospital in Delhi had been providing women from resettlement colonies with Depo-Provera. The hospital had received the stock of Depo directly from Pharmacia & Upjohn. This led to the decision to undertake a focused study on the procedures of administration, screening, follow-up and impacts of the injectable as experienced by the women.

Specifically, the objectives of the study were:

- To study and analyse the screening, follow-up and counselling procedures followed by the public health professionals and institutions while providing Depo-Provera;
- To assess the medical establishment's response to the health problems following the use of the injectable;
- To assess the impact of the use of these contraceptives on the health of the women;
- To explore what commercial interests lie behind the development and propagation of new contraceptive technologies;
- To understand the nuances and complexities of the decision making process within a family regarding the adoption of injectables;

Such a study, we hoped, would also enable us to understand how the concept of informed choice operates within the public health set-up and about the procedures regarding the procurement of injectables.

Methodology

At the outset, we felt it was extremely important to review a number of public hospitals, since these are the institutions that directly implement the FWP and have a wide outreach. Among the public hospitals that were prescribing injectables, two hospitals refused permission for the study. The study was finally undertaken only with one public hospital, which had administered Depo-Provera on 167 women between October 1999 and June 2000. According to hospital sources, the administration of Depo was discontinued due to the lack of supply of the injectable.

The objectives of the study were explained to the hospital authorities. Permission was sought to talk to the doctors, medical assistants and women patients visiting the OPD. Before interviewing the women, the team obtained permission from the hospital in writing. It must be acknowledged here that when the study team explained the objectives of the study, the hospital authorities and the staff were extremely cooperative and supportive.

The study team traced the women based on a list provided by the hospital. Some of the women who came to seek treatment at the OPD also provided information on women who they knew had been using "the injection". Initially the team faced many difficulties in locating the women. Constraints such as difficulty in tracing addresses, changed residences, incomplete addresses, etc., left us with a sample of 50 women. Among them, 38 (76%) were Hindu and 12 (24%) Sikh. Even though the sample size was small, we still felt it was important to go ahead with the study, as it was important to get a first-hand account of the women's experience with Depo, and to know directly from them how they were provided with information, how they perceived the side-effects, and what kind of follow-up services were available to cope with these. We also felt that the findings from even a small sample, would be able to provide at least an indication to what the larger picture could be.

The interview schedule was prepared in consultation with experienced medical and social science researchers and health activists. An initial interview schedule covered socio-demographic characteristics, obstetric and contraceptive history, side effects, informed consent, decision making in the family and perceptions regarding the method. After pre-testing it with five women, the questions were carefully reviewed for their appropriateness and further refined. The study team was oriented on the study objectives, methodology, procedures, observations, ethical issues and a detailed review of each question, so that all the team members fully understood the background behine0each question, how to ask these and how to record the answers. It was ensured that the investigators were fluent in both Hindi and Punjabi, as these were languages all the women were comfortable with.

The study made use of individual interviews and focus-group discussions. Personal in-depth interviews, more than once with each woman, were conducted after explaining the purpose and nature of the study. The length of the interviews varied from one to two hours. Generally two to three women a day were interviewed. The study followed the ethics of ensuring privacy and confidentiality of the women. Confidentiality of information was not only assured, but also strictly respected and maintained.

Some of the women were from the same neighbourhood, and they knew about each other's experiences. During group discussions, women felt comfortable as the group

setting was in their own locality and most of them came from similar cultural background. Women discussed very personal information without inhibition as they had all experienced similar side effects and felt connected to each other. These discussions were informally structured with a checklist of open-ended questions. The focus-group discussions lasted for three to four hours.

In the subsequent follow-up after data collection, a counselling session was undertaken with each woman, in which she was provided with an opportunity to learn about various reproductive health issues, contraception and also the debate around injectable contraceptives. For most women, this was the first time that they underwent such an experience, which they felt was very useful. We felt that women should be provided information and referrals for the problems that they were suffering from, so that they could seek treatment. The initial findings of the study were also shared with the women.

Findings

Section 1

Profile of respondents

I. Socio economic profile

Data pertaining to age, formal schooling level, occupation and details of the family were collected for all the women interviewed.

a) Age distribution of women

All the women included in the study were in the age group of 21-40 years. A majority of them (43 out of 50) were in their prime reproductive period – between 21-30 years – a period when they are most likely to need and adopt one method of contraception or another.

Age	No. of women	%
21-25	23	46
26-30	20	40
31-35	5	10
36-45	2	4
Total	**50**	**100**

b) Educational level of women

A profile of the educational levels shows a varied range, from no formal schooling to post-graduation. However, a majority (26 out of 50) had studied beyond 10th standard, with 12 completing graduation.

If education is seen as an indicator of overall status and empowerment, this group can be perceived to be fairly priviledged when compared to the vast majority of women in the country.

Living in a metropolis like Delhi and having a relatively higher level of education, this group can also be expected to be more aware, and thus, in a better position to access information, weigh pros and cons to make decisions and negotiate with their spouses and families.

Education Levels	Number	%
Unlettered	4	8
Up to 5th	3	6
Up to 10th	12	24
Up to 12th	12	24
Graduation	12	24
Post-graduation	2	4
No response	5	10
Total	**50**	**100**

c. Distribution of women and men according to occupation

More than two-thirds of the women (38 of 50) were not employed, 6 were self-employed, 4 worked as domestic servants while 2 were in salaried occupations. Most of the women were living in extended families and economically dependent.

The occupation profile of the husbands shows that they were largely salaried employees and 40% were engaged in trading and business.

II. Obstetric History

To know about the obstetric history of the respondents, data pertaining to conceptions, live births, abortions, miscarriages and information about their children were collected.

a. Total number of conceptions

40% of the women had two conceptions, while 36% had three or more. It indicates that there was a felt need for contraception.

Conceptions	No. of women	Total Conceptions
1	12	12
2	20	40
3	8	24
4	7	28
5	3	15
Total	**50**	**119**

No. of children	Women with live children	Total Live Children
1	19	19
2	25	50
3	4	24
4	2	8
Total	**50**	**89**

b. Total number of children alive

The 50 women had a total of 89 live children, which is an average of 1.78 live child per woman.

c. Total number of induced abortions (MTP) in the reproductive period

Among the 14 women who had abortions, 3 women aborted for medical reasons. However, the rest did not disclose the reasons behind it.

No. of abortions	No. of women	Total abortions
0	33	0
1	12	12
2	1	2
Not disclosed	4	0
Total	**50**	**14**

d. Total number of miscarriages during the reproductive period

There seemed to be a high incidence of abortions and miscarriages among these women. One respondent had as many as 4 miscarriages. Many of the women spoke of having miscarriages, but could not articulate clear reasons for these. Two women felt that the miscarriages were the result of weakness.

Miscarriages	No. of women	Total Miscarriages
0	37	0
1	8	8
2	3	6
3	0	0
4	1	4
Not disclosed	1	0
Total	**50**	**18**

No. of male children	No. of women	Total male children
0	15	0
1	22	22
2	10	20
3	3	9
Total	**50**	**51**

e. Total number of male children

30% of the women had no male children. However, they expressed a strong desire to have a male child.

f. Total number of female children

26 women had one female child, while 6 had two female children. However, none had more than 2 girl children. There is a visible difference between the total numbers of male and female children (51 as against 38).

No. of female children	No. of women	Total female children
0	18	0
1	26	26
2	6	12
Total	**50**	**38**

Section 2

Ethics, guidelines and practice

Depo-Provera is not a simple formulation. Explained in very simple terms, it contains a progestin, similar to the natural hormone that a woman's body makes, which is released slowly into the bloodstream. It prevents pregnancy by inhibiting ovulation, thickening the cervical secretions making it difficult for sperm to pass through, changing the rate of ovum transport through the falopian tubes and making the endometrium less suitable for implantation (WHO, 1990). In the process, however, it manipulates and disrupts many of the natural hormonal functions in the body, giving rise to a series of complex side effects. In fact, initial tests of DMPA on animals showed such a high incidence of breast cancer, the Food and Drug Administration (FDA) in the USA took several years to approve it for human use.

The side effects of this long-acting injectable are still numerous, many of which are established; some of which are known, but yet to be established due to lack of long-term studies; some are not known at all. Thus, like other complex drugs, Depo too has a battery of complex procedures, precautions and strict do's and don'ts attached to it. Bodies like the WHO, or institutions such as the Johns Hopkins University, Indian Council of Medical Research, etc., have formulated elaborate medical guidelines on the use of Depo-Provera. Many ethical guidelines too have been formulated and upheld by several international conventions.

One of the primary objectives of this study was to see how effectively were these guidelines respected and practiced in a situation where a public health set-up was dispensing Depo-Provera – a concern that women's groups have consistently raised on the question of large-scale use of Depo-Provera through the Family Welfare Programme.

I. Informed choice

The 1994 International Conference on Population and Development (ICPD) Programme of Action states the following:

> *"... the aim of family planning programs must be to enable couples and individuals to decide freely and responsibly the number and spacing of their children and to have the information and means to do so and to ensure informed choice and make available a full range of safe and effective methods."*
>
> *– ICPD Programme of Action, para 7.3*

Informed choice refers to ensuring that each user has the information about methods and services – including their risks and benefits – that enables clients to make a fully informed decision about whether to obtain or decline treatment or services: which contraceptive method, treatment, or service to select; and whether to seek and follow-up a referral. The process of ensuring informed choice for contraceptive use involves considering a wide range of factors that could affect the person's method choice.

– From various sources

What the study shows

1. "Ensuring the user has information about methods and services"

- 31 out of 50 women were given no option other than the injection.
- 17 were given only one other option. 7 women were given Tubal Ligation (TL) as an option. Since TL is a permanent method, it is not surprising that women will opt for the other alternative, no matter which one it is. 10 women were given Intra-Uterine Device (IUD) as the other option.
- The remaining 2 were given two options: pills and IUD and IUD and TL.
- Those who were given a few other choices, still chose the three-monthly injection (once in 3

What is meant by Informed Choice?

When a person freely makes a thought-out decision based on accurate, useful information, this is an informed choice. One important purpose of family planning counselling is to help the client make informed choices about reproductive health and family planning.

***Informed** means that:*

• Clients have the clear, accurate, and specific information that they need to make their own reproductive choices including a choice among family planning methods. Good -quality family planning programmes can explain each family planning method as needed – without information overload-and can help clients use each method effectively and safely.

• Clients understand their own needs because they have thought about their own situations. Through person-to-person discussions and counseling and through mass media messages, good-quality family planning programmes help clients match family planning methods with their needs.

***Choice** means that:*

• Clients have a range of family planning methods to choose from. Good - quality family planning services offer different methods to suit people's differing needs - not just 1 or 2 methods. If programmes cannot provide a method or service, they refer clients somewhere else for that method.

• Clients make their own decisions. Family planning providers help clients think through their decisions, but they do not pressure clients to make a certain choice or to use a certain method.

– The Essentials of Contraceptive Technology, Johns Hopkins Population Information Programme, Pages 3-3

months) because it seemed to be more convenient in comparison to taking pills everyday, or inserting an IUD.

2. "Ensuring each user has information about ……risks and benefits"

- 42 out of the 50 women were not told about the probable side effects of Depo-Provera.
- Of the 8 women, 4 were told that they might have changes in their menstrual cycle (no menstruation or some other complication), 1 was told that there could be fever and dizziness, while one was simply given a handout, without ascertaining whether she has read it or not.
- 2 women said that they did not remember what or whether the doctor told them anything.

R, one of the women we interviewed, told us:

> *"The doctor never gave me any other option. She told me that this injection prevents pregnancy and is very effective."*

While another repondent, M, said,

> *"When I came to know from a friend that a 'teeka' (injection) is available in the hospital, I requested the doctor to give me the 'teeka'."*

However, neither of them was informed about any side effect before they were administered with the injection.

Those who were given any information, were told in an off hand manner, minimising the gravity of any possible effect: "their might be some problem, but don't worry."

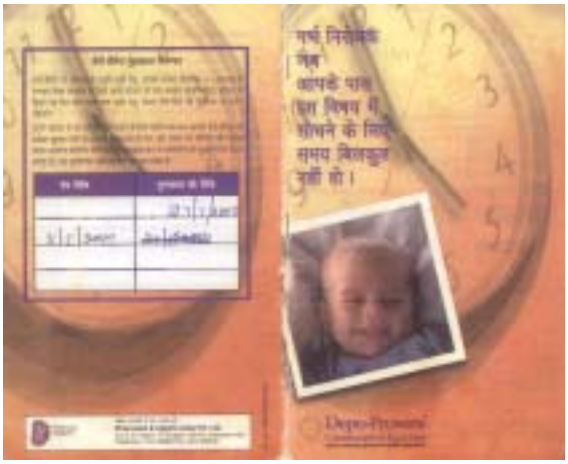
What must be told about side effects

Clients must be given adequate information about possible side effects and feel comfortable in seeking assistance if they encounter problems.

– WHO 1990

44% of the women, i.e., 22 out of 50, were provided with a **handout** after being administered with Depo-Provera. The rest never received any handout or literature. The manufacturers supplied the handouts to the hospital along with the samples of Depo for distribution to the recipients. The handout, a six-page booklet in Hindi, begins by congratulating the new mother. The following pages talk about why Depo is the right choice for contraception. After repeatedly highlighting the 'safety, effectivity and convenience' of the injection, it mentions the possibility of menstrual irregularity, the need to have calcium rich diet, control weight, exercise, and finally, the need for the mother to look after herself along with caring for the baby. The back cover of the handout contains a table for filling up the date of administration and future due dates.

However, nobody claimed to have read the handout. Some tried to read it but either could not understand the content, or could not relate with the information given in it. Since the handouts were given only after administering the injection, they did not play any role in the decision making process of the recipients. Many of the women in this study felt that the purpose of the handout was essentially to remind them about the date for the next dosage.



According to K,

> *"I was not asked to read the handout and then decide about the injection. It was given to me after administration. Once I came back home, I stored it along with my ration card and other important documents in the trunk (chest).*

Another respondent, P, told us,

> *"I thought it is like a chart where you write the dates of the 'teeka' (injection), because they have provided such a table on the back page of the handout."*

On examining the handout more closely, we found that the literature in the handout was translated into Hindi from one of Upjohn's original English handouts without any adaptation to the local context. The language used in the translation is difficult. Moreover, the pictures and information in the handout clearly cater to Depo users in

the USA. Even the information provided in the handout is very limited.

1. It does not mention the need for screening before taking Depo.
2. It does not talk about contraindications at all.
3. The few side effects mentioned are sketchy. Importance has been given only to weight gain.

The language used to explain the side effects puts the onus of post-injection problems on the user. This absovles the provider from taking any responsibility.

The introduction of the handout welcomes the reader with a note of congratulation on the birth of a child. This implies that Depo is being portrayed as a contraceptive for women who have just given birth, i.e., as a method for spacing. By doing so, it excludes women or adolescents who would like to use Depo only as a contraceptive method, irrespective of motherhood.

Moreover, the incomplete and inadequate information in the handout is bound to mislead the user. If the latter has to make a decision on something as crucial as an injectable contraceptive that is going to act inside her body; correct, complete and detailed information is not only an ethical requirement, but her right.

Thus, based on our findings related to the issue of informed choice, it can be concluded that by and large there was no informed choice as most of the women were not informed about other methods of contraception that they could use, the potential advantages and disadvantages of each, or the probable side effects that this injectable could cause.

II Screening

What kind of screening is mandatory?

Women should be medically screened, if possible examined, and thoroughly counselled by trained personnel before they are given injectable contraceptive.

– WHO 1990

The pretreatment and annual history and physical examination should include special reference to breast, and pelvic organs, as well as a pap smear.

– Depo-Provera package insert, Pharmacia

The study showed that

Tests Performed	No.	%
BP	1	2
BP + Weight	9	18
BP + Pelvic Exam	2	4
BP + Weight + Pelvic Exam	6	12
Pelvic Exam	6	12
Breast Exam	0	0
Pap Smear	0	0
No Tests	26	52

- No screening was done for more than half, i.e. 26 women out of the 50.
- Not even one woman went through all the stipulated screening tests.
- The maximum number of tests any woman went through was 3, which included blood pressure (BP), weight and pelvic examination, and 6 of the women were screened for these.
- The ones who were screened, did not undergo all the tests required. In fact, most of them were routinely screened only for BP and weight.
- None of the women went through a breast examination or pap smear.

It is essential to have a thorough screening before administering Depo-Provera. This should include detailed personal and family history, checking of blood pressure and weight, gynaecological examination and a pap smear. Pap smear is important to make sure that a woman is not going through any risk of infection. A pelvic examination before administering ensures that the woman is not already pregnant at the time of injection. It is equally important for administering subsequent injections, as some women might have contraceptive failure. A breast examination before the injection ensures that the woman is not having any breast nodule.

In our study, more than half (52%) of the users were not screened at all. Some of them had come to the hospital with a doubt of pregnancy or for an abortion. They were examined by the doctor (mostly an internal examination, as is required in such cases). It is important to note that pelvic examinations in these cases were not done as a part of the screening for Depo. In the case of S, she approached the hospital for an abortion and she had a pelvic examination by virtue of this. Immediately after the abortion, she was advised to take Depo.

Any medical drug creates certain reactions in the body's metabolism which are manifested as side effects. This makes it necessary for manufacturers to provide detailed instructions about contraindications and complications. It also requires providers to strictly follow such directions and warnings. Ignoring them means exposing the user to unnecessary risk and complications.

The findings pertaining to screening point towards serious lapses on the part of the providers, which could lead to irreversible damage to the health of the women.

III. Contraindications

Things to consider before choosing Depo-Provera

Before your doctor prescribes Depo-Provera, You will have a physical examination. It is important to tell your doctor, if you have had in the past any of the following conditions:

- Migraine, headache
- Diabetes or family history of diabetes
- Severe pain or swelling in the calf (indicating a possible clot in the leg, which may be called phlebitis)
- Post pulmonary embolism or stroke while using Depo-Provera
- Problems with your eye sight while using Depo-Provera
- Past history of depression
- Problems with your liver or liver diseases. History of heart diseases or cholesterol problems including any family history
- If you have recently had a hydatidiform mole which is a type of abnormal pregnancy.
- Taking other medicine
- Tell your doctor if you are taking aminoglutethimide as this may affect the way your Depo-Provera works.

– Depo-Provera, Patient information, Pharmacia & Upjohn, March 1998

Our study shows that

- 8 out of 50 women had a family history of diabetes.
- 7 out of 50 had a history of heart disease in the family.
- 11 of the women had migraine.
- 7 of them had jaundice.
- 6 were administered Depo although they had heavy bleeding.
- 5 women had a history of abnormal pregnancies.
- 8 women had hypertension.

31 women with such histories were administered Depo. One woman was administered Depo although she had hypothyroid. Another with uterine fibroid was given Depo.

"When my younger child was born, I had very high blood pressure. That is why I had a caesarean delivery. Even my parents have problems of high blood pressure. My father is diabetic as well. Still, I was advised to use Depo soon after my delivery".

The literature accompanying Depo clearly states that there are certain medical conditions that the doctor should inquire into before deciding whether or not a woman can be administered the injectable. This is because the changes that Depo creates in the body metabolism can have an adverse effect if the woman is prone to these conditions. It therefore requires intensive follow-up to monitor any possible sign of worsening of these conditions.

S.No	History of illnesses		No. of women
1	Hypertension		8
2	Family history of heart diseases		7
3	Diabetes		8
4	Jaundice		7
5	Calf pain		1
6	Migraine		11
7	Heavy bleeding		6
8	History of abnormal pregnancy		5
9	Any other	Fibroid	3
		Thyroid and Goitre	1
		Asthma	1

In order to diagnose any of the above conditions, there are specific prescribed tests, such as sugar and urine test for diabetes, liver function test for liver dysfunction. There are also specific tests for cardio vascular and thromboembolic disorders. It is also very important to have a detailed history of both the individual and her family for diabetes. However, in an OPD set-up, with the usual rush of patients and limited time for each patient, it seems impossible to imagine that all the required details will be inquired into and all the necessary tests undertaken. Moreover, in the absence of sophisticated equipment, facilities and skilled medical personnel, proper screening seems to be a remote possibility.

In a situation where the family planning workers themselves do not have adequate information to share with the users, one wonders how women are expected to judge and compare methods in order to make an informed choice.

IV. Conditions for administration of the injectable

Medical Eligibility Checklist for DMPA Injectable

Ask the client the questions below. If she answers NO to ALL of the questions, then she CAN use DMPA if she wants. If she answers YES to a question below, follow the instructions.

1. Do you have problems with your heart or blood vessels? Have you ever had such problems? If so, what problems?

☐ No ☐ **Yes** ▸ Do not provide DMPA if she reports *heart attack, stroke, heart disease due to blocked arteries, severe chest pain with unusual shortness of breath, severe high blood pressure, diabetes for more than 20 years, or damage to vision, kidneys, or nervous system caused by diabetes*. Help her choose another effective method.

2. Do you have severe cirrhosis of the liver, a liver infection or tumor? (Are her eyes or skin unusually yellow?)

☐ No ☐ **Yes** ▸ Perform physical exam or refer. If she has serious active liver disease (*jaundice, painful or enlarged liver, viral hepatitis, liver tumor*), do not provide DMPA. Refer for care. Help her choose a method without hormones.

Excerpt from "The Essentials of Contraceptive Technology," Johns Hopkins Population Information Programme, Page 7-6

1. When to administer ?

It is recommended that this injection be given only during the first 5 days after the onset of a normal menstrual period.

– Upjohn literature under "Dosage & Administration"

The initial injection should be given during the first 5 days of the menstrual period.

– WHO 1990

The study showed that

- providers did not take into account any information about the menstrual cycle of women before administering Depo, flouting Upjohn's own literature;
- providers did not check if any of the women had a normal menstrual cycle;
- also, none complied to the requirements of administering Depo to the users during the first five days of the onset of menstrual period;

- even while administering the first dosage, providers did not ask the user the date of her last menstruation;
- Depo was administered even when the women were not having a regular menstrual cycle;

2. Contraindicated period

An injectable can be given immediately after an abortion, but should be delayed for 6 weeks after childbirth.

– WHO 1990

... it is recommended that this injection be given only during the first 5 days after the onset of a normal menstrual period; within 5 days postpartum if not breast-feeding, or, if breast-feeding, at 6 weeks postpartum.

– Pharmacia, Package insert

The 6 weeks contraindicated period is specified to ensure that no traces of the injectable is passed on to the child through breast milk. However, the study shows that 3 women were given Depo within the contraindicated period. One of the respondents, S, was administered the injection three days after delivery. R was given Depo on the same day as she delivered a child. G was administered Depo five weeks after delivery, when she was still bleeding heavily. All of them had been breast feeding. The fact that in spite of the instructions provided in Pharmacia's literature, women were given the injectable during the contraindicated period, demonstrates the lack of knowledge of the providers.

The specification of the contraindicated period also raises some important questions. Firstly, it is difficult to understand why Pharmacia includes the clause within 5 days post partum if not breast-feeding when world over there is a rising consciousness about the importance of breast-feeding the new born.

Secondly, the WHO has specified the contraindicated period to be 6 weeks after childbirth. This is so because western women breast-feed their infants only for 6 to 12 weeks. In India, however, women feed their infants for up to 2 years, with breast milk outputs of 300 ml to 600 ml. Even though this is not enough for infant nutrition, after 6 months this volume is adequate for carrying all the unwanted drugs to the baby. Due to such differences in the local contexts, the contraindicated period should not be generalised.

Finally, there are not many studies on the long-term side effects on progeny, which have looked into the effects on the children exposed to Depo through breast milk.

Effect on breast feeding infants

- Depo-Provera is carried full strength in breast milk; more in the first months after an injection than in later months. It is not known how much of it is absorbed by the feeding infant and how much just passes out of his/her body. Most important, it is not known what the long-term effects on children might be. Most of the 'experts' agree that infants should not be exposed to Provera during the first 6 weeks after birth, when they are most likely to be affected by it.

– Sathyamala 2000

Implications for the health of lactating women

- Studies on Depo-Provera have so far concentrated on the effect of breast milk on the growth and development of infants. Little attention has been paid on the effect of Depo-Provera on the health of the lactating woman. It is our contention that administration of Depo during lactation could have a serious adverse effect on the health of the breast feeding woman because of its association with demineralisation of bone.

– Sathyamala 2000

3. How to administer

The injection site should not be massaged as this may accelerate the absorption rate of the steroid.

– WHO 1990

The study shows that

- Almost all the women massaged the injection site after receiving the injection.

In the Indian context, it is a normal practice to massage the injection site, since it is perceived that massaging makes it easier for the medicine to go into the body. No one was warned about the harmful effect of massaging the injection site.

4. Minimum Facilities

Recommended literature states certain minimal mandatory facilities in terms of the setting, as well as prescribes specific conditions and procedures under which the injectable should be administered.

The administration of hormonal injectable contraceptives requires a few facilities other than those normally associated with a field clinic. Thus a modest clinic facility for administering injections should contain:	
a)	A waiting area for clients
b)	An examination area where the health worker can counsel clients on the use, effects and side-effects of injectable contraceptives. As part of the counseling process, the potential acceptor should also be given similar information about other available methods of contraception. If possible, a suitable area where physical and gynaecological examinations can be carried out, and an area where the injections can be administered, should also be available;
c)	A cool, secure, well-ventilated storage area for keeping supplies at a temperature of less than 30 degrees;
d)	A suitable, secure office area for taking notes and keeping client records;
e)	Suitable washing facilities for clients and staff.
The facility should be large enough to accommodate the anticipated number of clients.	
– Organizing and managing a programme, Injectable Contraceptives, WHO (Geneva)	

The study findings indicate that **none of these norms** have been adhered to, and that a clear hiatus exists between prescribed norms and the actual administration of Depo-Provera, a concern that has been expressed over and over again by the groups campaigning against the new reproductive technologies.

Side effects

I. Side effects experienced by women

In the course of the study, almost all the women complained about a wide range of side effects that they experienced after being administered with Depo-Provera. We felt it is important to look into these in detail, because time and again, the manufacturers and propagators of Depo-Provera reiterate the safety, efficacy and convenience of the drug.

> ***Upjohn's PMS***
>
> The Post Market Surveillance study by Pharmacia & Upjohn included 1079 women enrolled from 10 centres in India from June 10, 1994 to December 31, 1997. In this study, each subject was given Depo for a period of 12 months and was followed up for a total period of 15 months. Among 1079 women, 72 women discontinued. According to Dr. Soonawala, the primary investigator of the study, these women have discontinued due to non-serious medical events such as spotting, irregular bleeding, amenorrhoea and prolonged menstruation.
>
> *Ref: PMS study in injection Depo-Provera, Final report, Pharmacia & Upjohn*

Even in a short-term study conducted with the women using Depo only for two years, the ramifications of the injectable were numerous. It is difficult, if not impossible, to ascertain what the long-term side effects would be. However, there are no long term studies on Depo that have been conducted in India. Even the post market surveillance study by Upjohn was conducted for three years, where the women were given Depo for one year and were followed up for fifteen months.

However, several longitudinal studies conducted elsewhere have highlighted the long-term side effects of injectable contraceptives, excerpts of which we have tried to compile in a later sub-section of this chapter.

What the study shows about side effects experienced by Depo users

It was understood from the study that 43 women out of 50 were in the reproductive age group. Two women did not experience any problems. 48 women reported problems after using the injectable and each woman had multiple problems. 26 of the women reported 5 or more problems, with one experiencing up to 13 problems. Thus, out of the sample, 96% had problems with the injection. The most common problems reported by women in the study were amenorrhoea (25), weakness (20), excessive bleeding

(16), headache and migraine (13), hot flushes (10), weight gain (10), hair loss (9), dizziness (9), lack of sexual desire (8).

Some women could not associate problems like headaches, weakness, etc., as side effects of the contraceptive. Many surrendered to the fact that they would have to suffer some discomfort or the other if they used any contraceptive. So they accepted some of the side effects like vaginal discharge, headache, weakness, etc.

L shared with the research team,

> *"I have a three year old daughter. She was born in 1998 and six months after that, I conceived again. I went for an abortion, as my daughter was still very young. After the abortion, I got a Copper-T inserted. But it was quite problematic and uncomfortable. Moreover, in spite of the Copper-T, I conceived again. So I got the Copper-T removed and had another abortion. Then the doctor informed me about the injection. There was no check up done before they gave me the injection. I took two injections. After the second injection, my menstruation stopped for a month. But when I got my periods, I was bleeding for 1 1/2- 2 months continuously. It would stop for one or two days, and start again. For nearly two months it carried on like this. I used to feel very weak and tired. I also had severe cramps. I felt that the injection was not suiting me.*

Problems	No. of women	%
No menstruation	25	50
Weakness	20	40
Swelling of ankle/wrist	5	10
Excessive bleeding	16	32
Hot flushes	10	20
Vaginal discharge	13	26
Irregular bleeding	12	24
Lack of sexual desire	8	16
Pain during intercourse	2	4
Headache and migraine	13	26
Dizziness	9	18
Backache	9	18
Weight gain	10	20
Palpitation	7	14
Hair loss	9	18
Leg cramps	7	14
Difficulty in sleeping	4	8
Digestive disorder	2	4
Darkening of skin/acne	3	6
Abdominal pain	5	10
Depression	6	12
Pelvic/breast pain	3	6
Problem with eyesight	4	8
Joint pain	2	4
Nervousness	2	4
Nausea	2	4
Bloated feeling	3	6
Any other	10	20

When I went to a private doctor, he asked me to discontinue the injection. He also said that if I had continue to take the injection, there was a possibility of not conceiving again. My mother-in-law was worried that I might never conceive again. Now she feels I should have another child."

Amenorrhoea

25 women in the study experienced the side effect of amenorrhoea, which is a complete absence of menstruation. It lasted for an average of 5 to 7 months to a maximum period of 18 months. Many women feared that they were pregnant, with some going for pregnancy tests.

As N said,

"My periods stopped soon after the injection. This caused a lot of worry and mental tension, as I thought I was pregnant again. I was very tense. Then I got a pregnancy test done. I was relieved when the report was negative. However, I had to spend money for the test."

Women who had taken Depo particularly to avoid pregnancy went through a lot of anxiety and tension. The stress and tension was more for those women who took the injection without the knowledge of husband or other family members.

According to P,

"I took the injection without informing my mother-in-law. Since I was not getting my periods for many months, she suspected that I was pregnant. But later when she discovered that I was on injection, it created a lot of tension in the family."

Apart from the social problems, many women reported that they were feeling bloated, heavy and often lethargic. They perceived the lack of periods as "abnormal and unhealthy."

Narrating her feeling, F said,

"Since I was not bleeding at all, the blood was stored up inside my body, which is not healthy. That could be one reason why I put on weight."

According to D,

> *"My skin started becoming dark because I did not bleed for many months".*

Some associated changes in pigmentation and discolouration of skin with amenorrhoea.

One of the respondents, M, said,

> *"When you are constipated, you feel uncomfortable and irritable. It is the same with menstruation. If you don't menstruate for months together, you feel fatigued and irritable. And this stored up blood also generates a lot of heat in the body".*

Women associated the other side effects with amenorrhoea and insisted on the importance of regular menstrual cycle.

There are sufficient grounds to disagree with the 'experts' as well as the manufacturers, who in many documents suggest that these are not serious side effects, but are subjects of 'counselling'. In fact, the manufacturers of Depo suggest that amenorrhoea is beneficial for women who otherwise suffer from anaemia.

These pronouncements have absolutely no scientific basis. The truth is, each of these 'common' side effects is a symptom of a serious malady, which is untreatable and pushed aside due to a one-track motive of promoting the drug.

Amenorrhoea is a reflection of the state of endometrium in the users of Depo-Provera. In the absence of priming with oestrogen, continuous administration of a progestin in sufficient dose is known to abolish the menstrual cycle for as long as it is given and leads to ovarian and endometrial atrophy (Goodman and Gilman 1985).

A WHO technical report admits that the administration of injectable progestogen results in endometrial atrophy (WHO 1971).

– Sathyamala 2000

Heavy Bleeding

16 women reported heavy bleeding as another side effect. Among the 16, 5 had heavy and prolonged bleeding for a period of 20 to 60 days. Heavy bleeding was also associated with weakness and giddiness.

One of the women in the study, G, told us,

> *"Earlier I used to have regular periods and normal bleeding. But now I bleed heavily and for several days. I feel weak and tired. I find it difficult to carry out all the domestic chores."*

Women experienced – and are still experiencing – the trauma and embarrassment associated with heavy bleeding.

According to S,

> *"In April 2000, I took the injection. After that, my periods begun and they are still going on. Sometimes the bleeding is less, but it never stopped. I live in a joint family. Sometimes in front of my father-in-law and brother-in-law I start bleeding, as if a tap has been opened. My clothes become soiled. They have to turn their faces away and my sisters-in-law take care of me. It is so embarrassing. I also have leg cramps, backache and stomach pain. Moreover, it has affected my sexual life terribly. How can I sleep with my husband when I am bleeding so heavily?"*

Heavy bleeding also has a tremendous bearing on women's productivity, in a country where women spend eighteen hours of the day working in the fields or at home. For undernourished women, heavy bleeding can be particularly serious because of iron deficiency and blood loss.

Similar findings were also reported from a study conducted on 138 women in Calcutta *(Mukherjea M. et al. 1980),* according to which the discontinuation rate due to severe menstrual disturbance was very high. Almost 32% of women discontinued after the first injection and another 38.8% before receiving the third dose.

Weight Gain

- An early trial among 138 women in Calcutta reported mean weight gains above 4.0 kg at 1 year, and above 6.0 kg at 2 years.

  – Mukherjea et al. 1980

- A WHO multicentred Phase-III clinical trial of DMPA reported a mean weight gain of 1.5 kg per year.

  – WHO 1986

- Most of the users gain 1.5kg - 2kg in the first year. The extra weight is mainly from fat rather than water retention.

– Population Reports 1996

20% of the women associated with this study put on weight after using Depo-Provera. Some of them could not fit into their existing clothes, while some weighed themselves to note the weight gain. The range of weight gain was between 10 to 30 kg. For instance, T was 60 kg after her second child was born. After taking three injections in a space of 9 months, she weighed 83 kg, thereby gaining 23 kg. Similarly, P experienced a weight gain of 10kg in nine months. Some others gained 20 kg in six months.

> Many women experience weight gain or loss with Depo-Provera. Whilst most doctors know you might gain weight, fewer are aware that you could lose weight instead, and we don't think the new license mentions weight loss either. The majority of women, whose weight changes, gain or lose up to 10 pounds (4.5 kilos). Weight changes seem to get worse the longer a woman is on Depo-Provera. Some women have said their appetite increases on the drug, yet neither diet nor exercise necessarily made any difference. Several women have found they could not lose all the weight they had gained, even after stopping the drug. Major weight changes may be the result of disturbances in our metabolism, which can have long-term health consequences, but there has been almost no research on this with Depo-Provera. Weight changes are not considered a serious problem by most researchers, and are rarely listed as one of the adverse effects of the drug. Women, however, feel very differently about this. It has been even said that for women who are underweight from malnutrition, weight gain caused by Depo-Provera is a good thing. This statement has been made to justify the use of Depo-Provera in the Third World on poor women. It is one of the worse examples of the hypocrisy involved in recommending this drug – saying it helps to mask a serious health condition, while in fact, the weight gain could even make the effects of malnutrition worse.
>
> *– Berer 1984*

During individual interviews with the women we asked them if they gained weight gradually over time or suddenly within few weeks of time. Most of the women said they had put on weight within few weeks. They were afraid of water retention in the body.

According to P,

> *"After the injection, I put on 10 kg. When I told the doctor, he said that this was not weight gain but healthy growth. When I complained about scanty bleeding, he said that menstrual blood is pure, so the less one menstruates the better."*

S shared with us,

> *"After taking the first injection, I experienced a tremendous weight gain. Before the injection I weighed 53 kg. But within a very short period, especially after my third injection, my weight went up to 70 kg. I also suffered from hair loss, joint pain and extreme tiredness. I am unable to work. However, weight gain has been my primary concern. It is very embarrassing when people constantly ask me whether I am expecting again. I look 8 months pregnant all the time. I am unable to plan for a second child because I feel if I can't bear my own weight, how will I bear the child? My mother-in-law also tells me that this injection has ruined my body and that I should do something about my weight. I am very distressed, but I feel helpless."*

According to most of the women, although initially their appetite had increased, they had the same quantity of food that they usually have.

According to K,

> *"We eat whatever we used to eat before. God alone knows from where and how we gained so much weight."*

Studies have pointed out that most women gain weight with use of Depo-Provera. The average gain has been found to be about 2.3 kg in the first year and varying after that. Some may gain much more. There are no clear reasons for this. It could be that by suppressing oestrogen, there is a higher ratio of androgenic (male) hormones, muscle growth and increased appetite.

Although not directly mentioning that weight gain is a problem with Depo-Provera, Upjohn's handout to the women suggests regular exercises as a method that can help women manage their weight. It implies that weight gain is due to the lack of exercise and not a side effect of Depo. This perception seems laughable in a situation where a majority of Indian women, especially the 'targets' for the injectable, tirelessly work, both at home and in the fields, for eighteen hours a day.

Lack of Sexual Desire

8 women in the study (16%) reported lack of interest in sexual intercourse. They said that after taking the injection, they gradually lost interest in sex, which resulted in stress and misunderstanding with their spouses.

"After the injection, I lost all interest in sex. I had constant fights and arguments with my husband on this issue. He also used to beat me up. What else would I expect?"

"I have completely lost the desire for sex. I don't feel like having intercourse at all. But I am forced to do so, which troubles me a lot."

Our study corroborates with the retrospective study of 363 women using Depo-Provera in Australia, which reported sexual difficulties (loss of interest, dry vagina, dyspareunia) to be the third most important method-related side effect leading to discontinuation (after bleeding and headaches), and the principal complaint cited by women (43%) continuing with the method *(Fraser & Dennerstein 1994)*

> Depo-Provera has proven to be an effective male contraceptive, but male complaints of loss of libido have kept it from being promoted as a male contraceptive. Yet the same side effect is casually dismissed when it occurs in women. This underscores the bias towards female-based methods and the devaluing of women's experience. It is known that Depo was initially introduced as a male contraceptive, but because of the potential side effects, which one knows would have created ruckus if men had to bear them, it was introduced as a contraceptive for women because it is expected that women are meant to suffer their pain and discomfort, and even poor health is of no consequence.
>
> *– Corea 1980, quoted in Hartmann 1987*

Skin Discolouration

3 women complained that after using Depo they noticed a gradual darkening of their skins. Their skin became normal after they discontinued the method.

According to B,

"Apart from menstrual irregularities, my skin colour darkened a lot. I didn't know what to do. I went through a lot of tension because of this."

M told us,

"Some time after taking the injection, I noticed that my skin was becoming darker. Initially I did not pay much attention. But when others began to point it out to me, I became very worried. I even started to apply fairness creams to get back my skin colour."

As mentioned earlier, many women also associated skin discolouration with amenorrhoea.

Hair Loss

9 women had hair loss during the period they were using Depo. Some continue to lose hair even after discontinuing.

R told us,

> *" I lost so much of hair. Even now, I am loosing hair. I have to tie a scarf on my head. It is so embarrassing."*

The above side effects, particularly weight gain, hair loss and skin discolouration, had a tremendous impact on their self-image, leading to lack of confidence, depression and anxiety. They all felt that these side effects were inimical to their notion of beauty.

Anxiety and Depression

The study also attempted to explore the relationship of various psychological problems with the use of injectable. The commonly cited emotional disturbances have been anxiety and depression. 6 women reported depression *(man udaas)* as a side effect after using Depo. For M, the depression was associated with weight gain; for S, it was due to the constant heavy bleeding, and for K, it was hair loss.

However, D said that even though she never faced any of the other problems like heavy bleeding etc., she generally feels a lack of interest in everything around her and is frequently depressed *(mann udaas rahta hai)*. Women strongly articulated that this kind of anxiety and depression was a result of the drug and not due to the usual household stress.

As R shared with us,

> *"We are generally under stress and tension in the house for various reasons. But this is a very different feeling.*

Depression can be a minor side effect that merely destroys the entire quality of a women life.

– Corea, quoted in Hartmann 1987

Other side effects

Several other side effects were reported by women in our study, which included headache, backache, abdominal cramps, tiredness, weakness, nausea, white discharge, diarrhoea, problems with vision and delayed return to fertility. These side effects are usually dismissed as "minor," but to the women suffering such reactions day after day, these problems are as debilitating and painful as the others mentioned earlier.

The Pharmacia package also mentions about ectopic pregnancy, loss of vision, sudden onset of protosis, diplopia, or migraine as other side effects that health care providers should be alert to. According to the insert, "if examination reveals papilledema or retinal vascular leisions, medication should not be re-administered."

II Long-term side effects

When the short-term side effects are so disturbing, it is not difficult to imagine how serious the long-term side effects will be. If such a small sample size, as in this study, returns with such startling figures, a more widespread use of this contraceptive can only be catastrophic. However, there are no long-term studies in India that can forewarn the impending disaster that the women in the country are likely to face if this injectable gains ground through the FWP. But various studies do exist in the world that underline the long-term hazards of Depo-Provera. Following are some of the long-term side effects highlighted by various studies conducted worldwide.

Endometrial atrophy

Endometrial atrophy due to Depo-Provera and consequent secondary amenorrhoea could have a bearing on the woman's future fertility status. This is a serious complication in women desiring more children after the discontinuation of the contraceptive.

– Sathyamala 2000

Breast Cancer

Two studies, one by the World Health Organization (WHO 1991) and one in New Zealand (Paul *et al.* 1989) showed increased risk of breast cancer among current and recent users of Depo-Provera, but that risk did not increase with prolonged use. The risk of breast cancer appeared to be increased in women diagnosed at younger than 35, and in women who had used Depo before the age of 25. Both groups of researchers suggested that Depo-Provera might promote the development of new tumours or accelerate pre-existing ones. Because younger women have dense breast tissue, screening methods like mammography are not effective in monitoring breast changes.

Bone mineral density

A study done in New Zealand has shown that DMPA users had significantly lower bone densities in the lumbar spine and femoral neck (7.5% and 6.6% respectively). This has been clearly established by Dr. Tim Cundy. The results of his studies on women using DMPA for a minimum of five years concluded that long-term use of the

drug was associated with significant reduction in the bone mineral density of the lumbar spine and femoral neck.

– Cundy et al. 1991

Upjohn has also acknowledged this risk. "Use of Depo may be considered among the risk factors for development of osteoporosis. The risk of bone loss is greatest in the early years of use and then subsequently approaches the normal rate for age related fall" *(Depo Intervention Petition)*. Though Upjohn is supposed to have completed a 7-year prospective study on bone density involving 450 women between ages 25-35. Till date there is no report.

Dr. Sathyamala, *et al.* have also pointed at the significance of bone loss for Indian women, who suffer from demineralisation anyway on account of breast-feeding. Yet, lactation is not a contraindication for this drug in India. *(Lancet, Vol 344, July 9, 1994)*

Heart Disease

New research has suggested that Depo-Provera may increase the risk of heart disease in women taking the drug for more than a year.

A study published recently in *Circulation,* the Journal of the American Heart Association, (available on-line at *www.circ.ahajournals.org*), shows that the contraceptive can impair arterial responsiveness to increased blood flow as a result of endothelial cell abnormality. Lead author Professor Dudley Pennell of the Royal Brompton Hospital, London, says that long term users with risk factors for heart disease "would be wise to review" with their doctor whether to continue using the drug. DMPA is one of several long acting hormonal contraceptive methods used by women in developing countries, where local health services are often inadequate or non-existent. In developed nations, where non-compliance may be problematic in teenagers, doctors have found the contraceptive useful because it does not have to be taken daily.

Given as a 150 mg intramuscular injection every 12 weeks, DMPA prevents ovulation by inhibiting the release of gonadotrophins. But the resulting decrease in circulating oestrogen might be harmful in the light of recent evidence pointing to the cardio protective effects of the hormone.

The researchers investigated the dilatation changes in the brachial artery using high-resolution magnetic resonance imaging. The degree of arterial dilatation is used as an indicator of endothelial cell function. This was carried out in 13 women who had used the contraceptive long term (more than one year) at the end of a three month cycle and

within 48 hours of a new injection, and in nine non-users during menstruation (when circulating oestrogen is lowest) and at mid-cycle (when it peaks). *(bmj.com/cgi/eletters/321/7259/461)*

Human Immuno-Deficiency Virus (HIV)

Patients should be counselled that this product (Depo-Provera) does not protect against HIV infections and other sexually transmitted diseases.

– Pharmacia & Upjohn, Physician Information 1994

Depo-Provera, like the pill and other hormonal contraceptives, does not protect its users against sexually transmitted diseases or HIV. In fact, as studies point out, it could even facilitate HIV transmission. The first danger is posed by the use of non-sterile needles and syringes or careless re-use of these. Given our dismal safety records and the absence of any formal system of monitoring, this malpractice could take on mammoth dimensions once the injectable is used in a large scale.

Depo-Provera is administered as an intramuscular injection. Injections given with non-sterile needles or syringes increase the risk of transmission of infection agents, including bacteria, the Hepatitis B virus and the HIV.

– WHO 1990

Another area of serious concern is the consequences of unsafe sex in the context of HIV transmission. Barrier methods or pills, because of the attention they require, encourage more self-awareness, responsibility and forethought for women. But in the case of Depo, as long as the drug is capable of preventing pregnancy – the primary reason for using such a method – it is difficult to expect a couple to think about using an additional method for safe sex, whether by using a barrier method or following other preventive measures that can protect them from HIV. This is especially true for adolescents and younger women who often find it difficult to negotiate with their male partners. However, this is not unique to Depo-Provera, but is an issue that health care providers must address, given increasing rates of STDs and HIV.

Several studies also indicate that long-term use of Depo-Provera creates conditions for easy transmission of HIV.

- A prospective study of sex trade workers in Thailand found higher HIV seroconversion rates among women using Depo-Provera. The researchers

speculate whether the thinning of the vaginal epithelium may create small tears and facilitate the transmission of HIV.

– Ungchusak et al. 1996)

- Whether hormonal contraceptive use near the time of HIV infection affects disease progression is also of concern. One study among 115 HIV-infected Kenyan sex workers found that those using hormonal contraceptives near the time of HIV acquisition were more likely to be infected with multiple strains of the virus than women not using hormonal contraceptives near the time of HIV acquisition. Infection with multiple strains may be associated with faster HIV progression.

– Sagar M. et al. 2002

- In a prospective cohort study of HIV acquisition among 1,337 sex workers in Mombasa, 230 of who acquired HIV during follow-up. The use of DMPA and presence of genital ulcer disease at the time of HIV infection were associated with a higher viral load set point (the blood level at which the HIV virus settles about six months after initial infection). The higher the viral load set point, the faster HIV-related deterioration of the immune system occurs. Thus, this research finding suggests that DMPA use and genital ulcer disease may hasten the natural course of HIV infection.

– Lavreys L. et al. 2002

Other long-term side effects

Depo-Provera affects insulin response, but there is little research on the implications for diabetes, especially in high-risk populations. Virtually no research has been done on the impacts of Depo-Provera on the children of lactating mothers. Not much is known about the impacts of Depo-Provera on a woman's post-partum or post-abortion hormonal conditions, when the drug is often administered.

III. DMPA and young women

As mentioned earlier, numerous studies worldwide have established that long-term use of Depo-Provera leads to reduction of bone mineral density. But the fact that this risk is more in younger women and adolescents using Depo-Provera for a long period is also substantiated by several studies (even though some of these studies vouch for the safety of the injectable).

- Women younger than 18 years can safely use DMPA, as the advantages of using the method generally outweigh the risks, according to the World Health

Organization's medical eligibility criteria. However bone demineralisation occurs in DMPA users, especially those younger than 21 years.

– Scholes D. et al. 1999

- Extent of bone loss in the spine and proximal femur depends upon the duration of use, with bone loss occurring as early as the first three months of use and becoming magnified by 15 years of use and longer.

– Cundy T. et al. 1996

- Biochemical studies of bone resorption and formation have confirmed an association between DMPA use and bone loss.

– Ott SM. et al. 2001

- A marked increase in bone density, especially at the spine, occurs following discontinuation, but complete recovery may not occur in all the bones.

– Scholes D. et al. 2002

- The adolescent years are the time of maximum bone deposition, and impairment of mineral deposition during this interval may have long-lasting effects. The concern is that women who have DMPA as adolescents may enter menopause with a bone deficit and thus be more likely to suffer fractures than those who have not used the contraceptive method.

– Network, FHI 2003

It is therefore well established that Depo-Provera causes bone demineralisation in women under the age of 21 years. It is also established that Depo-Provera does not protect users from STIs and HIV infections, but facilitates these. In a country where STIs are a social taboo and the numbers of HIV/AIDS victims are rising everyday, a contraceptive like Depo-Provera is particularly dangerous for young women and adolescent girls. STIs also place the younger women at a great risk of infertility, which will further affect their social status and accentuate violence and mental health problems.

Other side effects, such as weight gain and hair loss, contribute to low body image and anxiety, especially among adolescents and younger women. Further, depression and a decline in sexual desire will have a serious impact on their sexual life, making them vulnerable to violence and mental health problems at an early stage of life.

- The disadvantages of unplanned adolescent pregnancy probably outweigh the potential risk of bone loss. This client should be told, however, that DMPA

will not protect her from sexually transmitted infections (STIs). If she is at risk for STIs/HIV, she should consistently use – in addition to DMPA – a condom for STI protection.

– Network, FHI 2003

The entire discourse around risk and benefit seems to be revolving on the central concern of stopping the unwanted pregnancy. Even if women have to bear all the crippling side effects and destroy their health and lives, so be it. And it is only the women who have to sacrifice their well being to stop the numbers from growing. While measuring risks and benefits, no questions are raised about women's status in the family or the gender power relations and patriarchal values that exist in the society. There is no discussion about the responsibility of the male partner in planning a family; no suggestion about sex education and sexual health awareness for adolescent.

One cannot but question, who takes the risk and who benefits from it? Even though the pro-injectable lobby claims that Depo will benefit women, the only benefit seems to be that they will not be pregnant. However, for the rest of their lives, they could be physically crippled. They could also be devastated mentally with low self-image, anxiety and depression. Economically speaking, they are likely to suffer permanent indebtedness because for the rest of their lives, they might have to seek endless treatments for a range of serious ailments.

IV. Discontinuation

- In India, studies have been undertaken to assess its (Depo-Provera's) utility in the Family Planning Programme. In a study in which 138 women participated for a total of 907 woman-months, no pregnancy occurred. However, the discontinuation rates due to severe menstrual disturbances were very high. Almost 32% of women discontinued after the first injection and another 38.8% before receiving the third dose.

– Mukherjee M. et al. 1996

- In a multicentric study conducted by the World Health Organisation in 13 countries, a total of 1,587 women were observed for 20,550 woman-months over a 2-year period in which only 3 pregnancies occurred. The discontinuation rate in the 13 participating countries ranged between 33.3 to 75.0 and 49.5 to 91.3 per 100 women at one and two years of use, respectively. The major reasons for discontinuation were menstrual irregularities, weight gain, and headache.

– Contraception 1983

What the study shows

The hospital had no records of how many women were still using Depo, how many had discontinued the method and for what reasons. But on talking to women, we found that 48 out of the 50 women in the study discontinued using Depo-Provera. Looking into the reasons why such a large proportion of women (96%) discontinued using the injectable, we found that 24 women out of 50 discontinued the method due to the side effects. Out of the 24, 3 were advised by the medical personnel to discontinue, and 21 discontinued on their own.

Reasons for discontinuation		No. of women
Side-effects	Self decision	21
	Doctor's advice	2
	Nurse's advice	1
Non-availability/Out of stock in hospital		19
Family pressure		2
Mobility/Distance to hospital		3
Total		**48**

Out of the 48 women who discontinued the use of Depo-Provera, 19 did so because the drug was no longer available free in the hospital. Since most of the women came from the lower income strata, they could not afford to spend Rs. 180 on the contraceptive. This applies to most women in the country, especially the prime targets for all birth control measures.

V. Follow-up

Taking into consideration the available infrastructure at primary health centres, the need for counselling, screening and appropriate back up for medical intervention, injectable contraceptives should preferably be introduced selectively in suitably equipped centres and hospitals. It is stressed that the introduction should be gradual and with emphasis on good clinical practice and rigorous post introduction surveillance of the side effects and patient care.

– ICMR 1986

It is not sufficient to administer the injection and forget about the woman for the next three months. Invasive technologies like Depo require close monitoring for years to study the long term effects. Detailed records of medical history and regular monitoring of side effects are mandatory.

> *"After taking the injection , I was told to come back for the next dose after 3 months. I was not asked to come for any follow-up in between."*

Though not asked for, they went for a check-up due to severe problems that they encountered after taking Depo.

> *"I got myself sterilised after aborting my two-month-old foetus. Since then, I have experienced very heavy bleeding, leg cramps, nervousness, dizziness and backache. Despite these problems, I did not go back to the hospital. The hospital staff does not seem to be interested in following up with their patients. Even while administering the injection, they never assured us about any follow-up and did not bother to check on the post injection side effects."*

The public health delivery system in the country is woefully inadequate in any of these areas. Current government policies favouring privatisation of primary health care threaten to further decimate even the meagre existing facilities. Invasive technologies like injectables require close, individual monitoring not for a few months only, but for years, to study the long-term side effects.

Do women get the environment that enables them to share?

The attitude of the health providers, who are expected to advise about the contraceptive, administer it and take care of its follow-up, becomes important here. 60% women in our study expressed that when they had gone for follow-up or complained about side effects, the hospital staff – including few doctors – was particularly harsh and prejudiced towards them, often displaying complete apathy towards their complaints.

It becomes important to understand how the attitude of health service providers influence the nature of services, the diagnosis and treatment, because it is ultimately they who take care of the health of the women.

According to 22 year-old S,

> *"After my first child was born, I had taken the injection, but it did not suit me... When I went to the doctor for a remedy, he said that I would get well on my own. When I asked why it was like this for me, he said: I don't know. There are so many who come and go. It is not only difficult to keep track of everyone, but also impossible."*

Another respondent said,

> *"When I had heavy bleeding, I thought it was because of the injection. However, I could not dare to ask the doctor."*

Most women complained that they had to wait for long hours at the hospital to see the doctor. And when they finally managed to do so, the actual consultation time was

barely 10 minutes. This was very inadequate and too short for either any discussion, check-up or getting the necessary information about the injectable. Having taken out time from their work and daily chores, this consultation was often meaningless for the women as they hardly got the time or the attention to share their concerns and problems. Further, women, while taking the injection or going for an abortion, constantly hid the actual number of children they have from the fear of the doctors taunting them on their large family size. They also did not want the doctors to force them to get sterilised. One of the respondents in the study had four children, but on being probed by the medical personnel, mentioned only three. She feared that the doctor would force her to undergo sterilisation. This single case is enough to demonstrate the different world views that exist between the health providers and the health care seekers. There is even a lot of anecdotal as well as user-reported evidence on the harsh and prejudiced attitudes of gynaecologists towards poor women regarding contraception. The latter is in a position of constant threat, guilt and awe.

Commercial Interests

I. Translating 'unmet' need into market demand

An important area of the study was to see what commercial interests lie behind the development and propagation of certain contraceptive technologies, and to understand the close connection between the pharmaceutical companies, public institutions and population lobbies.

> The pharmaceutical companies spend a large part of their budget on R&D activities and promotion of their products. The budget for promotion is spent mainly on medical practitioners on conferences for specialties and gifts. Gifts and other rewards are offered to specialists as part of promotional campaigns for a product, to conduct surveys, to write prescriptions for a particular product and so on. More than 20% of the budget is spent on promotional activity, through the media as well as personal visits by medical sales representatives
>
> *– Wolffers 1983;Chetley 1993: p.5*

During our hospital visits, we often interacted with medical sales representatives of various pharmaceutical companies promoting new products. We had one such interaction with a medical representative of the firm that is marketing Depo-Provera in India. He gave us a brief insight into their marketing strategy to propagate Depo through the public hospitals, which was later corroborated by a project officer of Pharmacia & Upjohn. According to both of them, the aim is to convince the authorities to advocate both the method as well as the product — even if that meant supplying it free of cost – so that there is a gradual increase in the demand and brand consciousness. This wider acceptance is likely to convince the practitioners, public health institutions, as well as the Ministry of Health and Family Welfare to accept and prescribe the product.

> Interestingly, a former President of the Federation of Obstetrics and Gynaecological Societies of India (FOGSI) went on to serve as Research Director of Upjohn in India between 1980-82.

Pharmacia (which now incorporates Upjohn) is, in fact, a pioneer in aggressive drug marketing. Interestingly, Pharmacia merged with the pharmaceutical division of Monsanto in 1999, another company that is known for its aggressive and unscrupulous marketing techniques. In July 1997, Pharmacia & Upjohn began airing commercials for Depo in the US, becoming the

first company to advertise a female contraceptive on television in that country. The company spent $7.7 million in advertisements in magazines and on TV spots in the first six months of starting the campaign.

> Since 1995, R&D staff of U.S. brand name drug companies has decreased by 2%, while marketing staff have increased by 59%. Currently, 22% of staff is employed in research and development, while 39% are in marketing. The "Research-based" pharmaceutical industry spends more on marketing and administration than it does on research and development.
>
> *(www.nofreelunch.org)*

It is important to understand that Depo-Provera, though an old product, is still seen to be very important by Pharmacia. Global sales of Depo-Provera were about $250 million in 2000. Its sales increased by 20% in 2001(over 2002) and it is still the seventh highest selling brand in Pharmacia's stable. This is extremely unusual for a drug that is almost forty years old. It also means that the drug is able to generate high profits for the company, as development costs incurred on the drug would have been recouped long back.

The company's interest in India is obvious. While global sales of Depo-Provera are set to reach over $250 million, a major part (over 70%) of this is in the US. The company is obviously interested in penetrating the huge Indian contraceptive "market" to boost sales outside the US. While Depo sales are still rising in the US, the company is also facing a lot of flack for the fact that Depo is largely being used by teenage girls, who wish to hide that they are taking contraceptives. This is seen as a problem, as teenage users, then, are also likely to be less careful about reporting side effects. Pharmacia & Upjohn claims in their advertising, "Depo-Provera has been used safely by millions of women in over 100 countries around the world for more than 30 years. Since its introduction in the USA, millions of American women have started using it." They fail to mention that only 1.1 million women are currently using Depo-Provera in the US, and that over 70% of all American women who have ever used Depo-Provera discontinued it's use within the first year due to it's side effects. *(Obstetrics and Gynaecology, 1996)*

> Global representative sales represent something between $2.6 billion and $2.9 billion per year (Fathalla 1994). Based on this huge economic power, pharmaceutical companies influence not only Southern Governments policies, but the priorities and conduct of health providers as well. Doctors are frequently approached by pharmaceutical companies' representatives, their participation in seminars and conferences is funded by these private sources and, in some cases, they are explicitly bribed. Entire regions are fully dependent on imports of contraceptives, as in Africa, where pills and injectables are manufactured only in South Africa. As purchase of contraceptives by the public sector is still subsidised in many Southern countries, donors may play a strong role in linking government consumers to major private suppliers. As a result, the method mix provided by public health systems is determined not by women's needs, but by commercial interests.
>
> *– Correa, S., Reichmann, R.. 1994*

Can our country afford such expensive contraceptives for large-scale use? While the government claims that it has no resources to augment basic health systems, including primary health centres, such decision to use expensive contraceptives defies logic. As a hypothetical exercise, let us assume that the government introduces Depo into the FWP, and targets to use it on 2,00,000 women. This figure is rather modest when the country's population is crossing one billion. Each shot currently costs Rs. 180/- for a 3 monthly period, which means that the money involved for each woman would be Rs. 180 x 4 shots a year, i.e. Rs. 720 per year for each woman. So the annual expenditure on 2,00,000 women would be Rs. 14,40,00,000. The question is, who is going to bear this cost?

If we look at the cost-benefits or economics of the drug, it clearly shows who are benefiting, the women users or the drug companies. Women's desire to regulate the number of children, as well as spacing births, is crucial for the commerce of the contraceptive commodities. There is an "unmet need" for contraceptives, it is argued, so that the need should be met. The "unmet need" is really to identify new markets. The marketing interests of the pharmaceutical companies coincide with and complement the urge of the population controllers to reduce the number of children that the women give birth to.

II. Violation of Drug Technical Advisory Board (DTAB) recommendations

In 1993, the Drug Action Forum had filed a writ petition in the Supreme Court pertaining to the banning of hazardous and irrational drugs. Further to this petition, judgment on which was still pending, on 7 November 1994, the Aids Awareness Group, Jagori and Kalpana Mehta filed an Intervention Petition seeking the inclusion of Depo-Provera and Net En in the list of banned drugs.

Following were some of the reasons underlined by the Intervention Petition:

- Insufficient research within the country, and not enough research on dose determination and on side effects;

- Adequate evidence of serious side effects from studies carried out in India and abroad;
- Manner in which licenses were granted for the sale of these drugs;
- Sale of the above products without prescription and the inability of the Drugs Controller of India to monitor the same and to take punitive action;
- Intent of the Government of India to introduce these in the family planning programme of the country, where informed consent, adequate screening, monitoring and follow up are all severe constraints. Further, there is a gross potential of abuse and coersion;

– Intervention Petition of 7 November, 1994

The Supreme Court directed the matter to the DTAB, which issued its recommendations on 16 February 1995. On Depo-Provera, the DTAB recommended the following:

> *The members had agreed for continued private marketing of Depo-Provera injection. The drug, however, is not recommended for inclusion in the Family Planning Programme.*
>
> *– Minutes of the special meeting of the Drug Technical Advisory Board held on 16 February 1995: Pg 5*

According to the hospital records, Depo-Provera was directly administered on 167 women during the period of October 1999 to June 2000. In the public health system, contraceptives are usually supplied to the hospitals as part of the Family Planning Programme. The fact that a public hospital administered Depo-Provera when it is not officially introduced in the family planning programme, clearly violates the recommendations of the DTAB, which has categorically stated that Depo is not recommended for inclusion in the Family Planning Programme. And the DTAB is the body that was entrusted to make a conclusive decision about Depo-Provera by none other than the Supreme Court of India.

Autonomy or bondage?

> *Injectable contraceptives – both DMPA and Net En – offer several advantages as a method of contraception, and have been shown in a number of clinical trials to be effective in preventing pregnancy and acceptable to many women.*
>
> *– WHO, 1990*

> *DMPA has several advantages for teenagers. Its use is discreet. Also, it offers long-term pregnancy protection, convenience, high effectiveness, and low cost.*
>
> *– Davis, 1996*

> *"We believe that Depo-Provera empowers women, by allowing them to decide when they wish to conceive and how many children they like to have. Unlike other methods, Depo-Provera allows women to be in complete control," – Medical Director, Pharmacia & Upjohn*
>
> *– TOI, 2000*

These quotes are the reflection of a notion that has rapidly gained ground in our country in the past two decades. It asserts that new contraceptive technologies are the ultimate solution to women's problems and a means to advance women's choice and convenience. Terms like empowerment and reproductive freedom are used with great emphasis while proclaiming the excellence of contraceptives like Depo-Provera, Net En or Norplant. Time and again, women's groups opposing the new contraceptives are accused of coming in the way of women's choice. We felt it is important to place concepts like choice, convenience or freedom in the context of the women who are the potential targets of these technologies, and gauge how these notions actually operate in their daily lives.

Targeting women

Apart from condoms and vasectomy, all the other contraceptive methods in use today, have been devised with women as targets. These include diaphragms, ligation, pills, injectables, vaccine, implants and, of course, abortion when there is no other option. Neither condoms, nor vasectomy is preferred by men for reasons ranging from inconvenience, lack of sexual pleasure, to the fear of weakness and impotency, all of

which have an underlying apprehension about the loss of manhood and power. As a natural consequence, women become the 'soft targets' of all contraceptive methods.

It is interesting to note that Depo-Provera was initially intended to be a contraceptive for men. But due to some of its side effects like loss of libido, it was kept away from being promoted as a male contraceptive. Paradoxically, when women face the same side effects, they are either ignored or devalued as "minor" or "normal". It is as if women are habituated to suffering as in menstruation, pregnancy or childbirth; what difference could a few more sufferings make in exchange of a contraceptive that is so "effective" in preventing pregnancy?

Between the peasant "target groups" and the population experts yawns a wide social gulf, which is rarely crossed. The family planners plan, the contraceptive deliverers deliver, the acceptors accept. What could be simpler? The people on top decide what is best for the people on the bottom. Thus family planning becomes a profoundly technocratic exercise. This is no accident, but rather the direct outcome of three decades in which the philosophy of population control has won intellectual and political ascendancy.

– Hartmann, 1987

There are many levels at which a poor, marginalised woman in India – or any Third World country – is targeted for birth control. At one level is the First World-Third World dichotomy that ultimately frames the Third World woman as the prime accused for population explosion. Within a country, the state, in alliance with the rich and powerful classes, holds her responsible for the ever increasing population that is seen as the reason behind all evils that plague that country, thus making her its sole target for birth control measures. Finally, within her own family and society, there exists a strong male hegemony that pushes the entire burden of fertility control on her shoulders.

Family dynamics

In the initial days of the study, one of the respondents, K, was keen to attend the focus group discussions. She requested our research team to pick her up from her residence. When we reached her house, her husband said, "I wouldn't have permitted her to go if you people hadn't come. I don't trust her. I am letting her go only because you have come to fetch her."

During the focus group discussion, K burst into tears. She said,

> "*I am living with my husband for five years, but he doesn't trust me. Even though you are total strangers, he trusts you. My in-laws*

always taunt me because I come from a poor family. I am not invited for any of the family gatherings. Even my children are not treated properly. But they like my sister-in-law. She comes from a wealthy family. In the last two years, this is the first time I have come out of the house. It is so nice to meet people like you and share my feelings. I hope I can come for such meetings even in the future."

Another respondent, R, is 30 years old. She had fibroids before she took Depo. After taking the injection, her weight increased by nearly 20 kg within a period of 3 months. She also had heavy bleeding. She has discontinued Depo after one dose. In the past one year, she has been consulting her doctor for her fibroids. R said,

"Recently I got an ultrasound done. The fibroids have grown bigger and have multiplied. The doctor advised me to go for a hysterectomy. Even though we have a son, my husband is very eager about another child. He doesn't want to use condoms; neither does he let me use anything. He says he doesn't care even if I die. My life doesn't mean anything to him. I don't think I can have a child with these fibroids. I don't see why we cannot adopt a child instead of going through another."

To the limited extent that gender-based inequalities within family are recognised, these problems are perceived as intrafamilial, rather than recognising the interconnection between women's position within families and their position vis-à-vis other social institutions like religion, state, media and markets.

– Murthy R., 1994

As mentioned in Section 1, most of the women in the study live in extended families and are economically dependent on their husbands and other family members. Usually in such families, the social identity and status of women are tied with their husbands. Their exposure to the outer world being limited, they are dependent on their husbands for social negotiations and interactions with the outer world. Because of this dependence, women find little space in the family to express their opinions, or make decisions, whether about their own life or the family. The reflection of her subordinate position is particularly more glaring when it comes to matters of sexuality and reproduction, since these directly threaten to challenge the power equation. If such a challenge is posed, it is ruthlessly dealt with. It is not a coincidence that wife beating has been found to be the most common form of violence in the world, cutting across regions, cultures and classes.

The question of choice

When we explored the question of choice with the women in the study, we were confronted with some harsh realities.

One respondent, R, shared with us,

> *"I had no idea about contraception. After the first child, my husband suggested that I should use Depo. I had many problems with the injection. After the second dose I stopped taking the injection. Now I am using pills. Even the pills are not suiting me. But my husband refuses to use condoms."*

P's experience was different, but the end result was the same.

> *"We already had three children. Then I had a miscarriage. I wanted to go for sterilisation. But my husband did not agree. Since the hospital is not giving Depo for free anymore, he insists that I should use either Copper-T or pills."*

According to K,

> *"After the first child, I became very weak and was unable to do any housework. My mother-in-law was not very happy with this. She insisted that I should not have a second child. She pushed me to see the local doctor, who suggested that I should use Depo."*

In the focus group discussions, many women said that they do not have any choice in deciding their family size. It is the husband, other family members or the mothers-in-law who decide which contraception method they should use. Only 5 out of the 50 women in the study, i.e. 10%, took the decision of adopting Depo-Provera completely on their own. 11 women reported that the health-staff of the hospital took the decision for them when they had gone for deliveries or for other gynaecological complications. For the rest of the 34 women, i.e. 68%, their husbands or mothers-in-law took the decision.

Women are also keen to control fertility

Through the study, we came across another intriguing tendency. Although only 2 of the 50 women continued using Depo-Provera, many of the others – even those who suffered from serious side effects and later discontinued – felt that Depo-Provera was more advantageous than the other options. Some pointed out that with Depo, they do not have to remember to take pills every day; some said that it can be taken without anyone's knowledge; while many admitted that it relieved them of repeated pregnancies.

One of the women, V, told us,

> *"I was not keen on the third child. I had a lot of arguments with my husband because of this. I have tried to convince him, but in vain. I became pregnant again. At that time, I ate a lot of hot stuff like munakke (a herb), hoping to have a miscarriage, but nothing happened. I also went to the local doctor and took a medicine for abortion, but the child still survived. My husband refuses to use anything, nor does he let me use any contraceptive. I am sick of him. We have plenty of condoms lying in the house, but he never uses them. After the third child I decided to use some contraceptive method without his knowledge. I came to know about the injection and took it from the hospital without telling anyone. I did have a lot of problems after the second injection. I was bleeding after every three or four months, or twice in a month, I put on weight, and I had severe back pain, nausea, palpitations, headache and joint pain. Despite these problems, for me the injection was a blessing, as I was relieved of conceiving again and again."*

V is one among the 5 women who decided to take Depo-Provera on their own. According to another participant in the study, F, a graduate,

> *"After my second girl was born, I took Depo-Provera without telling anyone. Nobody in the house knew about it. My mother in law came to know much later. She kept asking me why I was not conceiving. She wanted me to have a son to carry on the family name. She used to tell me, "these two girls you have will go away after marriage, then we won't have an heir!"*

F is one of the current users of the injection. Another respondent, **N,** said,

> *"I am 28 years old and have studied till the 12th standard. I have two children – a girl and a boy. I took the injection after my first child was born, which led to many fights at home. I did not want the second child immediately, but I had to discontinue the injection, as I was afraid of tensions at home. My mother-in-law threatened that she will drive me out of the house if I continued taking the injection."*

These experiences, on the one hand, underline the abysmally poor inter-spousal communication and the negative attitude that men have towards family planning and/or contraception. Usually dominance and violence mar the conjugal relationship between men and women. On the other hand, these experiences strongly emphasise

the fact that women by and large, no matter how poor or subjugated they may be, have a strong desire to control their fertility; and in order to do so, they are willing to go to any extent, whether it means going against the wishes of their spouses and families, or bearing all the sufferings and long-term health risks associated with the contraceptive methods they use.

Why women want to space or limit births is not difficult to fathom. The physical hardship of repeated pregnancies can exact a terrible toll on a woman's health. Between the ages of fifteen and forty-five, a woman in rural Bangladesh can now expect to have an average of eight pregnancies and to spend nearly seventeen years either pregnant or breast-feeding. This would be hard for any woman, but for already undernourished women the difficulty is greatly magnified. An estimated two-thirds of all pregnant women in the Third World are anaemic.

– Hartmann, 1987

There is little doubt therefore that women are in dire need of contraceptive methods that are both convenient and safe. From the experiences of the women in the study it may seem that Depo-Provera was able to provide some degree of convenience to some of them. But this is only one side of the story. In fact, due to these apparent conveniences, propagators of Depo go to the extent of claiming that it gives reproductive freedom to women. However, when these are contrasted with all the debilitating side effects that the injectable had on the women, one wonders whether Depo-Provera gave freedom to the women or further enslaved them. Even if some of the women chose Depo on their own, or some felt that Depo was a blessing in spite of its side effects, these can barely be read as realisations derived out of freedom or empowerment. Rather, these perceptions stem from a severe desperation and lack of control, which is far from empowering. Besides, some of the side effects such as heavy bleeding, spotting or lack of desire for sex, could affect their ability to work at home or outside, putting them through severe tension with their spouses and the families.

As N told us,

> *"I am always worried about what will happen if I cannot bear a child in the future? Will my husband marry again?"*

Even those women who decided to use Depo-Provera on their own live with a lingering fear of being abandoned by their husbands if they cannot become 'mothers' in future. They are living under continuous threat and anxiety. The same tension prevails on the women, who were forced by their family members, especially husbands, to use Depo-Provera.

R shared with us,

> *"Since I have lost interest in sex after using Depo-Provera, my husband forces me to have sex."*

Many other respondents also acknowledged the frequent sexual coercion they have to face and any resistance on their part leads to violence and mental torture. Many a time women are coerced in subtler ways, where they are made to feel that they are taken care of. G told us,

> *"Initially I used Depo-Provera, but I had a lot of problems. Then I used Copper-T. That too didn't suit me. Now I am on pills. Even if I forget, my husband doesn't. He hands me a pill every morning, before breakfast."*

There is a more fundamental question that needs to be addressed here. Why, in the first place, do women have to carry the burden of contraception on their shoulders? Why does the husband not use condoms, instead of subjecting his wife to switch from one method to another? Should the husband not take equal responsibility?

The study showed very clearly the negligible involvement of men in the use of contraception. Though men were often the key decision-makers about the size of the family and use of contraceptive methods, they never took the responsibility of using any method themselves. Only 10 % of the women told us that their husbands had started using condoms lately, since the former were not in a position to use any contraceptive method because of the side effects from Depo. However, under no circumstances did the men take any initiative to go for vasectomy. They preferred to take a backseat when it came to bear the reproductive responsibility.

Women need safe and effective contraceptive that they can control. Yet, 'reproductive rights' cannot be asserted in isolation. Certainly women have the right to choose, but with full informed consent, with complete awareness of the risks involved. When 'choice' is guided by a population control lobby, backed by sophisticated marketing by pharmaceutical companies who stand to make huge profits, the trumpeting of such 'choice' should be viewed with caution".

– Murthy L. 2000

This refusal of men to take any reproductive responsibility on the one hand, and imposing their reproductive choice on women on the other, represents the overarching patriarchal values, which have given them the power to control both production processes and the reproductive potential of women. What comes out clearly from the study is that the adverse effects of Depo-Provera far outweigh the handful of superficial

conveniences that it has to offer. It is here that we must pause to think whether Depo-Provera, or any of the new contraceptive technologies, can in any possible way empower women. In a patriarchal society, where power relations make women passive and subordinate, technology can only reinforce existing stereotypes and further oppress them. In the guise of choice, freedom and empowerment, more and more women will be subjected to relentless suffering, as long there is no 'true' awareness of the politics of population policies, commercial interests of pharmaceutical companies and a concomitant refusal to tackle the critical issue of gender power inequalities. In talking of the illusory 'choice', however, till now Depo-Provera seems to have given women only that much option to choose between the devil and the deep blue sea.

Interview Schedule

A study on experiences, perceptions and attitude of women who have used Depo-Provera from public hospitals

by Sama

I. General information

Sr.no: ..... Date: .....
Name of the Hospital: .....
Duration of the method: .....
Name of the Investigator: .....

II. Socio Economic Profile

1. Name: .....
2. Address: .....
3. Age: .....
4. Religion:
   - 4.1 Hindu .....
   - 4.2 Muslim .....
   - 4.3 Christian .....
   - 4.4 Sikh .....
   - 4.5 Other .....
5. Marital Status:
   - 5.1 Married .....
   - 5.2 Unmarried/Single .....
   - 5.3 Divorced .....
   - 5.4 Widowed .....
   - 5.5 Separated .....
   - 5.6 Any other .....
6. Education:
   - 6.1 Unlettered .....
   - 6.2 Primary .....
   - 6.3 Middle .....
   - 6.4 High School .....
   - 6.5 Graduation .....

	6.6 Post Graduation	.....
	6.7 Any Other	.....
7. Occupation	7.1 Domestic servant	.....
	7.2 Unemployed	.....
	7.3 Salaried employment (private)	.....
	7.4 Own business	.....
	7.5 Daily wage labourer	.....
	7.6 Services (Govt)	.....
	7.7 Home based work	.....
	7.8 Agricultural work	.....
	7.9 Others	.....
8. Husband's Occupation	8.1 Domestic servant	.....
	8.2 Unemployed	.....
	8.3 Salaried employment (private)	.....
	8.4 Own business	.....
	8.5 Daily wage labourer	.....
	8.6 Services (Govt)	.....
	8.7 Home based work	.....
	8.8 Agricultural work	.....
	8.9 Others	.....
9. Average income of the family	9.1 Location of house	.....
	9.2 Resettlement Colony	.....
	9.3 Jhuggi Jhopdi	.....
	9.4 Slum	.....
	9.5 Residential areas	.....
10. Housing	10.1 Own House	.....
	10.2 Rented house	.....
	10.3 Government quarter	.....
	10.4 Jhuggi Jhopdi	.....
	10.5 Semi Pucca house	.....
	10.6 Pucca House	.....
	10.7 Kutcha House	.....
	10.8 Any other	.....

11. How many children do you have? .....
12. No. of pregnancies .....
13. No of miscarriages .....
14. No of abortions .....
15. How many boys and girls do you have?.....
16. Age of the youngest child .....

17. What do your children doing?
    - 17.1 Studying .....
    - 17.2 Working .....
    - 17.3 Others .....

III. Knowledge of Contraceptives

18. Why do you want to use contraceptives?
    - 18.1 Economic reasons .....
    - 18.2 Repeated pregnancies .....
    - 18.3 Health reasons .....
    - 18.4 Family pressure .....
    - 18.5 Spacing .....
    - 18.6 Adviced by Doctor .....
    - 18.7 Any other .....

19. Have you ever used any contraceptive method ?
    - 19.1 Yes .....
    - 19.2 No .....

20. If yes, what was the method?
    - 20.1 Rhythm method .....
    - 20.2 Condom .....
    - 20.3 Withdrawal .....
    - 20.4 Copper T .....
    - 20.5 Diaphragm .....
    - 20.6 Abstinence .....
    - 20.7 Abortion .....
    - 20.8 Injectable .....
    - 20.9 Any other .....

21. How long did you use the method?
    - 21.1 Three months .....
    - 21.2 Six months .....

21.3 6-9 months .....
21.4 9-12 months .....
21.5 More than 1 year .....
21.6 More than 2 years .....

22. Why did you opt for it?

22.1 Convenient .....
22.2 Privacy .....
22.3 Used earlier and it suits me .....
22.4 Doctor advised .....
22.5 Any other .....

23. Who informed you about this method?

23.1 Health worker .....
23.2 Relatives .....
23.3 Read about it .....
23.4 Media. TV .....
23.5 Doctor .....
23.6 Friends .....
23.7 Used it earlier .....
23.8 Any other .....

24. Why did you discontinue the method?

24.1 To become pregnant .....
24.2 Not suiting me/complication .....
24.3 Inconvenient .....
24.4 Family pressure .....
24.5 Abuse .....
24.6 Any other .....

25. What is the current method you have chosen?

25.1 Pills .....
25.2 Copper T .....
25.3 Sterilization .....
25.4 Injectables .....
25.5 Any other .....

IV. Procedures

26. Did the doctor tell you about the other options available?

27. Before administering did the doctor tell you about the probable side effects of the injection?

    27.1 Yes .....
    27.2 No .....
    27.3 If yes what information was given?
    .....

28. Before administering the injection, did the doctor or health staff performed any tests, examinations?

    28.1 BP .....
    28.2 Weight .....
    28.3 Breast examination .....
    28.4 Vaginal examination/pv.....
    28.5 Pap Smear .....
    28.6 Any other .....

29. Is there any prescription given for tests, if yes what are the tests?

    .....

30. Did you give anything in writing /signed or any other form?

    30.1 Yes .....
    30.2 No .....

31. Were you provided with any hand outs?

    31.1 Yes .....
    31.2 No .....

32. Did the doctor ask about any history of following things? If yes , which of the following?

    32.1 Hypertension .....
    32.2 History of heart disease/family history .....
    32.3 Diabetes /Family history of diabetes .....
    32.4 Hepatitis .....
    32.5 Jaundice .....
    32.6 Calf pain .....
    32.7 Swelling/pain of arm/leg .....

32.8 Headache/Migraine .....
32.9 Lump in the breast .....
32.10 Vaginal bleeding/discharge .....
32.11 Depression .....
32.12 Abnormal pregnancy .....

33. Were you informed about which day of menstruation you should be administered Depo?

.....
.....

34. If you were lactating, which day after the delivery depo was given to you?

.....
.....
.....

35. Did you rub the site of injection immediately after administering? Or were you given any instructions?

.....
.....
.....

36. Were you asked to visit the hospital for regular follow up ? If yes,

36.1 For next dose .....
36.2 For any health problem .....
36.3 Any other .....

V. General and obstetric History

37. Did you have any history of following ?

37.1 Hypertension .....
37.2 History of heart disease/family history .....
37.3 Diabetes /Family history of diabetes .....
37.4 Hepatitis .....
37.5 Jaundice .....

37.6	Calf pain	.....
37.7	Swelling/pain of arm/leg	.....
37.8	Lump in the breast	.....
37.9	Vaginal bleeding/discharge	.....
37.10	Depression	.....
37.11	Abnormal pregnancy	.....
37.12	Any other	.....

VI. Health after Depo

38. Did you experience any problems after the injection?

38.1	No menstruation	.....
38.2	Excessive bleeding	.....
38.3	Irregular bleeding	.....
38.4	Weight gain	.....
38.5	Headache/ migraine	.....
38.6	Abdominal pain	.....
38.7	Nervousness	.....
38.8	Dizziness	.....
38.9	Palpitations	.....
38.10	Digestive disorder	.....
38.11	Hair loss	.....
38.12	Skin problems/acne	.....
38.13	Lack of sexual desire	.....
38.14	Depression	.....
38.15	Leg cramps	.....
38.16	Nausea	.....
38.17	Difficulty in sleeping	.....
38.18	Vaginal discharge/Inflammation	.....
38.19	Backache	.....
38.20	Pelvic /breast pain	.....
38.21	Feeling bloated	.....
38.22	Hot flushes	.....
38.23	Swelling of ankles and wrists	.....
38.24	Problems with your eye sight	.....
38.25	Any other	.....

39. Did you talk to the medical professional about the problems?

39.1 Yes .....
39.2 No .....

40. If yes, what were you suggested? .....

.....

41. If no, why? .....

.....

42. Did you approach anyone for treatment for these problems? If Yes,

42.1 Another private doctor .....
42.2 Another government doctor .....
42.3 Local practitioner .....
42.4 Nurse .....
42.5 Friend .....
42.6 Any other .....

43. If no, why ? .....

.....

44. How were your complaints received by the health professionals?

44.1 Treated immediately .....
44.2 Completely ignored .....
44.3 Treated after some delay .....
44.4 Dismissed completely .....
44.5 Any other .....

45. Did you go regularly for the follow up?

45.1 If yes, how many times? .....
45.2 If no, why? .....

46. Have you thought of discontinuing it?

46.1 Yes .....
46.2 No .....

47 If yes, why? .....

48. If no, why? .....

49. Did you pay for the drug or was it free/prescription based?

.....

50. If paid, how much did you pay? .....

51. When were you asked to come for follow up? .....

52. Will you suggest this method to any body? Yes..... No .....

52.1 If yes, why? .....
52.2 If no, why? .....

53. What is your personal experience/opinion about this method?

.....

.....

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    - Contraceptive Choices – which is a satire on the existing state of affairs in the backdrop of an oppressive social atmosphere, with improper housing, lack of food, education or employment, women are being given a choice in contraception. *(Hindi and English)*

    - New Reproductive Technologies – which pictures the fertility control lobby targeting women with invasive and hazardous contraceptive in the name of providing choice. *(Hindi and English, Price: Rs. 15 each, Rs. 50 for a set)*

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